**What is an Institutional Review Board (IRB)?**

- An ethics committee
- What does the IRB do?
  - Formally review, approve, and monitor human subjects research to ensure the safety, rights, and welfare of subjects are protected
  - IRBs are also tasked with determining the degree and likelihood of risk
  - Minimal risk: "the probability and magnitude of harm or discomfort anticipated ... are not greater ... than those ordinarily encountered in daily life or during ... routine physical or psychological examinations or tests."

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**Agenda**

- Our goal and mission / approach
- Levels of IRB review
  - Types of studies that qualify
- Criteria for Approval
- Consent and HIPAA Authorization
- HSERA
- Submission Tips
- Questions
Levels of IRB Review

- NHSR
- Exempt / Limited Review
- Expedited Review
- Convened Board Review

**Types of Studies:** NHSR, exempt, and expedited

**Not Human Subjects Research (NHSR):**
- Not Research Example:
  - Quality Improvement
  - Educational Project
  - Not involving HB Examples:
  - Case study of 3 or fewer patients
  - Using existing publicly available data (e.g., anyone can download from internet)
  - Receiving de-identified data or specimens where no link exists with identifiers
  - Research involving cadavers

**Examples of Exempt Studies:**
- Surveys/ interviews/ focus groups with adults collecting non-sensitive data
- Benign behavioral interventions with adults
- Secondary research with existing, non-sensitive data or specimens
- Limited datasets from data registries or research studies
- Chart reviews

**Examples of Expedited Studies:**
- Research with drug and device products that is exempt from FDA IND & IDE regulations
  - Risks must be minimal
- Non-invasive collection of saliva, hair, nails, teeth, skin swabs, lipids, etc.
- Venous or fingerstick blood collection considering frequency, amount, and subject
- Collection of data via non-invasive means (e.g., MRI, EEG, ECG, pulse ox, etc.)

**How does the IRB determine approval?**

- Risks to subjects are minimized
- Risks are reasonable in relation to benefits
- Equitable subject selection
- Adequate protections to protect privacy and confidentiality
- Additional safeguards for vulnerable subjects
- Assessment of risk to benefit ratio
- Consent will be sought / documented
Consent and HIPAA Authorization

Informed Consent/HIPAA
- Administering a drug or device for research purposes
- Administering a clinical or behavioral intervention

Alteration of IC/HIPAA
- Must be minimal risk as determined by the IRB
- Participants given option to opt out because intervention is being implemented across a whole hospital or health system

Waiver of Documentation of IC
- Interviews, Focus Groups, Surveys, Questionnaires
- Prospective chart review plus phone survey
- Non-invasive collection of such as saliva, teeth, etc.

Waiver of IC and HIPAA
- Retrospective chart review
- Collection of leftover tissue usually discarded

IRB Guidance: irb.upenn.edu

IRB Application: hsera.apps.upenn.edu
Best Practices

- Review Submission Guidance on our website
- Utilize our template protocols & consent forms
- Don’t repeat:
- Make sure everyone has taken their CIT training
- Tell us what you want to do
- Use simple language in consents and application
- Provide rationale
- Give yourself enough time & don’t rush

Best Practices Continued

- Complex and/or Greater than Minimal Risk Research
  - Utilize a protocol template from our website
  - Clearly delineate research aspects from usual care: required by the protocol = research
  - Consider whether independent safety monitoring is appropriate based on the risk
- If administering a drug or device product, the study can only be reviewed at the expedited level if:
  - The protocol qualifies for an exemption from FDA IND and IDE regulations, AND
  - The protocol is minimal risk

Other Educational Options

- Come to IRB Office Hours with specific questions: Thursdays 10am-12pm
- Join as a convened board IRB member for more experience!
- Commitment Details:
  - Full time: 8 meetings a year, or
  - Alternate: attend meetings as needed (e.g., 3-4 mtgs per year), or
  - Serve as a consultant reviewer
  - Flexible attendance options: tele-conference or video-conference
- Benefits
  - Improved knowledge of IRB processes facilitates IRB submissions
  - Exposure to new research topics, designs and technologies in various fields
  - New networking opportunities with faculty, staff, and students in related fields
- Interested? Email me: jessyoos@upenn.edu
ADDITIONAL INFORMATION

Levels of Review & Submission Requirements

- Not Human Subjects Research: No review required
- Exempt/Limited Review: Initial Review Required, Modifications with Limited Review
- Minimal Risk w/ Expedited or Full Review: Initial Review Required, Modifications Required, Continuing Review required if informed by IRB
- Greater than Minimal Risk w/ Full Review: Initial Review Required, Modifications Required, Continuing Review Required

Types of Drugs and Devices

- **Drug Products**
  - Prescription Drugs
  - OTC Drugs
  - Biologics
  - Vaccines
  - Cosmetics
  - Food / Food Additives
  - Dietary supplements, vitamins, other GRAS products, etc.

- **Device Products**
  - Commercially marketed device (e.g., Fitbit)
  - Research only devices
  - Assays, lab developed tests, In vitro diagnostic tests
  - Other diagnostic devices (e.g., MRI, EEG, Ultrasound, Blood pressure cuff, etc.)
  - Implants, sutures, catheters ...
  - And more!
How Studies are Processed

Study is Approved by PI & Chair of Dept.

Study is Received by the IRB Electronically

Submitted Exempt/Expedited & Minimal Risk

Reviewed by Analyst Team

Screened by Administrator & then Full Board Review

Submitted as Convened and GTMR

Screened by Administrator & then Full Board Review

Submitted Exempt/Expedited but risk unclear

Screened by Administrator & then Full Board Review

Submitted as Convened and GTMR

Screened by Administrator & then Full Board Review

Helpful Links

- HSERA Application Portal: https://hsera.apps.upenn.edu
- Problems with HSERA? See: https://irb.upenn.edu/mission-institutional-review-board/guidance/help
- IRB Website How to Submit Guidance: https://irb.upenn.edu/how-submit-penn-irb
- All types of submissions including Expanded Access
- IRB Forms and Templates: https://irb.upenn.edu/forms
- IRB General Guidance: https://irb.upenn.edu/mission-institutional-review-board/guidance
  - Required Education
  - Information about QI project review processes
  - Special processes for grants
- Who to Contact? See: https://irb.upenn.edu/Help

Review Timelines

Exempt/Expedited Review

Greater than Moderate Risk

10 business days for initial
2 business days for response
3 business days for modification
3 business days for expedited modification
2 business days for response

NOTE: Allow 2-5 business days for approval and after drafting.

Greater than Minimal Risk

Approx. 30 days for initial or convened review
3 business days for expedited modification
2 business days for response