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Welcome!

- The session will begin shortly; for those that are joining via Zoom, please take a moment to make sure your microphone is muted.
- The presentation portion of this session will be recorded.
- Please hold your questions to the end of presentation.
- Not registered? Please register now using the QR code.

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HRPP vs. IRB

Human Research Protection Program versus Institutional Review Board

Melissa A. Epstein, PhD, MBE, CIP
Executive Director, Human Research Protections

hrp.weill.cornell.edu

Melissa A. Epstein, PhD, MBE, CIP

18+ years of experience in human research protections,

10 years of research experience in production and perception of speech, specializing in mathematical modeling of vocal cord vibration and 3 dimensional modeling of tongue motion.

Masters in Bioethics specializing in Research Ethics

Joined WCM in 2021

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Today's Presentation

- What is the scope of the IRB?
- What is a Human Research Protection Program?
- How did single IRB change our understanding of HRPP?
- How does the HRPP represent instutional approval?

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What is the scope of the IRB?

Secondary Title

What is an IRB?

An IRB is a committee that performs ethical review of proposed human subjects research.

What is it?

- Have at least five members
- Sufficiently qualified through the experience, expertise, and the diversity of the members
- Diverse:
  - Demographics
  - Scientific/non-scientific
  - Affiliate/non-affiliate

What does it do?

- Purpose is to safeguard the welfare of participants
- IRB determinations
  - Approves
  - Disapproves
  - Requires Modifications
- Monitor active projects
- Suspend/terminate approval
- Investigate allegations

The WCM IRB

- Institutional Official
  - Dr. Timothy Wilkin, M.D. *Assistant Dean for Clinical Research Compliance*
- IRB Committees
  - General IRBs 1 & 2
  - Cancer IRB
  - Executive

Human Research Protections Office

Melissa Epstein PhD, CIP
Executive Director, HRP & Compliance

Lauren Blumberg MPH, MS
Assistant Director, Regulatory Compliance

Rui Ferreira MA, CIP
Associate Director, HRP Operations

Sarah Leon
Assistant Director, IRB Operations

Lauren Odynocki
Sr. Human Research Compliance Specialist
ClinicalTrials.gov
Reportable Events

Kelly Ann Balem RN, CPN
Sr. Human Research Compliance Specialist
Cancer DSMC

Sabrina Paul
Human Research Compliance Administrator
General DSMC
ESCRO
Audit

Jessica Kisenwether PhD, CIP
Human Research QA & Education Manager

Kaori Germano PhD
Clinical Research Program Manager & Sr. Research Navigator

Cecilia Brooke Cholka PhD, CIP
Human Research QA & Education Manager

German Jimenez
Human Research Compliance & Reliance Administrator
Single IRB
BRANY*plus*

Isabel Bustamante
Human Research QA & Education Manager

Kristine Panglilinan
IRB Regulatory Manager
GENERAL TEAM

Alyssa Wheeler RN
IRB Regulatory Manager
EXPEDITED TEAM

Cynthia Franco MHA
IRB Regulatory Manager
CANCER TEAM

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Approval Criteria (45 CFR 46.111/ 21 CFR 56.111)

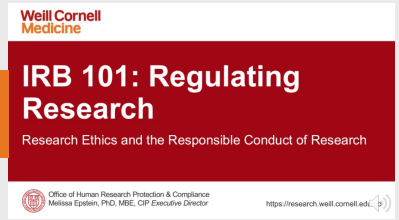
Risks to subjects are minimized
Risks to subjects are reasonable in relation to anticipated benefits
Selection of subjects is equitable
Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, § 46.116
Informed consent will be appropriately documented or appropriately waived in accordance with § 46.117
When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
Appropriate additional safeguards for vulnerable populations

For a discussion on which regulations apply when, please watch our METS from September 2023

Regulations

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 Requirements	

For a discussion on which regulations apply when, please watch our METS from September 2023



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What is a Human Research Protection Program?

Human Research Protection Program

A system of interdependent groups and individuals interacting to protect research participants in the conduct of human research.

What is it?

- Various entities, departments, and committees, who are involved in some aspect of human research (funding, oversight, conduct, monitoring, etc.)
- Each institution's HRPP is different

What does it do?

- Develops and implement policies and practices that ensure the adequate protection of research participants
- Each office in the HRPP has a unique responsibility to research participants
  - Develops and follows their own policies, procedures, regulations, etc.

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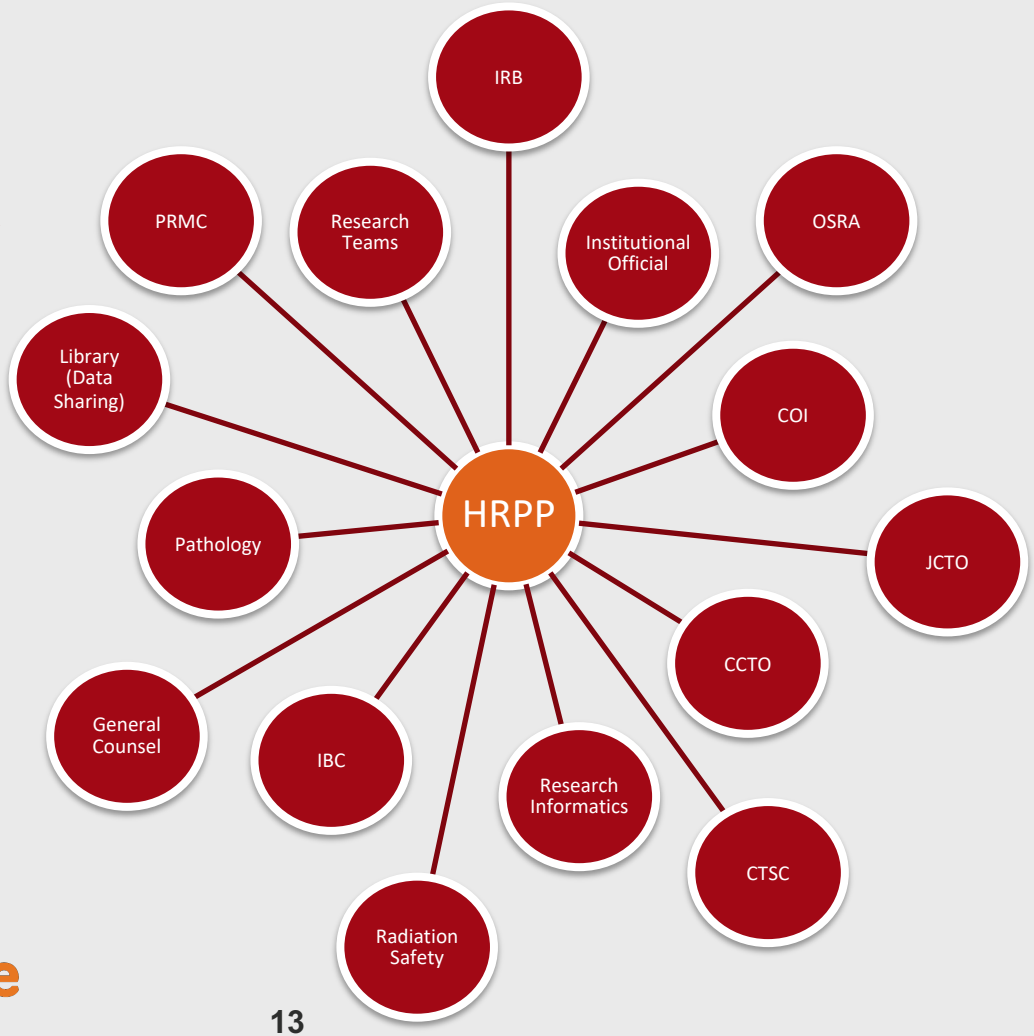
HRPP Components at WCM



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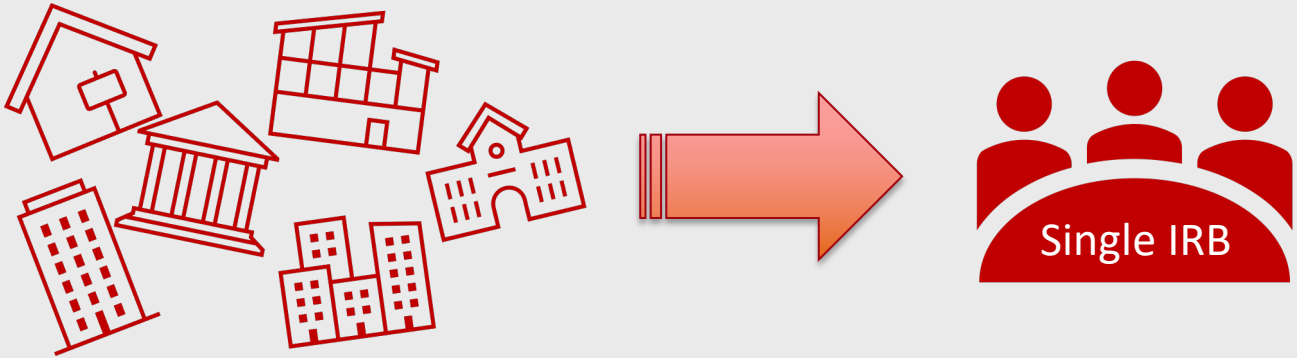
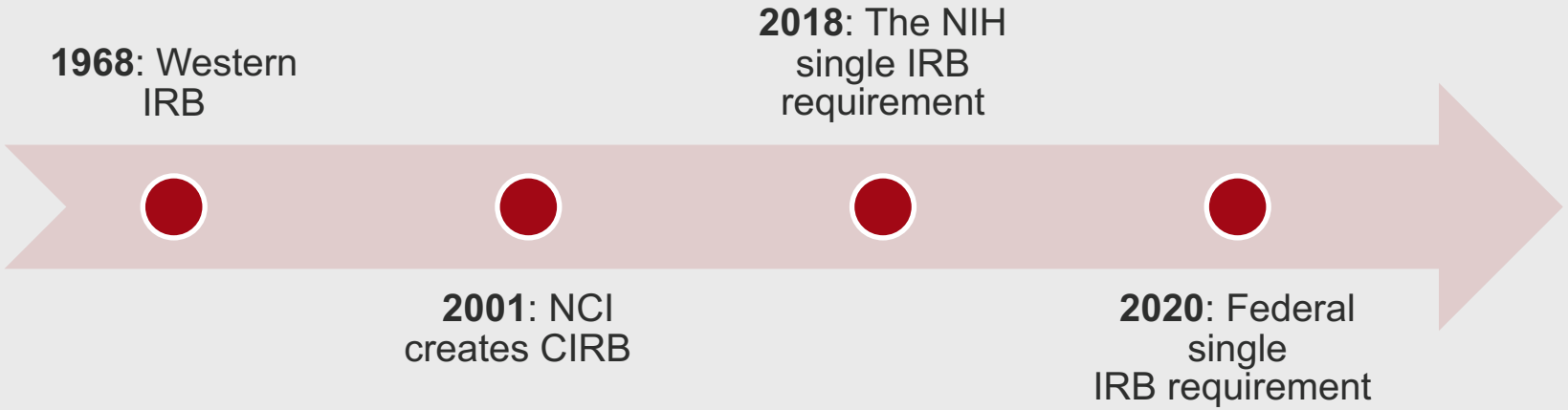
How Did Single IRB Change Our Understanding of HRPP?

What is a Single IRB (sIRB)?

A Single IRB is the Reviewing IRB or (IRB of Record), that provides the ethical and regulatory review for all relying sites participating in a multisite/multi-center study.



History of Single IRB Review



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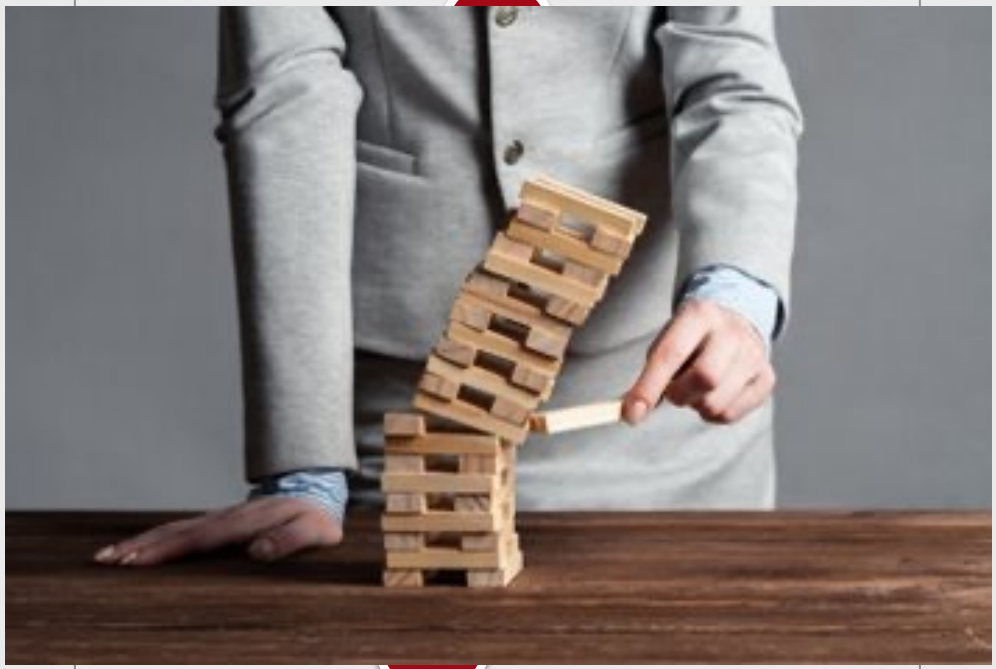
What happens when the IRB is removed?



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Case study: Digital Health Technologies for Long-term Self-management of Osteoporosis

- Relying on an External IRB
- Conflict of Interest (COI) review
- Oura ring – Digital Health Technology (DHT) review
- Bone density scan (Dexa) - Radiation safety

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How Does the HRPP Represent Institutional Approval?

Not Just Regulations

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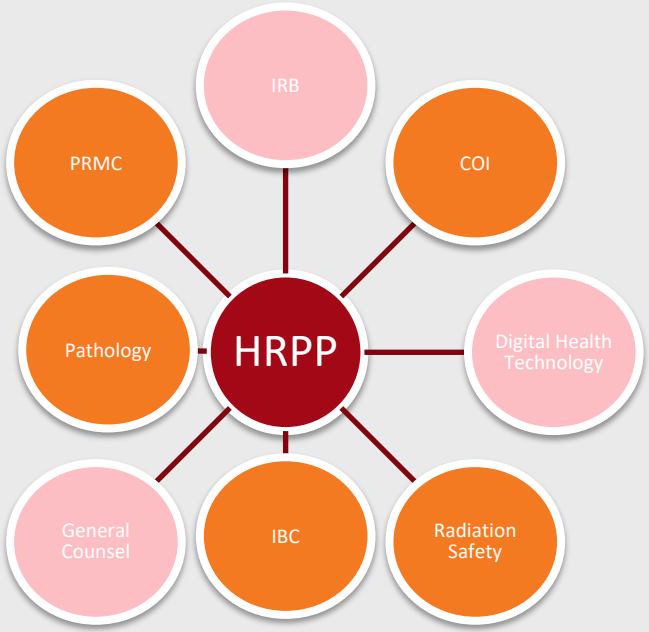
State and Local, and Institutional Requirements	

Transparency: Independent Process vs. Managed by IRB/PRMC

Requirements	Status	Next Step	Office Contact
+ CITI Training: Biomedical Research	Not Started	Next Step	Office Contact
+ CITI Training: Good Clinical Practice	Not Started	Next Step	Office Contact
Clinical and Translational Science Center	✓ Completed	Next Step	Office Contact
Coverage Analysis	✓ Completed	Next Step	Office Contact
Institutional Review Board	✓ Completed	Next Step	Office Contact
Investigational Pharmacy	✓ Completed	Next Step	Office Contact
+ CITI Training: Conflicts of Interest	Not Applicable	Next Step	Office Contact
Clinical Trial Agreement	Not Applicable	Next Step	Office Contact
ClinicalTrials.gov	Not Applicable	Next Step	Office Contact
Conflict of Interest	Not Applicable	Next Step	Office Contact
Data Safety Monitoring Committee	Not Applicable	Next Step	Office Contact
EpicTogether Readiness	Not Applicable	Next Step	Office Contact
Institutional Biosafety Committee	Not Applicable	Next Step	Office Contact
MCC Activation Readiness	Not Applicable	Next Step	Office Contact
Pathology	Not Applicable	Next Step	Office Contact
Pediatrics Resident Research Oversight Committee	Not Applicable	Next Step	Office Contact
Protocol Review & Monitoring Committee - Cancer	Not Applicable	Next Step	Office Contact
Protocol Review & Monitoring Committee - General	Not Applicable	Next Step	Office Contact
Radiation Safety Committee	Not Applicable	Next Step	Office Contact



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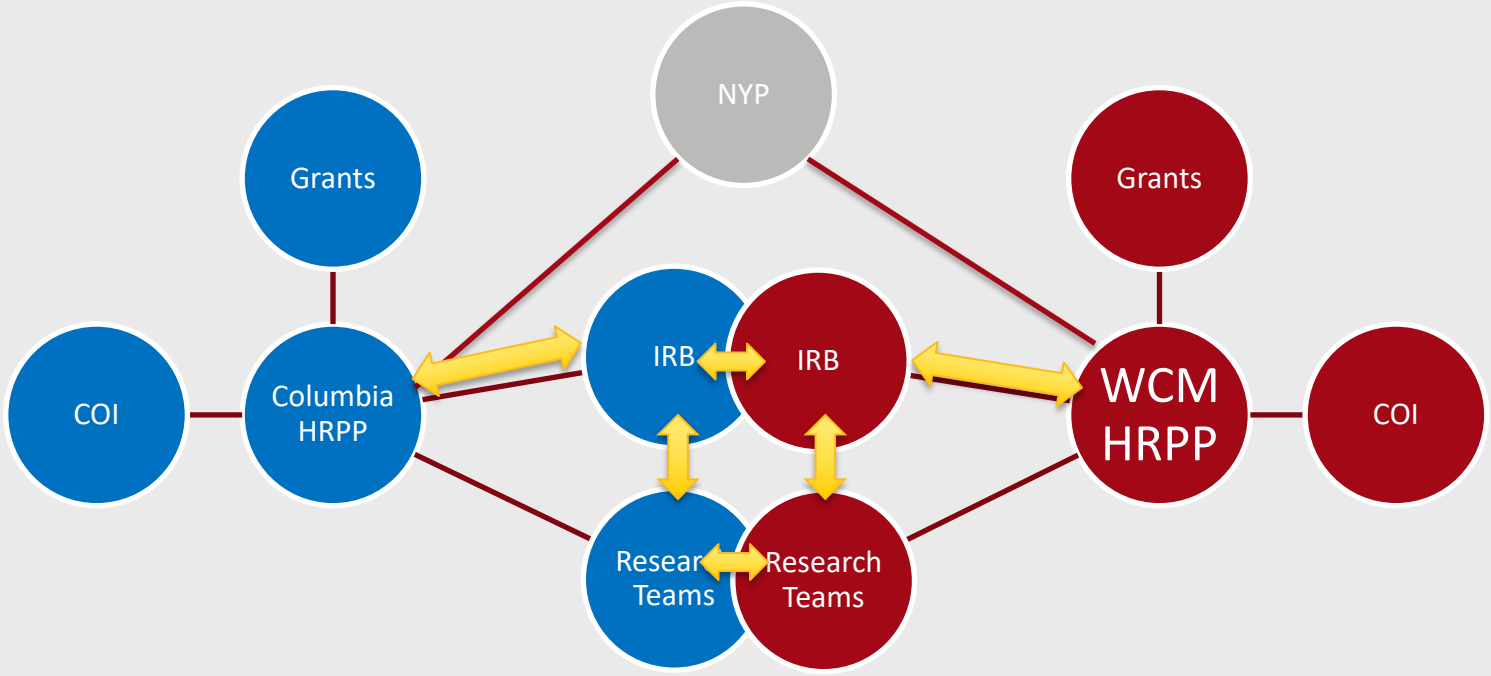
HRPP and Institutional Approval

- Do we have all the necessary review and oversight?
- How do we communicate across the components and with the researchers?
- How is final Institutional Approval documented and communicated?

Case Study: Collaborating Across NYP



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Questions?

Contact Us

IRB Member Portal

Forms, Templates & Guidelines

Request a Consultation

Weill Cornell Medicine Human Research Protections
575 Lexington Avenue
New York, NY 10022
Phone: (646) 962-8200
irb@med.cornell.edu

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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

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