



AAHRPP®

Association for the Accreditation of
Human Research Protection Programs, Inc.®

Evaluation Instrument for Accreditation

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(Errata added April 5, 2011)

Use of the Evaluation Instrument for Accreditation

The Evaluation Instrument for Accreditation is intended for use by Organizations seeking accreditation and by site visitors who evaluate organizations. To achieve accreditation, an Organization must meet all the accreditation Standards and Elements. If an Organization meets the Elements for a particular Standard, it meets the Standard. This Evaluation Instrument provides the information necessary to meet each Element.

AAHRPP has defined Domains of responsibility: Organization, Institutional Review Board (IRB) or Ethics Committee (EC), and Researchers and Research Staff. Within each Domain are Standards, and for each Standard there are Elements that provide more specificity for the Standard. Each Element contains four parts: Commentary, Regulatory and Guidance References, Required Written Materials, and Outcomes.

For some Elements, Common Types of Materials That May Be Used to Meet the Element are included. Listed under this heading are examples of written materials that Organizations have used to meet the Element. They are not required, and Organizations may use other types of written materials to meet the Element. If an Element refers to written policies and procedures it generally means that a written procedure (e.g., standard operating procedure) is required to meet the Element. In some cases, an application form or reviewer checklist can serve the same purpose as a written procedure. AAHRPP has attempted to identify those Elements.

By designating certain types of written materials that may be used to meet an Element, AAHRPP does not desire to reduce the flexibility of the accreditation or limit creativity. The listing of Common Types of Materials That May Be Used to Meet an Element is intended to be helpful by providing guidance on the types of materials that can meet an Element.

This Evaluation Instrument is designed to be used by Organizations in the United States as well as Organizations in other countries that are obligated to follow U.S. federal regulations and those that are not so obligated. The Evaluation Instrument separately designates regulations and guidance from various U.S. federal agencies as well as the International Committee on Harmonisation – Good Clinical Practice Guideline (ICH-GCP) (E6). This includes regulations and guidance from the Department of Health and Human Services (DHHS) and the U.S. Food and Drug Administration (FDA), as well as other departments or agencies that have additional requirements, such as the Department of Defense, the Department of Justice, the Department of Education, the Department of Energy, the Environmental Protection Agency, and the Department of Veteran Affairs.

For each Element, there are essential requirements that all Organizations must follow. These essential requirements meet many U.S. and international government requirements for protect human research participants. For some Elements, additional requirements are listed for specific U.S. federal agencies and ICH-GCP.

Each Element (or Standard without Elements) begins on a separate page. This gives the appearance that the Evaluation Instrument is longer than it actually is. Separating each Element provides discrete documents to print and consider.

The five sections of the Evaluation Instrument for Accreditation are:

1. Commentary: This section provides an explanation of how to interpret the Element.

2. Regulatory and Guidance References: Listed here are regulatory and guidance citations from the U.S. federal agencies that oversee research with human participants. These citations were updated on December 15, 2010. Also, listed here are the guidance citations from the International Committee on Harmonisation - Good Clinical Practice (E6).

Organizations that must follow a certain set of regulations (e.g., DHHS or FDA) must meet the regulatory requirements. Organizations that are not bound to follow a particular set of regulations are not required to meet them, but they should describe and provide equivalent protections, when applicable.

3. Required Written Materials: This section contains the requirements for written materials an Organization must have to meet the Element.

AAHRPP uses the generic term “policies and procedures” to refer to all types of written materials. Policies and procedures include any written materials that the Organization uses to define and communicate its practices, such as standard operating procedures, policy statements, procedure descriptions, checklists, guidelines, educational materials, job descriptions, memoranda, forms, templates, strategic plans, Web sites, charters, by-laws, mission statements, or other forms, that are used to administer the Human Research Protection Program. Policies and procedures are not limited to IRB or EC policies and procedures; other organizational procedures are likely to be relevant, such as some policies related to human resources, budgeting, pharmacy, contracting, student orientation, corporate compliance, or corporate ethics.

A policy is generally defined as a strategy, goal, or objective. It defines an expectation regarding a behavior or course of action. A procedure is a method by which a policy can be accomplished. Procedures should describe the operational steps that are followed to meet regulatory requirements. A restatement of the regulations or guidance is generally insufficient to provide the necessary specificity. Procedures should include: 1) An explanation of how key regulatory terms are interpreted, 2) The actions that are taken, 3) The title of the person, office, or entity responsible for taking the action, and 4) The timing of actions.

No single format is required for policies and procedures, and no specific wording is required to be used in policies and procedures. Organizations have used a range of models for writing policies and procedures. Procedures should provide enough detail to be understandable to individuals within the Organization who use them. Procedures should reflect actual practice within the Organization.

AAHRPP has provided a description of the content for many policies and procedures. U.S. regulatory requirements, such as the criteria for approval of research, elements of disclosure for the consent process, or types of disclosure for financial interests, are not listed. The Organization must use the federal regulations to obtain these requirements.

4. Common Types of Materials That May Be Used to Meet the Element: These are examples of the types of materials Organizations have provided to meet the Element. Sometimes, materials are listed under this section when there is requirement for written materials to meet the Element. AAHRPP has included this section under the Element to assist organizations in meeting the Element. Organizations that do not have the materials should not create them to meet the Element. The listing is intended only a facilitative tool.

In this section, “procedures” are not listed as an example of a written material that may be used to meet the Element. In some cases, the combination of an application form and reviewer evaluation tool will be sufficient to meet the Element, and a written procedure in addition to the application form and reviewer evaluation tool is not needed. This must be judged uniquely for each Element and for each Organization.

5. Outcomes: These are the practices that an Organization should have in place.

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Errata April 5, 2011

- Element II.2.C. – page 65 – changed “affiliated” to “unaffiliated.”
- Element II.2.D. – page 67 – add “or designee.”
- Element II.2.F. – page 76 – changed “research” to “record.”
- Element II.2.G. – page 79 – changed “research” to “record.”
- Element II.3.G. – page 99 – corrected formatting error in columns
- Element III.2.D. – page 16 – changed “participant” to “report”

Domain I: Organization

Commentary

This Domain describes the structural characteristics of the entity that assumes responsibility for the Human Research Protection Program (HRPP) and applies for accreditation. The organizational structure is the means by which the Organization meets the range of responsibilities of the HRPP.

The Organization applies its HRPP to all research regardless of funding source, type of research, or place of conduct of the research. The Organization exercises these responsibilities through relationships with Researchers and Research Staff, IRBs or ECs, Sponsors, participants, and the community.

An Organization has the responsibility not only to protect the rights and welfare of human research participants but also to involve research participants in the research enterprise. The involvement of research participants at every stage of the research enterprise helps everyone to achieve the ethical principle of respect for persons. In addition to enhancing the appropriate safeguards and protecting

the rights and welfare of research participants, involving research participants in the research process can improve recruitment and retention of participants and also improve the overall quality of research.

The conduct of research is highly dependent upon the partnership between Organizations and Sponsors. A Sponsor is the company, institution, individual donor, or government agency responsible for the initiation, management, or financing of a research study. Sponsors may enter into agreements with intermediaries that act as agents, such as clinical research organizations or coordinating centers. In sponsored research, both the Sponsor and the Organization have obligations to protect human research participants. In this Domain, the focus is on the obligations of the Organization. In seeking accreditation, the Organization must address human research protection requirements with all Sponsors and apply its HRPP to all sponsored research.

Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants. Individuals within the Organization are knowledgeable about and follow the policies and procedures of the Human Research Protection Program.

Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program.

Commentary

An Organization should have a policy to differentiate activities that are research involving human participants from activities that are not research involving human participants. Activities that are determined to meet the definition of research involving human participants subsequently fall under the auspices of the HRPP.

A determination of whether an activity is research involving human participants must consider the regulations, laws, codes, and guidance that the Organization follows. Many organizations oversee or conduct activities that are covered by two or more sets of laws, regulations, codes, and guidance. In these cases, the Organization must apply all relevant definitions of research and participant or develop a plan that guides the

HRPP in determining which definitions apply in specific research instances.

If the Organization follows neither the DHHS nor the FDA regulations, the Organization should define “research” as a systematic investigation designed to produce or contribute to generalizable knowledge and “human participant” as living individuals about whom information is obtained or with whom there is interaction, or develop an equivalent definition.

The person making a decision about whether an activity represents research involving human participants should have the authority to represent the Organization and have no direct involvement in the activity he or she is examining. The person making the decision should be familiar with regulations, organizational policies, and the nature of research. Policies and procedures should

describe the communication of such decisions to the person seeking a decision.

[See AAHRPP Tip Sheet 2.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.101(a), 45 CFR 46.102(d), 45 CFR 46.102(f), 45 CFR 46.102(f)(1), 45 CFR 46.102(f)(2)
- FDA: 21 CFR 50.1, 21 CFR 50.3(a), 21 CFR 50.3(c), 21 CFR 50.3(g), 21 CFR 50.3(j), 21 CFR 56.101, 21 CFR 56.102(c), 21 CFR 56.102(l),
- VA: 38 CFR 16.101(a), 38 CFR 16.102(d), 38 CFR 16.102(f), 38 CFR 16.102(f)(1), 38 CFR 16.102(f)(2), VHA Handbook 1200.05, 4
- DOJ: 28 CFR 512.10

Required Written Materials

- Essential requirements:
 - Policies and procedures provide a definition of “research involving human participants” so that all involved in the HRPP understand which activities are overseen by the HRPP.
 - General definitions:
 - Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, or an equivalent definition.
 - Define “a systematic investigation” relevant to the Organization’s research portfolio.
 - Define “generalizable knowledge” relevant to the Organization’s research portfolio.
 - Human participant means a living individual about whom a Researcher conducting research obtains data through intervention or interaction with the individual, or identifiable private information, or an equivalent definition.
 - Policies and procedures describe the process to provide determinations about whether an activity is research involving human participants, which includes:
 - The entity or office that can provide a determination.
 - Criteria used to make determinations.
 - Process to inform individuals whether an activity is research involving human participants.
 - Policies and procedures include:
 - A description of the scope of human participants research that requires review by the Organization’s IRB or EC (e.g., all research by employees or all research in facilities).
 - A description of the criteria by which persons are considered engaged (agents) in the research and come under the requirements of the IRB or EC.
- Policies and procedures provide guidance to Researchers and IRBs or ECs concerning activities that sometimes are or are not overseen by the HRPP at the Organization, such as classroom research, quality improvement, case reports, program evaluation, and surveillance activities.
- When the Organization includes other activities outside the scope of activities covered by regulations or laws, the definition includes those activities (e.g., research on non-living individuals).
- When activities are covered under other laws, the definition encompasses activities that are “research involving human participants” as defined by those laws.
- When following DHHS regulations and guidance:
 - The definition encompasses activities that are “research” and involve “human subjects” as those terms are defined by DHHS regulations.
- When following FDA regulations and guidance:
 - The definition encompasses activities that are “clinical investigations” and involve “human subjects” as those terms are defined by FDA regulations.
- When following VA regulations and guidance:
 - Policies and procedures indicate classified research involving human participants cannot be approved by a VA facility IRB or Research and Development Committee or performed at VA facilities.
- When following Department of Justice regulations and guidance:
 - For research conducted within the Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

Common Types of Materials That May Be Used to Meet the Element

- Application form
- Reviewer checklist
- Template letters to Researchers

Outcomes

- The Organization is able to determine and recognize when an activity is research involving human participants as defined by its policies and procedures.
- Decisions about whether an activity is research involving human participants are made promptly.
- Decisions about whether an activity is research involving human participants are made accurately.

- Researchers and others receive a decision about whether an activity is research involving human participants

Element I.1.B. The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.

Commentary

An Organization should have an identified, knowledgeable leader of the HRPP who is responsible for the program and has the authority to implement the program. Although this individual may rely on others for the interpretation of laws, regulations, codes, and guidance and the day-to-day operations of the HRPP, this individual should have a basic understanding of the relevant laws, codes, regulations and guidance that govern research involving human participants, the responsibilities of an organizational official as well as the responsibilities of the IRB or EC and Researchers and Research Staff in protecting research participants. This individual should be directly involved in the allocation of resources to the HRPP. In some circumstances, more than one individual serves in this capacity.

This Element is applicable to all Organizations, regardless of whether the Organization has a federal assurance of compliance. If an Organization has a federal assurance of compliance, the identified leader of the HRPP might or might not be the official who signs the assurance.

Regulatory and Guidance References

- DHHS: 45 CFR 46.103(c)
- VA: VHA Handbook 1200.05, 6

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the responsibilities of the organizational official.
 - If more than one person is designated as an organizational official, the unique responsibilities of each individual that relate to the HRPP are stated.
- When following VA regulations and guidance, policies and procedures describe the responsibilities of the medical center director:
 - Is responsible for the facility's research program, and is assisted by the Research and Development Committee.
 - Oversees both the IRB and all VA Researchers and Research Staff.
 - Ensures that IRB members, Researchers and Research Staff are appropriately knowledgeable to conduct research in accordance with ethical standards and all applicable regulations.

- Develops and implements an educational plan for IRB members, staff, Researchers, and Research Staff including initial and continuing education.
- Fulfills all educational requirements mandated by the VA Office of Research and Development (ORD) and OHRP.
- Appoints one or more research compliance officers to conduct annual research consent document audits and triennial regulatory audits, and to assist in the VA facility's assessments of regulatory compliance.
 - Unless a waiver for a part-time research compliance officer is approved by the under secretary for health, each VA facility conducting research must designate at least one full-time research compliance officer.
 - The medical center director must report any appointment, resignation, or change in status of the research compliance officer to Office of Research Oversight VHA Central Office, with a copy to the relevant ORO research officer, within 10 business days after the appointment, resignation, or change takes effect.
- Reports to ORO in writing within five business days after being notified of a research problem or event (including serious and continuing non-compliance, unanticipated problems involving risks to participants or others, and suspensions and terminations) for which such reporting is required.
 - The medical center director's written report is required regardless of whether disposition of the event has been resolved at the time of the report.
 - Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the relevant ORO office at intervals and in a manner specified by that office.
- Provides a copy of any ORO compliance reports regarding the research program to the associate chief of staff for research, Research and Development Committee, any relevant research review committee(s), and the research compliance officer in a timely fashion.
- Reports the following research events to ORO Central Office, with a simultaneous copy to the appropriate ORO research officer, as indicated in the following:
 - IRB changes in number of IRBs and changes in membership rosters.

- Substantive Memorandum of Understanding (MOU) changes must be reported to ORO Central Office within five business days.
- Accreditation Problems must be reported to ORO Central Office within five working days.

Common Types of Materials That May Be Used to Meet the Element

- Letter or memorandum from senior management stating the delegation

- Job description of the organizational official

Outcomes

- The organizational official has overall responsibility for the HRPP.
- The organizational official is identifiable by those within the Organization.
- The organizational official has sufficient standing, authority, knowledge, and independence to ensure implementation and maintenance of the program.

Element I.1.C. The Organization has and follows written policies and procedures that allow the Institutional Review Board or Ethics Committee to function independently of other organizational entities in protecting research participants.

Commentary

To ensure that the IRB or EC functions independently of other organizational entities, the IRB or EC should be granted specific authorities to approve, require modifications to secure approval, disapprove research, to suspend or terminate IRB or EC approval of research, and to observe, or have a third party observe, the consent process or the research. The highest appropriate organizational person or entity should grant and recognize these authorities. Statements in the IRB or EC policies and procedures alone granting the IRB or EC such authorities are insufficient.

The Organization should have policies and procedures that respond to attempts to influence the IRB's or EC's independence or others responsible for the oversight of research.

[See AAHRPP Tip Sheet 12.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.109(a), 45 CFR 46.109(e), 45 CFR 46.112, 45 CFR 46.113
- FDA: 21 CFR 56.109(a), 21 CFR 56.109(e), 21 CFR 56.112, 21 CFR 56.113, VHA Handbook 1200.05, 5
- VA: 38 CFR 16.109(a), 38 CFR 16.109(e), 38 CFR 16.112, 38 CFR 16.113

Required Written Materials

- Essential requirements:
 - Policies and procedures approved by the Organization grant the IRB or EC the authority:
 - To approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the Organization.
 - To suspend or terminate IRB or EC approval of research not being conducted in accordance with the IRB's requirements or that had been associated with unexpected serious harm to participants.

- To observe, or have a third party observe, the consent process and the conduct of the research.
- Policies and procedures describe the steps the Organization takes to ensure that research involving human participants does not commence until the research has received all approvals required by the Organization.
- Policies and procedures approved by the Organization do not allow the Organization to approve research that has not been approved by the IRB or EC.
- Policies and procedures describe to whom IRB or EC members and staff report undue influence.
- Policies and procedures describe the Organization's response to attempts to unduly influence the IRB or EC.
- When following VA regulations and guidance:
 - Policies and procedures indicate:
 - The medical center director is responsible for ensuring that the IRB functions independently.
 - The chair, or co-chairs, and members have direct access to the medical center director for appeal if they experience undue influence or if they have concerns about the IRB.

Outcomes

- The Organization does not allow officials of the Organization to approve research that has not been approved by the IRB or EC.
- Individuals responsible for the oversight of research know how to report undue influence.
- The Organization responds to attempts to unduly influence the individuals responsible for the oversight of research.
- Individuals responsible for the oversight of research do not experience undue influence from the organizational official or others.
- The IRB or EC functions independently.

Element I.1.D. The Organization has and follows written policies and procedures setting forth the ethical standards and practices of the Human Research Protection Program. Relevant policies and procedures are made available to Sponsors, Researchers, Research Staff, research participants, and the Institutional Review Board or Ethics Committee, as appropriate.

Commentary

The protection of research participants is the responsibility of many individuals involved with the HRPP, including IRB or EC members, chairs, and staff; Researchers and Research Staff; and the organizational official. The Organization should define the roles and responsibilities of individuals responsible for the conduct or oversight of human research. Individuals should understand their roles and responsibilities. This Element includes both the responsibility to follow laws, regulations, codes, and guidance and the requirement to understand and apply ethical principles governing research.

An Organization should communicate its expectations of those involved in research. The level of communication required depends on the degree of involvement and role within the HRPP. For example, the policies and procedures most relevant to Researchers and Research Staff are different from those relevant to the IRB or EC staff. An Organization should make copies available of policies and procedures, or provide guidelines, abstracts, or summaries that communicate the relevant points.

Organizations with a federalwide assurance may choose to extend the DHHS regulations, including Subpart A and Subparts B, C, and D, to all research regardless of funding. If the Organization chooses not to extend the regulations to non-funded research, AAHRPP requires that the Organization has and applies equivalent protections for participants in non-funded research.

An Organization should define all of the components (internal and external) that are involved with human research protection and ensure that those components communicate among themselves and function as an integrated program of protection.

Independent IRBs or ECs should consider not only components within their Organization but also the components of Organizations for which they serve as the IRB of record.

[See AAHRPP Tip Sheet 11.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.103(b)(4), 45 CFR 46.103(b)(5)
- FDA: 21 CFR 56.108(a), 21 CFR 56.108(b)
- VA: 38 CFR 16.103(b)(4), 38 CFR 16.103(b)(5), VHA Handbook 1200.05, 7,8
- DOJ: 28 CFR 512
- EPA: 40 CFR 26, 40 CFR 26.201-203, 40 CFR 26.304, 404-405, 40 CFR 26.1101-1125, 40 CFR 26.12.01-1203.
- ICH-GCP: 2.1, 2.3, 2.6, 2.13, 3.3.1, 3.3.6

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the ethical principles that the Organization follows to govern the conduct of research involving human participants.
 - Policies and procedures describe the ethical obligations and expectations of:
 - Researchers and Research Staff, including students involved in the conduct of research.
 - IRB or EC members and chairs.
 - IRB or EC staff.
 - The organizational official.
 - Employees.
 - Students.
 - Policies and procedures describe the mechanism for communicating or making available the policies and procedures of the HRPP to all individuals.
 - Policies and procedures describe the mechanism for communicating changes in the policies and procedures to all individuals.
 - Policies and procedures include a description of all components that are involved with human research protection, including:
 - The roles and responsibilities for each component.
 - The relationships among the components.

- A description of the ways the components of the Organization communicate and work together to protect participants.
 - When following DHHS regulations and guidance:
 - If the Organization chooses not to apply Subpart A to all research regardless of funding as indicated on the federalwide assurance, policies and procedures include equivalent protections for participants in non-funded research.
 - When following VA regulations and guidance:
 - The provision of services by the IRB is established through a memorandum of understanding or other written agreement that outlined the responsibilities of the VA facility and the academic affiliate.
 - When following Department of Justice regulations and guidance:
 - For research conducted within the Bureau of Prisons, the Organization, IRB or EC, and Researchers and Research Staff must follow the requirements of 28 CFR 512, including:
 - The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
 - The research design must be compatible with both the operation of prison facilities and protection of human participants. The Researcher must observe the rules of the institution or office in which the research is conducted.
 - Any Researcher who is a non-employee of the Bureau must sign a statement in which the Researcher agrees to adhere to the requirements of 28 CFR 512.
 - All research proposals will be reviewed by the Bureau Research Review Board.
 - When following Environmental Protection Agency (EPA) regulations and guidance:
 - Policies and procedures include that for research conducted or supported by the EPA:
 - EPA prohibits research involving the intentional exposure of pregnant women, nursing women, or children to any substance.
 - EPA requires application of 40 CFR 26 Subparts C and D to provide additional protections to pregnant women and children as participants in observational research, i.e., research that does not involve intentional exposure to any substance.
 - EPA requires submission of IRB determinations and approval to the EPA human subjects research review official for final review and approval before the research can begin.
 - Policies and procedures include that for research not conducted or supported by any federal agency that has regulations for protecting human research participants and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research participants apply, including:
 - EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance.
 - EPA prohibits the intentional exposure of pregnant women, nursing women, or children to any substance.
 - When following ICH-GCP guidance (E6):
 - Policies and procedures include a statement that clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice and the applicable regulatory requirements.
-
- Common Types of Materials That May Be Used to Meet the Element**
- HRPP plan
 - IRB or EC policies and procedures
 - Researcher handbook
-
- Outcomes**
- The Organization follows ethical standards and practices.
 - Individuals in the Organization follow ethical standards and practices.
 - The Organization makes available to individuals involved or likely to be involved in research policies and procedures governing research with human participants.
 - Individuals are kept up to date with new information and policies and procedures.
 - Individuals are able to access policies and procedures.

Element I.1.E. The Organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.

Commentary

The protection of research participants is the responsibility of many individuals in an HRPP, including IRB or EC members, chairs, and staff; Researchers and Research Staff; and the organizational official. To protect research participants these individuals need to understand and be able to apply several areas of knowledge, including ethical principles, professional standards, organizational policies and procedures, and laws, regulations, codes, and guidance.

The depth of knowledge and skill required depends on each individual's specific task and role. For example, IRB or EC chairs or reviewers designated to use the expedited procedure of review should have more knowledge and skill than a new IRB or EC member. Researchers need different skills depending on the nature of their research or the expertise of their support staff.

An Organization should have a process to ensure that individuals involved with human research protection have appropriate knowledge and skills. Such a process can include formal training and evaluation of previous training and experience. The size and breadth of the education program should be customized to meet the needs of the Organization.

An Organization should periodically evaluate the knowledge and skills of individuals involved in the HRPP.

Regulatory and Guidance References

- VA: VHA Handbook 1200.05, 61
- DoD: DoDD 3216.2, para. 4.5, SECNAVINST 3900.39D para. 6a(2)

Required Written Materials

- Essential requirements:
 - The Organization maintains a list of educational activities designed to contribute to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.
 - Policies and procedures include initial education requirements, including timeframes, for Researchers and Research Staff; IRB or EC staff, IRB or EC chairs, and members; and others.

- Policies and procedures indicate how education requirements are monitored.
- Policies and procedures describe continuing education requirements and time frames.
- Policies and procedures describe what actions the IRB or EC or the Organization takes if education requirements are not fulfilled.
- When following VA regulations and guidance:
 - Policies and procedures indicate:
 - All individuals who are subject to VA regulations are required to:
 - Complete training in good clinical practice and the ethical principles on which human research is to be conducted before they may participate in human participants research.
 - Update such training every two years thereafter. Local VA facilities have the option of defining every two years as within 730 days after the previous training, within the second full calendar year after the previous training, or within the second full fiscal year after the previous training. Each VA facility must specify which definition of every two years it uses in its policies and procedures for this training requirement.
 - When following Department of Defense (DoD) regulations and requirements:
 - Policies and procedures require initial and continuing research ethics education for all personnel who conduct, review, approve, oversee, support, or manage human participants research.
 - There may be specific DoD educational requirements or certification required.
 - Policies and procedures indicate how the IRB or EC staff, chair, and members; and Researchers and Research Staff become aware of the specific requirements contained in Department of Defense regulations and requirements and educated about these requirements when appropriate.

Common Types of Materials That May Be Used to Meet the Element

- Lists of educational activities
- Education plans

- Education records

Outcomes

- The Organization has an education program to ensure that individuals involved in the HRPP have appropriate knowledge and skills.

- The Organization periodically evaluates and improves the knowledge and skills of individuals involved in the HRPP.

Element I.1.F. The Organization has and follows written policies and procedures for reviewing the scientific or scholarly validity of a proposed research study. Such procedures are coordinated with the ethics review process.

Commentary

This Element requires an Organization to have a level of science or scholarly review sufficient to fulfill two criteria for approval of research used by the IRB or EC:

- Risks to participants are minimized by using procedures consistent with sound research design and that do not unnecessarily expose participants to risk.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result.

An Organization may use various mechanisms to evaluate scientific or scholarly validity of proposed research. The IRB or EC may draw on its own knowledge and disciplinary expertise, or the IRB or EC may draw on the knowledge and disciplinary expertise, of others, such as review by a funding agency, an organizational scientific review committee, or department chairs. The Organization may also use a combination of these mechanisms. In all cases, the conduct of the scientific or scholarly review requires the reviewers to have the expertise to understand the background, aims, and methods of the research to answer the above questions and to draw on the discipline's standards for conducting research.

The results of the review should be communicated to the IRB or EC as part of the process for review and approval. The IRB or EC cannot delegate its responsibility to judge whether the criteria for approval are met.

This Element does not require a merit review that compares the value of the research to other research studies or a peer review designed to maximize scientific quality. Therefore, this Element does not require the level of disciplinary expertise required for review of relative merit or peer review.

[See AAHRPP Tip Sheet 11.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.111(a)(1)(i), 45 CFR 46.111(a)(2)
- FDA: 21 CFR 56.111(a)(1)(i), 21 CFR 56.111(a)(2)
- VA: 38 CFR 16.111(a)(1)(i), 38 CFR 16.111(a)(2), VHA Handbook 1200.05, 15
- DoD: SECNAVINST 3900.39D, para 8c(6)
- DOJ: 28 CFR 512.11(a)(2)

- ICH-GCP: 2.4, 2.5

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the Organization's evaluation of proposed research for scientific or scholarly validity.
 - Policies and procedures indicate the individuals or entities that are responsible for scientific review.
 - Scholarly or scientific review of proposed research addresses the following issues:
 - Does the research use procedures consistent with sound research design?
 - Is the research design sound enough to yield the expected knowledge?
 - If scientific review is conducted by an entity other than the IRB or EC, policies and procedures describe how the review is documented and communicated to the IRB or EC.
- When following VA regulations and guidance:
 - Policies and procedures indicate the Research and Development Committee conducts scientific review or to whom the Committee has delegated this responsibility.
- When following Department of Defense regulations and requirements:
 - Policies and procedures have substantive amendments to approved research undergo scientific review prior to IRB or EC review or conducted by the IRB or EC.
- When following Department of Justice regulations and guidance:
 - Policies and procedures include that for research conducted within the Bureau of Prisons, the project must have an adequate research design and contribute to the advancement of knowledge about corrections.
- When following ICH-GCP guidance (E6):
 - Policies and procedures include the evaluation of the available nonclinical and clinical information on an investigational product is adequate to support the proposed clinical trial.

Common Types of Materials That May Be Used to Meet the Element

- Reviewer checklist

- Written evaluations

Outcomes

- Individuals who conduct scientific or scholarly review include members who have relevant expertise and draw upon the standards to conduct research applicable to the scientific or scholarly discipline.
- The scientific review process evaluates:
 - The soundness of the research design.
 - The ability of the research to answer the proposed questions.
 - The scientific review process provides the IRB or EC the information it needs to determine whether the regulatory criteria are met.

Element I.1.G. The Organization has and follows written policies and procedures that identify applicable laws in the localities where it conducts human research, takes them into account in the review and conduct of research, and resolves differences between federal or national law and local laws.

Commentary

Sometimes, there are laws other than federal or national, such as state, provincial, or local, that govern the conduct of research involving human participants.

Policies and procedures should include the definitions and applicability of these laws or define a process to determine definitions and applicability, in the jurisdiction in which the Organization resides, as well as in the locations where research is conducted. This would normally include obtaining legal counsel. An Organization may have its own legal counsel or rely on external legal counsel. Policies and procedures should describe the application of laws so that the laws are understandable to IRB or EC members, IRB or EC staff, and Researchers and Research Staff, rather than simply restate the law.

Independent IRBs or ECs should have a process to determine the particular international, national, and local laws that influence IRB or EC determinations within the specific locality where the research is conducted.

When research is conducted that involves children or adults who have impaired decision-making, policies and procedures should define which individuals meet the legal definitions of “legally authorized representative,” “child,” and “guardian.”

In some jurisdictions, there are other laws that provide additional protections for participants of research and are applicable to IRB or EC decisions to approve research. Such laws include privacy, genetic testing, genetic information, and reporting of child, elder, or spousal abuse.

This Element applies to research conducted in the resident country; transnational research is covered in Standard I-3.

Regulatory and Guidance References

- DHHS: 45 CFR 46.101(e)-(f), 45 CFR 46.102(c), 45 CFR 46.402(d)-(e)
- FDA: 21 CFR 50.3(l), 21 CFR 50.3(o), 21 CFR 50.3(s), 21 CFR 56.103(c)

- VA: 38 CFR 16.101(e)-(f), 38 CFR 16.102(c), 38 CFR 17.32(e), 38 CFR 17.32(g), VHA Directive 2001-028, VHA Handbook 1200.05, 7,8,45,48,49

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the application of laws relevant to research involving humans as participants, when the research is conducted:
 - In the jurisdiction where the Organization resides.
 - Outside the jurisdiction where the Organization resides.
 - Policies and procedures describe the process to resolve conflicts between federal or national law and other applicable laws.
- When following DHHS and FDA regulations and guidance:
 - If the Organization oversees research that involves adults unable to provide legally effective consent, policies and procedures describe the Organization’s decision about or process to determine who is a “legally authorized representative” as defined by DHHS and FDA regulations.
 - If the Organization oversees research that involves children as participants, policies and procedures describe the Organization’s decision about or process to determine who is a “child” as defined by DHHS and FDA.
 - If the Organization oversees research that involves children who are wards as participants, policies and procedures describe the Organization’s decision about or process to determine who is a “guardian” as defined by DHHS and FDA regulations.

Outcomes

- The Organization has access to legal counsel for assistance in applying laws to research involving human participants.
- Research complies with applicable laws relevant to research involving human participants.
- Conflicts among applicable laws are resolved.

Standard I-2: The Organization ensures that the Human Research Protection Program has resources sufficient to protect the rights and welfare of research participants for the research activities that the Organization conducts or oversees.

Commentary

Resources include all needs of an HRPP, such as staff, consultants, IRBs or ECs, equipment, finances, information technology systems, and space to store records securely, permit private conversations, accommodate computer and office equipment, and hold meetings.

There are no standards or formulas for sufficient resources; the determination is made based on outcome. If an Organization meets all other Elements, resources will be judged sufficient. If an Organization does not meet an Element, insufficient resources will be considered as a possible reason.

An Organization may rely on the services, such as the IRB or EC, contracting office, or conflict of interest committee, of another Organization to supplement its resources. If an Organization relies on the services of another organization, policies and procedures should describe the steps followed by the Organization to ensure that the external service meets the relevant accreditation standards.

[See AAHRPP Tip Sheet 11.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.103(b)(2), 45 CFR 46.103(d), 45 CFR 46.114, OHRP Guidance on Knowledge of Local Research Context
- FDA: 21 CFR 56.114, FDA Information Sheets: Non-Local IRB Review
- VA: 38 CFR 16.103(b)(2), VHA Handbook 1200.05, 6,7,8
- ICH-GCP: 4.2.3

Required Written Materials

- Essential requirements:
 - The Organization maintains adequate resources for support of the operations of the HRPP, including but not limited to administrative resources including space and personnel, in order to meet the accreditation standards.
 - Policies and procedures describe the plan to evaluate resources needed for the HRPP.
- If the Organization relies on the services or components of another Organization, policies and procedures describe the steps followed (e.g., criteria, evaluation, or monitoring) to evaluate whether the service or component meets the relevant accreditation standards.
- When following VA regulations and guidance:
 - Policies and procedures indicate the medical center director is responsible for ensuring provision of adequate resources to support the operations of the HRPP so that those operations are in compliance with all VA and other federal requirements that govern human participants research protection.
 - The VA facility has an established or designated IRB by:
 - Establishing its own IRB.
 - Securing the services of an OHRP- registered IRB established by another VA facility, VA central IRB, VA regional IRB, or affiliated medical or dental school. In policies and procedures:
 - The IRB agrees to comply with VA requirements when reviewing VA research.
 - The provision of services by the IRB is established through a memorandum of understanding or other written agreement that outlines the responsibilities of the VA and the academic affiliate.
 - If using the VA Central IRB, the provision of services by the VA Central IRB is established through a memorandum of understanding between VHA Central Office and the local VA facility.
 - A VA facility's own internal IRB cannot serve as an IRB of record for any non-VA entity except a Department of Defense (DOD) facility or a VA nonprofit research and educational foundation.
 - Securing a waiver from the chief research and development officer to use the services of an IRB within another federal agency that has federal regulations to protect research participants.
 - Policies and procedures do not allow the VA facility to use a commercial IRB for VA research.

- The medical center director is responsible for ensuring an annual evaluation of the facility's HRPP. This function may be delegated to the Research and Development Committee.
- If using the VA Central IRB, the medical center director delegates authority to one or more individuals from the local VA facility to:
 - Provide comments or suggestions to VA Central IRB, in response to VA Central IRB's initial review considerations.
 - Respond to VA Central IRB's approval of the study on behalf of the VA facility as to whether the VA facility chooses to participate or declines to participate in the study.
 - Serve as liaison between the VA facility and both the local site Researcher and VA Central IRB.

Outcomes

- The Organization has allocated the financial and personnel resources necessary to carry out the operations of the HRPP in order to meet the accreditation standards.
- The Organization periodically reviews the resources allocated to the HRPP and adjusts resources as needed.
- The Organization periodically evaluates key functions of the HRPP, such as the number of IRBs or ECs, the conflict of interest committee, the quality improvement program, the educational activities, sponsored programs, and pharmacy services, and makes adjustments so that key functions of the HRPP are accomplished in a thorough and timely manner.
- When the Organization relies on the services of another organization, the Organization ensures that the services meet the relevant accreditation standards.

Standard I-3: The Organization's transnational research activities are consistent with the ethical principles set forth in its Human Research Protection Program and meet equivalent levels of participant protection as research conducted in the Organization's principal location while complying with local laws and taking into account cultural context.

Commentary

Researchers often conduct studies in other countries as well as in their own country. IRBs or ECs that review such research must be knowledgeable about the laws, regulations, codes, and guidance that govern such research in addition to the cultural context in which the research will be conducted.

Both Researchers and the IRB or EC have the responsibility to ensure the research performed in other countries meets equivalent levels of protection that would be required in the Organization's principal location, taking into account local laws and cultural context.

When research is sponsored by a U.S. federal agency, the regulations of that agency apply. Providing equivalent protections is unacceptable in lieu of providing the required federal protections.

Regulatory and Guidance References

- DHHS: 71 Fed Reg 10511 (July 7, 2006)
- DoD: DoDD 3216.2, para. 4.9; SECNAVINST 3900.39D, para. 6i
- VA: VHA Handbook 1200.05, 4, 5, 56

Required Written Materials

- Essential requirements:
 - The Organization has policies and procedures for reviewing transnational research including:
 - Ensuring appropriate expertise and knowledge of the country either through IRB membership or consultants.
 - Confirming the qualifications of the Researchers and Research Staff for conducting research in that country.
 - Initial review, continuing review, and review of modifications.
 - Knowledge of local laws.
 - Post-approval monitoring.
 - Handling of complaints, non-compliance, and unanticipated problems involving risk to participants or others.

- Consent process and other language issues.
- Communication and coordination with local IRBs or ECs when appropriate.
- All policies and procedures that are applied to research conducted domestically should be applied to research conducted in other countries, as appropriate.
- When following VA regulations and guidance:
 - Policies and procedures indicate:
 - Permission must be obtained from the chief research and development officer, or designee, prior to initiating any VA-approved international research.
 - The VA facility director must approve any request for permission to conduct international research prior to forwarding it to the chief research and development officer.
 - All international sites must hold an international federalwide assurance, and the research must be approved by the IRB or Ethics Committee of the participating sites listed on the international federalwide assurance.
 - The Researcher must conduct the research in accordance with VA requirements and all other applicable federal requirements for protecting human participants, tissue banking, use of databases, federal criminal laws, and the standards of ethical conduct for employees of the executive branch.
- When following Department of Defense regulations and requirements:
 - Policies and procedures include additional safeguards for research conducted with international populations:
 - The Organization or Researcher has permission to conduct research in that country by certification or local ethics review.
 - The Researcher follows all local laws, regulations, customs, and practices.

Common Types of Materials That May Be Used to Meet the Element

- Applications
- Checklists
- Copies or summaries of local laws

Outcomes

- Researchers provide the same or equivalent protections to human participants in research conducted in other countries.
- When conducting transnational research, Researchers are aware of local laws and cultural

context in all locations where the research is conducted and comply with local laws and adhere to cultural norms.

- When reviewing transnational research, IRBs or ECs ensure that equivalent protections are provided to research participants enrolled in research in other countries.
- IRBs or ECs make determinations and decisions based on laws and knowledge of the country in which the research will be conducted.

Standard I-4: The Organization responds to the concerns of research participants.

Element I.4.A. The Organization has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol or plan.

Commentary

Organizations should provide information to current, former, and prospective research participants about whom to contact for concerns, questions, or complaints about the research; obtain information; or offer input. Organizations should also have a mechanism to solicit concerns, questions, or input from prospective participants. The Organization should have policies and procedures that describe the steps followed by the Organization to respond to contacts from participants or others.

Regulatory and Guidance References

- DHHS: 45 CFR 46.116(a)(6)-(7)
- FDA: 21 CFR 50.25(a)(6)-(7), FDA Information Sheets: A Guide to Informed Consent
- VA: VHA Handbook 1200.05, 5

Required Written Materials

- Essential requirements:
 - Contact information for an individual or office that is unaffiliated with a specific research study is available to current, former, and prospective research participants to:
 - Discuss problems, concerns, and questions.
 - Obtain information.
 - Offer input.

- Policies and procedures describe the steps followed when the Organization responds to contacts from participants or others.
- When following VA regulations and guidance:
 - Policies and procedures indicate:
 - The medical center director is responsible for ensuring a local research participant outreach program is implemented that includes a reliable mechanism for research participants to communicate with Researchers and with an informed VA representative who is independent of the research study in question (e.g., providing contact information in the consent document).

Common Types of Materials That May Be Used to Meet the Element

- Web site
- Pamphlet or brochure
- Consent template

Outcomes

- The Organization provides information to current, former, and prospective participants or others about whom to contact in the Organization to discuss problems, concerns, and questions; obtain information; and offer input.
- The Organization responds to contacts from participants or others.

Element I.4.B. The Organization conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate. These activities are evaluated on a regular basis for improvement.

Commentary

To enhance the public’s understanding of research, Organizations should perform outreach activities. The scope of the outreach activities should be proportional to the size and complexity of the research program. There is no requirement that a single activity will result in measurable changes in community understanding.

Regulatory and Guidance References

- VA: VHA Handbook 1200.05, 5

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the plan and methods for enhancing the understanding of participants, prospective participants, and communities.
 - Policies and procedures describe the periodic evaluation of outreach activities.
- When following VA regulations and guidance:
 - Policies and procedures indicate:
 - The medical center director is responsible for ensuring a local research participant outreach program implemented that includes:
 - Researchers making every reasonable effort to provide the informational brochure, “Volunteering in Research – Here Are Some Things You Need To Know,” (<http://www.research.va.gov/programs/pride/veterans/tri-fold.pdf>) to prospective research participants in settings where participants might be recruited (e.g., clinic waiting areas)

and to each prospective participant when that individual is approached to take part in a study.

- Providing venues for research participants and their designated representatives to obtain information, discuss their questions and concerns, and offer their input.
- When appropriate, making educational activities available for research participants and their communities.

Common Types of Materials That May Be Used to Meet the Element

- Pamphlet or brochure
- Web site
- Research Day
- Mini-medical school
- Speaker bureau
- Evaluation reports
- Quality improvement plans

Outcomes

- The Organization provides information designed to enhance the understanding of research involving participants and their community.
- IRB or EC members and Researchers can describe the characteristics and culture of the communities in which they oversee or conduct research, respectively.
- The Organization makes improvements to its outreach activities as needed, based upon a periodic assessment.

Element I.4.C. The Organization promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results.

Commentary

In some instances, the design and implementation of research can be enhanced when individuals from the community in which the research will be conducted are involved in the design, conduct, and analysis of data from the research. This can occur for an individual study or group of studies. This Element is not applicable, or appropriate, for all research studies.

An Organization can facilitate the involvement of community members by supporting community or patient advocacy boards, supporting Researchers who wish to conduct community-based participatory research or other types of research that involve community members, or supporting the IRB or EC in developing the expertise to review community-based participatory research.

Regulatory and Guidance References

- None

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the additional considerations for reviewing research involves community members in the research process,

including the design and implementation of research and the dissemination of results.

Common Types of Materials That May Be Used to Meet the Element

- Research studies using a community-based participatory research design
- Use of community advisory boards
- Use of participant advocates
- Partnerships with community-based organizations

Outcomes

- When appropriate, the Organization supports mechanisms that allow Researchers to involve community members in the research process, including the design and implementation of research and the dissemination of results.
- When appropriate, Researchers involve community members in the design, conduct, and analysis of data.
- When appropriate, Researchers inform community members about the results of the research study and utilize community members to help disseminate results.

Standard I-5: The Organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization also measures and improves, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program.

Element I.5.A. The Organization conducts audits or surveys or uses other methods to assess compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization makes improvements to increase compliance, when necessary.

Commentary

An Organization's quality improvement program should include measures of compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization's quality improvement program should include an evaluation of the HRPP to determine whether it is effective in achieving compliance.

The Organization should collect objective data through audits, surveys, or other methods and use the data to make improvements and monitor compliance on an ongoing basis.

The number of audits or surveys, or the breadth of the audits or surveys, conducted should be determined by the Organization and sufficiently robust to provide data that inform the quality improvement program.

Regulatory and Guidance References

- VA: VHA Handbook 1058.01, VHA Handbook 1200.05, 14, 29
- DOE: DOE O 443.1A

Required Written Materials

- Essential requirements:
 - The Organization has a quality improvement plan that periodically assesses compliance of the HRPP.
 - The plan states the goal of the quality improvement plan with respect to achieving and maintaining compliance.
 - The plan defines at least one objective to achieve or maintain compliance.
 - The plan defines at least one measure of compliance.
 - The plan describes the methods to assess compliance and make improvements.
- When following VA regulations and guidance:

- Policies and procedures indicate:
 - The medical center director is responsible for ensuring appropriate auditing of local human participants research studies to assess compliance with all applicable local, VA, and other federal requirements including, but not limited to, Office of Research Oversight requirements.
 - A research compliance officer is an individual whose primary responsibility is auditing and reviewing research projects relative to requirements for the protection of human participants.
 - Conducts annual consent document audits.
 - Conducts triennial regulatory audits on all research protocols.
 - The VA facility's lead research compliance officer must report directly to the medical center director. The activities of the research compliance officer may not be determined or managed by the Research Service, research investigators, or any other research personnel.
- The IRB is required to conduct audits.
 - Procedures must include, but are not limited to:
 - Criteria that might prompt increasing the frequency of audits beyond the minimal required frequency.
 - The timeframe for reporting audit findings to the IRB.
 - Types of corrective actions the IRB can require based on the audit findings.
 - Who should implement and review the corrective actions.
 - How to evaluate the results of any corrective actions.
 - The IRB can accept audits conducted by the research compliance officer to fulfill auditing requirements.

- The IRB may require more frequent audits by the research compliance officer or by other means. The IRB also may require the research compliance officer to conduct more focused audits of one or more aspects of the study. The requirement to increase the frequency of audits or to audit specific aspects of the study might be based on considerations including, but not limited to:
 - Involvement of vulnerable populations.
 - Level of risk.
 - Phase I or Phase II studies.
 - Involvement of FDA approved drugs for which there has been a new safety warning issued, or change in the labeling that indicates increased risks.
 - Issues of noncompliance.
 - Data confidentiality or security concerns.
- When following Department of Energy regulations and guidance:

- The Organization must periodically conduct self-assessments to ensure compliance with the HRPP procedures and other requirements.

Common Types of Materials That May Be Used to Meet the Element

- Compliance plans
- Audits, surveys, or data collection tools
- Surveys
- Evaluation reports

Outcomes

- The Organization monitors compliance based on objective data and makes improvements, when necessary.

Element I.5.B. The Organization conducts audits or surveys or uses other methods to assess the quality, efficiency, and effectiveness of the Human Research Protection Program. The Organization identifies strengths and weaknesses of the Human Research Protection Program and makes improvements, when necessary, to increase the quality, efficiency, and effectiveness of the program.

Commentary

An Organization's quality improvement program should include measures of quality, efficiency, and effectiveness to evaluate the performance of the HRPP. The Organization should use results from the quality improvement program to design and implement improvements.

The Organization should collect objective data through audits, surveys, or other methods and use the data to make improvements and monitor quality, efficiency, and effectiveness on an ongoing basis.

Regulatory and Guidance References

- None

Required Written Materials

- Essential requirements:
 - The Organization has a quality improvement plan that periodically assesses the quality, efficiency, and effectiveness of the HRPP.
 - The plan states the goals of the quality improvement plan with respect to achieving targeted levels of quality, efficiency, and effectiveness of the HRPP.
 - The plan defines at least one objective of quality, efficiency, or effectiveness.
 - The plan defines at least one measure of quality, efficiency, or effectiveness.

- The plan describes the methods to assess quality, efficiency, and effectiveness and make improvements.

Common Types of Materials That May Be Used to Meet the Element

- Quality improvement plan
- Audits, surveys, or other data collection tools.
- Evaluation reports

Outcomes

- The Organization:
 - Identifies targets for quality, efficiency, and effectiveness of the HRPP.
 - Plans improvements based on measures of quality, efficiency, and effectiveness.
 - Implements planned improvements.
 - Monitors and measures the effectiveness of improvements.

Element I.5.C. The Organization has and follows written policies and procedures so that Researchers and Research Staff may bring forward to the Organization concerns or suggestions regarding the Human Research Protection Program, including the ethics review process.

Commentary

The HRPP should have open communications with Researchers and Research Staff under its oversight and be responsive to questions, concerns, and suggestions. Policies and procedures should describe the ways Researchers and Research Staff may communicate with representatives of the HRPP.

Regulatory and Guidance References

- None

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the process for Researchers and Research Staff to obtain answers to questions, express concerns, and convey suggestions regarding the HRPP.

Outcomes

- Researchers and Research Staff know how to obtain answers to questions regarding the HRPP.
- Researchers and Research Staff know how to express concerns or convey suggestions about the HRPP.
- Researchers and Research Staff find the Organization responsive to their questions, concerns, and suggestions.

Element I.5.D. The Organization has and follows written policies and procedures for addressing allegations and findings of non-compliance with Human Research Protection Program requirements. The Organization works with the Institutional Review Board or Ethics Committee, when appropriate, to ensure that participants are protected when non-compliance occurs. Such policies and procedures include reporting these actions, when appropriate.

Commentary

Non-compliance refers to not following laws or regulations that govern research involving human participants, the Organization's policies and procedures, or the requirements or determinations of the IRB or EC. Non-compliance can be relatively minor or serious. Non-compliance can also be a one-time event or a continuing problem. Policies and procedures should consider a range of corrective actions that are applicable to the spectrum of non-compliance. Corrective actions should be appropriate to the nature and degree of the non-compliance. Some laws or regulations specify reporting requirements to regulatory agencies, Sponsors, or other entities that should be incorporated into the Organization's policies and procedures.

[See AAHRPP Tip Sheets 14, 15, and 21.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.103(b)(5)(i), 45 CFR 46.116(b)(5), OHRP Guidance on Reporting Incidents to OHRP
- FDA: 21 CFR 50.25(b)(5), 21 CFR 56.108(b)(2)
- VA: 38 CFR 16.103(b)(5)(i), 38 CFR 16.116(b)(5), VHA Handbook 1200.05, 14,29, VHA Handbook 1058.01
- DoD: DoDD 3216.2, para. 4.10; SECNAVINST 3900.39D, para. 8d(2) and 6k;

Required Written Materials

- Essential requirements:
 - Policies and procedures define:
 - Non-compliance.
 - Serious non-compliance.
 - Continuing non-compliance.
 - Policies and procedures describe the various mechanisms for informing the Organization or IRB or EC of non-compliance:
 - Reporting requirements for Researchers, staff, and employees.
 - Consideration of complaints and protocol deviations.
 - Results of audits.
- Policies and procedures describe:
 - The Organization's process to decide whether each allegation of non-compliance has a basis in fact.
 - The Organization's process to decide whether each incident of non-compliance is serious or continuing.
- Policies and procedures describe the Organization's process to manage non-compliance that is neither serious nor continuing.
- Policies and procedures describe the process for management of serious or continuing non-compliance by the convened IRB or EC, including:
 - If a primary reviewer system is used, documents distributed to primary reviewers.
 - Documents distributed to all IRB or EC members.
 - The range of possible actions considered by the IRB or EC:
 - Required actions:
 - Suspension of IRB approval the research.
 - Termination of IRB approval the research.
 - Notification of current participants when such information might relate to participants' willingness to continue to take part in the research.
 - Optional actions:
 - Modification of the protocol.
 - Modification of the information disclosed during the consent process.
 - Providing additional information to past participants.
 - Requiring current participants to re-consent to participation.
 - Modification of the continuing review schedule.
 - Monitoring of the research.
 - Monitoring of the consent process.
 - Referral to other organizational entities.
- Policies and procedures describe the reporting of serious or continuing non-compliance, including:
 - A requirement for the report to be distributed to:
 - Specific organizational officials.
- Other agencies when the research is overseen by those agencies.

- The maximum time allowed between the recognition of a reportable event and fulfilling reporting requirements.
 - When following DHHS regulations and guidance:
 - Policies and procedures describe the reporting of serious or continuing non-compliance to OHRP.
 - When following FDA regulations and guidance:
 - Policies and procedures describe the reporting of serious or continuing non-compliance to FDA.
 - When following VA regulations and guidance:
 - Policies and procedures include the following definitions, procedures, and timeframes:
 - Serious and continuing non-compliance:
 - Serious non-compliance is a failure to adhere to the laws, regulations, or policies governing research involving human participants that may reasonably be regarded as:
 - Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research participants, research staff, or others.
 - Substantively compromising the effectiveness of a VA facility's HRPP.
 - Continuing non-compliance is a persistent failure to adhere to the laws, regulations, or policies governing human research.
 - The determination that non-compliance is "serious" or "continuing" rests with the IRB.
 - Apparent serious or continuing non-compliance:
 - Within five business days of becoming aware of any apparent or possible serious or continuing non-compliance, members of the VA research community are required to ensure that the apparent non-compliance has been reported in writing to the IRB.
 - Research compliance officer reports of apparent serious or continuing non-compliance.
 - Within five business days of identifying apparent serious or continuing non-compliance based on an consent document audit, regulatory audit, or other systematic audit of VA research, the research compliance officer must provide a written report of the apparent non-compliance directly (without intermediaries) to:
 - Medical center director.
 - Associate chief of staff for research
 - The Research and Development Committee
 - The IRB
 - Other relevant research review committees.
 - Within five business days of receiving such notification, the medical center director must report the apparent serious or continuing non-compliance to:
 - The appropriate Office of Research Oversight research officer.
 - Veterans Integrated Service Network (VISN) director.
 - Office of Research Development.
- IRB review of apparent serious or continuing non-compliance.
 - The IRB must review a report of apparent serious or continuing non-compliance at its next convened meeting.
 - Should the IRB determine that the reported incident constitutes serious non-compliance or continuing non-compliance, within five business days after the determination the IRB chair, or designee must provide a written report of the determination directly to:
 - Medical center director.
 - Associate chief of staff for research.
 - Research and Development Committee
 - Other relevant research review committee.
 - Unless the non-compliance has already been reported, within five business days after receiving such notification, the medical center director must report the determination to:
 - The appropriate Office of Research Oversight research officer.
 - The VISN director.
 - Office of Research Development.
 - An initial report of an IRB determination that serious non-compliance or continuing non-compliance occurred is required, even where the determination is preliminary or disposition of the matter has not been resolved at the time of the report.
 - The IRB must reach a determination that serious or continuing non-compliance did (or did not) occur within 30-45 days after receiving a report of apparent non-compliance.
 - Remedial actions involving a specific study or research team must be completed within 90-120 days after the IRB's determination.

- Remedial actions involving programmatic non-compliance must be completed within 120-180 days after the IRB's determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, or legal negotiations.
- Members of the VA research community must report possible serious or continuing non-compliance with VA or other federal requirements related to human research or with IRB requirements or determinations to the associate chief of staff for research and development and the IRB within five business days after becoming aware of it.
- Policies and procedures describe the reporting of serious or continuing non-compliance to:
 - The Office of Research and Development, if VA-funded.
 - The Regional Office of Research Oversight.
 - The VA Privacy Office, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information.
 - The VHA Information Security Officer when the report involves violations of VA information security requirements.
- A research compliance officer identifying serious or continuing noncompliance, during an informed consent or regulatory audit, must report the noncompliance to the facility director, the associate chief of staff for research and development, the Research and Development Committee, and the IRB as soon as possible but no later than five business days after becoming aware of the noncompliance.
- IRBs of academic affiliates that are the IRB of record for VA facilities must follow the VA requirements.
- When following Department of Defense (DoD) regulations and requirements:
 - Policies and procedures describe the reporting of serious or continuing non-compliance to DoD.

Outcomes

- Researchers and Research Staff report allegations of non-compliance to the IRB or EC.
- Non-compliance is identified and managed.
- The IRB or EC or organizational official reports serious or continuing non-compliance as required.

Standard I-6: The Organization has and follows written policies and procedures to ensure that research is conducted so that financial conflicts of interest are identified, managed, and minimized or eliminated.

Element I.6.A. The Organization has and follows written policies and procedures to identify, manage, and minimize or eliminate financial conflicts of interest of the Organization that could influence the conduct of the research or the integrity of the Human Research Protection Program.

Commentary

An Organization that conducts or reviews research involving human participants has an obligation to protect the rights and welfare of participants, ensure the integrity of the research, and ensure the credibility of the HRPP.

An Organization or key organizational leaders sometimes have financial interests that conflict with the Organization's obligation to protect participants, preserve the integrity of the research, or maintain the credibility of the HRPP. For example, an Organization or key organizational leader might have a proprietary or ownership interest in research that is being reviewed or conducted by the Organization. The fact that a financial interest exists does not necessarily indicate that an Organization will act contrary to the best interests of research participants. Policies and procedures should describe the process the Organization uses to identify, evaluate, manage, and minimize or eliminate such interests.

Regulatory and Guidance References

- VA: VHA Standards of Ethical Conduct for Employees of the Executive Branch

Required Written Materials

- Essential requirements:
 - Policies and procedures provide a definition of organizational financial conflict of interest that includes:
 - Licensing, technology transfer, patents
 - Investments
 - Gifts
 - Financial interests of senior administrators
 - Other financial interests
 - Policies and procedures describe the process to identify or disclose financial conflicts of interest of the Organization:
 - A policy addressing financial conflict of interest pertaining to technology transfer and patents is not

required if this matter is addressed in other policies and procedures.

- A separate policy addressing the identification and management of financial conflicts of interest of senior administrative officials is not required, if this is covered in the Organization's financial conflict of interest policy for individuals.
- Policies and procedures describe the process that the Organization uses to evaluate organizational financial conflict of interest.
 - The evaluation criteria do not vary by funding or regulatory oversight.
- Policies and procedures describe the process the committee or individual who evaluates and manages financial interests of the Organization uses to inform the IRB or EC of the evaluation, including any management plan, when appropriate.

Common Types of Materials That May Be Used to Meet the Element

- Financial disclosure form
- Organizational policy and procedure on individual conflict of interest that cover senior administrative officials
- Organizational policy and procedure on technology transfer and patents

Outcomes

- The Organization follows policies and procedures for recognizing and managing organizational financial conflicts of interest.
- Financial conflicts of interest are identified, managed, and minimized or eliminated to maintain protection of research participants, ensure the integrity of the research, and ensure the credibility of the HRPP.

Element I.6.B. The Organization has and follows written policies and procedures to identify, manage, and minimize or eliminate individual financial conflicts of interest of Researchers and Research Staff that could influence the conduct of the research or the integrity of the Human Research Protection Program. The Organization works with the Institutional Review Board or Ethics Committee in ensuring that financial conflicts of interest are managed and minimized or eliminated, when appropriate.

Commentary

A financial conflict of interest of a Researcher or Research Staff can be broadly defined to refer to any financial interest that competes with the Researcher's or Research Staff's obligation to protect the rights and welfare of research participants. Not all financial interests are equal. Provided that Researchers and Research Staff understand and act upon their obligation to protect participants, some financial interests will not interfere with their obligation to protect participants, while others might interfere. An Organization should have a process to identify the financial interests of Researchers and Research Staff and judge which financial interests affect the protection of participants and which do not.

The primary goals of the conflict of interest policy are to prevent financial interests from adversely affecting the protection of participants, the credibility of the HRPP. The process to manage these types of interests usually involves three steps: 1) Financial interests are disclosed to the Organization; 2) Financial interests are evaluated to judge whether they might adversely affect the protection of participants or the credibility of the HRPP; 3) Problematic financial interests are managed or eliminated so they no longer affect the protection of participants or the credibility of the HRPP.

Financial interests that might adversely affect the protection of participants should be managed. An Organization has several options for managing financial interests, such as partial or complete financial divestiture, requiring an independent Researcher to obtain consent or conduct the research, independent safety monitoring, frequent continuing review, or disapproval of the research. An Organization may also elect to disclose the financial interests and their management to participants.

Funding agencies and regulatory agencies have various criteria for reporting, evaluating, and managing financial interests. An Organization should consider policies and procedures for disclosure, evaluation, and management of financial interests of Researchers and Research Staff that do not vary according to funding source or regulatory oversight.

When funding or regulatory agencies have reporting requirements, the Organization should have policies and procedures to ensure that reporting requirements are met.

[See AAHRPP Tip Sheet 10.](#)

Regulatory and Guidance References

- DHHS: 42 CFR 50, 45 CFR 690
- FDA: 21 CFR 54.2(a)-(d), 21 CFR 54.2(f), 21 CFR 54.4(a)(3), 21 CFR 54.4(b)
- VA: VHA Handbook 1200.1 7, VHA Handbook 1200.05, 9
- DoD: DoDD 3216.2, para. 4.4.4; SECNAVINST 3900.39D, para. 6b

Required Written Materials

- Essential requirements:
 - Policies and procedures define the financial interests of Researchers and Research Staff for which the Organization requires disclosure.
 - Policies and procedures require disclosure of:
 - Financial interests of Researchers and Research Staff.
 - Financial interests of immediate family members.
 - Policies and procedures define immediate family members.
 - Immediate family members at a minimum include the spouse and each dependent child.
 - Financial interests that require disclosure include:
 - For Organizations that must follow Public Health Service (PHS) and FDA regulations: Both PHS and FDA regulations.
 - For Organizations that must follow only FDA regulations: FDA regulations.
 - For Organizations that must follow PHS and National Science Foundation (NSF) regulations: Both PHS and NSF regulations.
 - For organizations that must follow only PHS research: PHS regulations.
 - For organizations that must follow only NSF regulations: NSF regulations.

- For organizations that are not required to follow FDA, NSF, or PHS regulations: Disclosures equivalent to FDA, NSF, or PHS regulations.
- Others: Evaluate on a case-by-case basis.
- Disclosure criteria do not vary by funding or regulatory oversight.
- Policies and procedures describe the process the Organization uses to evaluate financial interests.
 - The evaluation criteria do not vary by funding or regulatory oversight.
- If a committee or individual other than the IRB or EC evaluates and manages financial interests of Researchers and Research Staff, policies and procedures describe:
 - The process to inform the IRB or EC of the results of this evaluation, including any management plan.
 - The process that allow the IRB or EC to have the final authority to decide whether the interest and

its management, if any, allows the research to be approved.

- Policies and procedures ensure that reporting requirements for funding or regulatory agencies are met.

Common Types of Materials That May Be Used to Meet the Element

- Financial disclosure form
- Organizational policy and procedure on Researcher conflict of interest
- Reviewer checklist

Outcomes

- Conflicts of interest are identified, managed, and minimized to maintain protections of participants, ensure the integrity of research, and ensure the credibility of the HRPP.
- Conflicts of interest are reported to regulatory agencies when required by policies and procedures.

Standard I-7: The Organization has and follows written policies and procedures to ensure that the use of any investigational or unlicensed test article complies with all applicable legal and regulatory requirements.

Element I.7.A. When research involves investigational or unlicensed test articles, the Organization confirms that the test articles have appropriate regulatory approval or meet exemptions for such approval.

Commentary

This Element applies only to an Organization that conducts research or an independent IRB or EC that oversees research involving investigational articles regulated by a national regulatory body (e.g., the U.S. FDA).

As an example using the U.S. FDA requirements, research that involves the use of a drug other than a marketed drug in the course of medical practice must have an investigational new drug (IND), unless the research meets one of the five exemptions from the requirement for an IND (21 CFR 312.2(b)). When research involves the use of a drug other than marketed drug in the course of medical practice, the Organization should confirm that the drug either has an IND or the protocol meets one of the FDA exemptions from the requirement to have an IND.

Under FDA regulations, research that is conducted to determine the safety or effectiveness of a device must have an IDE issued by the FDA, unless the device meets the requirements for an abbreviated investigational device exemption (IDE) (21 CFR 812.2(b)(1)) or the research meets one of the five exemptions from the requirement for an IDE (21 CFR 812.2(c)).

When research is conducted to determine the safety or effectiveness of a device, Organizations should confirm that the device has an IDE, the device fulfills the requirements for an abbreviated IDE, or the research meets one of the FDA exemptions from the requirement to have an IDE. When research involves a drug or device with an IND or IDE, respectively, the Organization should evaluate whether the IND or IDE number is valid. This prevents situations where Researchers begin FDA-regulated studies that require an IND or IDE before the FDA has issued a number. Validation can be done by determining that the IND or IDE number matches the Sponsor protocol, communication from the Sponsor, or communication from the FDA. In the case of a Researcher who holds the IND or IDE, the number should match

information provided by the FDA. An investigator's brochure should not be used because one investigator brochure often covers multiple INDs or IDEs.

Regulatory and Guidance References

- FDA: 21 CFR 11, 21 CFR 54, 21 CFR 210, 21 CFR 211, 21 CFR 312, 21 CFR 314, 21 CFR 320, 21 CFR 330, 21 CFR 601, 21 CFR 807, 21 CFR 812, 21 CFR 814, 21 CFR 820, 21 CFR 860]
- VA: VHA Handbook 1108.04, VHA Handbook 1200.05, 39

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the legal and regulatory requirements that apply to the use of investigational test articles.
 - Policies and procedures describe the process the Organization uses to confirm that test articles have appropriate regulatory approval, such as a clinical trial certificate or an IND or IDE, or meet exemption requirements for such approvals.
- When following FDA regulations and guidance:
 - When research involves the use of a drug other than a marketed drug in the course of medical practice, policies and procedures describe the process to confirm that:
 - The drug has an IND or the research meets one of the FDA exemptions from the requirement to have an IND.
 - When research is conducted to determine the safety or effectiveness of a device, policies and procedures describe the process to confirm that the device has an IDE issued by the FDA, the device fulfills the requirements for an abbreviated IDE, or the research meets one of the FDA exemptions from the requirement to have an IDE.

- The IRB or EC makes a determination whether the device is a significant or non-significant risk device.
- When research involves a drug with an IND or a device with an IDE, policies and procedures describe the process to confirm that the IND or IDE number is valid.
- When following VA regulations and guidance:
 - Policies and procedures have the Researcher:
 - Ensure the local Pharmacy Service or Research Service Investigational Pharmacy receives:
 - Documentation of IRB and any other relevant approvals.
 - A copy of VA Form 10-9012 (if applicable).
 - A copy of the current approval protocol.
 - A copy of the consent document for each participating participant with all appropriate signatures.
 - Documentation of IRB continuing review approval.
 - Copies of sponsor-related correspondence specific to the drugs as appropriate.
 - Copies of all correspondence addressed to the Researcher from the FDA specific to the investigational drugs as appropriate.
 - Inform the chief, pharmacy service, the research pharmacy when applicable, and the IRB in writing with a study involving

investigational drugs has been suspended, terminated, or closed.

- Comply with all dispensing requirements.
- Comply with all documentation requirements and make relevant records accessible to the investigational drug pharmacist when requested.

Common Types of Materials That May Be Used to Meet the Element

- Application form
- Reviewer checklist

Outcomes

- Research involving the use of investigational articles complies with regulations governing investigational articles.

Element I.7.B. The Organization has and follows written policies and procedures to ensure that the handling of investigational or unlicensed test articles conforms to legal and regulatory requirements.

Commentary

This Element applies only to an Organization that conducts research with investigational or unlicensed test drugs or devices or an independent IRB or EC that reviews a Researcher's plan to control test articles.

An Organization should describe the process for handling investigational or unlicensed test articles so that they are used only in approved protocols and under the direction of approved Researchers. Possible methods Organizations can use to control investigational drugs and devices are:

- Protocol-by-protocol review and approval of the Researcher's plan to control test articles along with training or evaluation of Researchers on knowledge and compliance with the plan.
- Organizational control of test articles. For example, Organizations can control investigational drugs by having a pharmacy store them and dispense them only under the prescription of an approved Researcher.

Procedures for the control of investigational drugs and devices should apply to all settings in which the Organization uses investigational drugs and devices, such as inpatient, outpatient, on-site, and off-site settings.

[See AAHRPP Tip Sheet 11.](#)

Regulatory and Guidance References

- FDA: 21 CFR 312.61, 21 CFR 312.62, 21 CFR 312.69, 21 CFR 812.100, 21 CFR 812.110, 21 CFR 812.140(a)
- ICH-GCP: 2.12, 4.6.1, 4.6.2 – 4.6.4

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the control of investigational drugs.

- Policies and procedures describe the control of investigational devices.
- When following ICH-GCP guidance (E6):
 - Policies and procedures include:
 - A description of the manufacturing, handling, and storage in accordance with applicable good manufacturing practice.
 - Where allowed or required, the Researcher or Organization assigns some or all duties for investigational articles accountability at the clinical trial sites to an appropriate pharmacist or another appropriate individual who is under the supervision of the Researcher or Organization.
 - The Researcher, pharmacist, or other designated individual maintains records of the product's delivery to the clinical trial site, the inventory at the site, the use by each participant, and the return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial participants.
 - The Researcher maintains records that document adequately that the participants are provided the doses specified by the protocol and reconcile all investigational products received from the Sponsor.

Outcomes

- Investigational test articles are used only in approved research protocols and under the direction of approved Researchers.
- The Organization has a process to ensure the proper handling of investigational test articles.

Element I.7.C. The Organization has and follows written policies and procedures for compliance with legal and regulatory requirements governing emergency use of an investigational or unlicensed test article.

Commentary

This Element applies only to Organizations that use investigational or unlicensed test articles in emergency situations, and the use constitutes research and is regulated. The Element also applies to independent IRBs or ECs that review research involving the emergency use of test articles.

Under the U.S. FDA regulations, the use of an investigational test article in an emergency situation is usually exempt from prior IRB or EC review. This exemption is used in a life-threatening situation in which no standard acceptable treatment is available and in which there is insufficient time to obtain IRB or EC approval.

Even without IRB or EC review, the consent of the participant or the participant's legally authorized representative should be obtained in order to use the investigational article. There are situations in which an exception can be made to the requirement to obtain consent.

An Organization should allow Researchers to notify the Organization in advance of an emergency use to obtain guidance. The Organization should review these notifications to determine whether the circumstances will follow regulatory or legal requirements for the emergency use of a test article.

The IRB or EC should be notified of all emergency uses within five days of the use and notified in writing of all exceptions to the requirement for consent within five days of the exception. IRBs or ECs should review these reports to determine whether the circumstances follow regulatory requirements for the emergency use of a test article, and whether consent was obtained in accordance with regulations or the circumstances met the exception to the requirement for consent.

The Organization should monitor the emergency use of test articles to ensure that continued use does not occur, which constitutes research.

Regulatory and Guidance References

- FDA: 21 CFR 50.23, 21 CFR 50.24, 21 CFR 50.25(d), 21 CFR 56.102(d), 21 CFR 56.104(c), FDA Information Sheets: Frequently Asked Questions: IRB Procedures, FDA Information Sheets: Emergency Use of an Investigation Drug or Biologic, Emergency Use of Unapproved Medical Devices

- VA: VHA Handbook 1200.05, 41

Required Written Materials

- Essential requirements:
 - In order to use a test article in an emergency situation, policies and procedures describe the criteria that permit the emergency use of a test article.
 - Policies and procedures indicate consent will be obtained in accordance with regulations or laws or meet the requirements for an exception to obtain consent.
 - Policies and procedures describe the role of the IRB or EC as appropriate.
- When following DHHS regulations and guidance:
 - Policies and procedures state that patients receiving a test article in an emergency use as defined by FDA regulations may not be considered to be a research participant.
 - DHHS regulations do not permit data obtained from patients to be classified as human participants research, nor permit the outcome of such care to be included in any report of a research activity subject to DHHS regulations.
- When following FDA regulations and guidance:
 - In order to use a test article in a life threatening situation without prior IRB or EC review, policies and procedures include the following criteria:
 - The participant is in a life-threatening or severely debilitating situation.
 - No standard acceptable treatment is available.
 - There is not sufficient time to obtain IRB or EC approval.
 - The use is reported to the IRB or EC within five working days.
 - Any subsequent use of the test article is subject to IRB or EC review.
 - Policies and procedures indicate consent will be obtained in accordance with FDA regulations, or the circumstances meet the exception to the requirement for consent in FDA regulations.
 - Policies and procedures state that under FDA regulations, the emergency use of a test article, other than a medical device, is a clinical investigation, the patient is a participant, and the

FDA may require data from an emergency use to be reported in a marketing application.

- When following VA regulations and guidance:
 - Policies and procedures state that a patient receiving a test article in an emergency use that is regulated by FDA is not considered to be involved in research and is not a research participant.
 - VA regulations pertaining to research involving human participants do not permit data obtained from patients to be classified as human participants research, nor may the outcome of such care be included in any report of a research activity subject to VA regulations

pertaining to research involving human participants.

Common Types of Materials That May Be Used to Meet the Element

- Policies and procedures

Outcomes

- Emergency uses of investigational or unlicensed test articles follow regulations or laws.

Standard I-8: The Organization works with public, industry, and private Sponsors to apply the requirements of the Human Research Protection Program to all participants.

Element I.8.A. The Organization has a written agreement with the Sponsor that addresses medical care for research participants with a research-related injury, when appropriate.

Commentary

When appropriate, arrangements for medical care for research-related injury should be defined before the research starts and communicated to prospective participants (see Element II.3.F). This Element does not require any particular party, among the Organization, Sponsor or its agents, or participant to be responsible for such care; it requires that it be made clear to participants who will provide medical care and who will be responsible to pay for it.

This Element primarily applies only to the Organization that conducts clinical research. If an Organization conducts other types of research in addition to clinical research, this Element is generally not applicable, although there might be instances where research-related injury requiring medical care could occur. The Organization should evaluate the risk of injury in the research conducted under its auspices and should make determinations whether medical care for research-related injury might be needed.

Regulatory and Guidance References

- DHHS: 45 CFR 46.116(a)(6), 45 CFR 46.116(a)(7),
- FDA: 21 CFR 50.25(a)(6), 21 CFR 50.25(a)(7)

Required Written Materials

- Essential requirements:
 - Policies and procedures have contracts or other funding agreements indicate who will provide care and who is responsible to pay for it.
- For independent IRBs:
 - If the Organization contracts with Sponsors or clinical research organizations, contracts or other funding agreements state that Sponsors are required to indicate who will provide care and who is responsible to pay for it.
 - Policies and procedures include the process used to obtain an attestation or other written statement from the Researcher or clinical research organization that contracts indicate who will provide care and who is responsible to pay for it.

Common Types of Materials That May Be Used to Meet the Element

- Contract template
- Reviewer checklist for contract language

Outcomes

- When appropriate, arrangements for medical care for research-related injury are defined before the research starts.

Element I.8.B. In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Organization has a written agreement with the Sponsor that the Sponsor promptly reports to the Organization findings that could affect the safety of participants or influence the conduct of the study.

Commentary

This Element does not apply when the Sponsor is not responsible for monitoring the research. Monitoring of the research refers to overseeing the progress of a research study. An Organization that works directly with a Sponsor should require the Sponsor or its agents to report to the Organization findings of serious or continuing non-compliance detected during the monitoring process that could affect the safety of participants or influence the conduct of the study.

If an independent IRB or EC or an Organization does not work directly with the Sponsor, the independent IRB or EC or Organization should have a mechanism to ensure it receives copies of the monitoring reports that contain findings that could affect the safety of participants or influence the conduct of the study. An Organization in this case should make the findings available to the IRB or EC.

Regulatory and Guidance References

- None

Required Written Materials

- Essential requirements:
 - Policy and procedures have contracts or other funding agreements require the Sponsor to promptly report to the Organization any findings that could:
 - Affect the safety of participants.
 - Influence the conduct of the study.
- For independent IRBs:
 - If the Organization contracts with Sponsors or clinical research organizations, contracts or other funding agreements state that Sponsors are

required to promptly report to the IRB findings that could affect the safety of participants or influence the conduct of the study.

- Policies and procedures include the process used to obtain an attestation or other written statement from the Researcher or clinical research organization that contracts obligate the Sponsor to promptly report any findings of study monitors that could affect the safety of participants or influence the conduct of the study to the Researcher or organization conducting the research.
- Policies and procedures require Researchers or the organization conducting the research to promptly forward this information to the IRB.

Common Types of Materials That May Be Used to Meet the Element

- Contract template
- Reviewer checklist for contract language

Outcomes

- Contracts and other funding agreements require the Sponsor to promptly report to the Organization any findings that could:
 - Affect the safety of participants.
 - Influence the conduct of the study.
- An independent IRB or EC or an Organization that does not work directly with the Sponsor has a mechanism to receive findings that could affect the safety of participants or influence the conduct of the study. An Organization in this case makes the findings available to the IRB or EC.

Element I.8.C. When the Sponsor has the responsibility to conduct data and safety monitoring, the Organization has a written agreement with the Sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the Organization.

Commentary

IRB or ECs have the responsibility to ensure that provisions for data and safety monitoring are adequate and that results from data and safety monitoring justify the continuation of IRB or EC approval of the research study.

When the Organization works directly with the Sponsor, or its agent, and the Sponsor, or its agents, has the responsibility for data and safety monitoring, the contract or funding agreement should include arrangements so that data and safety monitoring plans are provided to the Organization or provided to the Researcher who provides them to the IRB or EC. Contracts and funding agreements should stipulate that reports from data and safety monitoring are provided to the Researcher who provides them to the IRB or EC.

If an independent IRB does not work directly with the Sponsor, it should have a mechanism to ensure it receives the data and safety monitoring plan in order to review the research study and results of the data and safety monitoring to ensure that continuation of IRB or EC approval of the research study is justified.

Regulatory and Guidance References

- None

Required Written Materials

- Essential requirements:
 - Policies and procedures have contracts or other funding agreements require the Sponsor to send data and safety monitoring reports to the Organization.

- Contracts or other funding agreements specify the time frame for providing routine and urgent data and safety monitoring reports to the Organization.
- For independent IRBs:
 - If the Organization contracts with Sponsors or clinical research organizations, contracts or other funding agreements state that Sponsors are required to send routine and urgent data and safety monitoring reports to the IRB.
 - Policies and procedures include the process used to obtain an attestation or other written statement from the Researcher or clinical research organization that contracts obligate the Sponsor to send routine and urgent data and safety monitoring reports to the Researcher or organization conducting the research.
 - Policies and procedures require Researchers or the organization conducting the research to forward this information to the IRB.

Outcomes

- Contracts or other funding agreements require the Sponsor to provide reports of data and safety monitoring to the Organization.
- The independent IRB or EC has a mechanism to ensure it receives data and safety monitoring plans prior to IRB or EC approval of the research.
- The independent IRB or EC has a mechanism to ensure it receives routine and urgent reports of data and safety monitoring.

Element I.8.D. Before initiating research, the Organization has a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that Researchers and Sponsors will play in the publication or disclosure of results.

Commentary

If the Organization has a policy regarding the publication of findings from Sponsored research and works directly with a Sponsor or its agents, contracts or other funding agreements should require the Sponsor to follow that policy and procedure.

This Element does not apply to the Organization that does not directly work with Sponsors or to the Organization that has no policy regarding the dissemination of findings from sponsored research.

Regulatory and Guidance References

- None

Required Written Materials

- Essential requirements:
 - Policies and procedures have contracts or other funding agreements require the Sponsor to follow the Organization's policies and procedures regarding the publication of findings from sponsored research.

Outcomes

- Contracts or other funding agreements require the Sponsor to follow the Organization's policies and procedures regarding the publication of findings from sponsored research.

Element I.8.E. When participant safety could be directly affected by study results after the study has ended, the Organization has a written agreement with the Sponsor that the Researcher or Organization will be notified of the results in order to consider informing participants.

Commentary

In some cases, findings emerge after a research study has ended that directly affect the safety of past participants and were not anticipated at the time the study was designed or conducted. In such cases, past participants should be notified of the new findings. An Organization that works directly with a Sponsor or its agents should include in the contract or other agreement how such results will be communicated to the Organization.

Regulatory and Guidance References

- None

Required Written Materials

- Essential requirements:
 - Policies and procedures have contracts or other funding agreements describe the steps followed to communicate findings from a closed research study to the Researcher or Organization when those findings directly affect participant safety.
 - Policies and procedures have contracts or other funding agreements specify a time frame after closure of the study during which the Sponsor will communicate such findings (e.g., two years).
- For independent IRBs:
 - If the Organization contracts directly with Sponsors or clinical research organizations,

contracts or other funding agreements include a requirement that Sponsors communicate findings from a closed research study to the IRB when those findings directly affect participant safety.

- Specify a time frame after closure of the study during which the Sponsor will communicate such findings (e.g., two years), when appropriate.
- Policies and procedures include the process used to obtain an attestation or other written statement from the Researcher or clinical research organization that contracts obligate the Sponsor to notify the Researcher or organization conducting the research any study results after the study has ended that could directly affect participant safety.
- Specify a time frame after closure of the study during which the Sponsor will communicate such findings (e.g., two years), when appropriate.
- Policies and procedures require Researchers or the organization conducting the research to forward this information to the IRB.

Outcomes

- Contracts and other funding agreements describe the steps followed to communicate results from a research study to former participants when those results directly affect their safety or medical care.

Domain II: Institutional Review Board or Ethics Committee

Commentary

Within a Human Research Protection Program (HRPP), responsibilities must be delegated for providing ethical review and oversight of research. These responsibilities are distributed differently in different organizations; in many organizations, the Institutional Review Board (IRB) or Ethics Committee (EC), along with the support personnel and systems, provide these functions. In more complex organizations, there might be multiple IRBs and a general oversight office. This Domain of

Standards sets forth requirements for the ethical oversight of research.

An IRB or EC is a body established generally under laws, regulations, codes, and guidance to protect the rights and welfare of human research participants. The HRPP must have mechanisms in place to ensure the independence of its ethics review and oversight functions from other units within the Organization, particularly with respect to decision-making regarding the ethics of research involving human participants. IRB or EC structure, composition, operations, and review standards are set forth in laws, regulations, codes, and guidance.

Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws, regulations, codes, and guidance.

Element II.1.A. The IRB or EC membership permits appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB or EC roster. The IRB or EC has one or more unaffiliated members; one or more members who represent the general perspective of participants; one or more members who do not have scientific expertise; one or more members who have scientific or scholarly expertise; and, when the IRB or EC regularly reviews research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants.

Commentary

Laws, regulations, codes, and guidance usually define the requirements of the IRB or EC membership roster. The information in this roster should be used to provide for effective review of research and management of the IRB or EC. For example, if the IRB or EC directs protocols to primary reviewers with scientific or scholarly expertise, the information in the IRB or EC roster should be sufficient to implement this function. The IRB or EC roster should include at least one member who represents the perspective of research participants, such as a former or current research participant or a research participant advocate.

At least one individual whose primary interest is non-scientific and at least one non-affiliated member should attend meetings. IRB or EC minutes should demonstrate that IRB or EC meetings were convened with members appropriately representing regulatory

or legal requirements and the general perspective of participants.

When the IRB or EC reviews research that involves categories of participants vulnerable to coercion or undue influence, if there is not at least one person who is knowledgeable about or experienced in working with such participants present at the meeting, the IRB or EC should defer review until such expertise can be obtained through membership or consultation.

[See AAHRPP Tip Sheets 18 and 22.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.103(b)(3), 45 CFR 46.108(b), OHRP Step-by-Step Instructions on Registering an Institutional Review Board (IRB) or Independent EC (IEC)
- FDA: 21 CFR 56.108(c), 21 CFR 56.115(a)(5), FDA Information Sheets: Frequently Asked Questions: IRB Membership, FDA Information

Sheets: Frequently Asked Questions: IRB Procedures

- VA: 38 CFR 16.103(b)(3), 38 CFR 16.108(b), VHA Handbook 1058.01, VHA Handbook 1200.05,7, 12
- ICH-GCP: 3.2.1, 3.2.3, 3.2.4

Required Written Materials

- Essential requirements:
 - IRB or EC rosters include:
 - Names.
 - Earned degrees.
 - Representative capacities.
 - Scientific/nonscientific status.
 - Affiliation status (whether the IRB or EC member or an immediate family member of the IRB or EC member is affiliated with the Organization).
 - Indications of experience sufficient to describe each IRB or EC member's chief anticipated contributions.
 - Employment or other relationship between each IRB or EC member and the Organization.
 - Alternate members.
 - The primary members or class of primary members for whom each alternate member can substitute.
 - According to IRB or EC rosters:
 - Each IRB or EC has at least five members with varying backgrounds to promote complete and adequate review of research commonly conducted by the Organization.
 - No IRB or EC has members who are all males or all females.
 - No IRB or EC has members who represent a single profession.
 - Each IRB or EC has at least one member whose primary concerns are in scientific areas.
 - Each IRB or EC has at least one member whose primary concerns are in nonscientific areas.
 - Each IRB or EC has at least one member who is not otherwise affiliated with the Organization and who is not part of the immediate family of a person who is affiliated with the Organization.
 - Each IRB or EC has at least one member who represents the perspective of research participants.
- When following VA regulations and guidance:
 - For a VA using an academic affiliate's IRB or other local VA facility's IRB, policies and procedures indicate:
 - The IRB includes two or more VA employees who hold a minimum of 5/8ths VA-compensated appointments to serve as voting members unless a waiver is obtained from the chief research and development officer.
 - Individuals working on without compensation appointments from the VA facility and those with intergovernmental personnel act (IPA) appointments cannot be VA representatives.
 - At least one VA representative has scientific expertise.
 - The VA representatives serve as full members of the IRB and reviewed non-VA research matters coming before the IRB.
 - Policies and procedures indicate:
 - Veterans whose only relationship with the VA facility is receiving care at a VA facility or receiving benefits from the Veterans Benefits Administration are not considered to be affiliated for the purpose of being an IRB member. Individuals who perform occasional volunteer activities without compensation (WOC) are not considered affiliated. However, those who hold a WOC appointment for volunteer activities other than IRB service are considered to be affiliated. Individuals who have retired from the VA and who are receiving VA retirement benefits are considered affiliated.
 - The non-affiliated voting member must be given a VA WOC appointment if the non-affiliated voting member is performing the duties and responsibilities of an IRB voting member.
 - Officials in Research and Development administration including, but not limited to, the associate chief of staff for research and development and the administrative officer for research and development, and IRB administrative staff, do not serve as voting members of the IRB.
 - The research compliance officer may serve as a non-voting consultant, as needed, to the VA facility's IRB. The research compliance officer may not serve as a voting or non-voting member of the IRB. The research compliance officer may attend meetings of

the IRB when requested by the IRB or as specified by local procedure. These requirements are also relevant for an affiliate IRB.

Common Types of Materials That May Be Used to Meet the Element

- IRB or EC roster

Outcomes

- The IRB or EC roster contains all the required categories and information.
- The composition of the IRB or EC is periodically evaluated and, when necessary, adjusted so that the membership and composition of the IRB or EC meet legal or regulatory and organizational requirements.

Element II.1.B. The IRB or EC has qualified leadership (e.g., chair and vice chair) and qualified members and staff. Membership and composition of the IRB or EC are periodically reviewed and adjusted as appropriate.

Commentary

IRB or EC chairs, members, and staff involved in review should have the knowledge, skills, and abilities necessary to carry out the function of the IRB or EC. Which individuals have this expertise is unimportant, provided the expertise is available and applied. For example, the IRB or EC should have an in-depth understanding of applicable regulations relevant to research conducted by the Organization.

Policies and procedures should define the requirements to be an IRB or EC chair, member, staff, and describe the periodic evaluation of their performance. Policies and procedures should describe the periodic review and adjustment of the membership and composition of the IRB or EC.

[See AAHRPP Tip Sheet 7.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.107, 45 CFR 46.304, OHRP Guidance on Written Institutional Review Board (IRB) Procedures
- FDA: 21 CFR 56.107, FDA Information Sheets: Non-Local IRB Review, IRB Membership
- VA: 38 CFR 16.107, VHA Handbook 1200.05, 12
- ICH-GCP: 3.2.1, 3.3.1

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the appointment of:
 - IRB or EC members.
 - IRB or EC chairs and vice-chairs when appropriate.
 - Alternate members.
 - Policies and procedures describe the function of alternate members.
 - Policies and procedures describe the periodic assessment and feedback provided to:
 - IRB or EC members.

- IRB or EC chairs, and vice-chairs when appropriate.
- IRB or EC staff.
- When following VA regulations and guidance, policies and procedures indicate:
 - The medical center director is responsible for appointing the IRB chair (or co-chairs, or chair and vice chair), and IRB voting members.
 - Names of potential new IRB voting members for a VA facility's local IRB must be submitted to the medical center director in writing.
 - Policies and procedures indicate IRB members are appointed for a period of three years. They may be re-appointed to a new three- year term without lapse in service at the end of each term.
 - The IRB chair (or co-chairs, or chair and vice chair) are appointed for a term of up to one year, and may be re-appointed after each year indefinitely.
 - There may be one IRB chair, co-chairs, or a chair and a vice chair.
 - The IRB chair, co-chairs, and vice-chairs are voting members of the IRB.
 - The IRB chair at the VA facility must be a paid VA employee.
- The medical center director is responsible for suspending or terminating the IRB membership of any individuals who are not fulfilling their member responsibilities or obligations.

Outcomes

- The IRB or EC is sufficiently qualified through the experience, expertise, and diversity of its members to protect the rights and welfare of research participants.
- IRB or EC chairs, members, and staff are knowledgeable.

Element II.1.C. The Organization has and follows written policies and procedures to separate competing business interests from ethics review functions.

Commentary

The IRB or EC review process should be free of conflict of interest so that the IRB or EC member's obligation to protect participants or ensure the integrity of the review process is not compromised by competing business interests. Competing business interests can influence the review process when individuals responsible for business development serve on the IRB or EC or are involved in the day-to-day operations of the IRB or EC. For example, the director of grants and contracting, the vice president for research, or deans of research who are responsible for raising funds or garnering support for research should not serve as IRB or EC members or be involved in the daily operations of the IRB or EC.

For-profit independent IRBs or ECs should separate the business function of the company from the ethics review function. IRB or EC members should not own equity in the company and senior officers in the company who are responsible for business development should not be involved in the daily operation of the review process, such as reviewing or triaging protocols.

Regulatory and Guidance References

- None

Required Written Materials

- Essential requirements:
 - Policies and procedures prohibit individuals who are responsible for business development from:
 - Serving as members on the IRB or EC.
 - Carrying out day-to-day operations of the review process.
 - Policies and procedures prohibit IRB or EC members from owning equity in the Organization, if appropriate.

Outcomes

- The Organization separates the business functions from the ethics review function.
- Individuals involved in the business function or in research development do not serve as members of the IRB or EC and do not carry out the day-to-day operations of the review process.

Element II.1.D. The IRB or EC has and follows written policies and procedures so that members and consultants do not participate in the review of research protocols or plans in which they have a conflict of interest, except to provide information requested by the IRB or EC.

Commentary

The primary goal of the conflict of interest policy should be to prevent conflicting interests from interfering with the review process either by competing with an IRB or EC member's or consultant's obligation to protect participants or by compromising the credibility of the review process. Unlike financial conflict of interest of Researchers and Research Staff, there is no latitude for the management of an IRB or EC member's conflict of interest. IRB or EC members must not participate in the review of any protocol in which they have a conflict of interest, except to provide information requested by the IRB or EC.

From time to time, IRBs or ECs use consultants to supplement the review process. Consultants should be queried as to whether they have a conflict of interest. If a consultant has a conflict of interest and is allowed to review the protocol, the IRB or EC should determine by what means the conflict of interest will be disclosed to the convened IRB or EC.

An Organization should define the criteria for determining whether an IRB or EC member or a consultant has a conflict of interest. This definition should be designed to capture all conflicts of interest that might affect review. When IRB or EC members or consultants have a conflict of interest, they may remain in the room to provide information requested by the IRB or EC. However, they should leave the room before deliberation and voting.

The definition of a conflict of interest should consider both financial and non-financial interests of IRB or EC members and consultants. For example, a non-financial conflict of interest exists when an IRB or EC member or consultant who reviews research is the spouse of the Researcher. For financial interests, the level of interest considered to be a conflict should be at least as stringent as the level of a Researcher's financial interest that requires evaluation as a possible conflict of interest.

[See AAHRPP Tip Sheet 13.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.107(e)
- FDA: 21 CFR 56.107(e)

- VA: 38 CFR 16.107(e), VHA Handbook 1200.05, 3, 12, 28.
- ICH-GCP: 3.2.1, 3.2.5, 3.2.6

Required Written Materials

- Essential requirements:
 - Policies and procedures indicate IRB or EC members and consultants do not participate in any review in which they have a conflict of interest, except to provide information requested by the IRB or EC.
 - Policies and procedures define when an IRB or EC member has a conflict of interest.
 - The definition considers financial issues.
 - The definition considers non-financial issues.
 - The definition is at least as stringent as the level of a Researcher's financial interest that requires evaluation as a possible conflict of interest.
 - Policies and procedures describe the process to identify IRB or EC members and consultants with a conflict of interest. These policies cover each type of review, such as:
 - Review by a convened IRB or EC.
 - Review by the expedited procedure.
 - Review of unanticipated problems involving risks to participants or others.
 - Review of non-compliance with regulations or laws or the requirements of the IRB or EC.
 - Policies and procedures indicate IRB or EC members and consultants with a conflict of interest:
 - Are excluded from discussion except to provide information requested by the IRB or EC.
 - Are excluded from voting except to provide information requested by the IRB or EC.
 - Leave the meeting room for discussion and voting.
 - Are not counted towards quorum.
 - IRB members with a conflict are documented in the minutes as being absent with an indication that a conflict of interest was the reason for the absence.

- When following DHHS regulations:
 - The threshold for financial interest reporting is \$10,000.
- When following FDA regulations:
 - The threshold for financial interest reporting is \$50,000.

Common Types of Materials That May Be Used to Meet the Element

- Disclosure form
- Reviewer checklist

- IRB or EC agenda
- Announcement regarding conflict of interest

Outcomes

- Conflicts of interest of IRB or EC members and consultants are identified and disclosed.
- IRB or EC members and consultants do not participate in the review of any protocol in which they have a conflict of interest, except to provide information requested by the IRB or EC.

Element II.1.E. The IRB or EC has and follows written policies and procedures requiring research protocols or plans to be reviewed by individuals with appropriate scientific or scholarly expertise and other expertise or knowledge as required to review the research protocol or plan.

Commentary

The IRB or EC should have the competence and knowledge to review research so that it can protect the rights and welfare of research participants.

To review research, the IRB or EC should have or acquire the scientific or scholarly expertise and other expertise or knowledge to understand the protocol. Policies and procedures should describe the steps to follow so that each protocol undergoes an in-depth review by individuals with relevant expertise and knowledge.

Policies and procedures should describe the steps the IRB or EC uses to assess the scientific or scholarly expertise or other expertise or knowledge required for each protocol submitted for review so that one or more IRB or EC members or consultants with appropriate expertise perform an in-depth review. In the case of an Organization with multiple IRBs, this might involve directing the protocol to the IRB or EC with relevant expertise. In the case of an Organization that uses a primary reviewer system, this might involve directing the protocol to one or more primary reviewers with relevant expertise. In the case of an Organization with multiple IRBs and primary reviewer systems, this might involve both strategies.

If there is not at least one person on the IRB or EC with appropriate scientific or scholarly expertise to conduct an in-depth review of the protocol, the IRB or EC should defer review until such expertise can be obtained through membership or consultation.

When additional expertise is needed, policies and procedures should describe the steps followed to obtain consultation and communicate the results of the consultation to the IRB or EC.

IRB or EC members may obtain consultations by directly contacting colleagues for information. Such consultations are acceptable provided they are described in policies and procedures and the information is documented.

Regulatory and Guidance References

- DHHS: 45 CFR 46.107
- FDA: 21 CFR 56.107
- ED: 34 CFR 356.3
- ICH-GCP: 3.2.6

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the process so that at least one person with appropriate scientific or scholarly expertise conducts an in-depth review of the protocol.
 - Policies and procedures describe the process to determine whether other types of expertise or knowledge are required in order to conduct an in-depth review of the protocol.
 - Policies and procedures have the IRB or EC defer to another meeting, IRB or EC, or obtain consultation if there is not at least one person on the IRB or EC with appropriate scientific or scholarly expertise or other expertise or knowledge to conduct an in-depth review of the protocol.
 - Policies and procedures describe who evaluates each protocol to determine whether a consultant is needed.
 - Policies and procedures describe the process to obtain consultants.
 - Policies and procedures indicate consultants do not vote with IRB or EC members.
 - Policies and procedures describe the ways in which information provided by consultants is documented.
- When following Department of Education regulations and guidance:
 - Policies and procedures include that for research funded by the National Institute on Disability and Rehabilitation Research, when an IRB or EC reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, the IRB or EC must include at least one person primarily concerned with the welfare of these research participants.

Outcomes

- At least one IRB or EC member or consultant with appropriate scientific or scholarly expertise reviews each protocol in depth.
- When required by the circumstances of the research, at least one IRB or EC member or

consultant with appropriate expertise or knowledge other than scientific or scholarly expertise reviews the protocol in depth.

- When the IRB or EC needs additional expertise, the IRB or EC obtains consultation.
- When a consultant is obtained, the IRB or EC is made aware of the information provided by the consultant.

Standard II-2: The IRB or EC evaluates each research protocol or plan to ensure the protection of participants.

Element II.2.A. The IRB or EC has and follows written policies and procedures for determining when activities are exempt from applicable laws and regulations, when permitted by law or regulation and exercised by the IRB or EC. Such policies and procedures indicate that exemption determinations are not to be made by Researchers or others who might have a conflict of interest regarding the studies.

Commentary

If the laws, regulations, codes, and guidance under which an Organization conducts research involving human participants permit the use of exemptions, the Organization should have policies to differentiate between research involving human participants that is exempt and research involving human participants that is not exempt. A determination of exemption should consider the criteria for exemption of all applicable laws, regulations, codes, and guidance, because activities that are exempt from one set of rules might not be exempt from another set of rules.

The Organization should provide written decisions and maintain records of exemption determinations. The person making a decision about whether an activity is exempt should have the authority to represent the Organization, and have no direct involvement in the activity he or she is examining. The person making a decision should be familiar with laws, regulations, codes, and guidance governing the research, organizational policies, and the nature of the research to make sound judgments. Policies and procedures should describe the communication of exemption determinations to Researchers.

An Organization may elect to restrict or not use the categories of exemption, and to require such research to meet all regulatory criteria for approval. If so, this should be stated in policies and procedures.

Generally, the authority to make exemptions determinations rests with the IRB or EC. However, this is not a requirement to meet this Element. Organizations may choose to delegate to an entity other than the IRB or EC or an individual the authority to make exemption determinations.

[See AAHRPP Tip Sheets 8, 9, and 18.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.101(b), 45 CFR 46.301(a), 45 CFR 46.401(b), 45 CFR 46.101(b)(1), 45 CFR 46.101(b)(2), 45 CFR 46.101(b)(3), 45 CFR

46.101(b)(4), 45 CFR 46.101(b)(5), 45 CFR 46.101(b)(6). OHRP Guidance at 45 CFR 46.101(b)(5): Exemption for Research and Demonstration Projects on Public Benefit and Service Programs, OHRP Guidance on the Involvement of Prisoners in Research, May 23, 2003, Federal Register, Vol. 48, pp. 9266-9270, March 4, 1983

- FDA: 21 CFR 56.104(c)-(d)
- VA: 38 CFR 16.101(b), 38 CFR 16.301(a), 38 CFR 16.401(b), 38 CFR 16.101(b)(1), 38 CFR 16.101(b)(2), 38 CFR 16.101(b)(3), 38 CFR 16.101(b)(4), 38 CFR 16.101(b)(5), 38 CFR 16.101(b)(6), VHA Handbook 1200.05, 16

Required Written Materials

- Essential requirements:
 - Policies and procedures identify the entity or individuals who are authorized to make exemption determinations.
 - Policies and procedures define which research studies involving human participants are exempt.
 - Policies and procedures inform Researchers:
 - Whom to ask for an authoritative decision about whether research involving human participants is exempt from regulation.
 - What information to submit.
 - Policies and procedures describe the process to provide determinations about whether research involving human participants is exempt from regulation that includes:
 - Specific titles of persons or offices authorized to make determinations.
 - Criteria used to make determinations
 - The process used to communicate determinations.
- When following DHHS regulations and guidance:
 - The criteria for exemptions are consistent with:

- Subpart A of the DHHS regulations.
- Subpart B of the DHHS regulations.
- Subpart D of the DHHS regulations.
- When following FDA regulations and guidance:
 - The criteria for exemptions are consistent with FDA regulations.
- When following VA regulations and guidance:
 - The IRB chair or an experienced IRB member designated by the chair must review all requests for exemptions.
 - The determination must be recorded.
 - The determination must be signed by the IRB voting member who reviewed the research and made the determination that the research was exempt or denied the exemption.
 - The documentation must include the specific categories justifying the exemption or, if the request is denied, include the reason for the denial.

Common Types of Materials That May Be Used to Meet the Element

- Application form
- Reviewer checklist
- Template letters to Researchers

Outcomes

- The IRB or EC recognizes the difference between exemption criteria that are requirements of laws, regulations, codes, and guidance and additional criteria based on local policy.
- Decisions about whether research involving human participants is exempt are made promptly.
- Decisions about whether research involving human participants is exempt are made accurately.

Element II.2.B. The IRB or EC has and follows written policies and procedures for addressing protection of participants in research that is exempt from applicable laws and regulations. These functions may be delegated to an entity other than the IRB or EC.

Commentary

Generally, when a research study is determined to be exempt, it is exempt from the laws, regulations, codes, or guidance that govern the research, and there are no required provisions to protect the participants enrolled in the research study. For example, there is no requirement for IRB review or to obtain consent. There is also no prohibition against the use of coercion, undue influence, or deception to recruit participants. Although most exempt research requires no further oversight to be conducted ethically, some exempt research raises ethical concerns or requires measures to protect participants.

This Element looks for a process to address the ethical concerns of research that is exempt. The person who makes determinations of exemption may also conduct the ethical evaluation of exempt research.

[See AAHRPP Tip Sheets 8 and 18.](#)

Regulatory and Guidance References

None

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the evaluation of exempt research as to whether it fulfills the Organization's ethical standards. Such an evaluation might include:

- The research holds out no more than minimal risk to participants.
- Selection of participants is equitable.
- If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
- If there are interactions with participants, the IRB or EC should determine whether there should be a consent process that will disclose such information as:
 - That the activity involves research.
 - A description of the procedures.
 - That participation is voluntary.
 - Name and contact information for the Researcher.
- There are adequate provisions to maintain the privacy interests of participants.

Common Types of Materials That May Be Used to Meet the Element

- Reviewer checklist

Outcomes

- When appropriate, participants involved in exempt research are provided additional protections.

Element II.2.C. The IRB or EC has and follows written policies and procedures for conducting meetings by the convened IRB or EC.

Commentary

The IRB or EC should have policies and procedures describing the conduct of meetings of the convened IRB or EC. These policies and procedures should allow the IRB or EC to carry out its functions effectively and consistently according to applicable laws, regulations, codes, and guidance and the Organization's policies and procedures.

The IRB or EC should have policies and procedures for developing the meeting agenda and describing functions of the meeting agenda. This should include how the volume of the agenda is controlled or limited to allow for adequate time for discussion of all items on the agenda. If the agenda is used for purposes such as informing members of research protocols or plans approved using the expedited procedure, or identification of member conflict of interest, these uses should be described in policies and procedures.

Meeting agendas should be designed to allow for adequate discussion of each item on the agenda, resolution of controverted issues, and IRB or EC determinations.

The process of IRB or EC review takes time. The definition of timely review depends on organizational culture and the expectations of Researchers and those involved with the IRB or EC. Reviews should be timely within the context of the organizational culture.

IRB or EC meetings should be scheduled regularly based on the volume of research to be reviewed. The schedule should promote timely review or re-review of research.

The establishment and maintenance of quorum is essential for the IRB or EC to review and approve research during a meeting. This involves not only appropriate numbers of members, but composition (e.g., a non-scientist must be present). Policies and procedures should describe who determines quorum is established and how it is documented at the beginning and during a meeting.

The widespread use of technology in IRB or EC meetings has necessitated the development of policies and procedures to integrate the use of these technologies in the conduct of meetings and in accordance with any legal or regulatory requirements. This includes policies and procedures for teleconferencing or videoconferencing, or the use of technology or other materials to meet responsibilities,

such as displaying and confirming the criteria for approval of research.

Policies and procedures should describe how votes are taken and recorded. For example, votes may be taken by a show of hands, voice vote, or electronic polling. An affirmative vote may be by majority or by consensus.

The role of the IRB or EC chair and vice-chair, if any, should be described in policies and procedures, including whether they vote and have any specific role.

[See AAHRPP Tip Sheets 16 and 18.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.108(b), OHRP Guidance on Written Institutional Review Board (IRB) Procedures
- FDA: 21 CFR 56.108
- VA: 38 CFR 16.107, VHA Handbook 1200.05, 7
- ICH-GCP: 3.3.2

Required Written Materials

- Essential requirements:
 - Policies and procedures describe:
 - The timing of document distribution before convened IRB or EC meetings.
 - The timing and scheduling of IRB or EC meetings.
 - Limits placed on the number of items on the agenda, if any.
 - Other functions of the agenda, e.g., informing IRB or EC members of research protocols approved using the expedited process.
 - Policies and procedures indicate that at convened meetings:
 - A majority of IRB or EC members has to be present.
 - At least one member whose primary concerns are in non-scientific areas has to be present.
 - For research to be approved it has to receive the approval of a majority of members present at the meeting.
 - If quorum is lost during a meeting, the IRB or EC cannot take votes until the quorum is restored.

- When the convened IRB or EC reviews research involving prisoners, the prisoner representative is present.
- At least one unaffiliated member is present at convened meetings.
 - This may be accomplished by one of the following:
 - Requiring an unaffiliated member as part of quorum.
 - Placing an attendance requirement on the unaffiliated member (e.g. attend 10 of 12 meeting per year).
 - Documenting the general attendance of the unaffiliated member (e.g. minutes indicate attendance at 10 of 12 meetings).
- At least one member who represents the general perspective of participants is present at convened meetings.
 - This may be accomplished by one of the following:
 - Requiring a member who represents the general perspective of participants as part of quorum.
 - Placing an attendance requirement on the member (e.g. attend 10 of 12 meeting per year).
 - Documenting the general attendance of the member (e.g. minutes indicate attendance at 10 of 12 meetings).
- If the IRB or EC reviews research that involves categories of participants vulnerable to coercion or undue influence, one or more individuals who are knowledgeable about or experienced in working with such participants are present.
- Policies and procedures describe who determines quorum is established and how it is documented.
- Policies and procedures state that if quorum is lost during a meeting, the IRB or EC cannot take votes until the quorum is restored.
- If required members (e.g. non-scientific) leave the room and quorum is lost votes cannot be taken until the quorum is restored, even if half of the members are still present.
- Policies and procedures describe the use of any materials or technology used to conduct meeting or meet regulatory requirements. For example, all members have laptop computers to access materials; handouts, posters, or projections contain the criteria for approval; or meetings are conducted over the Internet.
- Policies and procedures describe how votes are taken and documented, and what constitutes approval.
- Policies and procedures describe the role of the chair and vice-chair, if there are vice-chairs:
 - Voting responsibilities.
 - Role of the chair and vice-chair prior to, during, and after the meeting.
- When following VA regulations and guidance:
 - When the IRB of record is an affiliate's IRB, policies and procedure indicate that at least one of the VA members has to be present during the review of VA research.

Common Types of Materials That May Be Used to Meet the Element

- Policies and procedures
- Meeting materials

Outcomes

- The IRB or EC conducts convened meetings according to policies and procedures.
- IRB or EC members receive materials in enough time prior to the meeting to review them.
- The IRB or EC meets regularly to promote timely reviews.
- Meeting agendas allow for adequate discussion and determinations for all research under review.
- During a meeting, the IRB or EC votes and takes actions only when there is a quorum.
- The chair and vice-chair, if any, fulfill their roles according to policies and procedures.

Element II.2.D. The IRB or EC has and follows written policies and procedures to conduct reviews by the convened IRB or EC.

Element II.2.D.1. – Initial review

Element II.2.D.2. – Continuing review

Element II.2.D.3. – Review of proposed modifications to previously approved research

Commentary

The IRB or EC should have policies and procedures that describe the review of research at convened meetings, including initial review, continuing review, and review of modifications to previously approved research.

The IRB or EC should obtain and review sufficient information to conduct initial review of research, continuing review, and review or modifications to previously reviewed research in accordance with the regulations and the organization's policies and procedures. When they are scheduled to attend an IRB or EC meeting, all members (including alternate members) should review enough information so that they will be able to determine whether the research meets the regulatory criteria for approval.

Policies and procedures should describe the information provided to all IRB or EC members and the information provided to all primary reviewers with the expectation that IRB members will review the materials and the primary reviewer will conduct an in-depth review. When an Organization has an electronic system that provides members access to materials, policies and procedures should describe what information primary reviewers are expected to review and what information all other members are expected to review.

An independent IRB or EC should have a policy and procedure for reviewing the addition of investigative sites to previously approved protocols. The independent IRB or EC may decide to review these additions as separate protocols or as modifications to previously approved research, and they may decide to handle such modifications using the expedited procedure rather than the convened IRB or EC for review. When the expedited procedure is used, the independent IRB or EC should specify the criteria for when the addition of an investigative site is considered to be a minor modification.

[See AAHRPP Tip Sheets 1, 16, 18, and 20.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.103(b)(4), 45 CFR 46.109, 45 CFR 46.116(b)(5), OHRP Guidance on Written Institutional Review Board (IRB) Procedures, OHRP Guidance on Continuing Review, OHRP Guidance on IRB Approval of Research with Conditions

- FDA: 21 CFR 50.25(b)(5), 21 CFR 56.108(a), 21 CFR 56.109, FDA Information Sheets: Continuing Review After Study Approval, Frequently Asked Questions: IRB Procedures
- VA: 38 CFR 16.103(b)(4), 38 CFR 16.109, 38 CFR 16.116(b)(5), VHA Handbook 1200.05, 10, 22, 44
- ICH-GCP: 3.2.2, 3.2.3, 3.3.3, 3.3.4

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the process the IRB or EC uses to review research for initial review, continuing review, and review of modifications to previously approved research:
 - The primary reviewer system used, if any.
 - The process used to supplement the IRB's or EC's review.
 - The range of possible actions that the IRB or EC is allowed to take.
 - If the IRB approves research with conditions:
 - Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB or EC.
 - Minor or prescriptive changes or requirements may be reviewed for approval by the IRB or EC chair.
 - The date of approval is the date the conditions were determined to be met.
- A process for the IRB or EC to determine which protocols need review more often than annually.
 - For initial review of research by a convened IRB, policies and procedures indicate that when they are scheduled to attend an IRB or EC meeting, all members (including attending alternate members) are provided and review:
 - The full protocol, application, or a protocol summary containing the relevant information to determine whether the proposed research fulfills the criteria for approval.
 - Proposed consent document.
 - Recruitment materials.

- At least one member is provided and reviews the investigator's brochure (when one exists).
- For continuing review of research by a convened IRB or EC, policies and procedures indicate that, when they are scheduled to attend an IRB or EC meeting, all IRB or EC members (including alternate members) are provided and review:
 - The full protocol, application, or a protocol summary containing the relevant information necessary to determine whether the proposed research continues to fulfill the criteria for approval.
 - The current consent document.
 - Any newly proposed consent document.
 - A status report on the progress of the research.
- For continuing review of research by a convened IRB or EC, policies and procedures indicate that at least one IRB or EC member is provided and reviews the complete protocol including any protocol modifications previously approved by the IRB or EC.
- The status report on the progress of the research includes:
 - The number of participants accrued.
 - A summary since the last IRB review of:
 - Adverse events and adverse outcomes experienced by participants.
 - Unanticipated problems involving risks to participants or others.
 - Participant withdrawals.
 - The reasons for withdrawals.
 - Complaints about the research.
 - Amendments or modifications.
 - Any relevant recent literature.
 - Any interim findings.
 - Any relevant multi-center trial reports.
 - The Researcher's current risk-potential benefit assessment based on study results.
- Policies and procedures have the IRB or EC use the required criteria for approval for all reviews of research, including initial review, continuing review, and review of a modification to previously approved (when the modification affects a criterion for approval).
- Policies and procedures have the IRB or EC determine whether continuing review should occur at an interval less than one year.
- Policies and procedures describe:
 - Whether the expiration date is the last date that the protocol is approved or the first date that the protocol is no longer approved.
 - The calculation of the expiration date.
- If the IRB approves research with conditions:
 - Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB or EC.
 - Minor or prescriptive changes or requirements may be reviewed for approval by the IRB or EC chair or designee.
 - The date of approval is the date the conditions were determined to be met.
 - IF the research expires before the conditions are reviewed and approved, all research activities must stop until approval is obtained.
- Policies and procedures describe:
 - The organizational offices and officials who are notified of the findings of the IRB or EC and the method of notification.
 - The person or office that is responsible for further approval or disapproval of research that is approved by the IRB or EC.
 - The process the IRB or EC uses for reporting its findings and actions to Researchers in writing, including:
 - The decision to approve, disapprove, or require modifications to secure approval.
 - Any modifications or clarifications required by the IRB as a condition for IRB approval.
 - If an IRB decides to disapprove a research activity, a statement of the reasons for its decision and giving the Researcher an opportunity to respond in person or in writing.
 - The review of Researchers' responses.
- For continuing review of research, policies and procedures have the IRB or EC determine:
 - That the protocol needs verification from sources other than the Researchers that no material changes had occurred since previous IRB or EC review.
 - That the current consent document is still accurate and complete.
 - That any significant new findings that arise from the review process and that might relate to participants' willingness to continue participation will be provided to participants.
- If a Researcher does not provide continuing review information to the IRB or EC or the IRB or EC has not approved a protocol by the expiration date, policies and procedures:
 - Have all research activities stop.

- Have interventions and interactions on current participants stop, unless the IRB or EC finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating.
- Do not allow new enrollment of participants to occur.
- For review of modifications to previously approved research by a convened IRB or EC, policies and procedures indicate that, when they are scheduled to attend a meeting, all members (including alternate members) receive and review all modified documents.
- Policies and procedures have:
 - The IRB or EC use the criteria to approve modifications to previously approved research when the modifications affect one or more criteria.
 - The IRB or EC determine that any significant new findings that arise from the review process and that might relate to participants' willingness to continue participation are provided to participants.
 - Changes in approved research that are initiated without IRB or EC approval to eliminate apparent immediate hazards to the participant:
 - Are promptly reported to the IRB or EC.
 - Are reviewed by the IRB or EC to determine whether each change was consistent with ensuring the participants' continued welfare.
 - Researchers report to the IRB or EC proposed changes in a research study.
 - Researchers report to the IRB or EC the premature completion of a study.
- Policies and procedures describe actions taken to ensure that proposed changes in approved research during the period for which IRB or EC approval had already been given cannot be initiated without IRB approval.
- When following DHHS regulations and guidance:
 - For initial review of research by a convened IRB or EC, policies and procedures indicate that at least one member is provided and reviews:
 - The DHHS-approved sample consent document (when one exists).
 - The complete DHHS-approved protocol (when one exists).
 - Any relevant grant applications.
- When following VA regulations and guidance:
 - Policies and procedures indicate:
 - When a study involves "usual care," in the protocol or a separate document in the IRB application the Researcher must clearly designate the individual or entity (e.g., the appropriate research personnel versus the subject's health care provider) responsible for relevant aspects of both the research and the usual care.
- The IRB determines whether the medical record has to be flagged to protect the participant's safety by indicating participation in the study and the source of more information on the study.
- Policies and procedures indicate that the patient medical record must be flagged if the participant's participation in the study involves:
 - Any invasive research procedure.
 - Interventions that will be used in the medical care of the participant, or that could interfere with other care the participant is receiving or may receive.
 - Clinical services that will be used in the medical care of the participant, or that could interfere with other care the participant is receiving or may receive.
 - The use of a survey or questionnaire that may provoke undue stress or anxiety unless that IRB determines that mandatory flagging is not in the best interest of the participant.
 - In other situations, the IRB determines whether flagging is necessary. The IRB might not want to require the medical record to be flagged if:
 - Participation in the study involves only one encounter.
 - Participation in the study involves the use of a questionnaire or previously collected biological specimens.
 - Identification as a participant in a particular study will place the participant at greater than minimal risk.
 - If the IRB determines and documents that the patient health record must be flagged in Computerized Patient Record System (CPRS) as participating in a research, then the health record must identify the Researcher, as well as contact information for a member of the research team that would be available at all times, and contain information on the research study or identify where this information is available.
 - The duration of flagging is determined by local policy.
- For continuing review of research by the convened IRB the status report on the progress of the research includes:
 - A brief summary of the research methodology.
 - The gender and minority status of those entered into the protocol, when appropriate.

- Number of participants considered as members of specific vulnerable populations.
- Information that might influence the risk - potential benefit relationship; such as serious adverse events and complaints regarding the research.
- Summaries, recommendations, or minutes of the data monitoring committee meetings (if applicable) or findings based on information collected by the data and safety monitoring plan submitted in the initial proposal.
- An assurance that all identified unanticipated internal or local serious adverse events, whether related or unrelated to the research, have been reported as required to the IRB of record.
- A summary of all unanticipated problems involving risks to participants or others, and all internal or local serious adverse events.
- A statement signed by the Researcher certifying that all participants entered onto the master list of participants for the study signed the consent document prior to undergoing any study interactions or interventions, unless the IRB has granted a waiver of the consent process or a waiver of the requirement for a signed consent document.
- If an Researcher does not provide continuing review information to the IRB or the IRB has not approved a protocol by the expiration date, policies and procedures:
 - Stop all research activities including, but not limited to, enrollment of new participants and continuation of research interventions or

interactions with currently enrolled participants, and data analysis.

- Immediately submit to the IRB chair a list of research participants who could be harmed by stopping study procedures.
- The IRB chair, with appropriate consultation with the chief of staff, determines whether participants on the list may continue participating in the research interventions or interactions.

Common Types of Materials That May Be Used to Meet the Element

- Reviewer checklist
- Template letters for notifications

Outcomes

- All IRB or EC members (including alternate members) review materials in enough depth to discuss the information when they are present at the convened meeting.
- At least one IRB or EC member conducts an in-depth review of all submitted materials.
- IRB or EC members can obtain information provided to any individual reviewer.
- Each approved research protocol or plan meets the required criteria for approval.
- The approval period for research is no longer than one year.
- The IRB or EC communicates its findings to the Organization and Researchers.

Element II.2.E. The IRB or EC has and follows written policies and procedures to conduct reviews by an expedited procedure, if such procedure is used.

Element II.2.E.1. – Initial review

Element II.2.E.2. – Continuing review

Element II.2.E.3. – Review of proposed modifications to previously approved research

Commentary

Review of research by the expedited procedure is an alternative to review by a convened IRB for a limited class of research. An IRB or EC is not required to use the option of an expedited procedure. The requirements to review and approve research using an expedited procedure are identical to those used by a convened IRB or EC.

When the IRB or EC requires modifications to research to secure approval, verification of those modifications by an IRB or EC chair or experienced IRB or EC reviewer without review by the convened IRB or EC represents review by the expedited procedure and should follow the laws, regulations, codes, and guidance governing such review. This process is sometimes referred to as “contingent approval.” When the IRB or EC grants contingent approval, the IRB or EC should provide the Researcher specific modifications required to secure approval. For example, “Participants must be 18 years or older” or “Drop the placebo controlled arm of this study.”

The IRB or EC should not grant approval contingent upon clarifications or modifications directly relevant to the determinations required of the IRB under the regulations. Such requests include: “Explain why participants younger than 18 years of age will be allowed to participate,” “Provide additional justification for the use of placebo,” or “Clarify whether participants will be offered counseling services at the end of the study.” The convened IRB or EC should review responses to requests that require determinations not allowed under the expedited procedure. The IRB or EC should exercise caution before using the expedited procedure to review clarifications, explanations, or additional information, or when a subcommittee seems to be needed to review requested modifications. In addition, the IRB or EC should exercise caution before delegating to an IRB or EC member the authority to negotiate changes without review of those changes by a convened IRB or EC.

[See AAHRPP Tip Sheets 1, 11, 17, 18, and 20.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.110, 21 CFR 56.110, Categories of Research That May Be Reviewed by

the Institutional Review Board (IRB) through an Expedited Review Procedure – FDA & DHHS, OHRP Guidance on Written Institutional Review Board (IRB) Procedures, OHRP Guidance on the Use of Expedited Review Procedures, OHRP Guidance on Continuing Review

- FDA: FDA Information Sheets: Continuing Review after Study Approval
- VA: 38 CFR 46.110, 45 CFR 46.110, 21 CFR 56.110, VHA Handbook 1200.05, 10, 22, 44
- ICH-GCP: 3.3.5
- DoD: SECNAVINST 3900.39D, para. 6e; OPNAVINST 5300.8B

Required Written Materials

- Essential requirements:
 - Policies and procedures describe:
 - That only experienced IRB or EC members may conduct reviews using the expedited procedure.
 - Experienced is defined.
 - The conduct of
 - Initial review.
 - Continuing review.
 - Review of modifications using the expedited procedure.
 - Modifications that are “minor” are defined.
 - The information that Researchers have to submit for review using the expedited procedure.
 - That at least one reviewer receives and reviews the same materials that the convened IRB or EC receives for protocols reviewed by the convened IRB or EC (refer to Element II.2.D).
 - The evaluation by the reviewer of research undergoing initial review and continuing review using the expedited procedure:
 - The evaluation by the reviewer of in modifications to previously approved research undergoing review represent “minor” modifications.
 - The criteria for approval using the expedited procedure are the same as those for review by a convened IRB or EC.

- The prohibition of the reviewer to disapprove research.
- The process for informing IRB or EC members about approvals by review using the expedited procedure, including:
 - Initial review.
 - Continuing review.
 - Review of modifications to previously approved research.
- Policies and procedures describe the contingent approval of revisions by the chair or designated IRB or EC member without subsequent review by the convened IRB or EC.
 - When the convened IRB or EC requests substantive clarifications or modifications that are directly relevant to the determinations required by the IRB or EC, policies and procedures have the protocol return to the convened IRB or EC and not be approved by the expedited procedure.
- For continuing review of research policies and procedures indicate that at least one IRB or EC member is provided and reviews the complete protocol, including any protocol modifications previously approved by the IRB or EC.
- The status report on the progress of the research includes:
 - Number of participants accrued.
 - A summary since the last IRB review of:
 - Adverse events, untoward events, and adverse outcomes experienced by participants.
 - Unanticipated problems involving risks to participants or others.
 - Participant withdrawals.
 - The reasons for withdrawals.
 - Complaints about the research.
 - Amendments or modifications.
 - Any relevant recent literature.
 - Any interim findings.
 - Any relevant multi-center trial reports.
 - The Researcher's current risk-potential benefit assessment based on study results.
- For continuing review of research, policies and procedures have the IRB or EC members determine:
 - That the protocol needs verification from sources other than the Researchers that no material changes had occurred since previous IRB or EC review.
 - That the current consent document is still accurate and complete.
 - That any significant new findings that arise from the review process and that might relate to participants' willingness to continue participation will be provided to participants.
- If a Researcher does not provide continuing review information to the IRB or EC or the IRB or EC has not approved a protocol by the expiration date, policies and procedures:
 - Have all research activities stop.
 - Have interventions and interactions on current participants stop, unless the IRB or EC finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating.
 - Do not allow new enrollment of participants to occur.
- When following DHHS or FDA regulations and guidance:
 - Policies and procedures describe:
 - The designation by the IRB or EC chair of IRB or EC members who may conduct review using the expedited procedure.
 - The evaluation by the reviewer of whether research undergoing initial review and continuing review using the expedited procedure:
 - Meets all applicability criteria.
 - Represents one or more approvable categories of research.
 - When following VA regulations and guidance:
 - When a study involves "usual care," in the protocol or a separate document in the IRB application the Researcher must clearly designate the individual or entity (e.g., the appropriate research personnel versus the subject's health care provider) responsible for relevant aspects of both the research and the usual care.
 - The IRB member determines whether the medical record has to be flagged to protect the participant's safety by indicating participation in the study and the source of more information on the study.
 - Policies and procedures indicate that the patient medical record must be flagged if the participant's participation in the study involves:
 - Any invasive research procedure.

- Interventions that will be used in the medical care of the participant, or that could interfere with other care the participant is receiving or might receive.
- Clinical services that will be used in the medical care of the participant, or that could interfere with other care the participant is receiving or may receive.
- The use of a survey or questionnaire that may provoke undue stress or anxiety unless that IRB determines that mandatory flagging is not in the best interest of the participant.
- In other situations, the IRB member determines whether flagging is necessary. The IRB member might not want to require the medical record to be flagged if:
- Participation in the study involves only one encounter.
- Participation in the study involves the use of a questionnaire or previously collected biological specimens.
- Identification as a participant in a particular study will place the participant at greater than minimal risk.
- If the IRB member determines and documents that the patient health record must be flagged in computerized patient record system (CPRS) as participating in a research, then the health record must identify the Researcher, as well as contact information for a member of the research team that would be available at a times, and contain information on the research study or identify where this information is available.
- For continuing review of research reviewed by the expedited procedure the status report on the progress of the research includes:
 - A brief summary of the research methodology.
 - The gender and minority status of those entered into the protocol.
 - Number of participants considered as members of specific vulnerable populations.
 - Information that might influence the risk-benefit relationship; such as serious adverse events and complaints regarding the research.
 - Summaries, recommendations, or minutes of the data monitoring committee meetings (if applicable) or findings based on information collected by the data and safety monitoring plan submitted in the initial proposal;
 - An assurance that all identified unanticipated internal or local serious adverse events, whether related or unrelated to the research, have been reported as required to the IRB of record.
- A summary of all unanticipated problems involving risks to participants or others, and all internal or local serious adverse events.
- A statement signed by the principal Researcher certifying that all participants entered onto the master list of participants for the study signed an consent document prior to undergoing any study interactions or interventions, unless the IRB has granted a waiver or informed consent or a waiver of the signed consent document.
- If an Researcher does not provide continuing review information to the IRB or the IRB has not approved a protocol by the expiration date, policies and procedures:
 - Stop all research activities including, but not limited to enrollment of new participants, continuation of research interventions or interactions with currently enrolled participants, and data analysis.
 - Immediately submit to the IRB chair a list of research participants who could be harmed by stopping study procedures.
 - The IRB chair, with appropriate consultation with the chief of staff, determines whether participants on the list may continue participating in the research interventions or interactions.
- When following Department of Defense regulations and requirements:
 - Surveys performed on Department of Defense personnel must be submitted, reviewed, and approved by the Department of Defense after the research protocol is reviewed and approved by the IRB.

Common Types of Materials That May Be Used to Meet the Element

- Application form
- Reviewer checklist

Outcomes

- Reviewers using the expedited procedures are experienced IRB or EC members.
- Research protocols or plans reviewed by the expedited procedure were eligible for such review and did not require review by a convened IRB or EC.

- Research approved by the expedited procedure meets the required criteria for approval.
- The approval period for research is no longer than one year.

Element II.2.F. The IRB or EC has and follows written policies and procedures for addressing unanticipated problems involving risks to participants or others, and for reporting these actions, when appropriate.

Commentary

An effective policy and procedure to ensure prompt reporting to the IRB or EC, appropriate organizational officials, and regulatory agencies of unanticipated problems involving risks to participants or others deals with informing Researchers of the type of information that needs to be reported to the IRB or EC. Each item of information reported by Researchers might or might not be an unanticipated problem involving risks to participants or others. For example, an IRB or EC might ask Researchers to report all breaches of confidentiality. The IRB or EC determines that some of these are unanticipated problems involving risks to participants or others and others are not.

When the IRB or EC obtains new information, including adverse event reports, publications, complaints, revised package inserts, data monitoring reports, breaches of confidentiality, or other material, it should decide whether the information represents an unanticipated problem involving risks to participants or others. If so, the IRB or EC should decide what actions need to be taken and then report the outcome to regulatory agencies and appropriate organizational officials. If not, no further evaluation is needed (unless the problem involves non-compliance.)

An Organization should develop a process for managing adverse event reports as they relate to unanticipated problems involving risks to participants or others. An Organization should limit the information reported to the IRB or EC to adverse events that are unexpected, involve increased risks, and are related to the research.

[See AAHRPP Tip Sheets 11, 15, 21, 23.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.103(b)(5)(i), 45 CFR 46.116(b)(5), OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events, OHRP Guidance on Reporting Incidents to OHRP
- FDA: 21 CFR 50.25(b)(5), 21 CFR 56.108(b)(1), 21 CFR 812.150(a)(1), FDA Information Sheets: Continuing Review After Study Approval, Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting to IRBs – Improving Human Subject Protection

- VA: 38 CFR 16.103(b)(5)(i), 38 CFR 16.116(b)(5), VHA Handbook 1058.01, VHA Handbook 1200.05, 11,14,42
- ICH-GCP: 3.3.8, 4.10.2
- DoD: SECNAVINST 3900.39D, para. 8d(2), para. 8e(6), and para. 8g(6)

Required Written Materials

- Essential requirements:
 - Policies and procedures define the problems Researchers have to report to the IRB or EC and the time frame for reporting.
 - The list of problems that need reporting includes:
 - Internal adverse events that are unexpected, involve new or increased risks, and are related to the research.
 - External adverse events that are unanticipated problems involving risks to participants or others.
 - Changes made to the research without prior IRB or EC approval in order to eliminate apparent immediate harm.
 - Other unanticipated information that is related to the research and indicates that participants or others might be at increased risk of harm.
 - Policies and procedures define unanticipated problems involving risks to participants or others.
 - Policies and procedures describe:
 - The review of problems reported by Researchers.
 - The determination of whether each reported problem is an unanticipated problem involving risks to participants or others.
 - Policies and procedures describe the review process of unanticipated problems involving no more than minimal risks to participants or others.
 - Policies and procedures describe the convened IRB's or EC's review of unanticipated problems involving more than minimal risks to participants or others, including:
 - If a primary reviewer system is used, documents distributed to primary reviewers.
 - Documents distributed to all IRB or EC members.

- Policies and procedures describe the range of actions considered by the IRB or EC:
 - Required actions:
 - Suspension of the research.
 - Termination of the research.
 - Notification of current participants when such information may relate to participants' willingness to continue to take part in the research.
 - Optional actions:
 - Modification of the protocol.
 - Modification of the information disclosed during the consent process.
 - Providing additional information to past participants.
 - Requiring current participants to re-consent to participation.
 - Modification of the continuing review schedule.
 - Monitoring of the research.
 - Monitoring of the consent process.
 - Referral to other organizational entities.
- Policies and procedures describe the reporting of problems determined to represent unanticipated problems involving risks to participants or others, including:
 - The distribution of the report to:
 - Specific organizational officials.
 - Regulatory agencies, when the research is overseen by those agencies, and they require separate reporting.
 - The maximum time allowed between the recognition of a reportable event and fulfilling reporting requirements.
- When following DHHS regulations and guidance:
 - Policies and procedures include a requirement that the report of unanticipated problems involving risks to participants or others be sent to OHRP, when the research is covered by DHHS regulations.
- When following FDA regulations and guidance:
 - Policies and procedures include a requirement that the report of unanticipated problems involving risks to participants or others be sent to the FDA, when the research is FDA-regulated.
- When following VA regulations and guidance:
 - Policies and procedures describe:
 - The terms “unanticipated” and “unexpected” refer to an event or problem in VA research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.
 - For unanticipated problems involving risks to participants or others, members of the VA research community are required to ensure that all unanticipated problems involving risks to participants or others in research are reported promptly to the IRB.
 - For serious unanticipated problems involving risks to participants or others, within five business days of becoming aware of any serious unanticipated problem involving risks to participants or others in VA research, members of the VA research community are required to ensure that the problem has been reported in writing to the IRB. Serious unanticipated problems involving risks to participants or others include:
 - Interruptions of participant enrollments or other research activities due to concerns about the safety, rights, or welfare of human research participants, research staff, or others.
 - Any work-related injury to personnel involved in human research, or any research-related injury to any other person, that requires more than minor medical intervention (i.e., basic first aid), requires extended surveillance of the affected individuals, or leads to serious complications or death.
 - Any VA National Pharmacy Benefits Management (PBM) Bulletins or Communications (sometimes referred to as PBM Safety Alerts) relevant to one or more of the VA facility's research projects.
 - Any data monitoring committee, data and safety monitoring board or data and safety monitoring committee report describing a safety problem.
 - Any sponsor analysis describing a safety problem for which action at the VA facility might be warranted.
 - Any unanticipated problem involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research participants, research staff, or others.

- Any problem reflecting a deficiency that substantively compromises the effectiveness of the VA facility's HRPP.
- Local unanticipated serious adverse events.
 - Policies and procedures indicate that within five business days of becoming aware of any local (i.e., occurring in the reporting individual's own facility) unanticipated serious adverse events in VA research, members of the VA research community are required to ensure that the serious adverse event has been reported in writing to the IRB.
 - This requirement is in addition to other applicable reporting requirements (e.g., reporting to the sponsor under FDA requirements).
 - The unfounded classification of an serious adverse event as "anticipated" constitutes serious non-compliance.
- IRB review of serious unanticipated problems and unanticipated serious adverse events.
 - Policies and procedures indicate that within five business days after a report of a serious unanticipated problem involving risks to participants or others, or of a local unanticipated serious adverse event, the convened IRB or a qualified IRB member-reviewer must determine and document whether the reported incident was serious and unanticipated and related to the research.
 - "Related" means the event or problem may reasonably be regarded as caused by, or probably caused by, the research.
 - If the convened IRB or the IRB reviewer determines that the problem or event was serious, unanticipated, and related to the research, the IRB chair or designee must report in writing the unanticipated problem or event within five business days after the determination to:
 - medical center director.
 - Associate chief of staff for research.
 - The Research and Development Committee.
 - The medical center director must report the problem or event to the appropriate Office of Research Oversight research officer within five business days after receiving such notification.
 - If the convened IRB or the IRB reviewer determines that the problem or event was serious, unanticipated, and related to the research, a simultaneous determination is required regarding the need for any action (e.g., suspension of activities; notification of participants) necessary to prevent an immediate hazard to participants in accordance with VA regulations.
- All determinations of the IRB reviewer (regardless of outcome) must be reported to the IRB at its next convened meeting.
- If it was determined that the problem or event is serious, unanticipated, and related to the research, the convened IRB must determine and document whether a protocol or consent document modification is warranted.
- If the convened IRB determines that a protocol or consent document modification is warranted, the IRB must also determine and document:
 - Whether previously enrolled participants must be notified of the modification.
 - When such notification must take place and how such notification must be documented.
- Policies and procedures include a requirement that the report of unanticipated problems involving risks to participants or others be sent to:
 - The Office of Research and Development, if VA-funded.
 - The Regional Office of Research Oversight.
 - The VA Central Office, if the unanticipated problem involving risks to participants or others is an adverse event.
 - The VA Privacy Office, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information.
 - The VHA Information Security Officer when the report involves violations of VA information security requirements.
- IRBs of academic affiliates and the IRB of record for VA facilities must follow these requirements
- When following ICH-GCP guidance (E6):
 - Policies and procedures define the problems Researchers have to report to the IRB or EC to include:
 - New information that may affect adversely the safety of the participants or the conduct of the clinical trial.
 - Any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.

Outcomes

- The IRB or EC evaluates each reported problem to determine whether it is an unanticipated problem involving risks to participants or others.
- The IRB or EC reviews problems that are unanticipated problems involving more than minimal risks to participants or others.
- The IRB or EC or an organizational official reports unanticipated problems involving risks to participants or others to appropriate organizational officials and applicable regulatory agencies.

Element II.2.G. The IRB or EC has and follows written policies and procedures for suspending or terminating IRB or EC approval of research, if warranted, and for reporting these actions, when appropriate.

Commentary

The IRB or EC must have the authority to suspend or terminate its approval of research that is not being conducted in accordance with the laws, regulations, codes, and guidance or the IRB's or EC's requirements. The IRB or EC should have policies and procedures to suspend or terminate approval of research, taking into account the rights and welfare of current participants. These policies and procedures should also describe the Organization's process for reporting terminations and suspensions of IRB or EC approval.

Sometimes Organizations use the term "administrative hold" or "voluntary hold" to describe a temporary halt of IRB approval. An administrative hold directed by the IRB is a suspension and must be classified and reported as such. This includes a suspension of enrollment alone. An administrative hold cannot be used to extend IRB approval beyond the expiration date of a protocol without IRB approval of continuing review.

[See AAHRPP Tip Sheets 14, 15, and 21.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.103(b)(5)(ii), 45 CFR 46.113, OHRP Guidance on Reporting Incidents to OHRP
- FDA: 21 CFR 56.108(b)(3), 21 CFR 56.113, FDA Information Sheets: Continuing Review After Study Approval
- VA: 38 CFR 16.103(b)(5)(ii), 38 CFR 16.113, What to Report to ORO: ACTION, Memorandum dated 9/08/05, VHA Handbook 1058.01, VHA Handbook 1200.05, 11, 14, 42
- ICH-GCP: 4.12.3

Required Written Materials

- Essential requirements:
 - Policies and procedures define:
 - Suspension of IRB approval.
 - Termination of IRB approval.
 - Policies and procedures indicate that the IRB or EC can suspend or terminate approval of research that:
 - Is not being conducted in accordance with the IRB's or EC's requirements.

- Has been associated with unexpected serious harm to participants.
- Policies and procedures describe who is authorized to suspend or terminate research.
- Policies and procedures describe who can suspend or terminate IRB approval on an urgent basis.
- Policies and procedures have suspensions and terminations by someone other than the convened IRB reported to and reviewed by the convened IRB.
- When study approval is suspended or terminated, policies and procedures have the IRB or EC or the person ordering the suspension or termination:
 - Consider actions to protect the rights and welfare of currently enrolled participants.
 - Consider whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., making arrangements for medical care outside of a research study, transfer to another Researcher, and continuation in the research under independent monitoring).
 - Consider informing current participants of the termination or suspension.
 - Have any adverse events or outcomes reported to the IRB or EC.
- Policies and procedures describe the prompt reporting of suspensions and terminations of IRB or EC approval.
 - The maximum time allowed between the recognition of a reportable event and fulfilling reporting requirements.
 - The distribution of the report to:
 - Specific organizational officials.
 - Regulatory agencies when the research is overseen by to those agencies, and they require reporting.
- When following DHHS regulations and guidance:
 - Policies and procedures describe the prompt reporting of suspensions and terminations of IRB or EC approval to OHRP.
- When following FDA regulations and guidance:

- Policies and procedures describe the prompt reporting of suspensions and terminations of IRB or EC approval to FDA.
- When following VA regulations and guidance:
 - Policies and procedures include the following definitions, procedures and timeframes:
 - Administrative hold:
 - An administrative hold is a voluntary interruption of research enrollments and ongoing research activities by an appropriate VA facility official, Researcher, or Sponsor (including the ORD when ORD is the sponsor).
 - The term “administrative hold” does not apply to interruptions of VA research related to concerns regarding the safety, rights, or welfare of human research participants, research investigators, research staff, or others.
 - An administrative hold must not be used to avoid reporting deficiencies or circumstances that otherwise require reporting by federal agencies.
 - Suspension or termination of IRB approval of research:
 - Suspension refers to a temporary interruption in the enrollment of new participants, activities involving previously enrolled participants, or other research activities.
 - Termination refers to a permanent halt in the enrollment of new participants, activities involving previously enrolled participants, or other research activities.
 - The terms “suspension” and “termination” apply to interruptions related to concerns regarding the safety, rights, or welfare of human participants, Researchers, Research Staff, or others.
 - Suspensions and terminations do not include:
 - Interruptions in research resulting solely from the expiration of a protocol approval period.
 - Administrative holds or other actions initiated voluntarily by a VA facility official, Researcher, or Sponsor for reasons other than those described in preceding items.
 - Reporting of terminations or suspensions of research.
 - Any termination or suspension of research (e.g., by the IRB or other research review committee, or by the associate chief of staff for research or other VA facility official) related to concerns about the safety, rights, or welfare of human research participants, Research Staff, or others must be reported in writing within five business days after the termination or suspension occurs to:
 - Medical center director.
 - Associate chief of staff for research.
 - Research and Development Committee.
 - IRB.
 - Other relevant research review committee.
- The medical center director must report the termination or suspension to the appropriate Office of Research Oversight research officer within five business days after receiving such notification.
- Policies and procedures describe the prompt reporting of suspensions and terminations of IRB or EC approval to:
 - The Office of Research and Development, if VA-funded.
 - The Regional Office of Research Oversight.
 - The Privacy Office, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information.
 - The Information Security Officer when the report involves violations of information security requirements.
 - IRBs of academic affiliates that are the IRB of record for a VA facility must follow these requirements.
- When following ICH-GCP guidance (E6):
 - Policies and procedures define the problems Researchers have to report to the IRB or EC to include:
 - New information that might affect adversely the safety of the participants or the conduct of the clinical trial.
 - Any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.

Outcomes

- The IRB or EC suspends or terminates approval of research in its policies and procedures.
- When the IRB or EC suspends or terminates approval of research, the rights and welfare of enrolled participants are protected.
- The IRB or EC or organizational official reports suspensions and terminations of approval of research to appropriate organizational officials and applicable regulatory agencies.

Element II.2.H. The IRB or EC has and follows policies and procedures for managing multi-site research by defining the responsibilities of participating sites that are relevant to the protection of research participants, such as reporting of unanticipated problems or interim results.

Commentary

This Element applies when the IRB or EC reviews research where the Researcher under the oversight of the HRPP is responsible for the overall conduct of the study. That is, the Researcher is the lead Researcher of a multi-site study or provides study-wide services such as for data coordination. In such cases, policies and procedures should describe the steps the IRB or EC follows to communicate among the sites involved in the multi-site study on issues other than IRB or EC review. Such communications might include reporting of unanticipated problems, protocol modifications, and interim results.

[See AAHRPP Tip Sheet 1.](#)

Regulatory and Guidance References

- VA: VHA Handbook 1200.05, 9; VHA Handbook 1200.01
- DoD: SECNAVINST 3900.39D 6f

Required Written Materials

- Essential requirements:
 - When the Researcher is the lead Researcher of a multi-site study, policies and procedures have applications include information about the management of information that is relevant to the protection of participants, such as:
 - Unanticipated problems involving risks to participants or others.
 - Interim results.

- Protocol modifications.
- When the Researcher is the lead Researcher of a multi-site study, policies and procedures have the IRB or EC evaluate whether the management of information that is relevant to the protection of participants is adequate.
- When following VA regulations and guidance:
 - Policies and procedures indicate that for a VA multi-site study, not only the principal Researcher, but also all local site Researchers, must obtain written approvals from the relevant local VA facilities' IRBs of record and all other local committees, subcommittees, and other approvals according to the respective applicable local, VA and other federal requirements.
 - Research cannot be initiated at any given site until the local Researcher has obtained written notification that the research can be initiated from the local associate chief of staff for research and development.
- When following Department of Defense regulations and requirements:
 - When conducting multi-site research, policies and procedures indicate that a formal agreement between organizations is required to specify the roles and responsibilities of each party.

Outcomes

- There is communication among the IRBs of sites participating in a multi-site study.

Standard II-3: The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes, and guidance.

Element II.3.A. The IRB or EC has and follows written policies and procedures for identifying and analyzing risks and identifying measures to minimize such risks. The analysis of risk includes a determination that the risks to participants are reasonable in relation to the potential benefits to participants and to society.

Commentary

- **Minimization of risks**

A criterion for approval of research is that risks to participants are minimized by using procedures that are consistent with sound research design and do not unnecessarily expose participants to risk, and whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes. The IRB or EC should evaluate whether research submitted for review satisfies this criterion. IRB or EC members should understand how to apply this criterion. They should recognize risks whose probability or magnitude can be reduced by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk. If the research context involves procedures already being performed for diagnostic or treatment purposes, the IRB or EC should recognize risks whose probability or magnitude can be reduced by using those procedures. If the research context does not involve such procedures, this strategy for minimizing risks is not applicable.

- **Risk-potential benefit analysis**

Another criterion for approval of research is that risks to participants are reasonable in relation to potential benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. The IRB or EC should evaluate whether research submitted for review satisfies this criterion. The IRB or EC should be able to recognize the likelihood and magnitude of harms and benefits, and understand the importance of the knowledge reasonably expected to result. The IRB or EC should be cognizant of the range of harms, including physical, social, economic, psychological, and legal harm. The IRB or EC should also be cognizant of the range of benefits. Direct benefits to participants can take the form of therapy, education, information, resources, or empowerment.

In all research, the IRB or EC should evaluate the importance of the knowledge that is likely to result from the research.

- **Resources**

The IRB or EC should evaluate each research study to ensure that it has the resources necessary to protect research participants. Such resources include staffing and personnel, in terms of availability, number, expertise, and experience; psychological, social, or medical services, including counseling or social support services that may be required because of research participation; psychological, social, or medical monitoring, ancillary care, equipment needed to protect participants, and resources for participant communication, such as language translation services.

An Organization, such as an independent review board, that does not provide all necessary resources should evaluate the resources of the local site. This might be accomplished by a case-by-case review of resources at each site. For example, an IRB can evaluate the adequacy of resources based on a description of facilities and personnel provided by the Researcher. The precise resources required are protocol specific.

[See AAHRPP Tip Sheets 1 and 20.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.111(a)(1), 45 CFR 46.111(a)(2), 45 CFR 46.111(a)(6)
- FDA: 21 CFR 56.111(a)(1), 21 CFR 56.111(a)(2), 21 CFR 56.111(a)(6)
- VA: 38 CFR 16.111(a)(1), 38 CFR 16.111(a)(2), VHA Handbook 1200.05, 17, 22
- ICH-GCP: 2.2, 2.3, 3.13, 4.2.3

Required Written Materials

- **Essential requirements:**
 - Applications include information allowing the IRB or EC to conduct an analysis of the risks and potential benefits, such as:

- The purposes of the research.
- The scientific or scholarly rationale.
- The procedures to be performed.
- A description of the procedures being performed already for diagnostic or treatment purposes.
- The risks and potential benefits of the research to participants.
- In order to approve research, policies and procedures have the IRB or EC determine that:
 - Risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk.
 - Risks to participants are minimized, when appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
 - Risks to participants are reasonable in relationship to the potential benefits, if any, to participants, and the importance of the knowledge that may be expected to result.
 - Research studies have the resources necessary to protect participants:
 - Adequate time for the Researchers to conduct and complete the research.
 - Adequate number of qualified staff
 - Adequate facilities
 - Access to a population that will allow recruitment of the necessary number of participants.

- Availability of medical or psychosocial resources that participants may need as a consequence of the research.

Common Types of Materials That May Be Used to Meet the Element

- Application form
- Reviewer checklist

Outcomes

- IRB or EC members approve research according to the criteria of approval pertaining to risks and potential benefits.
- When considering risks, the IRB or EC considers physical, psychological, social, economic, and legal risks.
- When considering benefits, the IRB or EC considers direct benefits, if any, to participants and the importance of the knowledge likely to result from the research.
- Research studies have the resources necessary to protect participants.

Element II.3.B. The IRB or EC has and follows written policies and procedures for reviewing the plans for data and safety monitoring, when applicable, and determines that the data and safety monitoring plan provides adequate protection for participants.

Commentary

A criterion for approval of research is that when appropriate, the research protocol or plan makes adequate provisions for monitoring the data to ensure the safety of participants. The IRB or EC should evaluate whether research submitted for review satisfies this criterion.

For clinical research involving no more than minimal risk and for most behavioral and social science research (because most involves no more than minimal risk), provisions for data and safety monitoring are not needed to protect participants. IRB or EC members should have criteria for determining when such monitoring is necessary.

IRB or EC members should understand the range of possible options for monitoring and that monitoring might occur at specific points in time, after a specific number of participants have been enrolled, or upon recognition of harm. IRB or EC members should understand that monitoring might be conducted by the Researcher, the Sponsor (e.g., medical monitor, safety monitoring committee), or by an independent monitoring board.

[See AAHRPP Tip Sheets 1, 6, and 20.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.111(a)(6)
- FDA: 21 CFR 56.111(a)(6)
- VA: 38 CFR 16.111(a)(6), VHA Handbook 1200.05, 10, 17, 22
- DoD: SECNAVINST 3900.39D, para. 6c

Required Written Materials

- Essential requirements:
 - Policies and procedures describe when the IRB or EC considers provisions for monitoring data to ensure the safety of participants to be appropriate.
 - When the IRB or EC considers provisions for monitoring data to ensure the safety of participants to be appropriate, policies and procedures have applications include descriptions of such provisions.
 - In order to approve research in which the IRB or EC considers provisions for monitoring data to ensure the safety of participants to be appropriate, policies and procedures have the IRB or EC determine that

the research plan makes adequate provisions. The IRB might consider provisions such as:

- What safety information will be collected, including serious adverse events.
 - How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
 - The frequency of data collection, including when safety data collection starts.
 - The frequency or periodicity of review of cumulative safety data.
 - The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the Sponsor.
 - For studies that do not have or are not required to have a data monitoring committee and are blinded, have multiple sites, enter vulnerable populations, or employ high-risk interventions, the IRB or EC needs to carefully review the data and safety monitoring plan and determine whether a data monitoring committee is needed.
 - If not using a data monitoring committee, and if applicable, statistical tests for analyzing the safety data to determine whether harm is occurring;
 - Provisions for the oversight of safety data (e.g., by a data monitoring committee).
 - Conditions that trigger an immediate suspension of the research, if applicable.
- When following Department of Defense regulations and requirements:
 - Policies and procedures have the IRB or EC consider the appointment of a research monitor:
 - Required for research involve greater than minimal risk, although the IRB or EC can require this for a portion of the research or studies involving no more than minimal risk, if appropriate.
 - The independent research monitor is appointed by name.
 - The research monitor has the authority to:
 - Stop a research study in progress.
 - Remove individuals from study.

- Take any steps to protect the safety and well being of participants until the IRB or EC can assess.

Common Types of Materials That May Be Used to Meet the Element

- Application form
- Reviewer checklist

Outcomes

- IRB or EC members articulate when provisions for data and safety monitoring are required.
- IRB or EC members determine that research protocols or plans include adequate provisions for monitoring the data to provide for the safety of participants.

Element II.3.C. The IRB or EC has and follows written policies and procedures to evaluate the equitable selection of participants.

Element II.3.C.1. The IRB or EC has and follows written policies and procedures to review proposed participant recruitment methods, advertising materials, and payment arrangements and determines whether such arrangements are fair, accurate, and appropriate.

Commentary

A criterion for approval of research is that selection of participants is equitable. The IRB or EC should evaluate whether research submitted for review satisfies this criterion. IRB or EC members should understand how to apply this criterion. In evaluating this criterion, IRB or EC members should consider both the selection (inclusion and exclusion) criteria and the proposed plans for recruitment of participants. IRB members should evaluate whether selection criteria and recruitment practices meet this criterion.

Recruitment methods, including advertisements, and participant payment arrangements affect the equitable selection of participants and an appropriate consent process.

A research study might have fair selection criteria, but use recruitment methods or payment arrangements that lead to inequitable selection. For example, recruitment methods, advertisements, or payment arrangements that target economically disadvantaged participants can lead to unfair selection of participants despite reasonable selection criteria. Therefore, the IRB or EC should evaluate whether recruitment processes, advertisements, and payment arrangements affect the equitable selection of participants.

Recruitment methods, advertising materials, and payment arrangements also represent a part of the consent process. Recruitment methods and advertisements are the beginning of the consent negotiations; payments for participation are provided to reimburse participants for their time, effort, or other expenses. Recruitment methods, advertisements, or payment arrangements that are misleading, inaccurate, exculpatory, coercive, or unduly influential violate ethical requirements for consent. Therefore, the IRB or EC should review proposed recruitment processes and advertising materials to judge whether they fulfill the requirements for consent.

Payment arrangements can place participants at risk of coercion or undue influence or cause inequitable selection. Two situations should be examined: finder's fees and recruitment bonuses. A finder's fee or referral is a payment from the Researcher or Sponsor to a person who refers a prospective participant. Recruitment bonuses are payments from the Sponsor to a Researcher or Organization based on the rate or

timing of recruitment. For example, a Sponsor might contract to pay the Researcher or Organization a fixed fee for each participant but promise an additional payment if more than a certain number of participants are enrolled in the first week or if the site has the highest enrollment at the end of the month. Policies and procedures should describe acceptable and unacceptable payment arrangements among the Sponsor, Organization, Researcher, and those referring research participants.

[See AAHRPP Tip Sheets 1 and 20.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 17.92, 45 CFR 46.111(a)(3), 45 CFR 46.116, OHRP Guidance on Written Institutional Review Board (IRB) Procedures
- FDA: 21 CFR 56.111(a)(3), 21 CFR 50.20, 21 CFR 56.111(a)(3), FDA Information Sheets: Frequently Asked Questions: Informed Consent Document Content, Frequently Asked Questions: IRB Organization, A Guide to Informed Consent, Recruiting Study Subjects, Payment to Research Subjects
- VA: 38 CFR 16.111(a)(3), 38 CFR 16.116, 38 CFR 17.45, VHA Handbook 1200.05, 5, 58, 59
- DoD: Dual Compensation Act, 24 U.S.C 301, DoDD 3216.2, para. 4.4.4; SECNAVINST 3900.39D, para. 6a(6)
- DOJ: 28 CFR 512.11(4,5)
- ICH-GCP: 3.1.8

Required Written Materials

- Essential requirements:
 - Applications include information that allows the IRB or EC to determine whether selection of participants will be equitable, such as:
 - The purposes of the research.
 - The setting in which the research will be conducted.
 - Whether prospective participants will be vulnerable to coercion or undue influence.
 - The selection (inclusion/exclusion) criteria.
 - Participant recruitment and enrollment procedures.

- The amount and timing of payments to participants.
- In order to approve research, policies and procedures have the IRB or EC determine that selection of participants is equitable.
- In making an assessment about whether selection of participants is equitable, policies and procedures have the IRB or EC take into account:
 - The purposes of the research.
 - The setting in which the research will be conducted.
 - Whether prospective participants will be vulnerable to coercion or undue influence.
 - The selection (inclusion/exclusion) criteria.
 - Participant recruitment and enrollment procedures.
 - The influence of payments to participants.
- Policies and procedures have the IRB or EC review:
 - The information contained in the advertisement.
 - The mode of its communication.
 - The final copy of printed advertisements.
 - The final audio or video taped advertisements.
- Policies and procedures have the IRB or EC review advertising to ensure that advertisements do not:
 - State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
 - Include exculpatory language.
 - Emphasize the payment or the amount to be paid, by such means as larger or bold type.
 - Promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation.
- Policies and procedures have advertisements limited to the information prospective participants need to determine their eligibility and interest, such as:
 - The name and address of the Researcher or research facility.
 - The purpose of the research or the condition under study.
 - In summary form, the criteria that will be used to determine eligibility for the study.
 - A brief list of benefits to participants, if any.
 - The time or other commitment required of the participants.
- The location of the research and the person or office to contact for further information.
- Applications include the amount and schedule of all payments.
- Policies and procedures have the IRB or EC review payments to determine that:
 - The amount of payment and the proposed method and timing of disbursement neither is coercive nor presents undue influence.
 - Credit for payment accrues as the study progresses and not be contingent upon the participant completing the entire study.
 - Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
 - All information concerning payment, including the amount and schedule of payments, is set forth in the consent document.
- Policies and procedures describe acceptable and unacceptable payment arrangements for the Sponsor, Organization, Researcher, and those referring research participants.
 - Policies and procedures on payment arrangements address the acceptability of payments in exchange for referrals of prospective participants (“finder’s fees” or “referral fees”).
 - Policies and procedures on payment arrangements address payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments”).
- When following FDA regulations and guidance:
 - Policies and procedures have the IRB or EC review advertising to ensure that advertisements do not:
 - Make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling.
 - Use terms, such as “new treatment,” “new medication,” or “new drug,” without explaining that the test article is investigational.
 - Allow compensation for participation in a trial offered by a Sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
- When following VA regulations and guidance:
 - Policies and procedures have the IRB allow non-veterans to be entered into VA-approved research

- studies only when there are insufficient veterans available to complete the study or when the Researcher can present a compelling argument to the IRB for the inclusion of non-veterans (e.g., survey of VA employees; study of active duty military; study involving veterans' family members), and the research is relevant to the care of veterans or active duty military personnel.
- Policies and procedures prohibit paying participants to participate in research when the research is integrated with a patient's medical care and when it makes no special demands on the patient beyond those of usual medical care.
 - Policies and procedures permit paying participants when:
 - The research is not directly intended to enhance the diagnosis or treatment of the medical condition for which the participant is being treated, and when the standard of practice in affiliated non-VA institutions is to pay participants in this situation.
 - The research is a multi-institutional study and participants at collaborating non-VA institutions are paid for the same participation in the same study at the same rate proposed.
 - In the opinion of the IRB or EC, payment of participants is appropriate in other comparable situations.
 - The participant will incur transportation expenses that would not be incurred in the normal course of receiving treatment and are not reimbursed by another mechanism.
 - Policies and procedures indicate that the medical center director is responsible for ensuring that recruiting documents, flyers, and advertisements for non-VA research are not posted within or on the premises of a VA facility.
 - General guidance may be posted within VA indicating that veterans may speak with their health care providers if they wish to participate in research and that information on clinical trials is available at: <http://clinicaltrials.gov>.
 - When following Department of Defense regulations and requirements:
 - When research involves U.S. military personnel policies and procedures include additional protections for military research participants to minimize undue influence:
 - Officers are not permitted to influence the decision of their subordinates.
 - Officers and senior non-commissioned officers may not be present at the time of recruitment.
 - Officers and senior non-commissioned officers have a separate opportunity to participate.
 - When recruitment involves a percentage of a unit, an independent ombudsman is present.
 - When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:
 - Prohibit an individual from receiving pay of compensation for research during duty hours.
 - An individual may be compensated for research if the participant is involved in the research when not on duty.
 - When following Department of Justice regulations and guidance:
 - Policies and procedures indicate that for research conducted within the Bureau of Prisons:
 - The selection of participants within any one organization must be equitable.
 - Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.
 - Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are both:
 - No longer in Bureau of Prisons custody.
 - Participating in authorized research being conducted by Bureau employees or contractors.

Common Types of Materials That May Be Used to Meet the Element

- Application form
- Reviewer checklist

Outcomes

- IRB or EC members determine that selection of participants is equitable.
- IRB or EC members determine that advertisements:
 - Provide prospective participants with sufficient opportunity to consider whether to participate.
 - Do not include any exculpatory language through which the participant or the legally authorized representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the Researcher, the Sponsor, or the institution, or its agents from liability for negligence.

- IRB or EC members determine that payment arrangements:
 - Provide prospective participants with sufficient opportunity to consider whether to participate.
 - Minimize the possibility of coercion or undue influence of participants.
- Based on the timing or rate of participant enrollment (often known as bonus payments or finder's fees), are prohibited unless they are judged not to interfere with providing prospective participants with sufficient opportunity to consider whether to participate and do not increase the possibility of coercion or undue influence on Researchers or participants.

Element II.3.D. The IRB or EC has and follows written policies and procedures to evaluate the proposed arrangements for protecting the privacy interests of research participants, when appropriate, during their involvement in the research.

Commentary

A criterion for approval of research is that there are adequate provisions to protect the privacy interests of participants. The IRB or EC should evaluate whether research submitted for review satisfies this criterion. IRB or EC members should understand how to apply this criterion.

Privacy refers to persons and their interest in controlling the access of others to themselves. (Confidentiality refers to the agreement between the Researcher and participant on how data will be managed and used.) For example, based on their privacy interests, people want to control:

- The time and place where they give information.
- The nature of the information they give.
- The nature of the experiences that are given to them.
- Who receives and can use the information.

For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy counseling center that is clearly identified as such by signs on the front of the building.

What is private depends on the individual and can vary according to gender, ethnicity, age, socio-economic class, education, ability level, social or verbal skill, health status, legal status, nationality, intelligence, personality, and the individual's relationship to the Researcher. For example, protecting the privacy interests of a young child might mean having a parent present at a session with a Researcher. Protecting the privacy interests of a teenager might mean having a parent absent.

IRB members should understand the concept of privacy and how it differs from confidentiality. IRB

or EC members should know strategies to protect privacy interests relating to contact with prospective participants and access to private information.

[See AAHRPP Tip Sheets 1, 5, and 20.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.111(a)(7)
- FDA: 21 CFR 56.111(a)(7)
- VA: 38 CFR 16.111(a)(7), VHA Handbook 1200.05, 10, 12, 17

Required Written Materials

- Essential requirements:
 - Applications include a description of provisions to protect the privacy interests of participants.
 - In order to approve research, policies and procedures have the IRB or EC determine that the research protocol or plan contains adequate provisions to protect the privacy interests of participants.

Common Types of Materials That May Be Used to Meet the Element

- Application form
- Reviewer checklist

Outcomes

- IRB or EC members understand the concept of privacy.
- IRB or EC members determine that the research protocol or plan contains adequate provisions to protect the privacy interests of participants.

Element II.3.E. The IRB or EC has and follows written policies and procedures to evaluate proposed arrangements for maintaining the confidentiality of identifiable data, when appropriate, preliminary to the research, during the research, and after the conclusion of the research.

Commentary

A criterion for approval of research is that there are adequate provisions to maintain the confidentiality of identifiable data. The IRB or EC should evaluate whether research submitted for review satisfies this criterion. IRB or EC members should understand how to apply this criterion.

Confidentiality refers to maintenance of the Researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated. IRB or EC members should understand the concept of confidentiality and how it differs from privacy. IRB or EC members should be knowledgeable about strategies to maintain confidentiality of identifiable data, including controls on storage, handling, and sharing of data.

When appropriate, the IRB or EC should also know how certificates of confidentiality can be used to maintain the confidentiality of identifiable data. When appropriate, the IRB or EC should also be aware of other standard methods to protect confidentiality, such as inter-file linkage, error inoculation, top coding, bracketing, and data brokering.

The confidentiality protections include information obtained preliminary to research; for example, information collected from personal records to determine potential sample size, as well as the maintenance of the confidentiality of information after the study has ended, when identifiable information is maintained.

[See AAHRPP Tip Sheets 1, 4, and 20.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.111(a)(7)
- FDA: 21 CFR 56.111(a)(7),
- VA: 38 CFR 16.111(a)(7), VHA Handbook 1200.05, 10, 12, 17, 38
- DOE: Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements
- DOJ: 28 CFR 22, 28 CFR 512.8,11,12,13,15
- ICH-GCP: 2.11

Required Written Materials

- Essential requirements:

- Applications include a description of provisions to maintain the confidentiality of data.
- In order to approve research policies and procedures have the IRB or EC determine that, when appropriate, the research protocol or plan contains adequate provisions to maintain the confidentiality of data.
- When following Department of Energy (DOE) regulations and guidance:
 - Policies and procedures require the IRB or EC to review and approve the "Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements" submitted by the Researchers to verify compliance with the DOE requirements for the protection of personally identifiable information.
- When following Department of Justice regulations and guidance:
 - Policies and procedures indicate that for National Institute of Justice (NIJ) funded research:
 - All projects are required to have a privacy certificate approved by the NIJ human subjects protection officer.
 - All Researchers and Research Staff are required to sign employee confidentiality statements, which are maintained by the responsible Researcher.
 - Policies and procedures indicate that for research conducted with the Bureau of Prisons:
 - A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency.
 - Except as noted in the consent statement to the participant, the Researcher must not provide research information that identifies a participant to any person without that participant's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
 - Except for computerized data records maintained at an official Department of Justice site, records

that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.

- If the Researcher is conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the Researcher may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

Common Types of Materials That May Be Used to Meet the Element

- Application form
- Reviewer checklist

Outcomes

- IRB or EC members understand the concept of confidentiality.
- IRB or EC members determine that, when appropriate, the research protocol or plan contains adequate provisions to maintain the confidentiality of identifiable data in accordance with agreements between Researchers and participants.

Element II.3.F. The IRB or EC has and follows written policies and procedures to evaluate the consent process and to require that the Researcher appropriately document the consent process.

Commentary

To approve research, the IRB or EC has to determine that the consent process meets these criteria for approval of research:

- The Researcher obtains the legally effective consent of the participant or the participant’s legally authorized representative.
- The consent process provides sufficient opportunity for the participant or the participant’s legally authorized representative to consider whether to participate.
- The consent process minimizes the possibility of coercion or undue influence.
- The consent discussion is in language understandable to the participant or the representative.
- The consent discussion is free of exculpatory language.

The IRB or EC should evaluate whether a research study satisfies these criteria. This cannot be accomplished solely by evaluating a written consent document, since the consent process is a discussion that should be culturally and linguistically appropriate to the study population, and not simply a consent document. Instead, the IRB or EC should know the nature and circumstances of the consent process, such as who will conduct the consent interview, the timing of obtaining consent, and any waiting period between informing the participant and obtaining consent, and based on this information determine whether the criteria for approval of research are met.

Another criterion for approval of research is that Researchers inform prospective participants of required disclosures. The IRB or EC should evaluate whether research submitted for review satisfies this criterion. This cannot be accomplished solely by evaluation of a written consent document, because the consent document does not reflect all the information communicated to the participant during the consent process. Therefore, the IRB or EC should evaluate the information that will be communicated to the participant during the consent process, and determine which information will be disclosed.

When reviewing research, the IRB or EC should evaluate whether the consent process will be documented using a consent document.

[See AAHRPP Tip Sheets 19 and 20.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.109(b), 45 CFR 46.109(e), 45 CFR 46.111(a)(4), 45 CFR 46.116, 45 CFR 46.117, OHRP Guidance on Exculpatory Language in Informed Consent, OHRP Guidance on Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English
- FDA: 21 CFR 50.20, 21 CFR 56.109(b), 21 CFR 56.109(f), 21 CFR 56.111(a)(4), 21 CFR 50.25(a), 21 CFR 50.25(b), 21 CFR 50.27(a), 21 CFR 50.27(b), 21 CFR 56.111(a)(5), FDA Information Sheets: A Guide to Informed Consent, Frequently Asked Questions: Informed Consent Document Content, Recruiting Study Subjects, IRB Procedures, FDA Information Sheets: Frequently Asked Questions: Informed Consent Process, Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials
- VA: 38 CFR 46.111(a)(4), 38 CFR 16.116, 38 CFR 16.117, VHA Handbook 1200.05, 9, 30, 31, 32, 33, 55, VHA Handbook 1200.12, VHA Handbook 1907.01
- DoD: DoDD 3216.2, para. 5.3.4; SECNAVINST 3900.39D, para. 6a(5)]
- DOJ: 28 CFR 512.16
- ICH-GCP: 2.9, 3.1.5, 3.1.9, 4.3.4, 4.8.1-4.8.9, 4.8.11

Required Written Materials

- Essential requirements:
 - Applications include a description of the consent process including:
 - The person who will conduct the consent interview.
 - The person who will provide consent or permission.
 - Any waiting period between informing the prospective participant and obtaining consent.
 - Steps taken to minimize the possibility of coercion or undue influence.
 - The language used by those obtaining consent.
 - The language understood by the prospective participant or the legally authorized representative.

- The information to be communicated to the prospective participant or the legally authorized representative.
- In order to approve research, policies and procedures have the IRB or EC determine that:
 - The Researcher will obtain the legally effective consent of the participant or the participant's legally authorized representative.
 - The circumstances of the consent process provide the prospective participant or the legally authorized representative sufficient opportunity to consider whether to participate.
 - The circumstances of the consent process minimize the possibility of coercion or undue influence.
 - The individuals communicating information to the participant or the legally authorized representative during the consent process will provide that information in language understandable to the participant or the representative.
 - The information being communicated to the participant or the representative during the consent process will not include exculpatory language through which the participant or the legally authorized representative is made to waive or appear to waive any of the participant's legal rights.
 - The information being communicated to the participant or the legally authorized representative during the consent process will not include exculpatory language through which the participant or the legally authorized representative releases or appears to release the Researcher, the Sponsor, the Organization, or its agents from liability for negligence.
- In order to approve research, policies and procedures have the IRB or EC determine that in seeking consent, the required disclosures will be provided to each participant or a legally authorized representative in accordance with legal and regulatory requirements.
- Policies and procedures have the IRB or EC consider whether additional disclosures are required for inclusion in the consent process.
- Policies and procedures have the IRB or EC determine that the consent process will be documented according to legal and regulatory requirements.
- When following DHHS regulations and guidance:
 - Policies and procedures have the IRB or EC determine that the required and appropriate additional elements of disclosure are included in the consent process.
- To allow use of the long form of consent documentation, policies and procedures have the IRB or EC determine that:
 - The consent document embodies the basic and required additional elements of disclosure.
 - The participant or the participant's legally authorized representative will sign the consent document.
 - A copy of the consent document will be given to the person signing the consent document.
 - The Researcher will give either the participant or the representative adequate opportunity to read the consent document before it is signed.
- To allow the use of the short form of consent documentation, policies and procedures have the IRB or EC determine that:
 - The consent document states that the elements of disclosure required by regulations have been presented orally to the participant or the participant's legally authorized representative.
 - A written summary embodies the basic and required additional elements of disclosure.
 - There will be a witness to the oral presentation.
 - For participants who do not speak English, the witness is conversant in both English and the language of the participant.
 - The participant or the participant's legally authorized representative will sign the consent document.
 - The witness will sign both the short form and a copy of the summary.
 - The person actually obtaining consent will sign a copy of the summary.
 - A copy of the signed short form will be given to the participant or the legally authorized representative.
 - A copy of the signed summary will be given to the participant or the legally authorized representative.
- When following FDA regulations and guidance:
 - Policies and procedures have the IRB or EC determine that the required and appropriate additional elements of disclosure are included in the consent process.
 - Policies and procedures have the IRB or EC determine that:
 - The consent document embodies the basic and required additional elements of disclosure.

- There is a statement noting the possibility that the FDA may inspect the records that will be provided to each participant.
- The participant or the participant's legally authorized representative will sign and date the consent document.
- The Researcher will give either the participant or the legally authorized representative adequate opportunity to read the consent document before it is signed.
- To allow the use of the short form of consent documentation, policies and procedures have the IRB or EC determine that:
 - The consent document states that the elements of disclosure required by regulations have been presented orally to the participant or the participant's legally authorized representative.
 - A written summary embodies the basic and required additional elements of disclosure.
 - There will be a witness to the oral presentation.
 - For participants who do not speak English, the witness is conversant in both English and the language of the participant.
 - The participant or the participant's legally authorized representative will sign the consent document.
 - The witness will sign both the short form and a copy of the summary.
 - The person actually obtaining consent will sign a copy of the summary.
 - A copy of the signed short form will be given to the participant or the legally authorized representative.
 - A copy of the signed summary will be given to the participant or the legally authorized representative.
- With regard to data retention when participants withdraw from a clinical trial, policies and procedures have the IRB or EC:
 - When a participant withdraws from a study, the data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the participant the option of having data removed.
 - A Researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant distinguishes between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information.
- The Researcher must obtain the participant's consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The IRB or EC must approve the consent document.
- If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the Researcher must not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent. However, a Researcher may review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status.
- When following VA regulations and guidance:
 - Department of Veterans Affairs (VA) Form 10-1086, Research Consent Form, or an electronic version of VA Form 10-1086, must be used as the consent document.
 - The only exception is that a Department of Defense (DoD) consent document may be employed for active duty military personnel participating in VA research at DoD sites when VA-specific language is not necessary.
 - When appropriate, VA requires one or more of the following elements of information be provided to each participant. Also, when any of these additional elements are appropriate, the VA requires them to be documented in the IRB-approved consent document, unless documentation of consent is waived.
 - Commercial product. If applicable, that the Researcher believes that the human biologic specimens obtained could be part of, or lead to the development of, a commercially valuable product.
 - Future use of specimens. If the specimens are to be retained after the end of the study for future research, where the specimens will be retained, who will have access to them, and how long they will be retained. Organizations, VA, and other federal requirements must be

met for handling, use and storage of biologic specimens and data.

- Future use of data. If any of the data will be retained after the study for future research, where the data will be stored, and who will have access to the data. Organizations, VA, and other federal requirements must be met for use and storage of data.
- Re-contact. If the participant will be re-contacted for future research whether within a VA facility or outside a VA facility.
- Payment for participating in the study. If appropriate, a statement regarding any payment the participant is to receive for participating in the study and how the payment is to be made.
- Disclosure of results. If the participant will receive a report of the aggregate results or any results specific to the participant.
- For research involving more than minimal risk, the consent process and document will disclose a statement that in the event of a research-related injury the VA has to provide necessary medical treatment to a participant injured by participation. VA regulations require the VA to provide care for all research-related injuries including those studies that are considered minimal risk even if a statement is not included in the consent process or document for research involving no greater than minimal risk.
- The consent process and document will disclose a statement that a veteran-participant will not be required to pay for care received as a participant in a VA research project except in accordance with federal law and that certain veterans are required to pay co-payments for medical care and services provided by the VA.
- The consent document needs to include language explaining the VA's authority to provide medical treatment to research participants injured by participation in a VA research project.
- Consent for research must be obtained from each research participant before taking photographs or making voice or video recordings that will be used for research purposes.
- Unless the IRB grants a waiver of documentation of the consent process for research, the consent document for research must include a discussion of why photographs, or voice or video recordings are being taken for the research, who will have access to them, and what their disposition will be after the research is completed.
 - When the research participant is a patient (either an inpatient or outpatient), the participant must sign VA Form 10-3203 to permit photographs or video and voice recordings that will be used for research purposes even if the IRB has waived the requirement for documentation of consent for research. Photography or recordings cannot occur prior to the patient's granting such permission.
- When the research participant is a patient, the participant's signed and dated VA Form 10-3203 must be placed into the medical record along with, if applicable, the signed and dated research consent document (i.e., VA Form 10-1086). The signed VA Form 10-3203 must be obtained and placed in the participant's medical record, even if the IRB has waived documentation of consent for research.
- A witness, if required by the IRB (e.g., the IRB may require a witness if the study involves an invasive intervention or an investigational drug or device).
 - The witness is required to observe only the participant's or participant legally authorized representative's signature, not the consent process, unless the Sponsor or IRB requires the witness to observe the consent process.
 - The witness cannot be the person who obtained consent from the participant, but may be another member of the study team or may be a family member.
- If someone other than the Researcher conducts the interview and obtains consent, policies and procedures have the Researcher formally and prospectively designate in writing in the protocol or the IRB application, the individual who will have this responsibility. The person so delegated must have received appropriate training to perform this activity. This person must be knowledgeable about the research to be conducted and the consenting process, and must be able to answer questions about the study. This designee must be a member of the research team.
- The IRB may waive the requirement for the investigator to maintain a master list for a given study if both of the following conditions are met:
 - There is a waiver of documentation of the consent process, and
 - The IRB determines that including the participants on such a master list poses a risk to the participants from a breach of confidentiality.

- If IRB waives the requirement to maintain such a master list, IRB must provide written documentation in the IRB minutes or IRB protocol file justifying the waiver.
- When following Department of Defense (DoD) regulations and requirements:
 - Policies and procedures have the IRB or EC determine that the disclosure includes that provisions for research-related injury follow the requirements of the DoD component.
- When following Department of Justice regulations and guidance:
 - Policies and procedures indicate that for National Institute of Justice-funded research:
 - The confidentiality statement on the consent document must state that confidentiality can only be broken if the participant reports immediate harm to participants or others.
 - Under a privacy certificate, Researchers and Research Staff do not have to report child abuse unless the participant signs another consent document to allow child abuse reporting.
 - Policies and procedures indicate that for research conducted within the Bureau of Prisons required elements of disclosure include:
 - Identification of the Researchers.
 - Anticipated uses of the results of the research.
 - A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
 - A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a Researcher may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.
 - A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.
- When following ICH-GCP guidance (E6):
 - Policies and procedures have the IRB or EC determine that the following disclosures are included:
 - The alternative procedures or treatment that might be available to the participant, and their important potential benefits and risks.
 - That the monitor, the auditor, the IRB or EC, and the regulatory authority will be granted direct access to the participant's original medical records for verification of clinical trial procedures or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written consent document, the participant or the participant's legally acceptable representative is authorizing such access.
 - The approval of the IRB or EC.
 - Policies and procedures on documentation of the consent process include:
 - Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the participant or by the participant's legally acceptable representative.
 - Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the person who conducted the informed consent discussion.
 - If a participant is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion.
 - After the written consent document and any other written information to be provided to participants, is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has orally consented to the participant's participation in the trial and, if capable of doing so, has signed and personally dated the consent document, the witness should sign and personally date the consent document.
 - By signing the consent document, the witness attests that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and that consent was freely

given by the participant or the participant's legally acceptable representative.

- Prior to participation in the trial, the participant or the participant's legally acceptable representative should receive a copy of the signed and dated written consent document and any other written information provided to the participants.

[See AAHRPP Tip Sheet 1.](#)

Common Types of Materials That May Be Used to Meet the Element

- Application form

- Reviewer checklist
- Consent template

Outcomes

- Unless waived, IRB or EC members determine that the consent process will seek the legally effective consent of participants or their legally authorized representatives.
- IRB or EC members determine that the required and additional elements of disclosure, when appropriate, are included in the consent process.
- IRB or EC members determine that the consent process will be documented as required.

Element II.3.G. The IRB or EC has and follows written policies and procedures for approving waivers or alterations of the consent process and waivers of consent documentation.

Commentary

Waiver or alteration of the consent process

In certain situations, the IRB or EC may waive or alter the consent process in accordance with laws, regulations, codes, and guidance.

When an IRB or EC waives the requirement to obtain consent, it waives the entire requirement for consent, both the attributes of the consent process and the elements of disclosure. When an IRB or EC alters the consent process, consent is still obtained, but the consent process or elements of disclosure differ from what is generally required. When the IRB or EC approves a waiver or alteration of the consent process, records should document why the IRB or EC judged that each criterion was met for the specific protocol being reviewed.

IRBs or ECs sometimes use the terms “passive consent,” “deferred consent,” or “implied consent” to describe consent processes that do not follow one or more requirements for the consent process. Each of these cases represents a waiver or alteration in the consent process. Research that proposes these consent procedures cannot be approved unless the IRB or EC approves a waiver or alteration of the consent process.

Waiver of consent documentation

In certain situations, the IRB or EC may waive the requirement to document the consent process. When the IRB or EC approves a waiver of the requirement to document the consent process, records should document the protocol-specific reasons justifying the waiver. An IRB or EC might require that a written statement describing the research be provided to participants, such as a copy of a consent document that might be used if the participant requests written documentation of the consent process.

[See AAHRPP Tip Sheets 1 and 20.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.116(c), 45 CFR 46.116(d), 45 CFR 46.117(c), OHRP Guidance on Informed Consent--Legally Effective and Prospectively Obtained
- FDA: 21 CFR 56.109(c)(1), 21 CFR 56.109(d)
- VA: 38 CFR 16.116(c), 38 CFR 16.116(d), 38 CFR 16.117(c), VHA Handbook 1200.05, 34

- DoD: DoD Directive 3216.2 E2.1.1, 10 USC 980(a,b)
- ED: 343 CFR 99

Required Written Materials

- Essential requirements:
 - Policies and procedures allow the IRB or EC to waive or alter the consent process by determining that the criteria for waivers or alterations are met.
 - Policies and procedures allow the IRB or EC to waive parental permission by determining that the criteria for waivers or alterations are met.
 - Policies and procedures allow the IRB or EC to waive the requirement for written documentation of the consent process by determining that the criteria for waivers are met.
 - Policies and procedures have the IRB or EC document its findings justifying the waiver or alteration.
- When following DHHS regulations and guidance:
 - Policies and procedures allow the IRB or EC to waive or alter the consent process by determining that the regulatory criteria for waivers or alterations of the consent process are met and that the research is not regulated by the FDA.
 - Policies and procedures allow the IRB or EC to waive the requirement to document the consent process by determining that the regulatory criteria for waivers are met.
 - When the IRB or EC considers waiving the requirement to obtain written documentation of the consent process, policies and procedures have the IRB or EC review a written description of the information that will be provided to participants.
 - When granting waivers of the requirement to obtain written documentation of the consent process, policies and procedures have the IRB or EC consider requiring the Researcher to provide participants with a written statement regarding the research.
- When following FDA regulations and guidance:
 - Policies and procedures prohibit the IRB or EC from waiving or altering the consent process.
 - Policies and procedures allow the IRB or EC to waive the requirement to document the consent

process by determining that the regulatory criteria for waivers are met.

- When the IRB or EC considers waiving the requirement to obtain written documentation of the consent process, policies and procedures have the IRB or EC review a written description of the information that will be provided to participants.
- When granting waivers of the requirement to obtain written documentation of the consent process, policies and procedures have the IRB EC consider requiring the Researcher to provide participants with a written statement regarding the research.
- When following VA regulations and guidance:
 - Policies and procedures require the IRB to document the reason when it waives the requirement to obtain written documentation of the consent process
- When following Department of Defense regulations and requirements:
 - Policies and procedures define “experimental subject.”
 - If the research participant meets the definition of “experimental subject,” policies and procedure prohibit a waiver of the consent process unless a waiver is obtained from the Secretary of Defense.
 - If the research participant does not meet the definition of “experimental subject,” policies and procedures allow the IRB or EC to waive the consent process.
- When following Department of Education regulations and guidance:
 - Policies and procedures include a process to comply with the Family Educational Rights and Privacy Act (FERPA). This process may occur outside the IRB or EC.
 - The Organization has in policies and procedures, a process to grant exceptions to parental or student consent to release student records for research. This responsibility may be delegated to the IRB or EC, another individual, or component of the Organization (e.g., a FERPA committee).
 - An educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:
 - Develop, validate, or administer predictive tests.
 - Administer student aid programs.
 - Improve instruction.
- A school district or postsecondary institution that uses this exception is required to enter into a written agreement with the Organization or Researcher conducting the research that specifies:
 - The determination of the exception.
 - The purpose, scope, and duration of the study.
 - The information to be disclosed.
 - That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in Department of Education regulations on redisclosure and destruction of information.
 - That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the Organization with legitimate interests.
 - That the Organization is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
 - The time period during which the Organization must either destroy or return the information.
- Education records may be released without consent under FERPA if all personally identifiable information has been removed including:
 - Student’s name and other direct personal identifiers, such as the student’s social security number or student number.
 - Indirect identifiers, such as the name of the student’s parent or other family members; the student’s or family’s address, and personal characteristics or other information that would make the student’s identity easily traceable; and date and place of birth and mother’s maiden name.
 - Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
 - Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant

circumstances, to identify the student with reasonable certainty.

Outcomes

- IRB or EC members waive the requirement to document the consent process according to criteria for waivers.

Standard II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.

Element II.4.A. The IRB or EC has and follows written policies and procedures for determining the risks to prospective participants who are vulnerable to coercion or undue influence and ensuring that additional protections are provided as required by applicable laws, regulations, codes, and guidance.

Commentary

The IRB or EC should evaluate research to judge whether the research involves participants who are vulnerable to coercion or undue influence. When some or all of the participants are likely to be vulnerable, the IRB or EC should ensure that additional safeguards are included in the research design to protect the rights and welfare of these participants. If the IRB or EC reviews research that involves children; pregnant women, fetuses, or neonates; prisoners; or adults who lack the ability to consent, or the IRB or EC regularly reviews research that involves other vulnerable individuals (for example, students, employees, or homeless persons), the IRB or EC should have written policies and procedures regarding additional protections for these categories.

It is impractical to have specific policies for every vulnerable population that might be involved in research. Therefore, when a research study involves vulnerable populations not otherwise covered by specific policies and procedures, policies and procedures should describe in general the steps followed by the IRB or EC to evaluate such research to determine the need for additional protections.

In research involving no more than minimal risk and vulnerable populations, the IRB or EC may decide that existing protections are sufficient and no additional protections are warranted. Conversely, sometimes when research involves no more than minimal risk, additional protections for vulnerable populations might be appropriate.

[See AAHRPP Tip Sheets 1, 11, 18, and 20.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.111(b), 45 CFR 46 Subpart B, 45 CFR 46 Subpart C, 45 CFR 46 Subpart D, 45 CFR 46.111(b), 45 CFR 46.205, OHRP Guidance on Special Protections for Children as Research Subjects, OHRP Guidance on the Involvement of Prisoners in Research, May 23, 2003, 45 CFR 46 Waiver of the Applicability of Certain Provisions of Department of Health and Human Services Regulations for Protection

of Human Research Subjects for Department of Health and Human Services Conducted or Supported Epidemiologic Research Involving Prisoners as Subjects (Federal Register, Vol. 68, No. 119, pp. 36929-36931, Friday, June 20, 2003)

- FDA: 21 CFR 50.3, 21 CFR 50 Subpart D, 21 CFR 56.111(b), 21 CFR 56.111(c)
- VA: 38 CFR 16.111(b), -VHA Directive 2001-028, VHA Handbook 1200.05, 36, 45, 46, 47, 48, 49
- DoD: DoDD 3216.2, para. 4.4.2; SECNAVINST 3900.39D, para. 6a(8), DoDD 3216.2, para. 4.4.1; SECNAVINST 3900.39D, para. 6a(6), DoDD 3216.2, para. 4.2; SECNAVINST 3900.39D, para. 6a(3); 10 U.S.C. 980
- EPA: 40 CFR 26.304, 40 CFR 26.404-405
- ICH-GCP: 3.3.1, 4.8.13, 4.8.14

Required Written Materials

- Essential requirements:
 - Applications include whether some or all of the participants are likely to be vulnerable to coercion or undue influence.
 - When some or all of the participants are likely to be vulnerable, applications include a description of additional safeguards included in the protocol to protect their rights and welfare.
 - In order to approve research where some or all of the participants are likely to be vulnerable, policies and procedures have the IRB or EC determine whether additional safeguards have been included in the protocol to protect their rights and welfare.
 - If research involves pregnant women, fetuses, or neonates, policies and procedures have the IRB or EC follow Subpart B of the DHHS regulations or equivalent protections as allowed by law.
 - If the Organization chooses not to apply Subpart B to all research regardless of funding, policies and procedures include equivalent protections for participants in non-funded research.

- If research involves prisoners as participants, policies and procedures have the IRB follow Subpart C of the DHHS or equivalent protections as allowed by law.
 - If the Organization chooses not to apply Subpart C to all research regardless of funding, procedures include equivalent protections for participants in non-funded research.
 - If the convened IRB or EC reviews research that involves prisoners, policies and procedures indicate that one or more individuals who are prisoners or prisoner representatives have to be present at the meeting.
- If research involves children as participants, policies and procedures have the IRB or EC follow Subpart D of the DHHS or equivalent protections as allowed by law.
 - If the Organization chooses not to apply Subpart D to all research regardless of funding, procedures include equivalent protections for participants in non-funded research.
- If research involves adults unable to consent, policies and procedures have the IRB or EC consider specific criteria for approval of such research that provides additional safeguards to protect their rights and welfare.
- If the IRB or EC regularly reviews research that involves other vulnerable populations, policies and procedures describe the steps the IRB or EC follows to evaluate whether additional safeguards are included in research to protect the rights and welfare of these participants.
- When following DHHS regulations and guidance:
 - Policies and procedures have the IRB or EC follow the requirements specified in Subpart B for research involving pregnant women, fetuses, or neonates; Subpart C for research involving prisoners; and Subpart D for research involving children.
- When following FDA regulations and guidance:
 - Policies and procedures have the IRB or EC follow the requirements specified in Subpart D for research involving children.
- When following VA regulations and guidance:
 - Policies and procedures have the IRB find and document in the minutes or IRB records specific findings in accordance with VA requirements.
 - Policies and procedures indicate:
 - Research involving fetuses is not allowed.
 - Research involving *in vitro* fertilization is not allowed.
- Research involving prisoners as participants is not allowed unless a waiver has been granted by the chief research and development officer.
- Research involving children as participants is not allowed unless a waiver has been granted by the chief research and development officer and is not approved unless specific requirements are met.
- International research is not initiated unless permission is obtained from the chief research and development officer or designee. The chief research and development officer, or designee, will not grant permission for an international research study involving prisoners as research participants.
- Research involving pregnant women as participants is not allowed unless specific requirements are met.
- Where relevant, the IRB must document why it considers an individual or population to be vulnerable, and that adequate safeguards have been included in the study to protect the rights and welfare of participants who are likely to be vulnerable. Individuals or populations that might be temporarily or permanently vulnerable include, but are not limited to, those who:
 - Are susceptible to coercion or undue influence (e.g., the homeless, prisoners, students, patients with limited or no treatment options, socially and economically disadvantaged).
 - Lack comprehension of the research and its risks (e.g., educationally disadvantaged, dementia, schizophrenia, or depression).
 - Have increased susceptibility to harm from the procedures of the specific study under review (e.g., individuals who would have to answer study survey questions about their sexual assault).
 - Are at risk for economic, social, or legal consequences from the study (e.g., individuals who would have to answer study survey questions about their drug use or HIV status).
- For adults unable to consent policies and procedures indicate:
- When Researchers are likely to approach adults who lack decision-making capacity, policies and procedures have the IRB evaluate whether:
 - The proposed plan for the assessment of the capacity to consent is adequate.
 - Assent of the participants is a requirement, and if so, whether the plan for assent is adequate.
 - A re-consenting process may be necessary for participants with fluctuating decision-making

- capacity or those with decreasing capacity to give consent.
- When following Department of Defense (DoD) regulations and requirements:
 - Policies and procedures prohibit research involving prisoners of war.
 - The IRB or EC is aware of the definition of “prisoner of war” for the DoD component granting the addendum.
- When following Environmental Protection Agency (EPA) regulations and guidance:
 - Policies and procedures include that for research conducted or supported by the EPA, research involving intentional exposure of pregnant women or children to any substance is prohibited and not approved by the IRB or EC.
 - Policies and procedures include that for research intended for submission to the EPA, research involving intentional exposure of pregnant women or children to any substance is prohibited and not approved by the IRB or EC.
 - Policies and procedures have the IRB review observational research involving pregnant women and fetuses using 40 CFR 26 and 45 CFR 46 Subpart B.
 - Policies and procedures allow the IRB to review and approve observational research involving children that does not involve greater than minimal risk only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 26.406.
 - Policies and procedures allow the IRB to review and approve observational research involving children that involves greater than minimal risk but presenting the prospect of direct benefit to the individual participants if the IRB finds and documents that:
 - The intervention or procedure holds out the prospect of direct benefit to the individual participant or is likely to contribute to the participant's well-being.
 - The risk is justified by the anticipated benefit to the participants.
- The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
- Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 26.406.
- When following ICH-GCP guidance (E6):
 - When adults are unable to consent, policies and procedures have the IRB or EC determine:
 - A non-therapeutic clinical trial (i.e. a trial in which there is no anticipated direct clinical benefit to the participant) should be conducted in participants who personally give consent and who sign and date the written consent document.
 - Non-therapeutic clinical trials may be conducted in participants with consent of a legally acceptable representative provided the following conditions are fulfilled: a) The objectives of the clinical trial cannot be met by means of a trial in participants who can give consent personally. b) The foreseeable risks to the participants are low. c) The negative impact on the participant’s well-being is minimized and low. d) The clinical trial is not prohibited by law. e) The opinion of the IRB or EC is expressly sought on the inclusion of such participants, and the written opinion covers this aspect. Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

Common Types of Materials That May Be Used to Meet the Element

- Application form
- Reviewer checklist

Outcomes

- IRB or EC members determine whether additional safeguards are required in research that involves vulnerable individuals in order to protect their rights and welfare.
- The IRB or EC documents required determinations and provides protocol-specific findings justifying the determinations.

Element II.4.B. The IRB or EC has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.

Commentary

The IRB or EC should determine whether the research involves participants whose decision-making capacity is in question. When some or all of the participants are likely to have diminished decision-making capacity, the IRB or EC should consider whether additional safeguards are needed as part of the consent process. The IRB or EC should evaluate whether research submitted for review satisfies this criterion. If the IRB or EC reviews research that involves children, fetuses, neonates, prisoners, or adults who lack the ability to consent, or the IRB or EC regularly reviews research involving other populations who have diminished decision-making capacity, the IRB or EC should have written policies and procedures regarding the consent process for these individuals. When a research study involves a population that has a diminished decision-making capacity not otherwise covered by specific policies and procedures, policies and procedures should describe in general the steps the IRB or EC uses to evaluate the consent process in this population.

[See AAHRPP Tip Sheets 1, 18, and 20.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.204, 45 CFR 46.205, 45 CFR 46.305, 45 CFR 46.402(a)-(c), 45 CFR 46.408
- FDA: 21 CFR 50.3(l), 21 CFR 50.3(n), 21 CFR 50.55
- VA: VHA Handbook 1200.05, 36, 45, 46, 47, 48, 49
- ED: 34 CFR 98.4
- ICH-GCP: 3.1.6, 4.8.12, 4.8.13, Public Law 107-110 Jan. 8, 2002 Part E

Required Written Materials

- Essential requirements:
 - Policies and procedures have the IRB or EC evaluate whether the research involves participants who have diminished decision-making capacity and, if so, provide additional safeguards to ensure an appropriate consent process.
 - When a research study involves populations with diminished decision-making capacity not covered by specific policies and procedures, policies and procedures describe, in general, the steps

followed by the IRB or EC to evaluate the consent process for these populations.

- When research involves pregnant women, fetuses, or neonates, policies and procedures have the IRB or EC follow Subpart B of the DHHS regulations or equivalent laws or regulations to approve an appropriate consent process.
- When research involves prisoners as participants, policies and procedures have the IRB or EC follow Subpart C of the DHHS regulations or equivalent laws or regulations to approve an appropriate consent process that includes a determination that:
 - The information will be presented in language that is understandable to prisoners.
 - Each prisoner will be informed in advance that participation in the research will have no effect on his or her parole.
- When research involves children as participants, policies and procedures have the IRB or EC follow Subpart D of the DHHS or FDA regulations or equivalent laws or regulations to approve an appropriate assent process for children and consent process for parents or guardians.
- When Researchers are likely to approach adults who lack the ability to consent, policies and procedures have the IRB evaluate whether:
 - The proposed plan for the assessment of the capacity to consent is adequate.
 - Assent of the participants is a requirement, and, if so, whether the plan for assent is adequate.
- When following DHHS regulations and guidance:
 - When research involves pregnant women, policies and procedures have the IRB or EC determine that the consent of the pregnant women is required if the research holds out:
 - The prospect of direct benefit to the pregnant woman.
 - The prospect of direct benefit both to the pregnant woman and the fetus.
 - No prospect of benefit for the woman or the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

- When research involves pregnant women, policies and procedures have the IRB or EC determine that the consent of the pregnant woman and the father is required, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest if the research holds out the prospect of direct benefit solely to the fetus.
- When the research involves neonates of uncertain viability, policies and procedures have the IRB or EC determine that the consent of either parent of the neonate is required or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective consent of either parent's legally authorized representative is required, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
- When the research involves non-viable neonates, policies and procedures have the IRB or EC determine that the consent of both parents is required, except:
 - If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the consent of one parent is required.
 - If the pregnancy resulted from rape or incest the consent of the father need not be obtained.
- When the research involves non-viable neonates, policies and procedures did not allow the IRB or EC to approve the consent of a legally authorized representative.
- When following DHHS or FDA regulations and guidance:
 - When research involves children, policies and procedures have the IRB or EC following the requirements in Subpart D pertaining to obtaining assent of children and permission of the parents or guardian.
 - For research that involves no more than minimal risk or more than minimal risk with the prospect of direct benefit to the individual children, policies and procedures have the IRB or EC determine whether:
 - The permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, or the permission of one parent is sufficient.
 - For research that involves more than minimal risk without the prospect of direct benefit to the individual children, policies and procedures have the IRB or EC determine that the permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
 - Policies and procedures have the IRB or EC determine and document that assent is a requirement of:
 - All children.
 - Some children.
 - None of the children.
 - When the IRB or EC determines that assent is not a requirement of some children, policies and procedures have the IRB or EC determine and document which children are not required to assent.
 - When the IRB or EC determines that assent is not a requirement for some or all children, policies and procedures have the IRB or EC determine and document one or more of the following:
 - The children are not capable of providing assent based on the age, maturity, or psychological state.
 - The capability of the children is so limited that they cannot reasonably be consulted.
 - The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.
 - Assent can be waived using the criteria for waiver of the consent process.
 - When the IRB or EC determines that assent is a requirement, policies and procedures have the IRB determine whether:
 - Assent will be documented.
 - If so, the process to document assent.
- When following VA regulations and guidance:
 - Policies and procedures:
 - Consent is limited by a legally authorized representative to situations where the prospective participant is incompetent or has impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note.

- Consent from the legally authorized representative of the participant can only be obtained from the following: a healthcare agent (i.e., an individual named by an individual in a durable power of attorney for health care); legal guardian or special guardian; next of kin in this order: a close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; or close friend, unless otherwise specified by applicable state law.
- If there is any question as to whether a potential adult participant has decision-making capacity, and there is no documentation in the medical record that the individual lacks decision-making capacity, and the individual has not been ruled incompetent by a court of law, the Researcher must consult with a qualified practitioner (who may be a member of the research team) about the individual's decision-making capacity before proceeding with the consent process.
- Individuals, who because of a known condition, are at high risk to temporary or fluctuating lack of decision-making capacity must be evaluated by a qualified practitioner to determine the individual's ability to provide consent. This evaluation must be performed as described in the IRB-approved protocol.
 - If the individual is deemed to lack decision-making capacity at the time of their participation in the study, a legally authorized representative must provide consent.
 - If the participant regains decision-making capacity, the Researcher must repeat the consent process with the participant, and obtain the participant's permission to continue with the study.
- Disclosures to be made to the participant must be made to the participant's legally authorized representative.
- The participant's legally authorized representative must be told that that his or her obligation is to try to determine what the participant would do if able to make an informed decision. If the prospective participant's wishes cannot be determined, the legally authorized representative must be told that he or she is responsible for determining what is in the participant's best interest.
- Have the Researcher explain the proposed research to the prospective participant when feasible even when the participant's legally authorized representative gives consent.
- Have the practitioner explain the proposed research to the prospective participant when feasible.
- Ensure the study includes appropriate procedures for respecting dissent. Prohibit participants from being forced or coerced to participate in a research study.
- When following Department of Education regulations and guidance:
 - Policies and procedures include a process to comply with the Protection of Pupil Rights Amendment. This process may occur outside the IRB or EC:
 - For certain types of research projects directly funded by the U.S. Department of Education: No student will be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:
 - Political affiliations or beliefs of the student or the student's parent.
 - Mental or psychological problems of the student or the student's family.
 - Sex behavior or attitudes.
 - Illegal, anti-social, self-incriminating, or demeaning behavior.
 - Critical appraisals of other individuals with whom respondents have close family relationships.
 - Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
 - Religious practices, affiliations, or beliefs of the student or student's parent.
 - Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).
 - Prior consent means:
 - Prior consent of the student, if the student is an adult or emancipated minor.
 - Prior written consent of the parent or guardian, if the student is an unemancipated minor.
 - For certain types of research projects not directly funded by the U.S. Department of

Education and conducted in a school that receives funding from the U.S. Department of Education: Policies and procedures include a process to verify compliance with U.S. Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

- The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student.
- Any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received.
- Arrangements to protect student privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items):
- Political affiliations or beliefs of the student or the student’s parent.
- Mental or psychological problems of the student or the student’s family.
- Sex behavior or attitudes.
- Illegal, anti-social, self-incriminating, or demeaning behavior.
- Critical appraisals of other individuals with whom respondents have close family relationships.
- Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
- Religious practices, affiliations, or beliefs of the student or the student’s parent.
- Income (other than that required by law to determine eligibility for participation in a

program or for receiving financial assistance under such program).

- The right of a parent of a student to inspect, upon the request of the parent, any instructional material used as part of the educational curriculum for the student.
- Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
- The administration of physical examinations or screenings that the school or agency may administer to a student.
- The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.
- The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.
- Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

Common Types of Materials That May Be Used to Meet the Element

- Application form
- Reviewer checklist
- Consent template

Outcomes

- IRB or EC members approve research involving participants with diminished decision-making capacity that includes additional safeguards for seeking their consent.

Element II.4.C. The IRB or EC has and follows written policies and procedures for making exceptions to consent requirements for planned emergency research and reviews such exceptions according to applicable laws, regulations, codes, and guidance.

Commentary

Waiver of consent for planned emergency research

An IRB or EC should have policies and procedures to consider a request for a waiver of the requirement for consent for planned emergency research, unless the Organization does not intend to conduct such research. Policies and procedures should account for the differences between various laws, regulations, codes, and guidance that govern such research, such as the FDA regulations and the DHHS regulations depending on whether the research is subject to FDA regulation.

[See AAHRPP Tip Sheets 1, 11, and 20.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46 Waiver of Informed Consent Requirements in Certain Emergency Research (Federal Register, Vol. 61, No. 192, pp. 51531-51533, October 2, 1996), 45 CFR 46.116(f),
- FDA: IRB Information Sheets - Exception From Informed Consent for Studies Conducted in Emergency Settings
- VA: VHA Handbook 1200.05, 4, 41
- ICH-GCP: 3.1.7, 4.8.15
- DoD: DoDD 3216.2, para. 4.2; SECNAVINST 3900.39D, para. 6a(3)and 7a(1); 10 U.S.C. 980 (a,b)

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the criteria to waive the requirement to obtain consent for planned emergency research.
- When following FDA regulations and guidance:
 - Policies and procedures describe the criteria to approve planned emergency research. The research plan must be approved in advance by the FDA and the IRB or EC, and publicly disclosed to the community in which the research will be conducted.
- When following VA regulations and guidance:
 - Policies and procedures do not allow the IRB to waive the requirement to obtain consent for planned emergency research.
- When following ICH-GCP guidance (E6):
 - Policies and procedures require that the participant or the participant's legally authorized representative is informed about the clinical trial as soon as possible and provides consent if the participant wishes to continue.
- When following Department of Defense regulations and requirements:
 - Policies and procedures include that an exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense.

Outcomes

- Waivers to the requirement to obtain consent for planned emergency research are granted in accordance with applicable laws, regulations, codes, and guidance.

Standard II-5: The IRB or EC maintains documentation of its activities.

Element II.5.A. The IRB or EC maintains a complete set of materials relevant to the review of the research protocol or plan for a period of time sufficient to comply with legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.

Commentary

IRB or EC record keeping should follow legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures. IRB or EC records for a protocol or research plan should also be organized to allow a reconstruction of a complete history of all IRB or EC actions related to the review and approval of the protocol.

The IRB or EC should have a policy and procedure governing document retention that follows legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures. The method for record retention should allow access by authorized personnel and ensure that documents are kept safely and confidentially.

Regulatory and Guidance References

- DHHS: 45 CFR 115(a)-(b), OHRP Guidance on Written Institutional Review Board (IRB) Procedures
- FDA: 21 CFR 56.115(a)(b), FDA Information Sheets: Frequently Asked Questions: IRB Records
- VA: VHA Handbook 1200.05, 26

Required Written Materials

- Essential requirements:
 - In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of the protocol, policies and procedures have IRB or EC records include copies of:
 - Protocols or research plans.
 - Investigator brochure, if any.
 - Scientific evaluations, when provided by an entity other than the IRB or EC.
 - Recruitment materials.
 - Consent documents.
 - Progress reports submitted by Researchers.
 - Reports of injuries to participants.
 - Records of continuing review activities.
 - Data and safety monitoring reports, if any.
 - Modifications to previously approved research.

- Unanticipated problems involving risks to participants or others.
- Documentation of non-compliance.
- Significant new findings.
- All correspondence between the IRB or EC and Researchers.
- Policies and procedures have IRB records for initial and continuing review of research by the expedited procedure include:
 - The justification for using the expedited procedure.
 - Actions taken by the reviewer.
 - Any findings required by laws, regulations, codes, and guidance to be documented.
- Policies and procedures have IRB or EC records document the justification for exempt determinations.
- Policies and procedures have IRB or EC records document determinations required by laws, regulations, codes, and guidance.
- When following VA regulations and guidance:
 - Policies and procedures indicate that the required records, including the Researcher's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1).
 - Policies and procedures have IRB records include:
 - Correspondence between the IRB and the Research and Development Committee.
 - Correspondence between the IRB and Researchers.
 - Internal serious adverse events.
 - Documentation of protocol deviations.
 - A resume for each IRB member.
 - All previous membership rosters.

Outcomes

- IRB or EC record keeping follows legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.

- Records of a research protocol or plan are organized to allow a reconstruction of a complete history of IRB or EC actions related to the review and approval of the research protocol or plan.
- Records are retained for the required period of time.
- Records are stored in a way that maintains confidentiality.

Element II.5.B. The IRB or EC documents discussions and decisions on research studies and activities in accordance with legal and regulatory requirements, Sponsor requirements (if any), and organizational policies and procedures.

Commentary

The IRB or EC must document discussions, decisions, and findings. This can be accomplished either through the minutes or, when the expedited procedure for review is used, through documentation in the protocol file or other records.

Minutes of IRB or EC meetings should be clear about the actions the IRB or EC takes and exactly what the IRB or EC approved. Minutes should specify the modifications required to secure approval and the reason the IRB or EC is requesting the modifications. Minutes should indicate proposals or motions voted upon by the IRB or EC, and the results of each vote. When conducting initial or continuing review, minutes should document the IRB's determination of the approval period.

[See AAHRPP Tip Sheet 3.](#)

Regulatory and Guidance References

- DHHS: 42 USC 498A(b)(1), 42 USC 498A(b)(2), 42 USC 498A(c), 45 CFR 46.115(a)(2), 45 CFR 46.116(c)-(d), 45 CFR 46.117(c), 45 CFR 46.204, 45 CFR 46.205, 45 CFR 46.206, 45 CFR 46.207, 45 CFR 46.305, 45 CFR 46.306, 45 CFR 46.404, 45 CFR 46.405, 45 CFR 46.406, 45 CFR 46.407, 45 CFR 46.408, 45 CFR 46.408, Appendix D, 45 CFR 46 Waiver of the Applicability of Certain Provisions of Department of Health and Human Services Regulations for Protection of Human Research Subjects for Department of Health and Human Services Conducted or Supported Epidemiologic Research Involving Prisoners as Subjects (Federal Register, Vol. 68, No. 119, pp. 36929-36931, Friday, June 20, 2003), 45 CFR 46 Waiver of Informed Consent Requirements in Certain Emergency Research (Federal Register, Vol. 61, No. 192, pp. 51531-51533, October 2, 1996), OHRP Guidance on Written Institutional Review Board (IRB) Procedures
- FDA: 21 CFR 50.51, 21 CFR 50.52, 21 CFR 50.53, 21 CFR 50.54, 21 CFR 50.55, 21 CFR 50.56, 21 CFR 56.109(c), 21 CFR 56.115(a)(2)
- VA: 38 CFR 16.115(a)(2), 38 CFR 16.116(c)-(d), 38 CFR 16.117(c), VHA Handbook 1200.05, 24, 28

Required Written Materials

- Essential requirements:
 - Policies and procedures have IRB or EC minutes document:
 - Actions taken by the IRB or EC.
 - Separate deliberations for each action.
 - Votes for each protocol as numbers for, against, or abstaining.
 - Attendance at the meeting.
 - When an alternate member replaces a primary member.
 - The basis for requiring changes in research.
 - The basis for disapproving research.
 - A written summary of the discussion of controverted issues and their resolution.
 - For initial and continuing review, the approval period.
 - The names of IRB or EC members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence.
 - Required determinations and protocol-specific findings justifying those determinations for:
 - Waiver or alteration of the consent process.
 - Research involving pregnant women, fetuses, and neonates.
 - Research involving prisoners.
 - Research involving children.
 - When following FDA regulations or guidance
 - Policies and procedures have IRB or EC minutes document the rationale for significant risk/non-significant risk device determinations.
 - When following VA regulations or guidance
 - Policies and procedures have:
 - Minutes document the determination of level of risk and the rationale for the IRB's determinations of the level of risk.

- Minutes provide a summary of the justification for including non-veterans as participants.
- Minutes provide a summary of the discussion when real social security numbers (SSNs), scrambled SSNs, or the last four digits of SSNs will be used in the study. The summary needs to include the security measures that are in place to protect the SSN instances embedded in the study.
- Minutes document the approval of research contingent on specific minor conditions by the chair.
- The approval is documented in the minutes of the first IRB meeting that takes place after the date of the approval.
- The IRB provide the minutes to the Research and Development Committee.
- The IRB write minutes and make them available for review within three weeks of the meeting date.

- Policies and procedures indicate that minutes cannot be altered by anyone including a higher authority once approved by the members at a subsequent IRB meeting.
- Attendance of members or alternate members who participate through videoconference or teleconference, and documentation that those members received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

Common Types of Materials That May Be Used to Meet the Element

- Minutes
- Other records, including documentations

Outcomes

- IRB or EC records reflect the actions of IRB or EC members.

Domain III: Researcher and Research Staff

Commentary

The environment in which Researchers and Research Staff conduct research and the type of research they conduct influence their roles and responsibilities.

Competent, informed, conscientious, compassionate, and responsible Researchers and Research Staff provide the best possible protection for human research participants. This Domain of Standards sets

forth requirements for Researchers and Research Staff involved in research using human participants. As part of its Human Research Protection Program, an Organization can improve its protection of research participants if it has arrangements ascertaining and enhancing the competence of Researchers and Research Staff.

Standard III-1: In addition to following applicable laws and regulations, Researchers and Research Staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, Researchers and Research Staff have the protection of the rights and welfare of research participants as a primary concern.

Element III.1.A. Researchers and Research Staff know which of the activities they conduct are overseen by the Human Research Protection Program, and they seek guidance when appropriate.

Commentary

Researchers and Research Staff should understand which activities are overseen by the HRPP or seek guidance. They should have an understanding of the definitions of what constitutes research involving human participants according to legal and regulatory definitions and the Organization's policies and procedures. When necessary, they should be aware of the process to obtain an opinion from the HRPP and whom to contact.

[See AAHRPP Tip Sheets 2, 18, and 22.](#)

Regulatory and Guidance References

- DHH: 45 CFR 46.102(d), 45 CFR 46.102 (f)
- FDA: 21 CFR 50.3(a), 21 CFR 50.3(c), 21 CFR 50.3(g), 21 CFR 50.3(j), 21 CFR 56.102(c), 21 CFR 56.102(l)
- VA: 38 CFR 16.101(a), 38 CFR 16.102(d), 38 CFR 16.102(f), 38 CFR 16.102(f)(1), 38 CFR 16.102(f)(2)

Required Written Materials

- Essential requirements:

- Policies and procedures pertaining to Element I.1.A. that address essential requirements.
- When following DHHS regulations and guidance:
 - Policies and procedures pertaining to Element I.1.A. that address DHHS-specific requirements.
- When following FDA regulations and guidance:
 - Policies and procedures pertaining to Element I.1.A. that address FDA-specific requirements.

Note: In the cases above, the policies and procedures pertaining to Element I.1.A also address the written material requirements for this Element. If the same policies and procedures are provided to Researchers and Research Staff, simply reference those documents in the application for this Element. If there are additional materials, such as an Investigator Handbook or Web pages for Researchers, that are not included in the materials used to support Element I.1.A, but are in support of Element III.1.A, include them here.

Outcomes

- Researchers and Research Staff understand which activities are overseen by the HRPP and when to seek guidance.

Element III.1.B. Researchers and Research Staff identify and disclose financial interests according to organizational policies and regulatory requirements and, with the Organization, manage, minimize, or eliminate financial conflicts of interest.

Commentary

Researchers and Research Staff should understand the Organization's financial conflict of interest policy in order to follow it. For example, Researchers and Research Staff should know which interests the Organization requires to be disclosed. Researchers and Research Staff should know how, when, and to whom to disclose financial interests.

Researchers and Research Staff should understand how financial conflicts of interest can influence the protection of research participants. Researchers and Research Staff should also work collaboratively with the Organization in the management of financial conflicts of interest.

Independent Researchers and Research Staff who work with independent IRBs should understand legal and regulatory requirements for disclosing, managing, minimizing, or eliminating financial conflicts of interest. Such Researchers and Research Staff should know how, when, and to whom to disclose financial interests and work collaboratively with independent IRBs in the management of financial conflicts of interest.

[See AAHRPP Tip Sheets 7 and 10.](#)

Regulatory and Guidance References

- DHHS: 42 CFR 50.603, 42 CFR 50.606(a), 45 CFR 690
- FDA: 21 CFR 54.1, 21 CFR 54.2, 21 CFR 54.4, 21 CFR 312.64(d), 21 CFR 812.110(d)
- VA: VHA Handbook 1200.05, 9

Required Written Materials

- Essential requirements:
 - Policies and procedures pertaining to Element I.6.B. that address essential requirements.

- When following DHHS regulations and guidance:
 - Policies and procedures pertaining to Element I.6.B. that address DHHS-specific requirements.
- When following FDA regulations and guidance:
 - Policies and procedures pertaining to Element I.6.B. that address FDA-specific requirements.

Note: In the cases above, the policies and procedures pertaining to Element I.6.B. also address the written material requirements for this Element. If the same policies and procedures are provided to Researchers and Research Staff, simply reference those documents in the application for this Element. If there are additional materials, such as an Investigator Handbook or Web pages for Researchers, that are not included in the materials used to support Element I.6.A, but are in support of Element III.1.B, include them here.

- When following VA regulations and guidance:
 - Researchers must disclose conflicts of interest. This means disclosing to the IRB any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of the research, and complying with all applicable VA and other federal requirements regarding conflict of interest.

Outcomes

- Researchers and Research Staff understand the concept of conflict of interest.
- Researchers and Research Staff disclose required financial interests.
- Researchers and Research Staff work collaboratively with the Organization or independent IRB to manage financial conflicts of interest.

Element III.1.C. Researchers employ sound study design in accordance with the standards of the discipline. Researchers design studies in a manner that minimizes risks to participants.

Commentary

Researchers should design research studies so that the research will most likely develop or contribute to generalizable knowledge. Studies should be designed according to standards and ethical practices of the discipline. When Researchers do not design a research study, they should judge the research design to be sound enough to meet the study's objectives before agreeing to enroll participants.

As part of their obligation to protect participants, Researchers should understand the concept of minimizing risks. When Researchers design research, they should consider designs that minimize risks. In protocols, Researchers should describe the rationale for the chosen procedures and provide a risk-potential benefit analysis of the research.

When appropriate, Researchers who design research should incorporate plans to monitor the data for the safety of participants. For example, research studies involving more than minimal risk are expected to have a plan for monitoring the data for the safety of participants. Researchers should understand that monitoring might occur at specific points in time, after a specific number of participants have been recruited, or upon recognition of harms. Monitoring might be conducted by a third party (e.g., the Sponsor, medical monitor, data monitoring committee, or another Researcher).

[See AAHRPP Tip Sheet 11.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.111(a)(1), 45 CFR 46.111(a)(2), 45 CFR 46.111(a)(6)
- FDA: 21 CFR 56.111(a)(1), 21 CFR 56.111(a)(2), 21 CFR 56.111(a)(6)
- VA: 38 CFR 16.111(a)(1), 38 CFR 16.111(a)(2), 38 CFR 16.111(a)(6),
- DOJ: 28 CFR 512.11(a)(6), 28 CFR 512.12
- ICH-GCP: 4.3.2, 4.7, 4.11.1 – 4.11.3

Required Written Materials

- Essential requirements:
 - Policies and procedures pertaining to Elements II.3.A., II.3.B., and II.4.A. that address essential requirements are consistent with educational

materials or Web site information for Researchers, or the Investigator Handbook.

Note: In the case above, the policies and procedures pertaining to Elements II.3.A., II.3.B., and II.4.A. also address the written material requirements for this Element. If the same policies and procedures are provided to Researchers and Research Staff, simply reference those documents in the application for this Element. If there are additional materials, such as an Investigator Handbook or Web pages for Researchers, that are not included in the materials used to support Elements II.3.A., II.3.B., and II.4.A., but are in support of Element III.1.C., include them here.

- When following Department of Justice regulations and guidance:
 - Policies and procedures indicate that for research conducted within the Bureau of Prisons, the Researcher must have academic preparation or experience in the area of study of the proposed research.
 - Policies and procedures indicate that for research conducted within the Bureau of Prisons, when submitting a research protocol, the applicant shall provide the following information:
 - A summary statement, which includes:
 - Names and current affiliations of the Researchers.
 - Title of the study.
 - Purpose of the study.
 - Location of the study.
 - Methods to be employed.
 - Anticipated results.
 - Duration of the study.
 - Number of participants (staff or inmates) required and amount of time required from each.
 - Indication of risk or discomfort involved as a result of participation.
 - A comprehensive statement, which includes:
 - Review of related literature.
 - Detailed description of the research method.
 - Significance of anticipated results and their contribution to the advancement of knowledge.

- Specific resources required from the Bureau of Prisons.
- Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.
- Description of steps taken to minimize any risks.
- Description of physical or administrative procedures to be followed to:
- Ensure the security of any individually identifiable data that are being collected for the study.
- Destroy research records or remove individual identifiers from those records when the research has been completed.
- Description of any anticipated effects of the research study on organizational programs and operations.
- Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
- A statement regarding assurances and certification required by federal regulations, if applicable.
- When following ICH-GCP guidance (E6):
 - Policies and procedures describe that Researcher and Research Staff are knowledgeable about the following responsibilities:
 - During and following a participant's participation in a clinical trial, the Researcher ensures that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory

values, related to the clinical trial. Researchers inform participants when medical care is needed for other illnesses of which the Researchers become aware (not applicable to independent IRBs or ECs).

- The Researcher follows the clinical trial's randomization procedures, if any, and ensures that the code is broken only in accordance with the protocol. If the clinical trial is blinded, the Researcher promptly documents and explains to the Sponsor any premature unblinding.

Outcomes

- Researchers use sound scientific designs in the conduct of research.
- Researchers design studies using methodologies and ethical standards consistent with the standards of the discipline.
- Researchers understand the concept of minimizing risk.
- Researchers consider whether other procedures involving less risk are appropriate when designing a research study.
- Researchers design studies that use procedures already being conducted on the participants for non-research reasons.
- Researchers modify research designs to mitigate potential injuries in on-going research.
- Researchers design studies to monitor data to ensure the safety and well-being of participants.

Element III.1.D. Researchers determine that the resources necessary to protect participants are present before conducting each research study.

Commentary

Researchers should have the resources required to conduct research in a way that will protect the rights and welfare of participants and ensure the integrity of the research. These resources might include personnel, time, and access to a study population. Researchers should not commence a research study without adequate resources to protect participants and should stop a research study if resources become unavailable.

[See AAHRPP Tip Sheet 11.](#)

Regulatory and Guidance References

- VA: VHA Handbook 1200.05, 9
- ICH-GCP: 4.2.1, 4.2.2, 4.2.4

Required Written Materials

- Essential requirements:
 - Policies and procedures pertaining to Element II.3.A. that address essential elements.

Note: The policies and procedures pertaining to Element II.3.A also address the written material requirements for this Element. If the same policies and procedures are provided to Researchers and Research Staff, simply reference those documents in the application for this Element. If there are additional materials, such as an Investigator Handbook or Web pages for Researchers, that are not included in the materials used to support Element II.3.A, but are in support of Element III.1.D., include them here.

- Researchers are responsible to:
 - Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
 - Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study.

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Outcomes

- When conducting a research study, Researchers have the resources necessary to protect human participants, including:
 - Adequate time for the Researchers to conduct and complete the research.
 - Adequate number of qualified staff.
 - Adequate facilities.
 - Access to a population that will allow recruitment of the necessary number of participants.
 - Availability of medical or psychosocial resources that participants may need as a consequence of the research.
 - A process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.

Element III.1.E. Researchers and Research Staff recruit participants in a fair and equitable manner.

Commentary

Researchers should use fair and equitable recruitment practices in research and avoid practices that place participants at risk for coercion or undue influence.

[See AAHRPP Tip Sheet 11.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.111(a)(3), 45 CFR 46.116
- FDA: 21 CFR 56.111(a)(3), 21 CFR 56.20, FDA Information Sheets: Recruiting Study Subjects, Payment to Research Subjects,
- VA: 38 CFR 16.111(a)(3), 38 CFR 16.116, VHA Handbook 1200.05, 9
- ICH-GCP 4.3.3, 4.3.4, 4.8.3

Required Written Materials

- Essential requirements:
 - Policies and procedures pertaining to Element II.3.C. that address essential requirements.
- When following FDA regulations and guidance:
 - Policies and procedures pertaining to Element II.3.C. that address specific FDA requirements.
- When following VA regulations and guidance:
 - Policies and procedures pertaining to Element II.3.C. that address specific VA requirements.
- When following Department of Defense (DoD) regulations and requirements:
 - Policies and procedures pertaining to Element II.3.C. that address specific DoD requirements.

Note: In the cases above, the policies and procedures pertaining to Element II.3.C. also address the written material requirements for this Element. If the same policies and procedures are provided to Researchers and Research Staff, simply reference those documents in the application for this Element. If there are additional materials, such as an Investigator Handbook or Web pages for Researchers, that are not included in the materials used to support Element II.3.C, but are in support of Element III.1.E, include them here.

- When following VA regulations and guidance:
 - Researchers are required to ensure appropriate telephone contact with participants. This pertains to contacting the participant by telephone. Research team members are prohibited from requesting social security numbers by telephone.

- During the recruitment process, the Researcher ensures that the research team makes initial contact with the prospective participant in person or by letter prior to initiating any telephone contact, unless there is written documentation that the participant is willing to be contacted by telephone about the study in question or a specific kind of research (e.g., if the prospective participant has diabetes, the participant may indicate a desire to be notified of any diabetes-related research studies). The initial contact must provide a telephone number or other means that the prospective participant can use to verify the study constitutes VA research.
- Researchers ensure that in later contact, the research team begins telephone calls to the participant by referring to previous contacts and, when applicable, the information provided in the consent document, and ensuring that the scope of telephone contacts with the participant is limited to topics outlined in IRB-approved protocols and consent documents.
- When following ICH-GCP guidance (E6):
 - Policies and procedures describe that Researchers are knowledgeable about the following responsibilities:
 - The Researcher informs the participant's primary physician about the participant's participation in the clinical trial if the participant has a primary physician and if the participant agrees to the primary physician being informed (not applicable to independent IRBs or ECs).
 - Although a participant is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the Researcher makes a reasonable effort to ascertain the reason, while fully respecting the participant's rights.

Outcomes

- Researchers and Research Staff develop and implement appropriate recruitment techniques.
- Researchers and Research Staff understand the importance of equitable selection of participants.
- Researchers and Research Staff use recruitment processes that are fair and equitable.

Element III.1.F. Researchers employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of comprehension and voluntary participation to foster informed decision-making by participants.

Commentary

Researchers and Research Staff should understand the concept of respect for persons and the obligation to obtain the consent of participants or their legally authorized representatives. Researchers and Research Staff should understand that consent is a continual process, and conduct the consent process in a way that meets the criteria for legally effective consent. Researchers and Research Staff should understand the difference between the consent process, itself, and documentation of the consent process. Researchers and Research Staff should know how to document the consent of a participant or a legally authorized representative.

[See AAHRPP Tip Sheet 11.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.116, 45 CFR 46.116(a)(7), 45 CFR 46.117(a)
- FDA: 21 CFR 50.20, 21 CFR 50.25(a)(7), 21 CFR 50.27(a), 21 CFR 50.27(b)(2), FDA Information Sheets: Frequently Asked Questions: Informed Consent Process, A Guide to Informed Consent,
- VA: 38 CFR 16.116, 38 CFR 16.116(a)(7), 38 CFR 16.117(a), 38 CFR 16.117(c), VHA Handbook 1200.05, 9
- ICH-GCP 4.6.6, 4.8.1, 4.8.2, 4.8.4 - 4.8.15

Required Written Materials

- Essential requirements:
 - Policies and procedures pertaining to Elements II.3.F., II.3.G., and II.4.B.
- When following DHHS or FDA regulations
 - When the long form of consent documentation is used, Researchers or Research Staff follow regulatory and IRB or EC requirements.
 - When the short form of consent documentation is used, Researchers or Research Staff follow regulatory and IRB or EC requirements.
- When following DHHS regulations and guidance:
 - Policies and procedures pertaining to Elements II.3.F., II.3.G., and II.4.B.
- When following FDA regulations and guidance:

- Policies and procedures pertaining to Elements II.3.F., II.3.G., and II.4.B. that address essential requirements.
- When following VA regulations and guidance:
 - Policies and procedures pertaining to Elements II.3.F., II.3.G., and II.4.B. that address specific VA requirements.
 - Researchers are required to maintain a master list of all participants from whom consent has been obtained whether the IRB granted a waiver of documentation of consent.
 - Researchers must not add a participant's name to the master list of all participants until after:
 - Consent has been obtained from that participant, and
 - When appropriate, consent has been documented using an IRB-approved consent document.
 - The Researcher must secure the master list appropriately in compliance with all VA confidentiality and information security requirements in the Researcher's file for each study.
- When following Department of Defense (DoD) regulations and requirements:
 - Policies and procedures pertaining to Elements II.3.F., II.3.G., and II.4.B. that address specific DoD requirements.

Note: In the cases above, the policies and procedures pertaining to Elements II.3.F., II.3.G., and II.4.B. also address the written material requirements for this Element. If the same policies and procedures are provided to Researchers and Research Staff, simply reference those documents in the application for this Element. If there are additional materials, such as an Investigator Handbook or Web pages for Researchers, that are not included in the materials used to support Elements II.3.F., II.3.G., and II.4.B., but are in support of Element III.1.F., include them here.

- When following ICH-GCP guidance (E6):
 - Policies and procedures describe that Researchers and Research Staff provide all the disclosures and follow the requirements pertaining to consent covered by ICH-GCP.

Outcomes

- Researchers and Research Staff understand the difference between the consent process and the documentation of the consent process.
- Researchers and Research Staff understand consent to be an ongoing process throughout the participant's involvement in the research.
- Researchers and Research Staff:
 - Obtain the legally effective consent of the participant or the participant's legally authorized representative.
 - Provide the prospective participant or the legally authorized representative sufficient opportunity to consider whether to participate.
 - Minimize the possibility of coercion or undue influence.
 - Communicate with the participant or the legally authorized representative in language understandable to the participant or the legally authorized representative. Do not use exculpatory language when communicating with a prospective participant or the legally authorized representative.
 - Document the consent process as required.

Element III.1.G. Researchers and Research Staff have a process to address participants' concerns, complaints, or requests for information.

Commentary

Researchers and Research Staff should be open to participants' complaints or requests for information. Researchers and Research Staff should respond appropriately to such complaints or questions.

Researchers should explain to research participants how to contact the Research Staff to ask questions about the research or express concerns or complaints about the research.

A common, although not exclusive, mechanism for providing contact information is language in the consent document.

[See AAHRPP Tip Sheet 19.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.116(a)(6), 45 CFR 46.116(a)(7)
- FDA: 21 CFR 50.25(a)(6), 21 CFR 50.25(a)(7)
- VA: 38 CFR 16.116(a)(6), 38 CFR 16.116(a)(7), VHA Handbook 1200.05, 9

Required Written Materials

- Essential requirements:
 - Policies and procedures describe the way in which the Organization provides research participants with information on how to contact the Researchers or Research Staff in regards to:
 - Concerns, complaints, or questions about the research study.

- Request for information.
- When following VA regulations and guidance:
 - Policies and procedures indicate:
 - Researchers are required to make every reasonable effort to make available the informational brochure, "Volunteering in Research – Here Are Some Things You Need To Know," to prospective research participants in settings where Researchers may recruit participants (e.g., clinic waiting areas), and to prospective participants, and their surrogates where applicable, when the individuals are approached to take part in a study.
- Common Types of Materials That May Be Used to Meet the Element
 - Consent template

Outcomes

- Researchers and Research Staff provide information and processes for participants to submit concerns, complaints or requests for information.
- Researcher and Research Staff respond to complaints and requests for information from participants.
- Researchers and Research Staff involve the IRB or EC and other components of the HRPP in response to complaints or request for information.

Standard III-2: Researchers meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the Organization’s policies and procedures for protecting research participants; and the IRB’s or EC’s determinations.

Element III.2.A. Researchers and Research Staff are qualified by training and experience for their research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and the Organization’s policies and procedures regarding the protection of research participants.

Commentary

Researchers and Research Staff should be qualified by training and experience for their roles and responsibilities in conducting research so that they follow the protocol and abide by the Organization’s policies and procedures. Researchers and Research Staff should have the knowledge to follow laws, regulations, codes, and guidance such as those concerning IRB or EC review, consent requirements, reporting requirements, maintenance of records, retention of records, and supervision of research conduct. When appropriate, Researchers and Research Staff should understand and apply relevant professional standards that are applicable to their research.

[See AAHRPP Tip Sheets 8, 9, 11, and 18.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.102(d), 45 CFR 46.102 (f)
- FDA: 21 CFR 50.3(a), 21 CFR 50.3(c), 21 CFR 50.3(g), 21 CFR 50.3(j), 21 CFR 56.102(c), 21 CFR 56.102(l)
- VA: 38 CFR 16.102(d), 38 CFR 16.102 (f), ICH-GCP: 2.7, 2.8, 4.1.1 – 4.1.4, 4.3.1, 4.3.2, 4.4.1 – 4.4.3, 4.5.1 – 4.5.4, 4.6.1 – 4.6.6, 4.7, 4.9.1-4.9.5

Required Written Materials

- Essential requirements:
 - Policies and procedures pertaining to Element I.1.D. that address essential requirements.

Note: The policies and procedures pertaining to Element I.1.D. also address the written material requirements for this Element. If the same policies and procedures are provided to Researchers and Research Staff, simply reference those documents in the application for this Element. If there are additional materials, such as an Investigator Handbook or Web pages for Researchers, that are not

included in the materials used to support Element I.1.D, but are in support of Element III.2.A., include them here.

- When following ICH-GCP guidance (E6):
 - Policies and procedures describe that the Researcher and Research Staff are knowledgeable about the following responsibilities:
 - The Researcher provides evidence of his or her qualifications through up-to-date curriculum vitae or other relevant documentation requested by the Sponsor, the IRB or EC, or the regulatory authority.
 - The Researcher is familiar with the appropriate use of the investigational product, as described in the protocol, in the current investigator brochure, in the product information, and in other information sources provided by the Sponsor.
 - A qualified physician (or dentist, when appropriate), who is a Researcher or a co-Researcher for the clinical trial, is responsible for all clinical trial-related medical (or dental) decisions (not applicable to independent IRBs or ECs).
 - During and following a participant’s participation in a clinical trial, the Researcher ensures that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the clinical trial (not applicable to independent IRBs or ECs).
 - The Researcher ensures the accuracy, completeness, legibility, and timeliness of the data reported to the Sponsor.

Outcomes

- Researchers and Research Staff are qualified by training and experience for their roles and responsibilities in conducting research.

- Researchers and Research Staff know which laws, regulations, codes, and guidance govern their research studies and are knowledgeable about requirements pertaining to specific research studies.
- Researchers and Research Staff are knowledgeable about the Organization's policies and procedures.

Element III.2.B. Researchers maintain appropriate oversight of each research study, as well as Research Staff and trainees, and appropriately delegate research responsibilities and functions.

Commentary

Researchers are ultimately responsible for the conduct of research. Although Researchers may delegate certain responsibilities and functions of the research, they must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

When Researchers delegate responsibilities or functions, they should ensure that Research Staff are trained and able to perform the function and assume the responsibility for the delegated function.

[See AAHRPP Tip Sheets 8 and 18.](#)

Regulatory and Guidance References

- FDA: 21 CFR 312.53(c) (1), 21 CFR 312.60, 21 CFR 312.61, 21 CFR 312.62, 21 CFR 812.43(c) (4), 21 CFR 812.100, 21 CFR 812.140
- VA: VHA Handbook 1200.05, 9, 63
- DOJ: 28 CFR 512.11(a)(7)
- ICH-GCP: 4.1.5, 4.2.3, 4.2.4

Required Written Materials

- When following VA regulations and guidance:
 - Policies and procedure indicate that if the principal Researcher or the local site Researcher does not personally obtain consent, the Researcher must formally and prospectively designate to another research team member in writing the protocol or the application for IRB approval the responsibility for obtaining consent, whether a waiver of documentation of the consent process has been approved by the IRB.
 - This designee must be a member of the research team.
 - Students and other trainees (including residents and fellows), including VA employees, from

schools with an academic affiliation agreement consistent with current VHA policy, may serve as Researcher within a VA facility, or use data, or human biological specimens that have been collected within VA for clinical, administrative, or research purposes.

- A Researcher sufficiently experienced in the area of the trainee's research interest must serve as principal Researcher or co-principal Researcher and is responsible for oversight of the research and the trainee.
- When following Department of Justice regulations and guidance:
 - Policies and procedures indicate that for research conducted within the Bureau of Prisons, the Researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the Researcher.
- When following ICH-GCP guidance (E6):
 - Policies and procedures describe that the Researcher maintains a list of appropriately qualified persons to whom they have delegated significant clinical trial-related duties.

Outcomes

- Researchers are involved in the conduct of the research, including recruitment and obtaining consent, and maintain oversight of recruitment, consent, and protocol procedures.
- Researchers hire qualified staff.
- Research Staff indicate that the Researcher delegates responsibility to them commensurate with their training and qualifications.
- Researchers are available to Research Staff when needed.

Element III.2.C. Researchers and Research Staff follow the requirements of the research protocol or plan and adhere to the policies and procedures of the Organization and to the requirements or determinations of the IRB or EC.

Commentary

Researchers and Research Staff should be knowledgeable about and follow all legal and regulatory requirements and the Organization's policies and procedures that pertain to their research. This includes adherence to the determinations and requirements of the IRB or EC. Once a research study is approved by the IRB or EC, Researchers and Research Staff should follow the research plan or protocol as approved by the IRB or EC, and not implement changes until they are approved by the IRB or EC.

[See AAHRPP Tip Sheet 15.](#)

Regulatory and Guidance References

- FDA: FDA-Good Clinical Practice
- VA: VHA Handbook 1200.05, 9
- DOE: Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements
- ED: 34 CFR 98.3
- ICH-GCP: 4.1.3, 4.4.1, 4.5.1

Required Written Materials

- When following VA regulations and guidance:
- Policies and procedures indicate:
 - The principal Researcher, local site Researcher, and Researcher must uphold professional and ethical standards and practices and adhere to all applicable VA and other federal requirements, including the local VA facility's standard operating procedures, regarding the conduct of research and the protection of human participants. The responsibilities of the Researcher may be defined in the protocol or IRB application.
- When following Department of Energy (DOE) regulations and guidance:

- Policies and procedures indicate Researchers are required to follow DOE requirements for the protection of personally identifiable information by completing and complying with the requirements of the "Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements."
- When following Department of Education regulations and guidance:
 - Policies and procedures indicate that for research funded by the U.S. Department of Education: Access to instructional material used in a research or experimentation program:
 - All instructional material--including teachers' manuals, films, tapes, or other supplementary instructional material--which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research.
 - Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.
 - Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

Outcomes

- Researchers and Research Staff are knowledgeable about and follow all legal and regulatory requirements and the Organization's policies and procedures that pertain to their research.
- Researchers and Research Staff adhere to the requirements of the IRB or EC.
- Researchers and Research Staff follow the requirements of the research plan or protocol.

Element III.2.D. Researchers and Research Staff follow reporting requirements during a research study in accordance with applicable laws, regulations, codes, and guidance; the Organization's policies and procedures; and the IRB's or EC's requirements.

Commentary

Researchers and Research Staff should understand the Organization's reporting requirements for events related to their research. This includes information related to unanticipated problems involving risks to participants or others or non-compliance. While Researchers or Research Staff do not make determinations of whether an event is an unanticipated problem involving risks to participants or others, they should know the type of events to report to allow the IRB or EC to make determinations. Likewise, Researchers and Research Staff should submit information related to possible non-compliance in order for the IRB or EC to make final determinations. In addition to reporting to the IRB or EC, regulations and organizational policies and procedures may require reporting to other people or entities within the Organization as well as to regulatory agencies. Researchers and Research Staff should also report suspensions or termination of the research, complaints, and data safety and monitoring reports when they occur or become available.

[See AAHRPP Tip Sheets 18, 20, and 23.](#)

Regulatory and Guidance References

- DHHS: 45 CFR 46.103(b)(5)(i), OHRP Guidance on Reporting Incidents to OHRP, OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events
- FDA: 21 CFR 56.108(b)(1), 21 CFR 312.66, 21 CFR 812.150(a)(1), Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting to IRBs – Improving Human Subject Protection
- VA: 38 CFR 16.103(b)(5)(i), VHA Handbook 1200.05, 9, VHA Handbook 1058.01
- DOE: DOE O 443.1A Contractor Requirements Document
- DOJ: 28 CFR 512.19,20
- ICH-GCP: 4.10.1, 4.11.1-4.11.3, 4.12.1-4.12.3, 4.13

Required Written Materials

- Essential requirements:
 - Policies and procedures pertaining to Elements I.5.D., II.2.F., II.2.G., and II.2.H. that address essential requirements.
- When following DHHS regulations and guidance:
 - Policies and procedures pertaining to Elements I.5.D., II.2.F., II.2.G., and II.2.H. that address specific DHHS requirements.
- When following FDA regulations and guidance:
 - Policies and procedures pertaining to Elements I.5.D., II.2.F., II.2.G., and II.2.H. that address specific FDA requirements.
- When following VA regulations and guidance:
 - Policies and procedures pertaining to Elements I.5.D., II.2.F., II.2.G., and II.2.H. that address specific VA requirements.
- When following Department of Defense (DoD) regulations and requirements:
 - Policies and procedures pertaining to Elements I.5.D., II.2.F., II.2.G., and II.2.H. that address specific DoD requirements.

Note: In the cases above, the policies and procedures pertaining to Elements I.5.D., II.2.F., II.2.G., and II.2.H. also address the written material requirements for this Element. If the same policies and procedures are provided to Researchers and Research Staff, simply reference those documents in the application for this Element. If there are additional materials, such as an Investigator Handbook or Web pages for Researchers, that are not included in the materials used to support Elements I.5.D., II.2.F., II.2.G., and II.2.H., but are in support of Element III.2.D., include them here.

- When following VA regulations and guidance:
 - Policies and procedures require the following of Researchers and Research Staff:
 - Within five business days of becoming aware of any local (i.e., occurring in the reporting individual's own facility) unanticipated serious adverse event in VA research, members of the VA research community are required to ensure that the serious adverse event has been reported in writing to the IRB.

- This requirement is in addition to other applicable reporting requirements (e.g., reporting to the Sponsor under FDA requirements).
- The unfounded classification of a serious adverse event as “anticipated” constitutes serious non-compliance.
- Researchers are required to report deviations from the protocol to the IRB in a time frame specified in local standard operating procedures.
- Researchers are required to report complaints to the IRB in a time frame specified in local standard operating procedures.
- When following Department of Energy (DOE) regulations and guidance:
 - Policies and procedures indicate:
 - Researchers must promptly report the following to the human subject research program manager:
 - Any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken.
 - Any suspension or termination of IRB approval of research.
 - Any significant non-compliance with HRPP procedures or other requirements.
 - The time frame for “promptly” is defined.
 - Any compromise of personally identifiable information must be reported immediately.
 - The time frame for “immediately” is defined.
- When following Department of Justice regulations and guidance:
 - Policies and procedures require that for National Institute of Justice-funded research, a copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.
 - Policies and procedures require that for research conducted with the Bureau of Prisons:
 - At least once a year, the Researcher shall provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
 - At least 12 working days before any report of findings is to be released, the Researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The Researcher shall include an abstract in the report of findings.
- In any publication of results, the Researcher shall acknowledge the Bureau's participation in the research project.
- The Researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
- Prior to submitting for publication the results of a research project conducted under this subpart, the Researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.
- When following ICH-GCP guidance (E6):
 - Policies and procedures describe that Researcher and Research Staff are knowledgeable about the following responsibilities:
 - The Researcher reports all serious adverse events (SAEs) to the Sponsor except for those SAEs that the protocol or other document (e.g., investigator’s brochure) identifies as not needing immediate reporting. The Researcher follows regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and the IRB or EC.
 - The Researcher reports adverse events or laboratory abnormalities identified in the protocol as critical to safety evaluations to the Sponsor according to the reporting requirements and within the time periods specified by the Sponsor in the protocol.
 - For reported deaths, the Researcher supplies the Sponsor and the IRB or EC with any additional requested information (e.g., autopsy reports and terminal medical reports).
 - The Researcher provides written reports to the Sponsor, the IRB or EC, and, where applicable, the Organization on any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.
 - If the Researcher terminates or suspends a clinical trial without prior agreement of the Sponsor, the Researcher informs the Organization, Sponsor, and the IRB or EC.
 - If the IRB or EC terminates or suspends approval of the clinical trial, the Researcher promptly notifies the Sponsor.

- Upon completion of the clinical trial, the Researcher informs the Organization; the IRB or EC with a summary of the trial's outcome; and the regulatory authority with any reports required.

Outcomes

- Researchers and Research Staff follow reporting requirements for research studies, including reporting:

- Events, incidents, and problems according to the Organization's policy on unanticipated problems involving risks to participants or others.
- Non-compliance.
- Suspensions or terminations of research.
- Complaints.
- Protocol deviations and violations.
- Data and safety monitoring reports.
- Other required information.

Glossary of Acronyms

DHHS	Department of Health and Human Services
DoD	Department of Defense
DoDD	Department of Defense Directive
DOE	Department of Energy
DOJ	Department of Justice
EC	Ethics Committee
ED	Department of Education
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FERPA	Family Educational Right and Privacy Act
GCP	Good Clinical Practice
HRPP	Human Research Protection Program
ICH-GCP	International Committee on Harmonisation – Good Clinical Practice
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
NIJ	National Institute of Justice
NSF	National Science Foundation
OHRP	Office for Human Research Protection
ORE	Office of Research and Evaluation
PHS	Public Health Service
SAE	Serious Adverse Effect
VA	Department of Veterans Affairs