Criteria for IRB Approval of Research

Bertha deLanda
Research Compliance Office
November 2009

“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

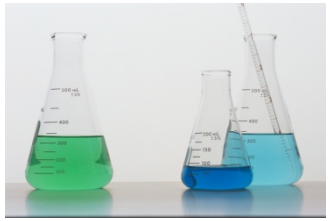
Criteria for Approval of Research	
Risk Selec etc	Risks to participants Selection of subjects When appropriate

Criteria #1

- Risks to subjects are minimized

1. by using procedures consistent w/ **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

eProtocol 1(b), 9,10

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

e.g., CAT scan

Criteria #2

- Importance of the resulting knowledge

<u>Should not consider:</u>

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

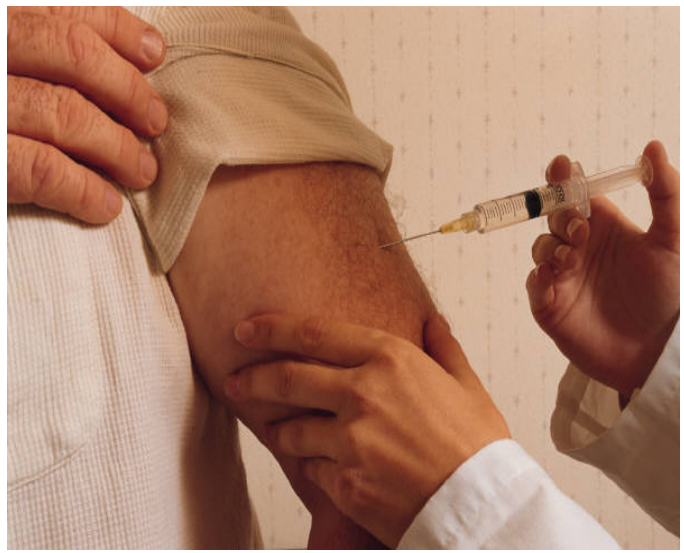
- Selection of subjects is equitable
- IRB must take into account:
  - Purpose of the research
  - Setting where it is conducted
  - Vulnerable populations:
    - Children
    - Prisoners
    - Mentally disabled
    - Economically/educationally disadvantaged

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

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

eProtocol 13

Criteria #4

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

eProtocol 13

Criteria #5

- Informed consent must be:
  - Appropriately documented

The IRB may approve a procedure which waives the documentation (signature) for informed consent

eProtocol 13

...and when appropriate...

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.

...and when appropriate...

7. Privacy/confidentiality is protected

eProtocol 9(c)(e)

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

...and when appropriate...

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…

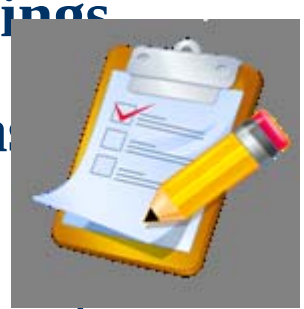



FDA-regulated research only: FDA includes "handicapped" in the list of vulnerable subjects
Stanford University includes students, employees and laboratory personnel as a vulnerable population

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



Reviewer Checklist

Protocol ID : Disney Jr., Leland

Title : MED-REG

Medical REGULAR

A-B | C | D-E | F-G | H-I | J-K | L | M | N | O

Reviewer Checklist

Print View

A. Purpose of Study *(eProtocol question 1a)*

Consider:

- Is the study likely to achieve its aims?

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.

B. Brief Description of Study *(eProtocol question 2a)*

Consider:

- Are procedures consistent with sound study design?

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