Criteria for IRB Approval of Research

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Research Compliance Office
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“Creation of new knowledge is good, but an optional good.”

“Respect and care for human beings is good – a mandatory good.”

Hans Jonas
“All (IRB) members should review enough information so that they will be able to determine whether the research meets the regulatory criteria for approval.”

AAHRPP Element II.2.D
Criteria for Approval of Research

- 45 CFR 46.111 (a) (OHRP)

“In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied…”

- We derive our criteria from federal regulations

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<th>Criteria for Approval of Research</th>
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Criteria #1

- Risks to subjects are minimized

1. by using procedures consistent with sound research design

2. by using procedures that do not involve unnecessary risk

3. when appropriate, by using diagnostic or treatment procedures already being performed

*eProtocol 2(a)(b); 4(c)-(f), 5(a)(c)*
Criteria #2

- Risks to subjects are reasonable in relation to anticipated benefits
- Importance of the resulting knowledge

Should consider:
only risks/benefits which may result from research

e.g., political risk
Criteria #2, cont.

Should not consider:

Possible long-range effects of applying knowledge gained in the research
Criteria #2, cont.

e.g., what if researcher was investigating the attitudes of the public on genetically altered vegetables?
IRB cannot consider the resulting effects of the research on public policies
Criteria #3

- Selection of subjects is **equitable**

- IRB must take into account:
  - **Purpose** of the research
  - **Setting** where it is conducted
  - **Vulnerable populations:**
    - Children
    - Prisoners
    - Mentally disabled
    - Economically/educationally disadvantaged

*eProtocol 2(a)(b), 4(a)-(g)*
Criteria #3 - Examples

Survey of battered woman implemented to meet their needs for a new facility.

Need to take into account the needs of mothers and their children as well.

*eProtocol 2(a)(b), 4(a)-(g)*
Criteria #4

Informed consent must be:

- Obtained from each subject or a legally authorized representative

The IRB may approve a consent procedure which waives or alters some or all of the elements of informed consent

eProtocol 2(c); 9
Criteria #5

- Informed consent must be:
  - Appropriately documented

The IRB may approve a procedure which waives the documentation (signature) for informed consent.
6. Data collection is monitored to ensure subject safety

IRB requires plan for > low risk studies

When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
...and when appropriate...

7. Privacy/confidentiality is protected

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
Additional safeguards for vulnerable populations

46.111 (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as

...and when appropriate...

eProtocol 4(c), 5(e)
Reviewer Checklist

Purpose:

✓ Aids the primary reviewer(s) in summarizing review of a protocol

✓ Used as a tool for presentation during panel meetings

✓ Self-populating; editing and additions are made as necessary

✓ Satisfies some of the important elements pertaining to a complete review
Yes, this study is being conducted by a qualified staff using previously approved treatments. This study is also a collaboration with an institution familiar with this type of research.

This study has gone through scientific and scholarly review via CCTO.