Intro To IRB
Agenda

- Mission of the IRB
- History of human research subject protections
- Levels of IRB review
- Compliance/Training requirements
- Getting started in the eIRB
- OHSU IRB Forms page
What’s Our Mission?

- The OHSU Research Integrity Office (ORIO) is charged with protecting and assuring compliance under the laws that govern the rights and welfare of human and animal subjects, and the oversight of basic and applied scientific research at OHSU.
  - Institutional Review Board (IRB)
  - Institutional Animal Care and Use Committee (IACUC)
  - Institutional Biosafety Committee (IBC)
  - Conflict of Interest in Research (CoIR)
What Rules and Regulations Apply?

- **OHRP – 45 CRF 46 “The Common Rule”**
  - Regulations and guidance that govern human research

- **FDA – 21 CFR (Var. Parts) – “GCP”**
  - Govern human research when drugs or devices are being tested

- **Health Information Portability and Accountability Act (HIPAA)**
  - These federal rules govern the protection of health information privacy.

- **Oregon Genetic Privacy Law (GINA)**
  - This state law describes protection of genetic information for Oregonians.
## History of human research subject protections

<table>
<thead>
<tr>
<th>Event</th>
<th>Year(s)</th>
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<tbody>
<tr>
<td>Tuskegee - Proven syphilis treatments purposefully withheld from African American patients</td>
<td>1932-72</td>
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<td>Nuremberg - Nazi doctors’ experiments in poisons, limb reattachment, hypothermia, drowning, starvation, etc.</td>
<td>1939-45</td>
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<td>Willowbrook - Intentional infection of mentally disabled children with viral hepatitis</td>
<td>1955-72</td>
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<tr>
<td>Jewish Chronic Disease Hospital - Injection of live cancer cells in unconsented elderly patients</td>
<td>1963</td>
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<tr>
<td>Common Rule - Federal regulations require IRBs be established to oversee human subjects research studies</td>
<td>1975</td>
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<tr>
<td>Jessie Gelsinger – At 18, Jessie suffered a fatal immune response after being injected with a viral vector being tested for gene therapy.</td>
<td>1999</td>
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Guiding Documents

- Nuremberg Code (1947) - The Nuremberg code includes principles such as voluntary and informed consent, absence of coercion; properly prepared and scientifically sound experimentation; and beneficence towards study participants.

- Declaration of Helsinki (1964) - The World Medical Association developed this set of ethical principles to provide guidance to physicians and others in the medical community who engage in medical research involving human subjects.

- Belmont Report (1979) – The Belmont Report explains three fundamental ethical principles for using any human subjects for research, affectionately known in our office as PB & J: Respect for Persons, Beneficence, & Justice
What is research and how is it reviewed?

- Definition of research and human subjects
- Levels of IRB review
  - Non Human Subjects
  - Exempt – IRB verifies that the plan adheres to the ethical principles in the Belmont Report
  - Expedited
  - Full Board
- Note: this is not always easy to discern
### Common examples

<table>
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<tr>
<th>Exempt</th>
<th>Expedited (Minimal Risk)</th>
<th>Full Board</th>
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</table>
| • Anonymous survey; no risk  
• Existing data or specimens; publically available and identifiable or linkable  
• Existing data or specimens; not publically available and de-identified or coded but OHSU investigator does not have access to code-break | • At the Chair’s discretion, a study may be reviewed through an expedited process and may not require full board review if it involves **ONLY** the procedures listed in one or more of the designated expedited categories and is minimal 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.  
• Examples: small blood draw, cheek swab, MRI (not contrast enhanced), chart review, surveys/questionnaires (minimally intrusive), and focus groups | • Clinical trial of drugs (investigational OR approved but being used for an unapproved purpose) or devices for use under an Investigational New Drug (IND)/Investigational Device Exemption (IDE)  
• Invasive prospective collection of specimens  
• Research procedures involving radiation exposure |
Compliance/Training Requirements

- Big Brain - Big Brain is a portal for online education at OHSU, including many courses required for researchers.

- Everyone:
  - Conflict of Interest in Research (CoIR): Everyone involved in research at OHSU must complete a CoIR disclosure annually.
  - HIPAA: Required institutional Health Insurance Portability and Accountability Act of 1996 (HIPAA) training.

- As needed:
  - Basic RCR for All: This training covers the general conduct required for conducting all types of research at OHSU.
  - rDNA & Infectious Agents: This training covers federal and university policies on conducting research involving recombinant DNA, infectious agents, and biological toxins.
  - Human Subjects Research: This training covers federal regulations, state, and university requirements for conducting research with human subjects or their information.
  - FDA Regulated Products: This training covers federal regulations and university requirements for research using FDA regulated products.
Getting Started in the eIRB

- **Registration – Must have an employee ID**
  - External Employee ID request

- **Navigating the eIRB**
  - Logging in
  - Inboxes
  - Expiration dates – click IRB submissions, click on the “active” tab, view the expiration date on the far left-hand side

- **Actions**
  - Submit – submits study
  - Notify PI – sends an automatic notification to the study PI prompting them to submit
  - Assign Primary Contact – can only assign one primary contact per study
  - Add comment – You can communicate with your IRB coordinator. Note: documents attached in the comment window **DO NOT** become part of the official study submission.

- **Note: If you see**
Preparing a new study submission

- **Preparing a new study submission**
  - Click “Create New Study” – run through new study submission
  - Different document types go in different fields
    - Protocol – Protocol, local context, request for determination, future human subjects forms
    - Funding – Funding source, grant application, ePPQ numbers, email awards@ohsu.edu if your funding agency is not found
    - External team info – External team training, COI documentation, credentials
    - Drugs, devices, medical foods
    - Recruitment Materials – Flyers, brochures, radio, tv, newspaper, Facebook, Twitter, letters to subjects, etc.
    - Consent Forms – Including short forms, information sheets, screening consents
    - HIPAA Documents – Waiver of auth, prep to research, decedents attestation
    - Supporting Documents – Questionnaires, collaborative agreements, memo to the IRB, subject instructions, translation certificates, IRB approval letters from other sites

- **Note:** if you are filling out the submission for the PI, you must add yourself as study staff or you will be locked out of your own submission.
## Common Study Designs

<table>
<thead>
<tr>
<th>Clinical Trial – industry sponsored</th>
<th>Chart Review – unfunded</th>
<th>Survey Study w/ Repository – funded</th>
<th>Curriculum Evaluation Study – unfunded</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Consent and Authorization Form</td>
<td>- List of Data Variables</td>
<td>- Consent and Authorization Form</td>
<td>- Information Sheet</td>
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<tr>
<td>- Cover Memo to IRB</td>
<td>- PPQ - fully signed</td>
<td>- Complete Grant</td>
<td>- Links to Curricula and Tests</td>
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<tr>
<td>- DSMP</td>
<td>- Protocol</td>
<td>- Protocol</td>
<td>- PPQ - fully signed</td>
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<tr>
<td>- Investigator’s Brochure</td>
<td></td>
<td>- Protocol - Repository</td>
<td>- Recruitment Email</td>
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<td>- Local Context Supplement</td>
<td></td>
<td>- Repository Sharing Agreement</td>
<td>- Survey</td>
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<tr>
<td>- Questionnaires</td>
<td></td>
<td>- Repository Tracking Sheet</td>
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<tr>
<td>- Recruitment - Facebook</td>
<td></td>
<td>- Recruitment - Flyer</td>
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<tr>
<td>- Recruitment - Brochure</td>
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<td>- Survey for Patients</td>
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<td>- Recruitment - Flyer</td>
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<td>- Survey for Providers</td>
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<td>- Recruitment - Telephone</td>
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<td>Screening Script</td>
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<td>- Waiver of Authorization</td>
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Modification/CR

Preparing a modification and/or continuing review

- Create Mod/CR
- Edit your documents using tracked changes/comments
- Stack your documents – this is very important
- Prepare a summary of changes memo
- Don’t forget your CR form (required for all studies)

Quirks:
- Once you select a pathway (mod vs mod/cr) you cannot revise
- Once you select what you are modifying (all parts vs study staff) you cannot revise
- You can only create one mod changing “other parts” at a time
Reportable new information (RNI)

- Mechanism for reporting:
  - New Risks
  - Protocol Deviations and Noncompliance
  - Written Reports
  - Other

- An RNI should be submitted within 5 days of learning about the event

- See the RNI quick guide on the IRB policies and forms page for guidance on what needs to be submitted

- Show RNI form in the eIRB
OHSU IRB Forms Page

- Make it your friend
- Consent and HIPAA forms and templates
- Submission forms and resources
- Repository forms and templates
- IRB help sheets and quick guides
Thank you!

Questions?

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<tr>
<th>eIRB - OHSU Research Integrity Office</th>
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<td><strong>Email:</strong></td>
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<td><strong>Website:</strong></td>
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<td><strong>Education &amp; Training:</strong></td>
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<td><strong>FAQ:</strong></td>
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