




Criteria for Institutional Review Board Approval

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Institutional Review Boards

-  Established by the National Research Act (1974) for the independent review, approval, and oversight of human research
-  Regulated by the Office of Human Research Protection (OHRP)
-  45 CFR 46 -- IRB membership, functions, operations, requirements

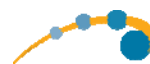
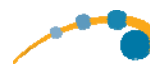
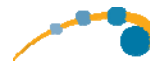
Belmont Principles

 Respect for persons

 Beneficence

 Justice

Respect for Persons

-  Treat individuals as autonomous agents with certain rights
-  Provide additional protections for persons with reduced autonomy (vulnerable populations)
-  Individuals have the right
 - To know
 - To choose
 - To privacy and confidentiality
 - To withdraw

Beneficence

 Do no harm

 Maximize possible benefits

 Minimize possible harms

 Benefits must outweigh risks

Justice

Equitable selection of subjects

Vulnerable subjects are not targeted for for convenience

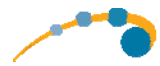
Equal share of risks to those who benefit most

People who are likely to benefit from research participation are not systematically excluded

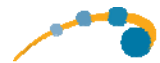
Criteria 1

Risks are minimized

Principle of Beneficence



Procedures are consistent with **sound research design**; do not expose subjects to unnecessary risks





Whenever appropriate, **use procedures already being performed** on the subjects for diagnostic or treatment purposes

Criteria 2

Acceptable Risk:Benefit Ratio

Principle of Beneficence

-  Procedures are consistent with **sound research design**; do not expose subjects to unnecessary risks
-  Whenever appropriate, **use procedures already being performed** on the subjects for diagnostic or treatment purposes

Risks are reasonable in relation to:

- Anticipated benefits to subjects, if any
- The importance of the knowledge that may reasonably be expected to result

Criteria 3

Equitable subject selection

Principle of Justice

- Inclusion criteria
- Exclusion criteria
- Recruitment methods

Equitable selection of research subjects impacts the generalizability of the findings

Principle of Respect for Persons

Criteria 4

Appropriate informed consent

from each prospective subject or the subject's legally authorized representative

Criteria 5

Appropriate documentation of consent

Consent Process: What the IRB must find

- Sufficient opportunity to consider whether or not to participate
- Possibility of coercion or undue influence is minimized
- Presented in language understandable to the subject
- No exculpatory language

Criteria 6

Acceptable data and safety monitoring plan

Principle of Beneficence

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

Criteria 7

Privacy and confidentiality measures

Principle of Respect for Persons

- **Privacy** is about people and their interest in controlling others' access to themselves
- **Confidentiality** is about data

Criteria 8

Additional Safeguards for Vulnerable Populations

Principle of Respect for Persons

Protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons

For children:

- Parental permission
- Assent
- Pediatric risk categories (45 CFR 46.404-407)

IRB Approval Criteria

1. Risks are minimized
2. Acceptable Risk:Benefit Ratio
3. Equitable subject selection
4. Appropriate informed consent
5. Appropriate documentation of consent
6. Acceptable data and safety monitoring plan
7. Privacy and confidentiality measures in place
8. Additional safeguards for vulnerable subjects