




IRBMED
New Member Workshops
SESSION ONE

June Inscó

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Workshop Agenda



10 min	Introductions
10 min	IRB Mission
30 min	Human Subject Protections Overview <ul style="list-style-type: none">■UM■IRBMED■IRBMED member duties and responsibilities
10 min	Break
40 min	Belmont Report and Case Study
10 min	Introduction to Regulations

Introductions

- Who are you?
- What are your perceptions of IRBs?
- What is the job of an IRB?
- Why are you here?



What is an IRB?

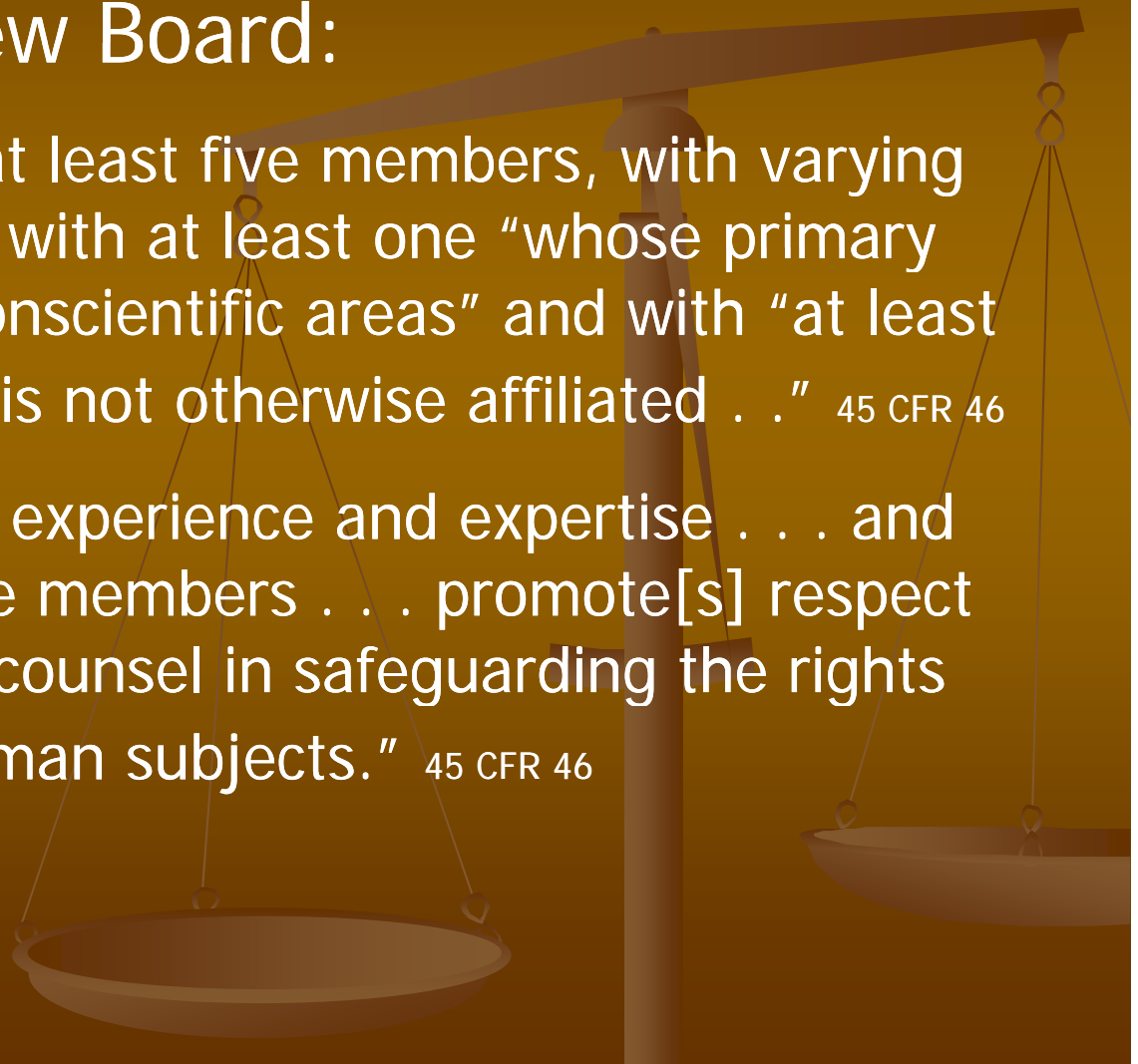
- An Ethical Review Board:

- Mandated by the government to oversee “all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency” 45 CFR 46
- That is “an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.” OHRP IRB GUIDEBOOK
- That “makes its independent determination whether to approve or disapprove the protocol based upon whether or not human subjects are adequately protected.” OHRP IRB GUIDEBOOK

What is an IRB?

■ An Ethical Review Board:

- That “must have at least five members, with varying backgrounds . . .” with at least one “whose primary concerns are in nonscientific areas” and with “at least one member who is not otherwise affiliated . . .” 45 CFR 46
- That “through the experience and expertise . . . and the diversity of the members . . . promote[s] respect for its advice and counsel in safeguarding the rights and welfare of human subjects.” 45 CFR 46



Mission of an IRB

- **Protect the rights and welfare of human research subjects**
(and future human welfare—i.e. keep science moving forward)
- **Protect ability of institution to conduct human subjects research**
 - An indirect mission, accomplished by carrying out our primary mission.



Mission of an IRB

Protect Human Subjects through knowledge of:

- Subject populations
- Factors that determine risks and benefits
- Factors affecting subjects' informed consent
- Ethical principles
- Laws and regulations
- Federal Wide Assurance, institutional policies and procedures

Achieved by:

- Member background, education, experience
- IRB participation and continuing education
- Institutional Support



UM Human Subject Protections



- Human Research Protection Program
 - <http://www.research.umich.edu/hrppp/om/>
- Office of the Vice President for Research
 - <http://www.research.umich.edu/policies/humans.html>
- UM Federal Wide Assurance
 - <http://www.irb.research.umich.edu/FWA.html>
- Office of Human Research Compliance Review
 - <http://www.research.umich.edu/orcr/index.html>
- UMMS Office of Research Regulatory Affairs
 - <http://www.med.umich.edu/medschool/research/regulations.htm>
- UMMS Office of Research
 - <http://www.med.umich.edu/medschool/research/>

IRBMED Human Subject Protections

■ UM Medical School Institutional Review Boards

The screenshot shows the top portion of the IRBMED website. It features the University of Michigan Medical School logo and name. A search bar is located in the top right corner. Below the header is a navigation menu with links for ABOUT US, STUDENTS, RESIDENTS & FELLOWS, GRADUATE & POSTDOCTORAL STUDIES, RESEARCH, FACULTY, STAFF, ALUMNI, and HOME. A sidebar on the left lists various resources: Forms, Informed Consent Templates, Guidance, Education, About IRBMED, and Resources. The main content area displays several images: a family with a doctor, a person in a lab coat, a DNA double helix, and a person in a lab coat working with equipment.

This screenshot shows the main content area of the IRBMED website. It includes a search bar and a navigation menu. The left sidebar contains a table of contents with links to IRBMED Home, Forms, Informed Consent Templates, Guidance, Education, About IRBMED, Resources, AE/ORIO, IRBMED Members, and Research Participants. The main content area is titled "Guidance" and contains a comprehensive list of links for various topics, including Adverse Event Reporting, Belmont Report, Blood Draw Guidelines, Certificate of Confidentiality, Children in Research, Assent, Food and Drug Administration Guidance, National Cancer Institute Guidance, Federal Regulations, FAQs, Expedited Review, Fees for IRBMED Review, HIPAA Guidance, and Informed Consent Guidance.

This screenshot shows a sidebar section of the IRBMED website. It includes a search bar and a navigation menu. The sidebar contains links for IRBMED Members, Feedback Form, and IRBMED contact information, including the address (117 W. William, Argus I, Arbor, MI 48103-4943), phone number (734) 763 4768, and fax number (734) 763 9603.

The four Institutional Review Boards of the University of Michigan Medical School (IRBMED) are charged with the oversight of human subjects research conducted by medical school faculty, students, and staff at any University of Michigan Health System (UMHS) facility or site. The purpose of an IRB is to protect the rights and welfare of human subjects in research. Guiding this process is the application of federal and state laws, university policies, ethical principles, particularly those articulated in the Belmont Report.

Investigators should not commence research involving human subjects until the IRBMED has approved the study or has determined it is exempt.

Federal regulations define a "Human Subject" as: "[A] living individual about whom an investigator . . . conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) Identifiable private information" (45 CFR 46.102[f]). "Research" is defined as: "[A] systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102[d]).

The IRBMED office welcomes comments and

News
[eResearch Cover Sheet](#) is now available on the [Forms](#) page for submission to the IRBMED office of three dimensional items that are needed for IRB review.

[eResearch Training Manual](#)

Conversion Update

We have determined that a delay in the conversion plan (to move studies approved in the paper-application system [legacy] to the eResearch system) is in the best interest of our investigators. A new date for conversion will be announced at a later time, but we do not expect to begin the conversion until after the new year. We will notify you when a new date is set for conversion.



What is “IRBMED”?

- The five “Institutional Review Boards” of the University of Michigan Medical School
 - ~80 members: physicians, scientists, non-scientists, community members
- A unit within Medical School Administration
 - ~25 member support staff for the Boards, the Dean’s office & the Medical School.



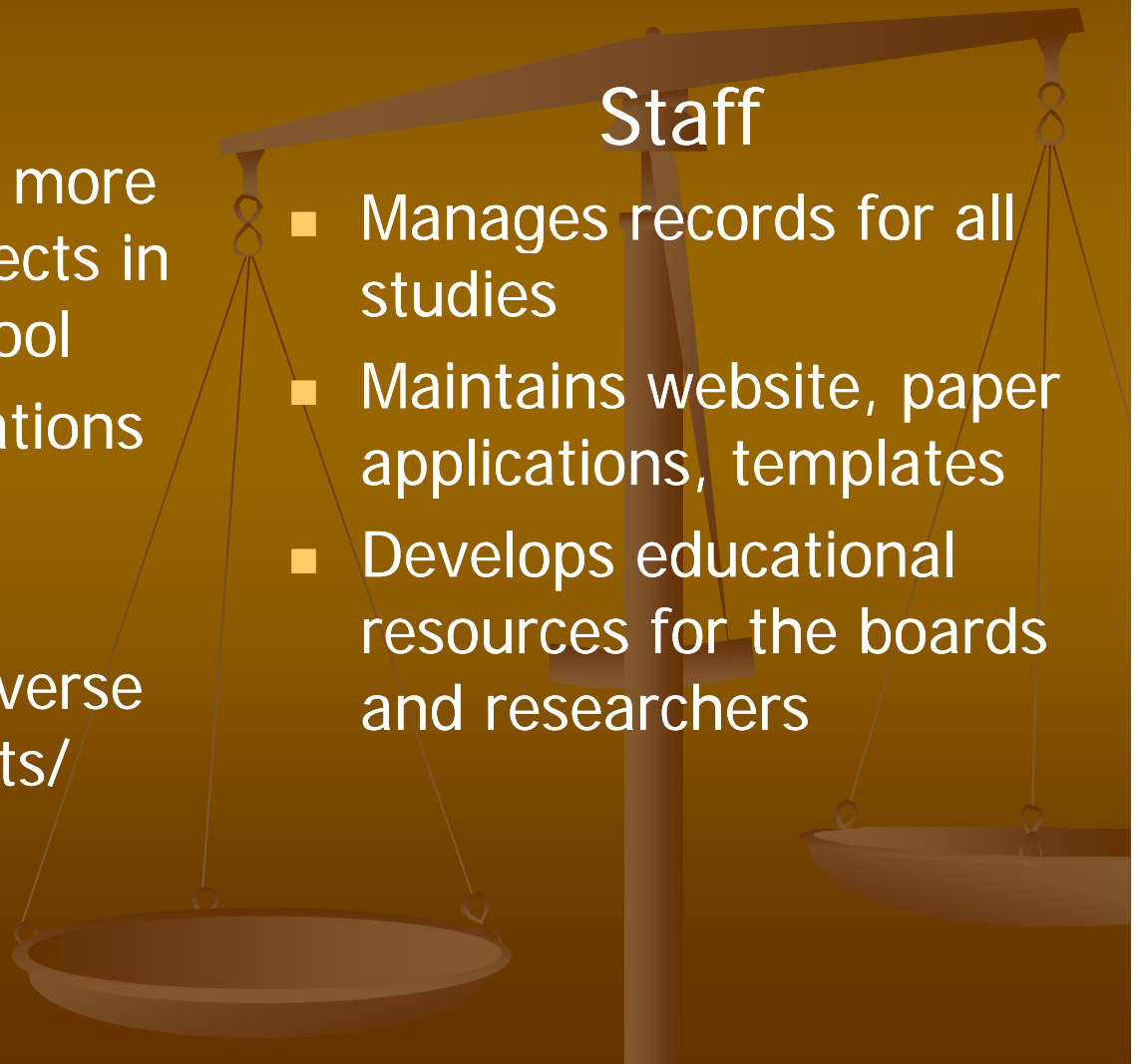
IRBMED Overview

Boards

- Have oversight of the more than 3000 active projects in the UMHS & Med School
- Review ~8000 applications each year
 - 1200 new studies
 - 7800 renewals/ adverse events/other reports/ amendments

Staff

- Manages records for all studies
- Maintains website, paper applications, templates
- Develops educational resources for the boards and researchers





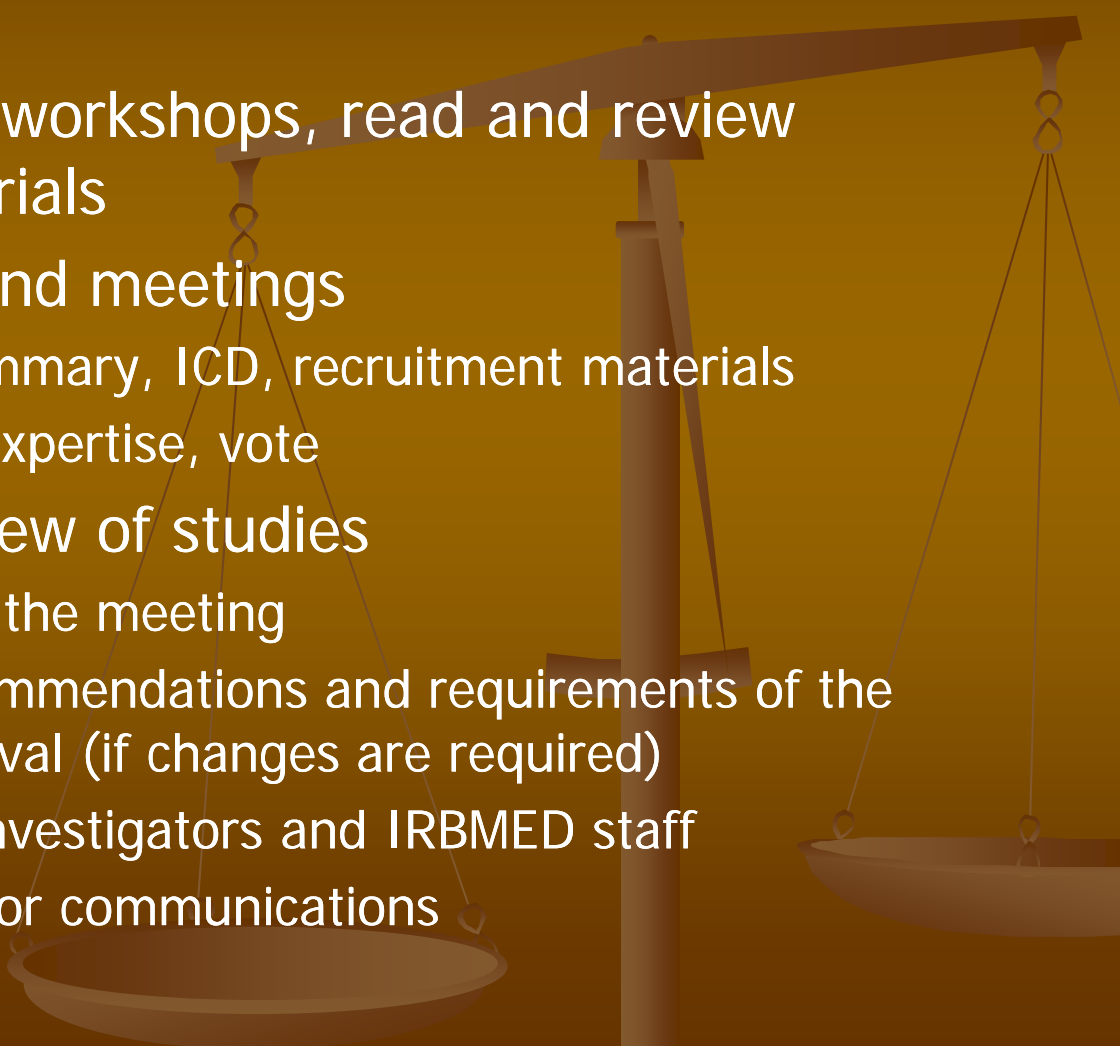
IRBMED Member Responsibilities

- Know principles, regulations, and national standards applicable to the conduct of human subjects research
- Review proposed and ongoing research

Other Responsibilities:

- Assist staff with complaints
- Assist staff with development of policies and procedures
- Assist staff with education and training of research community
- Liaison to other institutional entities (usually chairs)
- Interact with oversight authorities (usually chairs)

IRBMED Member Responsibilities

- Orientation—attend workshops, read and review recommended materials
 - Prepare for and attend meetings
 - Review narrative summary, ICD, recruitment materials
 - Raise issues, share expertise, vote
 - Provide primary review of studies
 - Present the study at the meeting
 - Document your recommendations and requirements of the board for final approval (if changes are required)
 - Communicate with investigators and IRBMED staff
 - Document investigator communications
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Break time



The Belmont Report

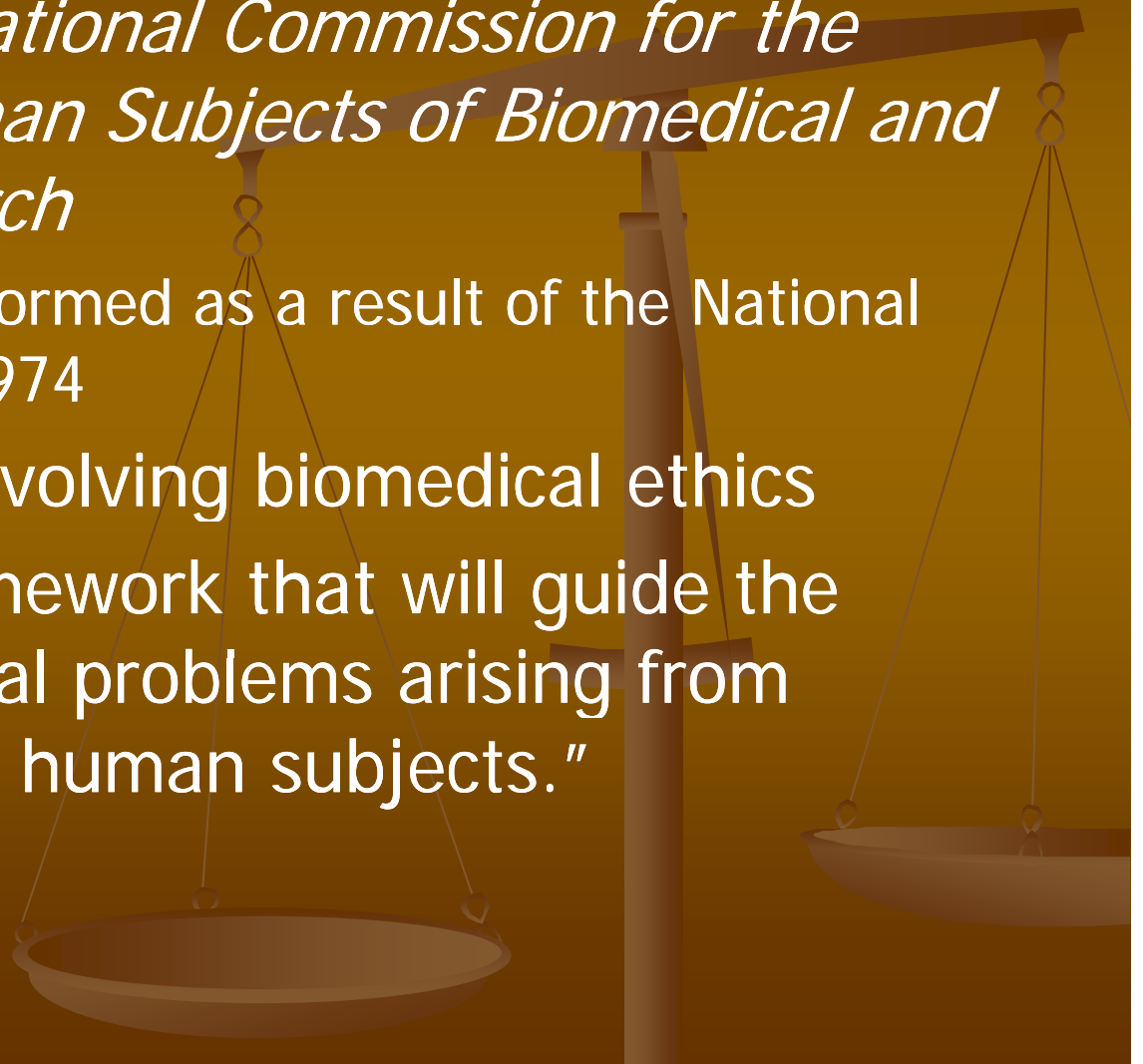
- What is it? How does it affect IRBMED review? How does it protect them?



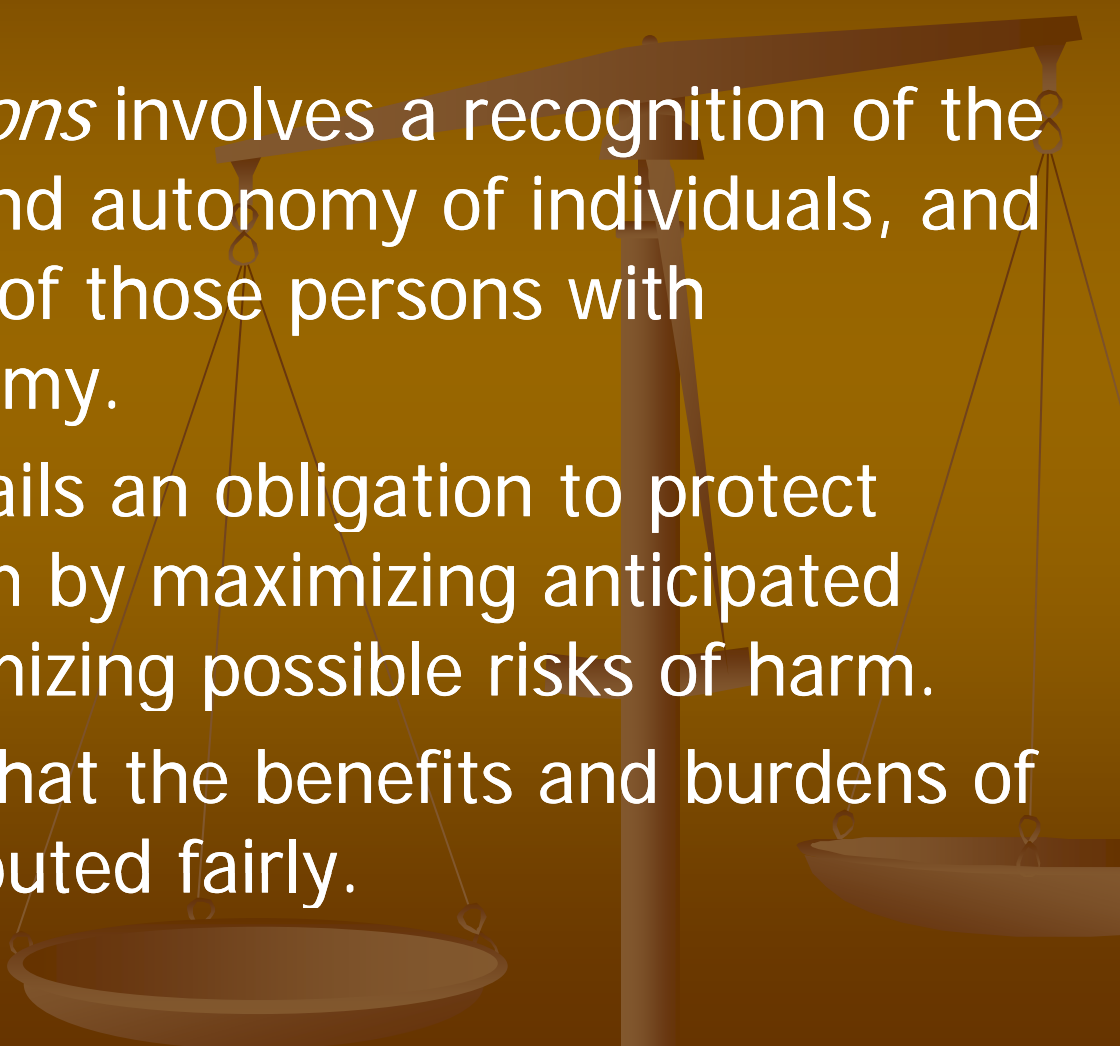
The Belmont Report

What is it?

- A report by the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*
 - Commission was formed as a result of the National Research Act of 1974
- A foundation for evolving biomedical ethics
- “An analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.”



The Belmont Report

- ***Respect for persons*** involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.
 - ***Beneficence*** entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.
 - ***Justice*** requires that the benefits and burdens of research be distributed fairly.
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Belmont Report

How does it affect IRBMED review?

- The Belmont principles represent our fundamental, shared values.
 - True?
- We promised to adhere to the principles.

U.S. Department of Health and Human Services (DHHS)
Office for Human Research Protections (OHRP)

University of Michigan
FEDERALWIDE ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS
(FWA 00004969)
Expires June 12, 2006

A. Human Subject Research Will be Guided by Ethical Principles

With regard to federally-conducted or --sponsored research, all of the University's activities and all activities of the Institutional Review Boards (IRBs) designated under this Assurance will be guided by the ethical principles in The Belmont Report; Ethical Principles and Guidelines for the Protection of Human Subject Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral research.

B. Applicability

- 1) These terms apply whenever the University becomes engaged in federally-supported* (i.e., conducted or supported) human subject research, which is not otherwise exempted from the Federal Policy for the Protection of Human Subjects. The University becomes so engaged whenever:
 - (a) the University's employees or agents intervene or interact with human subjects for purposes of federally-supported research;
 - (b) the University's employees or agents obtain individually identifiable private information about human subjects for purposes of federally-supported research; or
 - (c) the University receives a direct federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

[*Federally-supported is defined in this document and in the FWA as the U.S. Government providing any funding or other support (including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purpose) and/or the conduct of the research involves U.S. Government employees.]

C. Compliance with the Federal Policy for the Protection of Human Subjects

In its conduct of federally-supported human subjects research, the University and the IRB(s) designated under this Assurance will comply with the Federal Policy for the Protection of Human Subjects, known as the Common Rule. All federally-supported human subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All human subjects research conducted or supported by the Department of Health and Human Services (DHHS) will comply with all Subparts of DHHS regulations at Title 45 Code of Federal Regulations 46 (45 CFR 46 and its Subparts A, B, C, and D).

The reference in the Code of Federal Regulations is shown below for each Agency, which has adopted the Common Rule:

7 CFR 1c	Department of Agriculture
10 CFR 745	Department of Energy
14 CFR 123	National Aeronautics and Space Administration
15 CFR 27	Department of Commerce
16 CFR 1028	Consumer Product Safety Commission

University of Michigan Medical School
Institutional Review Boards

Standard Operating Procedures

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3. GOVERNANCE: ROLE OF THE IRBMED

The IRBMED operates under the authority of and in accordance with:

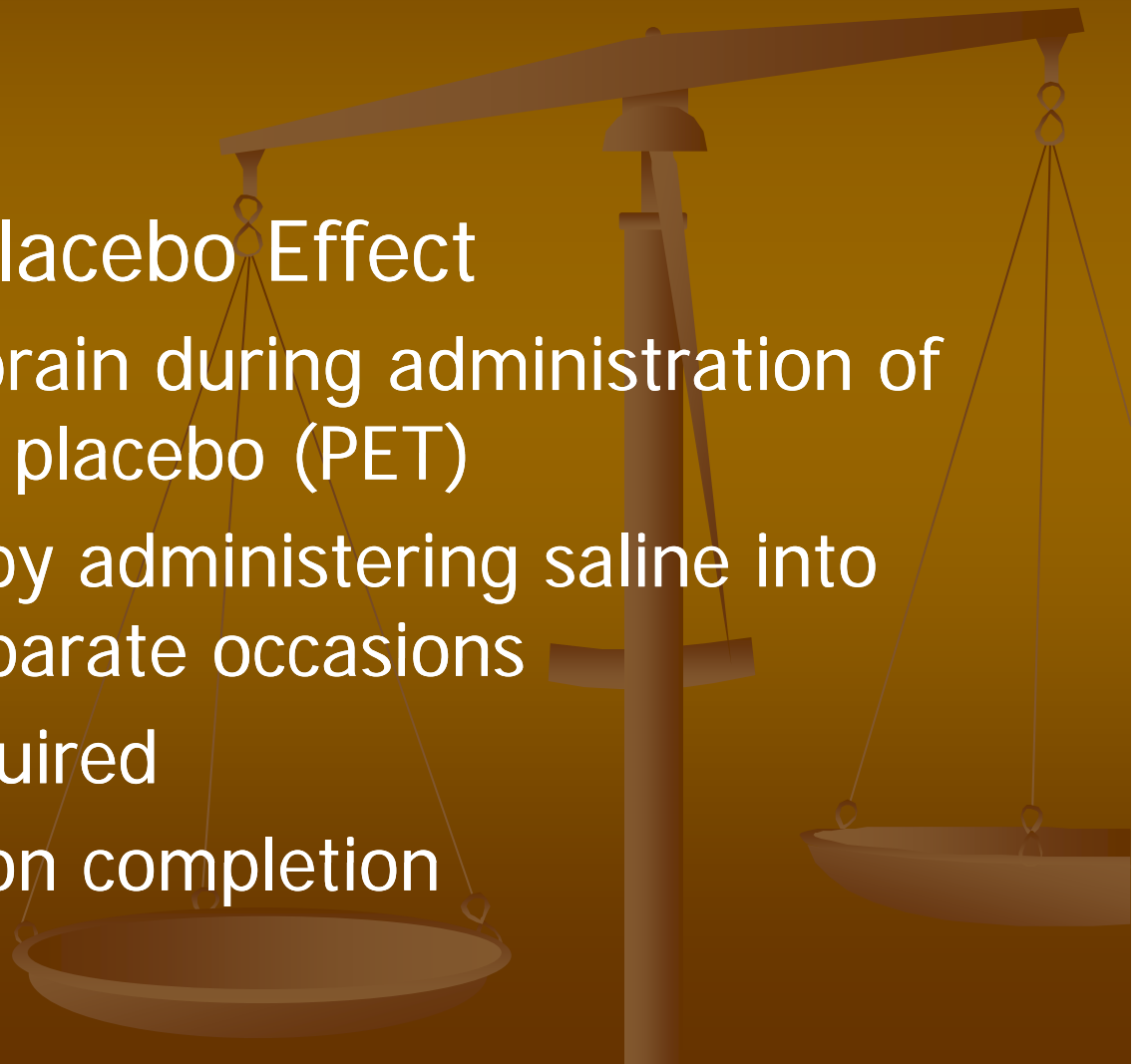
- (i) A *Federal Wide Assurance* (FWA) or applicable *Single Project Assurances* (SPAs) established by the University (through its Vice President for Research) and the United States Department of Health and Human Services (through OHRP) (these are referred to collectively as the "Assurances").
- (ii) Applicable federal regulations, including (1) for federally funded research, the "Common Rule" (45 C.F.R. part 46, subpart A) and special rules for research involving pregnant women, fetuses, and neonates (45 C.F.R. part 46, subpart B), prisoners (45 C.F.R. part 46, subpart C), and minors (45 C.F.R. part 46, subpart D); (2) parallel and additional rules for research regulated by the Food and Drug Administration, including human subjects protections (21 C.F.R. part 50), institutional review boards (21 C.F.R. part 56), investigational drugs (21 C.F.R. part 312), and investigational devices (21 C.F.R. part 812); (3) similar rules for research involving recombinant DNA or otherwise regulated by the National Institutes of Health Office of Biotechnology Activities; and (4) privacy regulations issued under the Health Insurance Portability and Accountability Act of 1996 (45 C.F.R. parts 160 and 164).
- (iii) Ethical principles set forth in the **Belmont Report**, as formally adopted by the United States Public Health Service. The IRBMED may, in its discretion, consider other ethical guidelines as well, such as those set forth in the Nuremberg Code, the Declaration of Helsinki, the International Conference on Harmonisation, and reports of the National Bioethics Advisory Commission.
- (iv) Applicable University policies and procedures.

Belmont Report

How would you apply it to this study?

Case Study

- Pain and the Placebo Effect
 - Examine the brain during administration of morphine and placebo (PET)
 - Pain induced by administering saline into gums on 3 separate occasions
 - Deception required
 - Pays \$900 upon completion



Homework



- For next week:

- Review 45 CFR 46, Subpart A

- <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

- Review 21 CFR 50 & 56

- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>

- Log into the eResearch Sandbox:

- <http://www.umich.edu/~eresinfo/errm/sandbox.html>