



Stony Brook University

FAR BEYOND

IRB Meeting - Discussion

Research with Human Subjects

Review Criteria

Each IRB member should participate in the criteria for IRB approval of research

- When some of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects

45 CFR 46.111

Research with Human Subjects

Vulnerable populations

- Children
- Prisoners
- Individuals with impaired decision-making capacity
- Individuals who are economically disadvantaged
- Individuals who are educationally disadvantaged

Research with Human Subjects

Review Criteria

Coercion

- The practice of persuading someone to do something by using force or threat
 - An investigator tells a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research

<https://legaldictionary.net/> Metropolitan State University of Denver

Research with Human Subjects

Review Criteria

Undue Influence

- Undue influence occurs when an individual is able to persuade another's decision due to the relationship between the two parties. Often one of the parties is in a position of power over the other due to an elevated status, higher education, or emotional tie
 - A staff member might participate in research in order to please her boss (the Principal Investigator of the study)

Research with Human Subjects

Non-monetary incentives

The Institutional Review Board should review consent documents to make sure that the information in the consent form does not include language that could cause someone to suffer a negative consequence

- If you decide that you don't want your child to be in this study, it will not affect how the school treats your child

Research with Human Subjects

Monetary Incentives

Institutional Review Boards should also check consent forms for financial compensation language and determine if the compensation will unduly influence someone to participate

- Financial compensation should be just and fair
- The IRB should determine if the financial incentives cause the individual to not fully appreciate the study risks

Metropolitan State University of Denver

Research with Human Subjects

Review Criteria

The IRB approves only those studies where this requirement is satisfied. If the criteria is not satisfied, the study must be deferred

Bankert and Amdur, 2006