Institutional Review Board

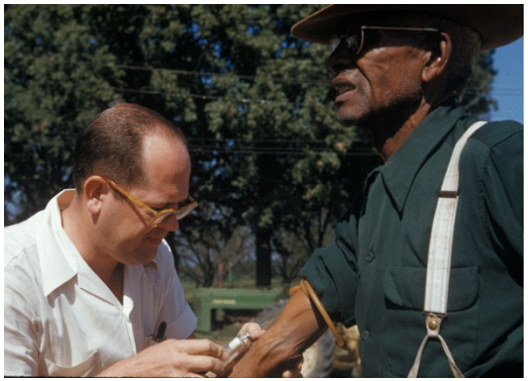
Overview for Residents

Why Do Human Research Subjects Need Protection?

Trigger Events

The Nazi Experiments

Tuskegee Syphilis Study



Ethical Milestones

Nuremberg Code 1947

National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research 1974

*** Belmont Report 1978**
*** Common Rule 1981**

NOT JUST AN ISSUE OF THE PAST…

On April 20, 2010, Arizona State University (ASU) agreed to pay $700,000 to 41 members of the Havasupai Indian tribe to settle legal claims that university researchers improperly used tribe members' blood samples in genetic research.

Floranda Uqualla, 46, whose parents and grandparents had diabetes. She said she felt shamed by the news that the samples had been used for research that could potentially damage the tribe.

Source: http://www.nytimes.com/slideshow/2010/04/21/us/0421DNA_7.html

Guidance Derived from the Belmont report

- **Respect for Persons**
  - ❖Informed Consent Process.
  - ❖Respect for Privacy.
  - ❖Provide extra protections for vulnerable subjects.
- **Beneficence**
  - ❖Good research design.
  - ❖Competent investigators/researchers.
  - ❖Favorable risk-benefit analysis.
- **Justice**
  - ❖Equitable selections of subjects and fair distribution of burdens and benefits of the research.

The Common Rule

The "Common Rule" is the set of regulations which were developed to ensure compliance with the principles of the Belmont Report.

- The regulations fall under the Department of Health and Human Services.
- The regulations have been adopted by many other federal departments which regulate human research.
- There are many other regulations with which MWMCIRB is sometimes required to comply, such as the Food and Drug Administration, but these are all *in addition* to the "Common Rule".

What's the Difference between the Belmont Report and the Common Rule?

- THE BELMONT REPORT is a *guidance document* that provides the basic ethical standards for researchers.

- The COMMON RULE (45 CFR 46) is a *set of federal policies* that this organization has agreed to adopt (via a legally binding document) as the standards for research.

Protective mechanisms established by The Common Rule

- Institutional assurances of compliance
- Review of research by an IRB
- Informed consent of subjects

Institutional Assurance

MWMCIRB has a signed agreement in place with the Office for Human Research Protections that all of the institution's human subject research activities, regardless of funding, will be guided by the Belmont Report, will comply with the Common Rule, and other regulations as applicable.

This is referred to as a Federalwide Assurance (FWA).

Institutional Review Boards (IRB)

The purpose of the IRB is to:

- review research and ensure that the rights and welfare of the human subjects involved in research are adequately protected.
- help *facilitate* research for MWMCIRB investigators.

IRB has authority to:

- **Approve** the research.
- **Require modifications** before approving research.
- **Disapprove** the research.
- **Table** the research protocol until changes are made.

The IRB Process at MWMCIRB

RESIDENT

- Completes required CITI online training.
- Completes IRB application electronically attaches instruments, consent forms and all applicable documents.
- Has application reviewed and signed by department chair.
- Submits materials to IRB
- Communicates with reviewer to revise application, if necessary.

IRB Pre-Review

- Reviews application for completeness, methods and adherence to ethical standards.
- Communicates requirements & revisions to Investigator.
- Sends final version of application to the IRB (if determined that it is not exempt)

IRB OFFICE

- Notifies Investigator via email that application has arrived in IRB office.
- Reviews level recommendation and evaluates the application for compliance with federal regulations.
- Verifies training requirements have been met.
- Communicates with Investigator regarding any additional requirements, or revisions needed.
- Sends final written notification of IRB determination to Investigator.

IRB Review of Research

All research projects are categorized into one of three categories for the IRB review process. Each category is different in the level of scrutiny and submission procedures. The IRB is responsible for making the final decision of which category a research project falls under.

- **Full review by convened IRB – (Level 3)**
  - Sensitive subjects, vulnerable subjects
- **Expedited – (Level 2)**
  - Involve children, audiotaping, research on individual or group behavior (focus groups)
- **Exempt from Annual review – (Level 1)**
  - anonymous surveys, evaluation of service programs, educational tests, class projects, food quality, research involving existing data

Types of Review

- **Initial** – Level of review is determined.
- **Continuing/Annual Review** – Level 2's and 3's.
- **Modifications** – changes to research. Must be reviewed and approved before implemented.
- **Adverse events** - safety Information or unanticipated problems for subjects or others.
- **Noncompliance** – a participant calls Research Compliance office and reports that investigator is doing something he/she shouldn't be.

Criteria for IRB Approval

- **Risks are Minimized** – (Consistent with a sound research design and does not unnecessarily expose subjects to risk)
- **Risks are Reasonable in Relation to Benefits**
- **Selection of Subjects is Equitable**
- **Informed Consent will be Sought –** for each prospective subject unless a waiver is granted.
- **Informed Consent will Be Documented**
- Research Plan Adequately Provides for **Monitoring the Data Collected to Ensure Safety** of the Subjects
- Research Plan Adequately **Protects the Privacy of Subjects and Maintains Confidentiality**
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, **additional safeguards** need to be included in the protocol to protect the rights and welfare of these subjects.

Consent Form Required Elements

- Statement that the study involves research
- Research is described
- Description of Risks
- Description of Benefits
- Disclosure of Alternatives (if applicable)
- Confidentiality
- If more than minimal risk, plans for compensation and/or medical treatment (Tenet has standard language).
- Participation is voluntary
- Whom to Contact (Include name and contact information for investigator and Institutional Review Board

Informed Consent Process

- Informed Consent process is more than just the use off the IRB-approved consent document!
- Initial
- Ongoing

Common Mistakes to Avoid when submitting IRB applications

- Indicating that data is anonymous when it is actually confidential.
- Stating that there are no risks involved in the activity. Even though the risks may be low, they need to be listed in the application.
- Not completing CITI online training, or completing the wrong online training.
- Signature page does not have all the required signatures.
- Consent forms, survey, or interview instruments are not attached for review.

Frequently Asked Questions

I am not sure if my project is human subjects research, what should I do?

Answer: Contact the Clinical Research Office and discuss the study relating to next steps

Can I begin my project without IRB approval?

No. Engaging in human subject research without IRB approval has serious ethical implications and violates university and federal policies. Students, residents, and staff are required to submit IRB applications before embarking on any data collection. Even pilot studies must be approved by the IRB. IRBs do no have the option of granting "retroactive" approval after research is done, so you are strongly encouraged to submit your research proposal or consult with the Research Office if you are unsure whether your project needs IRB approval.

How long does it take to get IRB approval for my protocol?

Answer: **Plan ahead.** Do not wait until the last minute to submit your application. Approval can take 1-6 weeks. The more complete your application is…the quicker you can get approval.

You will receive a "notification" email once your application reaches the IRB office. The email will contain information about the number assigned to your application and who to contact with questions.

Should I keep a copy of my IRB application?

Answer: YES, definitely save a copy of your application!

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