Criteria for IRB Approval of Research

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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) and 21 CFR 56.111

“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

<table>
<thead>
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<th>Criteria for Approval of Research</th>
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<tbody>
<tr>
<td>Risk</td>
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<tr>
<td>Selection of subjects</td>
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<td>When appropriate</td>
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</table>

Risks to participants
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, 8(c)-(f), 9
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., CAT scan

eProtocol 1(b), 9,10
Criteria #2

- Importance of the resulting knowledge

Should not consider:

Possible long-range effects of applying knowledge gained in the research

e.g., what if researcher was investigating the nutritional value of genetically altered vegetables?
Criteria #2

Importance of the resulting knowledge

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 1(a), 2(a)(b), 8(a)-(f), 9(f)*
Criteria #3

- Selection of subjects is **equitable**

  e.g., 90% of all new drugs tested prior to 1970 were done on prisoners

  e.g., testing a new flu vaccine on only adult males

  

  \textit{eProtocol 1(a), 2(a)(b), 8(a)-(f), 9(f)}
Criteria #4

- Informed consent must be:
  - Obtained from each subject or a legally authorized representative
Criteria #4

The IRB may approve a consent procedure which waives or alters some or all of the elements of informed consent.
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 > minimal risk studies

NIH requires DSMB for Phase III clinical trials

eProtocol 9(c)(e)

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

**FDA-regulated research only:** FDA includes "handicapped" in the list of vulnerable subjects.
Stanford University includes students, employees and laboratory personnel as a vulnerable population.
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.