

<b>This policy applies to:</b> <input checked="" type="checkbox"/> <b>Stanford Hospital and Clinics</b> <input checked="" type="checkbox"/> <b>Lucile Packard Children's Hospital</b> <input type="checkbox"/> <b>Stanford University</b>	<b>LPCH Approval Date:</b> December 2005
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## I. Purpose

This document describes the policies and procedures for conducting studies involving investigational new devices at Stanford Hospital & Clinics (SHC) and the Lucile Packard Children's Hospital (LPCH), in keeping with the policy of Stanford University's Human Research Protection Program (HRPP), formerly known as the Institutional Review Board (IRB) Policy. This policy does not cover use of investigational radiopharmaceuticals.

## II. Policy Statement

Clinical investigations of investigational medical devices at SHC and LPCH, collectively referred to in this document as Stanford University Medical Center (SUMC), are subject to Federal regulations and are required to comply with Investigational Device Exemption (IDE) regulations as outlined in FDA document 21 Code of Federal Regulations (CFR) § 812 and 21 CFR § 814, unless exempted under certain specified conditions. All principal investigators (PI) are expected to fulfill all of the responsibilities delineated in the FDA regulations, other federal and State laws and regulations that relate to clinical research and SHC and LPCH policies and procedures.

Investigational devices that are under the control of principal investigators which are used at Stanford University Medical Center must be procured, stored, secured, dispensed, used and monitored in accordance with the Stanford University Human Research Protection Program (HRPP) and specific device requirements.

Investigational devices may only be used after research studies and associated documentation have been approved by the Stanford University Institutional Review Board (IRB) and any other governing committees, excluding the exemption which permits emergency use of an investigational device on a one-time basis per institution without IRB review and approval (21 CFR 56.104(c)).

Devices are classified as a Significant Risk Device (21 CFR § 812.3m) or Non-significant Risk (NSR) Device, unless EXEMPT from the regulations for Investigational Device Exemptions (IDE).

- A. Device studies require review and approval by the Stanford University IRB.
- B. NSR device studies require Stanford University IRB review and approval with regard to informed consent, record keeping, and study monitoring.

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- C. If a principal investigator (PI) proposes the initiation of a NSR device investigation to the IRB, and if the IRB agrees that the device study is NSR and approves the study, the investigation may begin immediately, without submission of an IDE application to the FDA.

Note: If the IRB disagrees with a claim that a device is non-significant risk or agrees with the claim and disagrees with the investigator's rationale, the primary reviewer will document in the Presentation Guidelines the rationale for the IRB's determination.

- D. Any safety and efficacy data collection on a significant risk device for other than approved indication requires an IDE in advance of IRB approval.

Note: Contact the SHC or LPCH Chief of Staff and/or the Chairman of the SUMC Safety Committee (Safety Officer) and/or consult the IRB in situations where guidance is required in administering this policy.

### III. Definitions

- A. **Custom Device:** A device that: [21CFR § 812.3(b)]
1. Necessarily deviates from devices generally available or from an applicable performance standard or pre-market approval requirement in order to comply with the order of an individual physician;
  2. Is not generally available to, or generally used by, other physicians;
  3. Is not generally available in finished form for purchase or for dispensing upon prescription;
  4. Is not offered for commercial distribution through labeling or advertising; and
  5. Is intended for use by an individual patient named in the order of a physician, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician in the course of professional practice.
- B. **Emergency Use:** The use of an investigational device in a patient:

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1. Who is in a life-threatening situation and,
2. Where no standard acceptable treatment is available and,
3. Where there is not sufficient time to obtain IRB approval.

- C. **Investigational Device:** An *investigational device* is a medical device that is the object of an investigation [21CFR § 812.3(g)], i.e., the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device.
- D. **Investigational Device Exemption (IDE):** Permits a device that otherwise would be required to comply with a Federal Food, Drug and Cosmetic Act performance standard, or required to have pre-market approval, to be shipped lawfully for the purpose of conducting investigations of that device. [21CFR § 812.2(c)]
- E. **Life-Threatening:** Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted, and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subject-patient must be in a life threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.
- F. **Non-Significant Risk (NSR) Device Study:** A study of a device that does not meet the definition for a significant risk study.
- G. **Medical Device:** A *medical device* is defined, in part, as any health care product that does not achieve its primary intended purpose by chemical action or by being metabolized. Medical devices also include diagnostic aids, such as reagents and test kits for *in vitro* diagnosis.
- H. **Radiology Device:** A radiology device that is used as a diagnostic device, or is used as a therapeutic device, or has two or more types of uses (e.g., used both as a diagnostic device and a therapeutic device. See [21CFR § 892.1000 - 892.6500]) for specific listings of device types for each category.
- I. **Severely Debilitating:** Diseases or conditions that cause major irreversible morbidity, such as blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis, or stroke.

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J. **Significant Risk (SR) Device Study:** A study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and

1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a participant;
2. Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a participant;
3. Is for a use of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety or welfare of a participant; or
4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

K. **Unapproved Device:** A device that is used for a purpose or condition for which the device requires, but does not have and approved application for pre-market approval under section 515 FD&C Act & [21 United States Code (USC) chapter 9, subchapter IV, § 360(e)]. An unapproved device may be used in human subjects only if approved for clinical testing under an approved application for an Investigational Device Exemption (IDE) under the FDCA [21USC ch9, subch. IV § 360(j)(g) and [21CFR part 812.] Medical devices that have not received marketing clearance under section 510(k) of the FD&C Act are also considered unapproved devices.

#### IV. Procedures

A. Informed Consent

The PI is required to obtain informed consent from the research participant or their legally authorized representative, unless the FDA requirements for exception from informed consent are met [21CFR § 50.23(a)]. Note: The signed informed consent form for research, which is contained in the medical record, will serve to notify hospital personnel that the patient is a research participant in a clinical study involving an investigational device.

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B. Responsibilities of the Principal Investigator

1. **Prior to use** of the investigational device for any reason, the PI must:

- a. Submit a scientific protocol and all required initial and continuing documentation to the IRB committee. Follow all applicable policies of the Stanford University HRPP, including, but not limited to, record keeping by the PI under 21CFR § 812.140(a)
- b. Adhere to the IDE regulations [21 CFR § 812.] Research investigations involving NSR devices must adhere to the abbreviated requirements at 21 CFR § 812.2(b)
- c. Obtain both informed consent for research as well as the SHC/LPCH informed consent from the research participant or their legal representative [45 CFR § 46.116];
- d. Forward IRB acknowledgement of approval to the manufacturer and/or sponsor if / when required by the manufacturer/sponsor;
- e. Submit a copy of the research protocol and manufacturer's specifications to SUMC Materials Management to initiate procurement & tracking of the device (see SHC/LPCH Materials Management policies and procedures.)
  - (1) Procurement policies and procedures as outlined by Materials Management must be followed when obtaining the device for use.
  - (2) Resubmit corrected documentation to SUMC Materials Management if the study protocol is modified or amended.
- f. Have a current and complete conflict-of-interest disclosure statement on file.

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2. **During use** of the investigational device:

- a. Provide secure storage for all investigational devices according to their storage requirements and maintain proper control of the device.
- b. Ensure proper dispensing and utilization of investigational devices as defined in the research protocol to those authorized to receive and use it. Note: The PI is responsible for the education of co-investigators, study personnel, and hospital personnel who prescribe, distribute, or administer the investigational device.
- c. Protect the rights, safety, and welfare of the research participants enrolled in the study.
- d. Maintain complete records as required by the policy of the Stanford University HRPP.
- e. Use investigational devices only in approved research protocols.
- f. Maintain records of receipt, use or disposition of the investigational device. Records should include the type and quantity of the device, the dates of its receipt, the batch number or code mark, the names of all persons who received, used, or disposed of each device, and why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.

3. **After use** of the investigational device:

- a. The PI must *follow the policy of the Stanford University HRPP* when the investigational device is discontinued.
- b. Inform SUMC Materials Management (and Clinical Technology & Biomedical Engineering departments if applicable) that the investigational device is no longer in use.

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- c. Return or dispose of the device in accordance with the manufacturer's specifications (see Items B, C and D under the Procedure/Process section of this policy)
- d. Report any adverse effects of the investigational device appropriately (see Item G under the Procedure/Process section of this policy).

C. Responsibilities of the Sponsoring Department

- 1. The sponsoring investigator/department, in conjunction with the manufacturer or vendor sponsor of the device, must:
  - a. Provide for the ongoing security, storage, inventory, and dispensing of the investigational device to appropriate personnel for use by following the Stanford University HRPP and SHC and LPCH hospital policies, regulations and procedures.
  - b. Perform quality audits to insure security, integrity, and inventory of the investigational device.

D. Responsibilities of SUMC Materials Management

- 1. SUMC Materials Management will initiate the procurement process with the manufacturer or vendor, manage receiving, and will maintain documentation that the device is in-house and meets IRB approval and the labeling requirements specified in the Stanford University HRPP specified in 21CFR 815.5.
- 2. Upon IRB approval, the SUMC Purchasing Department will execute a purchase order (PO) for each investigational device. The PO number will be used for both incoming and outgoing shipments. The PO will indicate the type of investigational device, study, and approval information.
- 3. The SUMC Dock Services Department will verify receipt of the investigational device to SUMC and will confirm delivery to the correct clinical department. The PO will be updated to show date and time of receipt and final delivery.

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4. Once informed that the investigational device is no longer in use, the SUMC Purchasing Department will arrange and document the return of the investigational device via Dock Services and attach all records to the original Purchase Order.

E. Responsibilities of Clinical Technology and Biomedical Engineering

1. For investigational use of electrical devices, an incoming inspection for safety must be conducted prior to the use of the device. This will be conducted by the SUMC *Clinical Technology & Biomedical Engineering* Department (see Incoming Inspection Policy, MEMP)
2. The investigational device will be subject to incoming inspection procedures as outlined in this document, sections XII (B)(C).

F. Use of Investigational Radiology Devices

1. Clinical investigations of radiology devices at SUMC will be initiated only after approval is gained from the Stanford University IRB and the Stanford University Administrative Panel on Radiological Safety (see Stanford University Research Policy Handbook).
2. For workplace safety, instructions contained in the research protocol will be followed in the preparation, handling, storage, use, administration, discontinuation, and return, waste or disposal of the investigational device.
3. Policies and Procedures of the Department of Radiation Oncology at SHC's Center for Advanced Medicine ["Investigational New Devices"] will be followed when investigational radiation devices (e.g., brachytherapy) are implanted at the Radiation Oncology Department into consented research participants.
4. Hospital rooms at SUMC will be identified, properly labeled and marked for safety before research participants with investigational implanted radiology devices (e.g., brachytherapy) are admitted.
5. Hospital personnel at SUMC will follow the guidelines as established by SHC's Patient Care Manual [Document R.05, "Radiation Therapy: Health and Safety Guidelines for all Patient Care Personnel"] in providing care for research

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participants with implanted investigational radiology devices.

6. For studies involving investigational radiation devices for diagnostic or therapeutic procedures, SUMC staff will be trained by the PI as to, but not limited to, the proper operation of the investigational radiation device, setup and technique sufficient to permit safe use, discontinuance, storage, removal, and disposal, according to the policy of the Stanford University HRPP and all related SUMC policies and procedures.
  
7. The Health Physics Safety Officer of the Stanford University (SU) Department of Environmental Health & Safety will survey the equipment to see that it is operating in a safe manner, keep an inventory of the device, and verify that it has been registered with the state Radiological Health Branch of the Department of Health Services. For a device that is also radioactive, SU's Department of Environmental Health & Safety will also check to see that it is shielded in a safe manner, do a safety survey, and verify that the PI is authorized to use the device. [SU's "Research Policy Handbook" (1.4)(6.2)(6.3)(6.4)(6.7)]
  
8. This policy does not cover use of investigational radiopharmaceuticals.

G. Adverse Event Reporting

1. The PI who holds an IDE has responsibilities for reporting adverse events associated with use of an investigational device.
  - a. The PI must report any adverse effect to the sponsor, the IRB and the Medical Chief of Staff *within 10 days of discovery*.
  - b. The sponsor is required to evaluate the specific adverse event & investigate under a sponsor's monitoring requirements [21 CFR § 812.46(b)].
  - c. The sponsor must then report its findings to the FDA, to all participating investigators, and to (all) reviewing IRB committee(s) within 10 working days after the *sponsor* receives notice of the adverse effect.
  
2. The PI must also follow *all* SUMC reporting policies pertaining to Adverse Event

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Reporting, and must participate in any investigation and/or quality review, to include (but not limited to) instructions found in the following policies:

- a. "Protection of Evidence Related to an Adverse Event" Policy: Discontinue use, leave settings and disposables in place with the device, sequester and secure the device for further investigation, notify Risk Management.
  - b. Follow "Medical Devices Incident Investigation and Reporting (SMDA)" Policy and "Regulatory Agencies Reportable Events" Policy instructions immediately.
3. The PI of a study using an investigational radiology device must also report any adverse event to the Stanford University Clinical Radiation Safety Committee, which reports to the Stanford University Administrative Panel on Radiological Safety.

H. Emergency Use of Investigational Devices

1. An exemption under FDA regulations (21 CFR 56.104) permits emergency use of an investigational device on a one-time basis per institution without IRB review and approval (21 CFR 56.104(c)). Three conditions must exist to justify emergency use of an investigational device:
  - a. A patient is experiencing a life-threatening condition that needs immediate treatment;
  - b. No generally acceptable alternative is available for treating the patient; and,
  - c. Because of the immediate need to use the investigational device, there is no time to use existing procedures to get approval from the IRB or FDA.
2. The emergency use of an investigational device must be reported to the IRB within five working days. This reporting must not be construed as an approval for the emergency use by the IRB. The specific information and documents that must be submitted to the IRB after an incident of emergency use can be found in policy of

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the Stanford University HRPP.

3. Emergency use of an investigational device can be granted only **one time**. All future use must be under a regularly-approved protocol.
  4. An exception under 21 CFR 50.23 permits the emergency use of an investigational device without informed consent. Refer to the policy of the Stanford HRPP Policy for specific detail for this situation.
  5. Under extraordinary circumstances, a *Compassionate Use IDE* may be granted by the FDA to allow treatment of a small number of seriously ill patients who have no acceptable alternatives.
- I. Custom Devices for Clinical Research - Investigational Device Exemption (IDE)
1. Clinical application of custom and/or investigational devices must satisfy all of the requirements of *FDA 21 CFR part 812, Investigational Device Exemptions*. Custom devices are *exempt* unless the device is being used to determine safety or effectiveness for commercial distribution [21 CFR §812.2(c)(7)] . A custom device is as follows [21 CFR §812.3(b)]:
    - a. The device necessarily deviates from devices generally available or from an applicable performance standard or pre-market approval requirement in order to comply with the order of an individual physician.
    - b. The device is not generally available to, or generally used by, other physicians or dentists.
    - c. The device is not generally available in finished form for purchase or for dispensing upon prescription.
    - d. The device is not offered for commercial distribution through labeling or advertising.
    - e. The device is intended for use by an individual patient named in the order of a physician, and is to be made in a specific form for that patient,

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or is intended to meet the special needs of the physician in the course of professional practice.

2. Custom devices attached to catheters, electrode lead-wires, or any artificial conductive pathway to the heart will be the type of design which uses optical or transformer isolation (or some other equally effective technique) to separate the patient input circuit from the balance of the circuitry of the device. The maximum allowable ground leakage current for the patient connections of such devices shall not exceed 10 microamperes at the patient end of the lead when 120 Volts AC current is applied to the patient leads.
  
3. Inspection Procedure:
  - a. The device must pass an incoming inspection outlined in the SUMC Medical Equipment Management Plan Policy (MEMP) "*Acceptance Testing of New Equipment.*"
    - (1) The SUMC Department of Clinical Technology and Biomedical Engineering (CTBE) will test all custom medical devices to verify operation and compliance with MEMP Policy "*Leakage Current Limits for Electrically Operated Equipment*" and document the results in the CTBE equipment history database.
    - (2) If CTBE is unable to perform a full operational test due to manufacturer's proprietary information or technical requirements, the technician/engineer will indicate in the on-line work order the limit to which the testing has been performed.
  - b. The device must satisfy electrical safety standards outlined in SUMC MEMP Policy "*Leakage Current Limits for Electrically Operated Equipment.*"
  - c. All necessary monitoring and therapeutic equipment must be immediately available in the operating or other treatment room to assure that appropriate patient care in the event of custom device failure or malfunction.
  - d. If the equipment fails to meet acceptance requirements, CTBE will notify

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the requesting physician of the deficiencies and the necessary corrective action to affect acceptance.

- e. CTBE will verify that backup systems have been provided for in the treatment plan or in the operating or treatment room in which the custom device will be used.
- f. Upon acceptance CTBE will attach an Equipment Control Number sticker, initiate an equipment history record and inspection schedule in CTBE equipment history database (to include date of acceptance, model and serial number, and physician or primary investigator), and notify investigator of acceptance.

## V. Document Information

### A. Legal Authority/References

1. CDRH, 21 CFR § 812 and § 814, Investigational Device Exemptions, Center for Devices and Radiological Health, Food and Drug Administration
2. FDA, Department of Health and Human Services (DHHS), as reported in the Federal Register, Volume 62, No. 181, September 18, 1997
3. FD&C Act Section 510(k)
4. FD&C Act [21 USC § 50.23]
5. FD&C Act [21CFR {H} § 892(A)(B)(F)(G)]
6. FD&C Act [21 CFR 56.104]
7. FD&C Act [21 CFR 892.1000 – 892.6500]
8. FDCA Act [21 USC chapter 9, subchapter IV, § 360(e)(j)(g)]
9. FD&C Act [45 CFR § 46.116]
10. FD&C Act [21 CFR § 815.5]
11. Stanford University *Human Research Protection Program (HRPP) (8/05)*;  
Formerly Stanford University IRB Policy (9/02)
12. Stanford University *Research Policy Handbook* Chapter 1 (1.4) "Administrative Panels for Research Protection."
13. Stanford University *Research Policy Handbook* Chapter 6, "Environmental Health and Safety" (6.2), (6.3), (6.4), (6.7). {July 6, 2005}

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14. Stanford Hospital & Clinics & Lucile Packard Children's Hospital *Medical Equipment Management Plan*, Environment of Care.
15. SHC's Center for Advanced Medicine, Department of Radiation Oncology departmental policies, including "Investigational New Devices" policy.
16. SHC/LPCH Regulatory Agencies and Reportable Events Policy
17. SHC/LPCH/SOM HIPAA and Research Policy
18. SHC/LPCH Protection of Evidence Relating to an Adverse Event Policy
19. SHC/LPCH Patient's Rights and Responsibility Policy
20. SHC/LPCH Medical Devices Incident Investigation and Reporting (SMDA) Policy
21. SHC/LPCH Clinical Research Policy
22. SHC Patient Care Services Policy on "Radiation Therapy Health and Safety Guidelines for all Patient Care Personnel"

**B. Author/Original Date**

12/12/96, Glenn Jones ("Custom Devices for Clinical Research")

Rewritten 8/05 Vicki Running ("Investigational New Devices")

**C. Distribution and Training Requirements**

1. This policy resides in the  
Administrative Manuals of Stanford Hospital & Clinics and Lucile Packard Children's Hospital and the SUMC Medical Equipment Management Plan.
2. New documents or any revised documents will be distributed to Administrative Manual holders. The department/unit/clinic manager will be responsible for communicating this information to the applicable staff.

**D. Review and Renewal Requirements**

This policy will be reviewed every three years and as required by change of law or practice. The same entities or persons who provided initial approval must approve any changes to the policy.

Reviews: The SUMC Environment of Care Safety Committee will review this policy triennially, and the Committee must approve any changes. The Medical Board will also approve revisions after 9/03.

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E. Review and Revision History

12/97

12/98

11/99

12/00

9/03

8/05

F. Approvals

SUMC Environment of Care Safety Committee (September 29, 2003).

SUMC Environment of Care Safety Committee (August, 2005)

SHC Quality Improvement and Patient Safety Committee (September, 2005)

SHC Medical Board (October 2005)

SHC Board of Directors (October 2005)

LPCH Medical Board (November 2005)

LPCH Board of Directors (December 2005)

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