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Welcome!

- The session will begin shortly; please take a moment to make sure your microphone is muted
- The presentation portion of this session will be recorded
- Please hold questions until the end of the presentation
- Not registered? Please register now using the QR code

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Becoming an IRB Member

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Sarah Leon, *Assistant Director, IRB Operations*

hrp.weill.cornell.edu

Kristine Pangilinan, BSN

15 years of experience in human research protections.

Joined WCM in September 2008

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Sarah Leon, BA, CIP

15+ years of experience in human research protections

Joined WCM in March of 2020

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Yaritza Saavedra, BA, CIP

Sr. IRB Analyst

General Team

13+ years of experience in human research protections

Joined WCM in 2010

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Brandon Bryan

IRB Analyst

General Team

9 years of experience in human research protections

Joined WCM in February of 2020

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Sr. IRB Analyst

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4+ years of experience in human research protections.

Joined WCM in May of 2019

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Outline

This session provides a step-by-step introduction to the process on becoming an IRB member, including requirements and responsibilities

- What is an IRB, Brief History and Regulations
- Regulatory Requirements
- Becoming an IRB Member
- IRB Member Roles and Responsibilities
- IRB Member Reviews

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What is an IRB, Brief History and Regulations

What is an IRB?

- Institutional Review Boards review research studies to ensure that they comply with applicable regulations, meet commonly accepted ethical standards, follow institutional policies, and adequately protect research participants.
- IRB reviews help ensure that research participants are protected from research-related risks and treated ethically. This helps to maintain the public's trust in the research enterprise and allows science to advance for the common good.
- IRBs are only one of the ways that human subjects are protected. Protecting Humans in Research is a Shared Responsibility.

History of the IRB

Nuremberg Code (1947)

- Broader scope, involving any and all experimentation involving humans
- Laid the groundwork for today's psychological and medical ethical standards[1]

Declaration of Helsinki (1964)

- Statement of ethical principles for medical research involving human subjects
- Designed with a focus on clinical research.

[1]. Adapted from METS "IRB 101: Regulating Research"

A Brief History of Human Subjects Protection

1966

Ethics and clinical research by Henry Beecher

1972

AP reporter Jean Heller breaks Tuskegee Syphilis Study story

1974

National Research Act

- Created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

1979

Belmont Report

1981

Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) issue regulations based on the Belmont Report

1991

The Common Rule: the core DHHS regulations (45 CFR Part 46, Subpart A) were formally adopted by more than a dozen other Departments and Agencies that conduct or fund research

Adapted from METS "IRB 101: Regulating Research"

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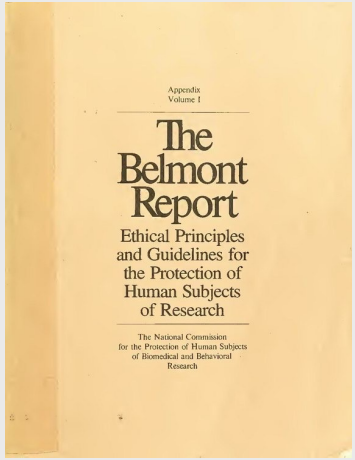
For an in-depth presentation on Research Ethics and regulations, including history, please watch our METS from September 2023

The Belmont Report:

Ethical Principles and Guidelines for the Protection of Human Subjects in Research

Issued by National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979.



- **Respect for Persons**
  - acknowledge autonomy
  - to protect those with diminished autonomy
- **Beneficence**
  - do not harm
  - maximize possible benefits and minimize possible harms
- **Justice**
  - distribute burdens and benefits: **(1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit.

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What Regulations Apply?

Adapted from METS “IRB 101: Regulating Research”

Organization	Regulation
OHRP	**Common Rule** (45 CFR §46)
FDA	Device, Drug and IRB regulations (21 CFR §812; §312, §50, and §56)
DoD	Instruction 3216.02
Office of Civil Rights	**HIPAA** (45 CFR §160 and §164)
ICH	International Conference on Harmonisation (ICH) Good Clinical Practice
EUGDPR	European Union General Data Protection Regulation
NIH	Imposes requirements on funded research
State, **Local**, and **Institutional** Regulations	

For an in-depth presentation on Research Ethics and regulations, including history, please watch our METS from September 2023

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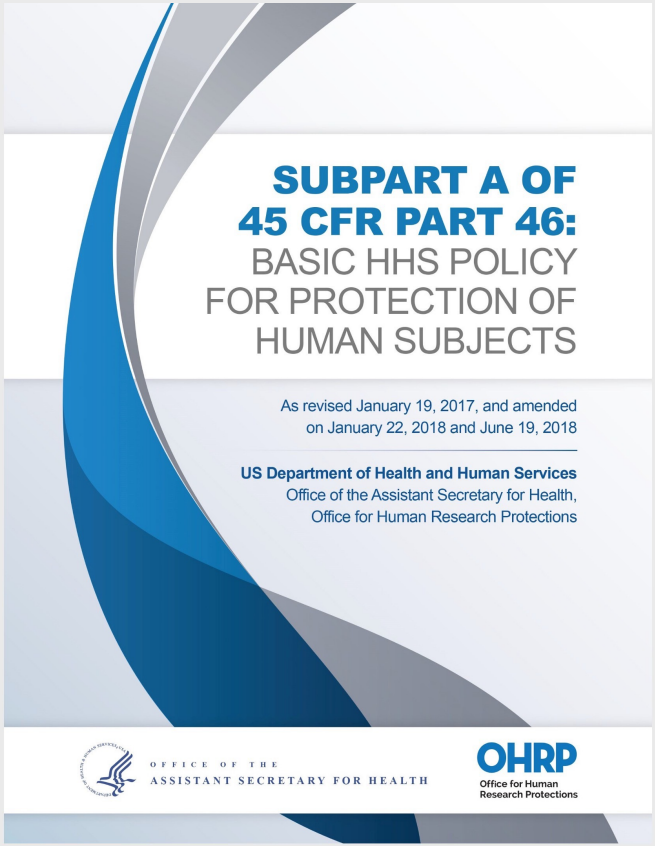
Common Rule (45CFR§46, Subpart A)

- Requirements for:
  - Assuring compliance by research institutions
  - Researchers obtaining and documenting informed consent
  - Institutional Review Board (IRB) membership, function, operations, review of research, and record keeping

- Additional protections for certain vulnerable research subjects (outside the Common Rule):
  - Pregnant women, fetuses, and neonates (Subpart B)
  - Prisoners (Subpart C)
  - Children (Subpart D)



Adapted from METS “IRB 101: Regulating Research”

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Regulatory Requirements

Requirements in HHS Regulations
(45 CFR 46.107)

- At least 5 members of ***varying backgrounds***
- Ensure representative distribution of experience/expertise and diversity among members
- At least ***one scientist*** member and ***one non-scientist*** member
- At least one member ***not affiliated*** with the institution
- ***Prohibit*** members from ***reviewing*** projects with ***conflicting interest***

Scientist vs Nonscientist

Scientist:

- member whose training, background, and/or occupation is conversant with the scientific method; and
- a member who would view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline

Nonscientist:

- member whose training, background, and occupation includes little to no scientific or medical emphasis or experience; and
- A member who does not work in scientific areas nor exercises past scientific training in his/her/their current work; and
- a member who would view research activities from a standpoint outside of any biomedical or behavioral scientific discipline

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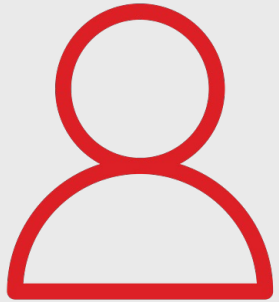
Affiliated vs Non-affiliated

Affiliated:

- Employee, agent, or immediate family member of an employee or agent of WCM

Non-affiliated:

- Individual that has no affiliation with WCM, other than as an IRB member, is considered unaffiliated with the entity operating the IRB



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Composition of WCM IRB

- **Institutional Official (IO)**
  - Dr. Timothy Wilkin, M.D. *Assistant Dean for Clinical Research Compliance*
- **IRB Committees**
  - General IRBs 1 & 2
  - Cancer IRB
  - Executive
- **IRB Member Roles**
  - Chair and Vice Chair
  - Primary members
  - Alternate members

Membership of WCM IRB Boards

General 1 IRB ○ 8 Primary members ○ 15 alternates	**Cancer IRB** ○ 7 Primary members ○ 5 alternates
General 2 IRB ○ 11 Primary members ○ 12 alternates	**Executive IRB** ○ 5 Primary members ○ 6 alternates

Expertise Represented in the WCM IRBs

- Anesthesiology
- Bioethics
- Biology
- Clinical Pathology and Laboratory Medicine
- Diagnostic Radiology
- Emergency Medicine
- Gastroenterology
- Health Informatics
- Hematology/Oncology
- Infectious Diseases
- Internal Medicine
- Interventional Cardiology
- IT Security
- Law
- Librarian
- Medical Ethics
- Molecular Biology
- Nursing
- Obstetrics/Gynecology
- Pastoral Care
- Pediatric Hematology/Oncology
- Pediatric Psychiatry
- Pediatrics
- Population Health
- Psychiatry
- Radiology
- Reproductive Medicine
- Retired H.S. Science Teacher

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Becoming an IRB Member

WCM IRB Member Appointment

- Potential IRB Members may self-nominate or be nominated by a colleague/department head to serve

- HRP Executive Director, in consultation with the Chairs and the IO, makes the final decision in appointing new members and the onboarding process begins

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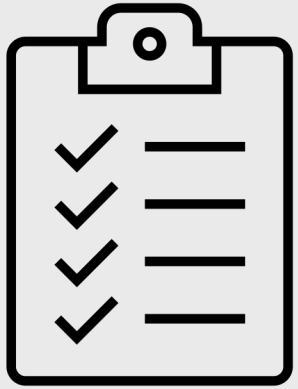
WCM Member Onboarding



1. Submit Curriculum Vitae to the IO and IRB Office
2. Satisfy Regulatory training & education requirements
3. Review IRB Member Handbook and Attestation
4. Schedule WRG-HS walkthrough with IRB staff
5. Submit IRB Member Confidentiality and Conflicts of Interest Agreement
6. Attend three (3) IRB meetings as an observer

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IRB Member Roles and Responsibilities

Approval Criteria & Ethical Principles

- (1) Risks Minimized — Beneficence
- (2) Risks vs. Benefits — Beneficence
- (3) Equitable Selection — Justice
- (4) Informed consent — Respect for Persons
- (5) Informed consent Documentation — Respect for Persons
- (6) Data Monitoring — Respect for Persons, Beneficence, Justice
- (7) Privacy and Confidentiality — Respect for Persons

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Determination of Risk

- Board members are required to evaluate studies and determine the appropriate level of risk
  - *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests
  - *Greater than Minimal Risk* means that the probability and magnitude of harm or discomfort anticipated in the research risks are more than minimal risk, but not significantly greater

Risks can include psychological risks, social risks, physical risks, etc.

What is Expected of an IRB Member?

- A considerable time commitment is required when serving to:
  - Review IRB applications and protocols
  - Attend meetings
  - Participate in Continuing Education
- Attendance at IRB meetings
  - 75% of convened IRB meetings
- Meeting participation
  - Active participation in meeting discussions with respectful communications
- Knowledge and application of federal requirements, ethical principles and institutional policies

IRB Member Expectations (*continued*)

- Fulfillment of training requirements
- Conflict of interest requirements
- Timeliness of reviews
- Quality of reviews
- Communication
- Confidentiality

IRB Member Evaluations

- HRP leadership and Chairs will periodically review the membership of the IRB and recommend re-appointments or additions as necessary to ensure adequate review of research and regulatory compliance
- Should a member of the IRB behave in a manner inconsistent with the policies, ethics, and professional responsibilities of the IRB, they may be promptly removed from the board
- Members are appointed for three-year terms, with renewal occurring annually and based on the member evaluations

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IRB Member Reviews

Types of IRB Submissions

- New Protocols (Initial Submissions)
- Continuing Reviews
- Amendments

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Types of IRB Reviews

- **Pre-review**
- **Expedited**
- **Full Board**

The IRB Meeting: *Sequence of events*

- Meetings may begin once quorum is established
- Review and approve prior meeting minutes
- Conflicts of Interest Disclosure, if any
- Order of Submission Reviews:
    - Continuing Reviews
    - Amendments
    - New Protocols
- After the review of each submission:
    - Chair confirms regulatory determinations
    - Chair ends the discussion for each item, states the action and votes are taken
- Researchers' Attendance

Wrap-up

- IRB members contribute to the advancement of research by ensuring that studies are conducted in an ethical and responsible manner

- These contributions can be seen in various aspects of research, such as reviewing and approving protocols, monitoring ongoing research, and providing guidance on ethical issues

- IRB members play a vital role in advancing research by ensuring the ethical conduct of studies involving human participants

Helpful Resources

- **Weill Cornell Human Research Protections**
  https://hrp.weill.cornell.edu/irb
- **Monthly Education and Training Series (METS)**
  https://hrp.weill.cornell.edu/educational-resources/monthly-education-training-series-mets
- **Office for Human Research Protections**
  https://www.hhs.gov/ohrp/index.html

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Questions?

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Contact Us

Scan the QR code to request a consult during our on-site
Tuesday, 1/9 through Thursday 1/11

Contact Us

IRB Member Portal

Forms, Templates & Guidelines

Request a Consultation

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