



UC DAVIS OFFICE OF RESEARCH

The Belmont Report

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Outreach and Training

What is the Belmont Report?

- ✧ The Belmont Report is a statement of basic ethical principles and guidelines that provide “an analytical framework to guide the resolution of the ethical problems arising from research with human subjects.”
- ✧ The framework of the Belmont Report is presented in three discussion topics: boundaries between practice and research; basic ethical principles, and applications



Boundaries between Practice and Research

- The distinction between practice and research is blurred; often because they occur together.
- The IRB must ensure that the researcher (and the participant) distinguishes practice from research in both social science and biomedical research
- Minimize the potential for therapeutic misconception – when one believes the purpose of clinical research is to treat rather than to gain knowledge

Basic Ethical Principles

- Respect for Persons
- Beneficence
- Justice



Respect for Persons

- Treat individuals as autonomous persons; allow individuals to choose for themselves
- Persons with limited autonomy need additional protection, even to the point of excluding them from activities that may harm them. The extent of protection should depend upon the risk of harm, and the likelihood of benefit.
- The judgment that any individual lacks autonomy should be periodically re-evaluated, and will vary across situations.

Beneficence

- The IRB should determine whether the risks to subjects are reasonable in relation to anticipated benefits
- Obligations of beneficence affect both the researcher and society –
 - investigators are required to give forethought on maximization of benefits and reduction of risk that may be involved in the research
 - society should recognize the longer term benefits and risk that may result from the improvement of knowledge, and from the development of novel medical, psychological, and social processes and procedures

Justice

- Treat people fairly
- Do not exploit those who are readily available or malleable
- Fair distribution of the risks and the benefits of research based upon the problem/issue under investigation

How does
the IRB
apply these
ethical
principles?



Application of Respect for Persons

- Informed Consent Process
 - Information - Does the consent form provide all the information necessary for the individual to make a reasoned decision?
 - Comprehension - Is the consent form crafted in language understandable to the potential participant?
 - Voluntariness - Does the consent form and clearly indicate that participation in the research is voluntary?
 - What additional protections can be in place to protect those with limited autonomy?
 - How to determine whether one lacks the autonomy to make a reasoned decision?

Application of Beneficence

- Assessment of Risks and Benefits
 - Risk refers to the probability of harm; when considering risk, one should consider both the probability and the severity of the envisioned harm; while the term, benefit refers to something that promotes health, well-being, or welfare.
 - What are the risks of harm to the participants (consider physical, psychological, social, and economic harms)? Are the risks justified? Can they be minimized?
 - Can the research design be improved to minimize risk and maximize benefit?
 - What are the benefits (to the participant; to society)?

Applications of Justice

- Selection of Subjects
 - Is the potential subject pool appropriate for the research?
 - Is it appropriate to involve vulnerable populations (e.g., economically disadvantaged; limited cognitive capacity) in the research or are they being enrolled because it is convenient or because they are easily manipulated as a result of their situation?
 - Are the recruitment procedures fair and impartial?
 - Are the inclusion and exclusion criteria fair and appropriate?

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