NAVIGATING THE IRB

Jessica L. Yoos, MA, CIP
IRB Assistant Director
Office of Regulatory Affairs

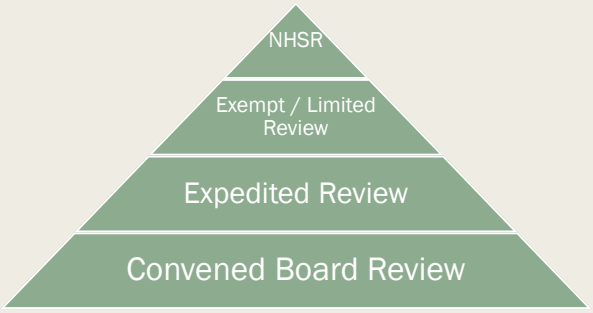
Agenda

- 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

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."*

Levels of IRB Review



Types of Studies: NHSR, exempt, and expedited

Not Human Subjects Research (NHSR)

- Not Research Example:
  - Quality Improvement
  - Educational Project
- Not involving HS 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

Exampled 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

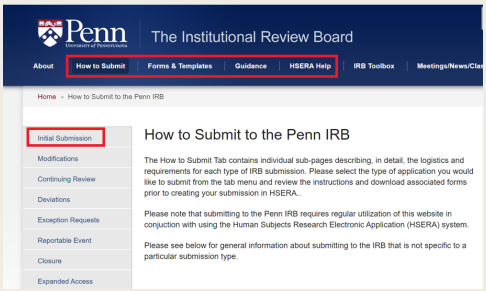
- Research with drug and device products that is exempt from FDA IND & IDE regulations
  - ***Risks must be minimal***
- Non-invasive collection of saliva, hair, nails, teeth, skin swab, sputum, etc.
- Venous or fingerstick blood collection *considering frequency, amount, and subject*
- Collection of data via non-invasive means (e.g., MRI without contrast, EEG, ECG, pulse ox, etc.)

How does the IRB determine approval?

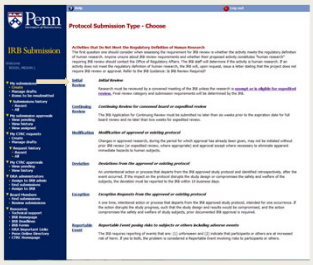
Consent and HIPAA Authorization

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.**
Don't leave blank space in HSERA. Refer to Section # in Protocol	Make sure everyone has taken their **CITI 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

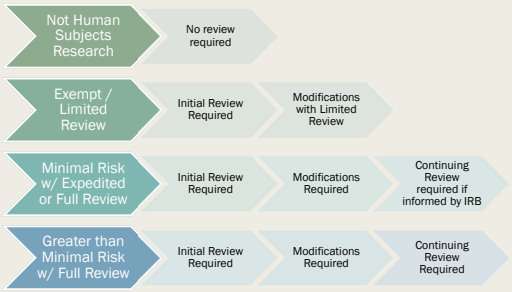
- Complex and/or Greater than Minimal Risk Research
  - *Utilize a protocol template from our website*
  - *Clearly delineate research aspects from usual care: required by the protocol = research*
  - *Consider whether independent safety monitoring is appropriate based on the risk*
- If administering 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



Types of Drugs and Devices

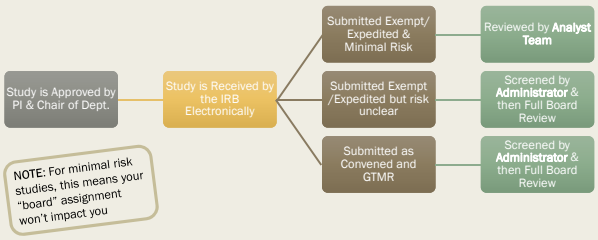
Drug Products

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

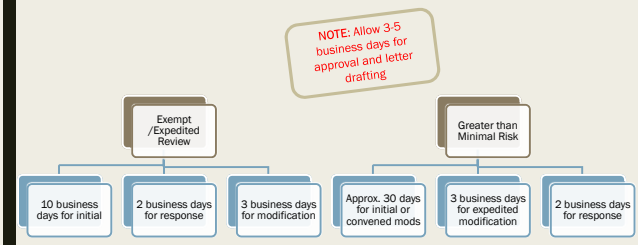
Device Products

- 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



Review Timelines



Helpful Links

- **HSERA Application** Portal: https://hsera.apps.upenn.edu
  - *Problems with HSERA? See: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/hsera-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-irb/guidance
  - *Required Education*
  - *Information about QI project review processes*
  - *Special processes for grants*
- **Who to Contact?** See: https://irb.upenn.edu/Help