

INSTITUTIONAL REVIEW BOARDS (IRBs): SAFEGUARDING HUMAN RESEARCH

MICHAEL BOLAND, CIM

IRB COORDINATOR

Baystate Health

DISCLOSURE

- I have no actual or potential conflict of interest in relation to this program/presentation.



- https://www.menti.com/al5gmrzbzhiw



Join at menti.com | use code 4474 8870

Who is ultimately responsible for protecting human subjec

Mentimeter MB

Open Menti to edit

Replace this slide

Add Menti slides



Show correct answer

GOALS AND OBJECTIVES

Define	**Define what an Institutional Review Board (IRB) is**	Explain the role of the IRB in protecting the rights, welfare, and safety of human research participants.
Describe	**Describe what the Baystate Health IRB does**	Understand how the IRB reviews research protocols, assesses risk, and evaluates informed consent.
Review	**Review the Baystate IRB review workflow**	Summarize the major steps from submission → review → determination → ongoing oversight.
Recognize	**Recognize who serves on the Baystate Health IRB**	Describe the required composition of an IRB, including scientific, non-scientific, and unaffiliated (community) members.

HUMAN RESEARCH PROTECTION PROGRAM



WHAT IS AN INSTITUTIONAL REVIEW BOARD (IRB)?

A federally mandated committee that reviews human subjects research.

Protects the rights, welfare, and safety of research participants.

Operates under federal regulations and institutional policies.

BAYSTATE HEALTH INSTITUTIONAL REVIEW BOARD (IRB)

Ensures the protection of human subjects in human subjects research conducted under the auspices of Baystate.

The Baystate Health IRB ensures research meets ethical, regulatory (local, state and federal), and institutional standards.

Applies to clinical, social/behavioral, and quality-related research involving human subjects.

REGULATORY AND ETHICAL FOUNDATIONS



45 CFR 46 – The Common Rule (U.S. federal regulations).

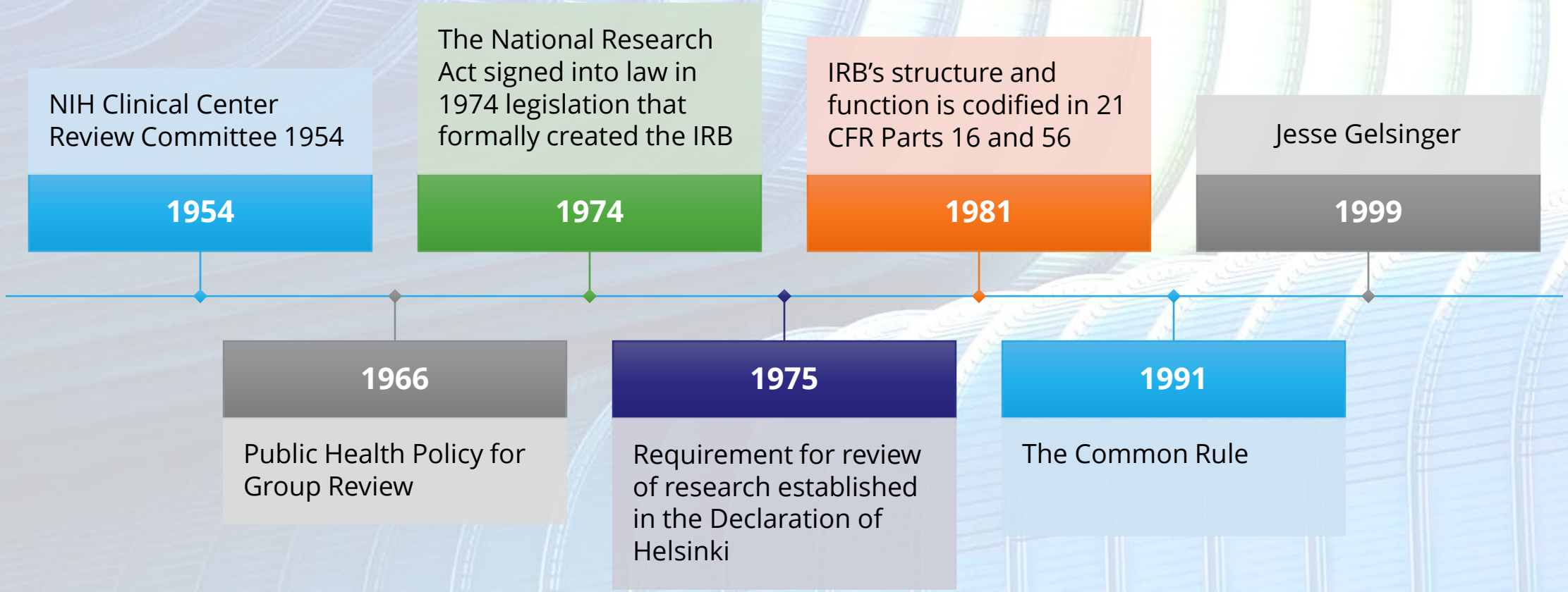


FDA regulations (21 CFR 50 & 56) when applicable.

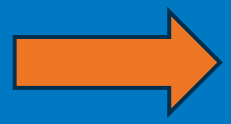


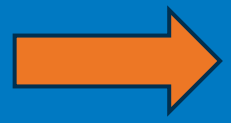
Belmont Report ethical principles.

The History of IRB's



EVOLUTION OF ETHICAL OVERSIGHT IN HUMAN SUBJECTS RESEARCH



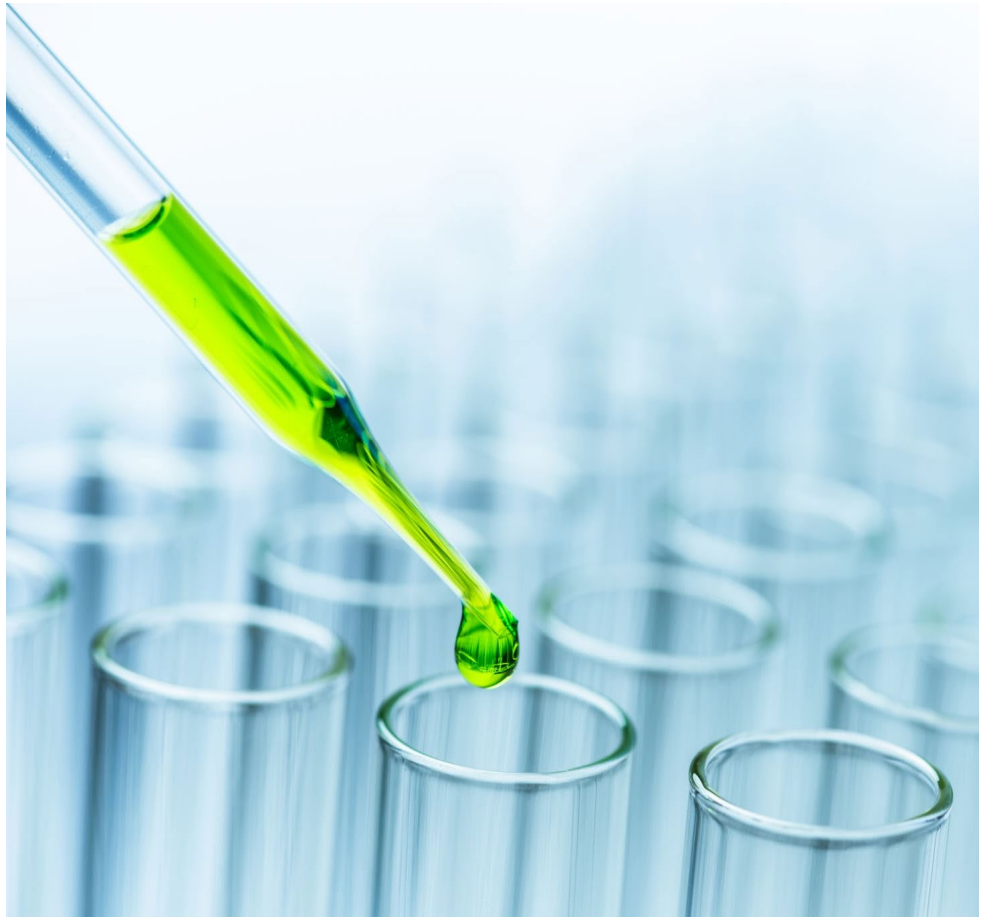


Year	Milestone	Significance for IRBs
1947	Nuremberg Code	Established voluntary informed consent and foundational ethical principles for human research
1964	Declaration of Helsinki	Introduced the concept of independent ethical review committees
1972	Tuskegee Study Exposed	Revealed systemic ethical failures, prompting U.S. regulatory reform
1974	National Research Act	Formally mandated IRBs and created the National Commission
1979	Belmont Report	Defined ethical principles guiding IRB review: respect, beneficence, and justice
1991	Common Rule	Standardized IRB regulations across federal agencies
2019	Revised Common Rule	Modernized IRB oversight with single-IRB review and consent transparency

NATIONAL RESEARCH ACT OF 1974

- **Enacted in 1974, the National Research Act established a federal framework for the protection of human subjects in biomedical and behavioral research. The Act accomplished this through three major actions:**

  - ❑ **Creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.**
  - ❑ **Mandating Institutional Review Boards (IRBs) for federally funded human subjects research.**
  - ❑ **Strengthening and requiring informed consent protections for research participants.**



HIPAA PRIVACY RULE (2000)

- The rule addresses uses and disclosures of private health information for research purposes.

Research Pathway	PHI Identifiability	Key Requirement	Typical Use Case
HIPAA Authorization	Identifiable	Written permission from participant	Prospective clinical studies
IRB/Privacy Board Waiver	Identifiable	Minimal risk & impracticability findings	Retrospective chart reviews
De-identified Data	Not identifiable	Removal of HIPAA identifiers	Secondary data analysis
Limited Data Set	Partially identifiable	Data Use Agreement required	Public health or outcomes research
Preparatory to Research	Identifiable (on-site only)	No PHI removal or contact	Feasibility assessments

BELMONT REPORT PRINCIPLES

Respect for Persons – informed consent and autonomy.

Beneficence – maximize benefits, minimize harms.

Justice – equitable selection of subjects.

JESSE GELSINGER



Jesse Gelsinger (1981–1999) was an 18-year-old participant in a gene therapy clinical trial at the University of Pennsylvania. He had a rare genetic disorder called ornithine transcarbamylase (OTC) deficiency, which prevents the body from properly removing ammonia.



In September 1999, Gelsinger volunteered for an experimental gene therapy study designed to test the safety of using a modified adenovirus to deliver a healthy OTC gene to liver cells.



Four days after receiving the treatment, Gelsinger suffered a massive immune reaction to the viral vector, resulting in multiple organ failure and death.

JESSE GELSINGER

- His death triggered federal investigations that uncovered concerns about the conduct of the trial, including questions regarding informed consent, reporting of adverse events, participant eligibility, and potential conflicts of interest among researchers. The case led to stricter oversight of clinical trials and significantly slowed the progress of gene therapy research for several years.
- The Jesse Gelsinger case is widely taught in research ethics and clinical trials education because it highlights the importance of:
  - Informed consent
  - Participant safety monitoring
  - Accurate reporting of adverse events
  - Managing conflicts of interest
  - Regulatory oversight of human subjects research

WHAT DOES THE BAYSTATE HEALTH IRB DO?

The Institutional Review Board (IRB) protects the rights, welfare, and well-being of individuals who participate in research at Baystate.



END-TO-END BAYSTATE IRB REVIEW PROCESS WITH DECISION POINTS

Submission Phase

- Investigators submit protocols and documents accurately to ensure smooth IRB processing through Baystate's web-based IRB system (IRBNet).

Administrative Review

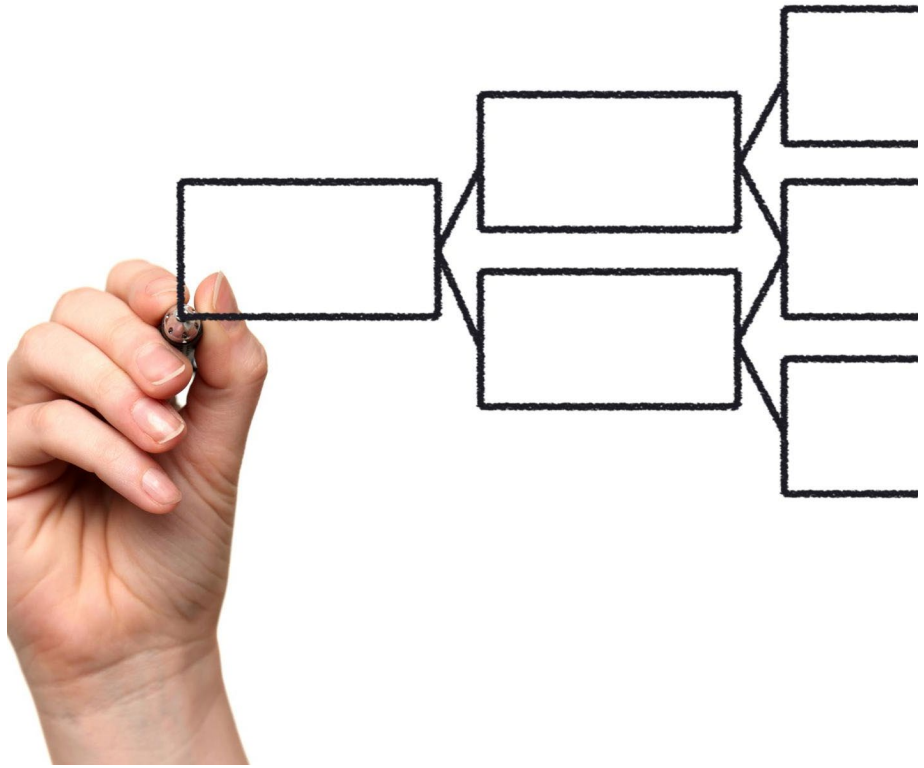
- This is a transparent preliminary assessment. IRB staff check for completeness and compliance; incomplete submissions are returned to investigators. Application checklists are available in the IRBNet library.

IRB Ethical Review

- Risk and ethical considerations are evaluated through exempt, expedited, or full board review.

Determination and Oversight

- Formal IRB decisions include approval, modifications required, deferral, tabled or disapproval.
- Ongoing oversight through amendments, continuing reviews and reportable events/protocol deviations ensures protection.

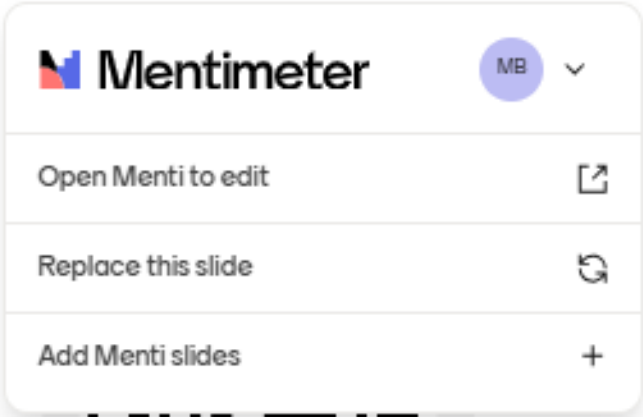


- https://www.menti.com/al5gmrzbzhiw



Expedited review means the study is less important.







menti.com
4474 8870

Waiting for participants

→ Show correct answer

TYPES OF IRB REVIEW

HSRD – Human Subjects Research Determination

Exempt – minimal risk, specific regulatory categories.

Expedited – minimal risk, reviewed by IRB designee.

Full Board – greater than minimal risk or vulnerable populations.

HUMAN SUBJECTS RESEARCH DETERMINATION

Investigators are responsible for making the initial determination of whether an activity qualifies as human subjects research based on the institution's definitions of "human subject" and "research."

Because investigators remain accountable if the determination is incorrect, they are encouraged to seek an official determination from the HRPP.

HUMAN SUBJECTS RESEARCH DETERMINATION



The HRPP cannot issue determinations after an activity has already occurred.



All research activities, whether they involve human subjects or not, must be registered with the institution through IRBNet and submitted to SPA.



Clear cases may be reviewed and determined by the HRPP Director, Medical Director, IRB Chair, or designated IRB members.



More complex or ambiguous cases are referred to the Institutional Review Board (IRB) for review.



All submissions and official determinations are documented and maintained in IRBNet.


ONE DOES NOT SIMPLY
SUBMIT THEIR PROJECT FOR IRB APPROVAL
FIVE WEEKS BEFORE THE DUE DATE
imgflip.com

WHY DOES THE IRB HAVE STRICT DEADLINES?



Participant Safety & Ethical Oversight



Deadlines ensure reviews happen before any research activity begins or changes occur.



Prevents unapproved procedures, outdated consent forms, or unassessed risks.



Keeps the focus on protecting human subjects in real time.



Core Idea: Safety Cannot Be Delayed

WHY DOES THE IRB HAVE STRICT DEADLINES?



Regulatory Compliance

→ Federal rules (e.g., Common Rule, FDA regulations) require:

- Prospective Review.
- Timely reporting of events and modifications.

→ Deadlines help institutions:

- Avoid violations and audits findings.
- Maintain authorization to conduct human subjects research.



Core Idea: Compliance Depends on Timeliness

WHY DOES THE IRB HAVE STRICT DEADLINES?



Operational Efficiency & Fairness

→ IRBs manage high volumes of submissions and scheduled meetings.

→ Deadlines allow:

Organized review cycles.

Equal treatment of all investigators.

Predictable turnaround times for research teams.



Core Idea: Structure Keeps the System Functioning Smoothly

WHO SERVES ON THE BAYSTATE IRB?



Scientific members (e.g. physicians, nurses, pharmacists, researchers, statisticians).



Non-scientific members (e.g. engineers, lawyers, HRPP staff).



Unaffiliated community members.



Members with special expertise as needed (consultants).

WHO SERVES ON THE BAYSTATE IRB?

Scientific Members: Individuals with a scientific or medical background. Their job is to evaluate the methodology, scientific validity, and clinical risks of the proposed research.

Non-Scientific Members: Members whose primary concerns are *not* in a scientific area. They ensure the research is understandable to the average person, focusing heavily on the informed consent process. A board cannot hold a convened meeting without at least one non-scientific member present.

Non-Affiliated Members: Individuals who have no ties to the institution conducting the research. They are usually drawn from the local community to represent the public interest and prevent institutional bias.

Specialist/Vulnerable Population Representatives: Members brought in specifically when a study involves vulnerable groups (e.g., prisoners, children, or individuals with cognitive impairments). They ensure the protocol includes appropriate safeguards and considers the specific sensitivities of those participants.

WHO SERVES ON THE BAYSTATE IRB?

- **IRB Membership Requirements (45 CFR 46.107)**

- An Institutional Review Board (IRB) must:
  - Have **at least five members**.
  - Include members with **varying backgrounds** to provide complete and adequate review of research.
  - Include at least **one scientist** (member whose primary concerns are in scientific areas).
  - Include at least **one non-scientist** (member whose primary concerns are in nonscientific areas).
  - Include at least **one unaffiliated member** who:
    - Is **not affiliated with the institution**, and
    - Is **not an immediate family member of someone affiliated with the institution**.
  - Include individuals **knowledgeable about the types of research being reviewed**, applicable regulations, institutional policies, and standards of professional conduct.
  - Be diverse enough in experience and perspective to protect the rights and welfare of research participants.

- **Gender Requirement**
  - An IRB **may not consist entirely of men or entirely of women**.

WHAT OCCURS AT AN IRB MEETING?

Robert's Rules of Order is the standard guide for conducting orderly, fair, and efficient meetings in the United States.

Principal Investigators/study team members are encouraged to attend when a new project is submitted.

Confirm quorum.

Review and approve previous meeting minutes.

Disclose and manage any conflicts of interest.

Review, discuss, and vote on study submissions.

Provide continuing education and updates to the members.

WHAT WOULD HAPPEN IF THERE WAS NO INSTITUTIONAL REVIEW BOARD?

- Increased risk of harm to participants
- Loss of informed consent protections
- Ethical violations would likely increase
- Reduced scientific validity and public trust
- Legal and institutional consequences
- International and regulatory isolation

WHAT WOULD HAPPEN IF THERE WAS NO INSTITUTIONAL REVIEW BOARD?

Research might move faster—but at the expense of human safety, ethical integrity, scientific credibility, and public trust.

IRBs are not perfect and can feel burdensome, but they exist because history demonstrated what happens when independent ethical oversight is absent.



IN CONCLUSION

The Baystate Health IRB protects research participants.

IRB review is required before starting human subjects research.

Ethical principles along with local, federal, state and institutional regulations guide all decisions.





Questions?

Baystate Health

MISSION

We deliver compassionate, quality and accessible care – advancing our communities' health for all.

VISION

A pillar of our community. Rooted here, serving here, and helping generations thrive here.

VALUES

Courage | Accountability | Respect
Agility | Teamwork