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.
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
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 institutional approval?
What is the scope of the IRB?
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
Approval Criteria (45 CFR 46.111/ 21 CFR 56.111)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risks to subjects are minimized</td>
<td></td>
</tr>
<tr>
<td>Risks to subjects are reasonable in relation to anticipated benefits</td>
<td></td>
</tr>
<tr>
<td>Selection of subjects is equitable</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td>Informed consent will be appropriately documented or appropriately waived in accordance with § 46.117</td>
</tr>
<tr>
<td>When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.</td>
<td></td>
</tr>
<tr>
<td>When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.</td>
<td></td>
</tr>
</tbody>
</table>

Appropriate additional safeguards for vulnerable populations

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

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

For a discussion on which regulations apply when, please watch our METS from September 2023
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
  o Develops and follows their own policies, procedures, regulations, etc.
HRPP
Components at WCM
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

1968: Western IRB

2001: NCI creates CIRB

2018: The NIH single IRB requirement

2020: Federal single IRB requirement
What happens when the IRB is removed?
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
How Does the HRPP Represent Institutional Approval?
# Not Just Regulations

<table>
<thead>
<tr>
<th>Organization</th>
<th>Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>OHRP</td>
<td>Common Rule (45 CFR §46)</td>
</tr>
<tr>
<td>FDA</td>
<td>Device, Drug and IRB regulations (21 CFR §812; §312, §50, and §56)</td>
</tr>
<tr>
<td>DoD</td>
<td>Instruction 3216.02</td>
</tr>
<tr>
<td>Office of Civil Rights</td>
<td>HIPAA (45 CFR §160 and §164)</td>
</tr>
<tr>
<td>ICH</td>
<td>International Conference on Harmonisation (ICH) Good Clinical Practice</td>
</tr>
<tr>
<td>EUGDPR</td>
<td>European Union General Data Protection Regulation</td>
</tr>
<tr>
<td>NIH</td>
<td>Imposes requirements on funded research</td>
</tr>
<tr>
<td></td>
<td>State and Local, and Institutional Requirements</td>
</tr>
</tbody>
</table>
Transparency: Independent Process vs. Managed by IRB/PRMC
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
Questions?

Weill Cornell Medicine Human Research Protections
575 Lexington Avenue
New York, NY 10022
Phone: (646) 962-8200
irb@med.cornell.edu
Scan the QR code to request a consult during our on-site Tuesday, 1/9 through Thursday 1/11