

## The Belmont Report

### Talking Points

#### Introduction

- The Belmont Report provides the ethical foundation for human subjects protection and the current human subjects protection regulations.
- 25<sup>th</sup> anniversary of the Belmont Report in 2004. OHRP conducted an oral history project with the remaining Belmont Commissioners. Transcripts from interviews are posted on the OHRP website: <http://www.hhs.gov/ohrp/belmontArchive.html>.

#### Historical background and context

- The National Commission for Protection of Human Subjects of Biomedical and Behavioral Research was created by the National Research Act of 1974—an outgrowth of:
  - Congressional hearings chaired by Senator Ted Kennedy—response to research abuses (alleged abuses in fetal research in Scandinavia; Tuskegee; Willowbrook).
  - Political climate—civil rights movement.
- Different from other Commissions in US history:
  - Not just advisory—was given statutory authority to write rules that would become law—DHEW was required to accept the recommendations/rules or explain why they would change them or not adopt them.
  - The Commission operated in public, despite very sensitive subjects.
  - Commissioners (not staff) actually wrote most reports, which is unusual for federal commissions.
- 11 Commissioners appointed: legislation prescribed that majority be non-scientists (3 medical, 3 behavioral, others from law, philosophy, public policy).
- Responsibilities of Commission drafted by Charles McCarthy (NIH Liaison to Commission, later became head of OPRR, OHRP).
  - First assignment: study and report on fetal research, given very short timeline.
  - Role was expanded to study and develop reports on other vulnerable populations and topics: children, women, prisoners, psychosurgery, impact of biotechnology.
  - McCarthy felt nothing really tied the topics together, at last minute added comprehensive study to identify basic general principles underlying human subjects research—resulted in Belmont
  - Commonly thought that Belmont came first, and regulations grew from Belmont principles—not the case. Belmont meetings began 2 years into Commission's work.
  - Final draft of Belmont written by Tom Beauchamp, Stephen Toulmin, and Al Jonsen.
  - Commissioners did not see Belmont as their most important assignment.

## **Belmont's relation to regulations**

- DHEW adopted Belmont as policy; several other reports were translated into regulations (45 CFR and subparts) by lawyers.
- Relationship between regulations and Belmont has never been clear: same goal, but different means—Belmont does not address how principles/applications relate to interpreting regulations, or provide examples of how to do this. Regulations, for the most part, do not mention ethics.
- In absence of clear connection—IRBs often focus on regulatory compliance and documentation, and tend to neglect or relegate ethics to periphery.
- Harold Vanderpool (*Institutional Review Board: Management and Function*, Bankert and Amdur) argues that:
  - “Regulatory rules only touch the hem of the ethical garment”.
  - Regulations are incomplete and inadequate in protecting human subjects.
  - Some review issues not answered by regulations, but require thoughtful ethical deliberations.
  - 45 CFR should be seen as a tool for implementing Belmont principles.
  - IRBs have a duty to go beyond regulatory compliance.
- Several Commissioners and former directors of OHRP (Kopski, Schwetz) voice concerns about shift away from ethics and Belmont to ensuring and documenting regulatory compliance:
  - Too much micro-regulation requiring time and resources with diminishing returns.
  - Too much emphasis on protecting institutions rather than subjects.
  - No empirical evidence that current emphasis on compliance and documentation results in improved protection.
  - Should focus on: which regulations matter, which don't matter as much, and where there should be more flexibility.
  - Almost all interviewed Commissioners feel there is a need for more ethics training for IRBs members and investigators to understand the ethics, or the “why” behind regulatory requirements, and how to apply them appropriately.

## **Going beyond compliance—Importance of ethics (Belmont principles)**

- Ensuring compliance is legal necessity and essential for review, but IRBs should not lose sight of the ethical reasoning behind the regulations.
- Example of the disconnect between Belmont principles and regulations—informed consent (derived from principle of respect for persons):
  - Belmont identifies 3 essential elements: information, comprehension, voluntariness.
  - Belmont provides some guidelines on information that should be included, but states that a simple list does not answer question of what information should be provided.

- 45 CFR provides a comprehensive list of required elements but does not adequately address comprehension or voluntariness.
  - Focusing exclusively on consent form elements does not ensure respect for persons—rather the focus should be on **process** of recruitment and consent, not the form. Ensure ongoing communication between subjects and researchers.
  - if Belmont guides us rather than regulations, consent monitoring would be much more productive and useful than extensive consent form editing—would get at the core of what IRBs are trying to do—but monitoring takes far more resources.
- Case example (adapted from UW):
    - Anthropological field research in a very remote area of Indonesia—looking at sea hunting practices, field work to coincide with active sea hunting season.
    - Researcher only has email access for one hour/month—several miles from field work.
    - Project approved, but upon arrival investigator realized compensation was too high in relation to local wages, also felt he needed to emphasize voluntariness more strongly than approved, also over-enrolled from approved numbers due to high enthusiasm in village.
    - Investigator changed consent to emphasize voluntariness and lowered compensation by half—tried to do what was most ethical.  
If he went ahead as approved, not ethical—but if change without approval, out of compliance.  
If waited for modification approval, would lose research opportunity given temporal and geographic circumstances of project.
    - Researcher sent letter to IRB chair:

“I am aware that modifications ordinarily are filed and approved before instituted. However, I hope members of the Committee will appreciate the unique nature of anthropological fieldwork, and understand that this is a good faith effort to comply as best as possible with HSD procedures given the constraints imposed me by conditions in the field, especially my limited ability to communicate with the outside world.  
I currently have access to email one hour a month, during supply trips to town. I will be in town on Aug. 28 and will be able to receive any messages sent by the committee then. I apologize for the inconvenience.”

Questions:

- 1) Given the researcher’s circumstances, was it acceptable for him to make modifications without prior IRB approval?
- 2) Can exceptions to IRB-requirements for prospective approval of changes be made by the IRB in circumstances like this?
- 3) Is there a way for researchers to better anticipate circumstances they may encounter?  
How can IRB assist?