Introduction to Human Subjects Research and KC IRB at Indiana University

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Agenda

• Brief History
• Role of Institutional Review Board (IRB)
• Is IRB Review Required?
  o Definitions
  o Levels of Review
  o Criteria for Approval
  o Informed Consent / Assent
• IRB Process Workflow
• KC IRB Training
A Brief History - Timeline of Events

Where We Came From...

1932-1972

1939-1945

1961

1970

1971
Where We Came From...

• 1974: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
  • Assess risks and benefits
  • Guidelines for choosing participants
  • Define informed consent
Where We Are...

Belmont Report

- Respect for Persons
- Beneficence
- Justice

Common Rule

Criteria for approval

- Minimization of risk
- Risk/benefit ratio
- Consent
- Vulnerable populations
Institutional Review Board

- 45 CFR 46.101 & 21 CFR 56.101 - federally mandated entity and process
- Regulations dictate much of the process
- Some issues not at discretion of members
- Investigators do not have the authority to determine level of risk
Role & Authority of IRB: Protecting Human Subjects

- Approve or disapprove research and require modifications
- Conduct initial and continuing review at least annually (except Exempt)
- Approve any changes in research before they can be implemented
- Evaluate unanticipated problems and noncompliance
- Suspend or terminate approval of research
IU Human Research Protection Program

• Nationally accredited
• One Human Subjects Office (HSO) – 2 office locations – support ALL IU campuses
• Six Institutional Review Boards (IRBs)
  ○ 2 Social/Behavioral Boards
  ○ 4 Biomedical Boards
  ○ IRB Executive Committee
• Supported by the Office of Research Compliance in the Office of the Vice President for Research
IRB or HSO – Which is It?

• Institutional Review Board (IRB)
  ✓ Reviews and approves non-exempt research
• Human Subjects Office (HSO)
  ✓ Staff and infrastructure supporting IRBs
  ✓ Regulatory support system for IRBs
  ✓ Support system for IU faculty and staff
• Two different functions
Does it Require IRB Review?

RESEARCH + HUMAN SUBJECT = IRB Review

Questions to ask:
- Is it research?
- Does it involve human subjects?
- Is it a student project involving risk to human subjects?
Research Defined - DHHS

- **Research**: A *systematic investigation*, including research development, testing and evaluation, designed to *develop or contribute to generalizable knowledge*

  - *Systematic Investigation* typically involves a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory.

  - *Develop or contribute to generalizable knowledge* typically requires that results (or conclusions) of the activity are intended to be extended beyond a single individual or an internal program.
Human Subject Defined - DHHS

• **Human Subject:** A *living individual* about whom an investigator (whether professional or student) conducting research obtains (1) data through *intervention or interaction* with the individual, or (2) *identifiable private information*.

  • *Intervention* includes both physical procedures (e.g. blood draws) and manipulations of the subjects or their environments.
  
  • *Interaction* includes communication or interpersonal contact between the investigator (or research team) and the subject.
Does it Require IRB Review?

Student Projects

• Class Assignments
  o Not intended for publication and are not considered research – no submission required
  o However, projects which may be more than minimal risk AND involve a vulnerable population – Application for Non-Research Student Projects

• Thesis/Dissertation Projects
  o Considered research – submission required
  o Faculty sponsor must serve as PI and has ultimate responsibility for the conduct of the research
  o Student serves as Co-PI
Does it Require IRB Review?
Program Evaluation / Quality Improvement

- **No.** If QA/QI activities only include routine data collection and analysis for operation monitoring, evaluation, and program improvement

- **Yes.** When the conceptualization, plan, or implementation of the QA/QI activity is supplemented or modified in order to produce information that expands the knowledge base of a scientific discipline or other scholarly field of study
  - For example, performing ‘extra’ analyses or collecting ‘extra’ data not needed for internal operations purposes
Most Exempt Common Categories

- Category 1: research in educational settings involving normal education practices
  - Ex. Curriculum evaluation, comparison
- Category 2: surveys, interviews, observation of public behavior
  - EXCEPTION: recording identifiable information; AND
  - Disclosure outside of research could place subjects at risk (criminal, civil, financial, reputation, employability, insurability)
- Category 4: research with existing data
  - Recorded in de-identified manner
Most Common Expedited Categories

- Category 5: research involving data collected for non-research purposes
  - Prospective collection of data
  - Retrospective collection of data that will be recorded with identifiers
- Category 6: collection of data from voice, video, digital, or image recordings made for research purposes
- Category 7: research on individual/group characteristics/behavior
  - Surveys/interviews involving children or recording identifiable information that could place subjects at risk
  - Focus Groups
  - Computer Tasks
# Does it Require IRB Review?

## Levels of IRB Review

<table>
<thead>
<tr>
<th>Type of Activity</th>
<th>No IRB Review*</th>
<th>Exempt (Low Risk)</th>
<th>Expedited (Minimal Risk)</th>
<th>Full Board (Greater than Minimal Risk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-human subjects research</td>
<td>Confirm only if necessary</td>
<td>Review by HSO staff</td>
<td>Review and approved by an IRB member</td>
<td>Review at a full IRB meeting</td>
</tr>
<tr>
<td>Student projects</td>
<td>No IRB Review</td>
<td>Confirmation of exempt status by HSO staff</td>
<td>Written informed consent (unless waived)</td>
<td>Written informed consent (unless waived)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Undocumented (verbal) consent</td>
<td>Renewal</td>
<td>Annual renewal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prospective approval of any changes</td>
<td>Prospective approval of any changes</td>
<td>Prospective approval of any changes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Review by qualified HSO staff</td>
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**Minimal Risk:** the risks of harm anticipated in the proposed research are not greater considering the probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests.
Criteria for Approval

Expeditied and Full Board Research

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result
- Selection of subjects is equitable
- Informed consent will be sought from each subject
- Informed consent will be documented (unless waived)
- Adequate data monitoring to ensure subject safety
- Adequate protection for privacy and confidentiality
Informed Consent Process

Expedited and Full Board Research

- Basic Elements of ICS Process
  - Full Disclosure
  - Adequate Comprehension
  - Voluntary Choice
- Informed consent is an ongoing educational process between the study team and the subject
- The consent form serves as a “script” for the face-to-face discussion
- Consent process begins at initial contact (recruitment)
- Consent is not valid unless the subject understands the information provided
Informed Consent Document

Expedited and Full Board Research

• Basic Elements of Consent Document
  • Research
  • Purpose
  • Duration of participation
  • Procedures
  • Reasonably foreseeable risks/discomforts
  • Benefits reasonably expected
  • Alternatives, if applicable
  • Confidentiality

• Compensation and medical treatment for injury (for research greater than minimal risk)

• Contacts
  • Research
  • Subject rights
  • Research-related injury

• Voluntary participation
  • No penalty or loss of benefits
  • Discontinuation without penalty

• Number of subjects
Informed Consent
Waivers and Modifications

• Modification of Required Elements
  o Ex. research involving deception

• Waiver of Consent Process
  o Ex. records review

• Waiver of Documentation of Consent
  o Ex. online or minimal risk surveys
Assent/Consent Requirements for Research Involving Children

• Assent
  • If capable - written or verbal
  • If NOT capable – justification required

• Parental (Guardian) Permission (Consent)
  • One parent vs two parents
  • Waiver
IRB Process Workflow

- Researcher Submission
- Intake
- Staff Review
- IRB Review
- Outtake
IRB Process Workflow

- Getting Started
  (http://researchcompliance.iu.edu/hso/hs_getting_started.html)
IRB Process Workflow

• Protocol Decision Tree
  (http://researchcompliance.iu.edu/hso.hs_pdt.html)
IRB Process Workflow

• Submission
  (http://researchcompliance.iu.edu/hso/hs_submission.html)
IRB Process Workflow

• E-Training Guides
(http://researchcompliance.iu.edu/hso/hs_elearning.html)
IRB Process Workflow

- Researcher completes and submits through KC IRB (one.iu.edu  search: KC IRB)
IRB Process Workflow

Welcome Sara Benken

Submitations to the Institutional Review Board (IRB)

Create IRB Protocol
Amend or Renew IRB Protocol
Notify IRB on a Protocol (FY) Item

Other Links
- KC IRB
- ISO Access

Search Institutional Review Board (IRB) Compliance

Search Protocols - Advanced Search

INDIANA UNIVERSITY
IRB Process Workflow

• Submission checked for basic completeness
  ✓ CITI Training – all key personnel or interacting
  ✓ COI Disclosure – all personnel
  ✓ Incomplete submissions will be returned (via email) with a list of requirements to be completed

• Assigned to StaffReviewer

• Volume: average 300 items per week
IRB Process Workflow

• Quality Assurance Check
• Confirm Level of Review
• Evaluate Item for:
  ✓ Completeness
    ➢ Necessary forms submitted
    ➢ All questions answered
  ✓ Accuracy
  ✓ Regulatory Considerations
  ✓ Compliance
Common Problems

• New Studies
  ✓ Incomplete CITI & COI
    ➢ Look for green checks on Personnel tab
    ➢ Remove anyone with outstanding CITI or COI – can be added later
  ✓ Missing Documents – if you mention a document in a questionnaire, upload it to the Notes & Attachments tab
  ✓ Only answer questions for one population when study involves more than one (e.g., students, adults)
  ✓ Inconsistency between questionnaire & informed consent document
IRB Process Workflow

- Staff pre-review sent to study team
  - Return to PI

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Staff Review cont’d

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Your Action List has an eDoc(electronic document) that needs your attention:

**Document ID:** 29988582
**Initiator:** Notification System
**Type:** Add/Modify Qualification
**Title:** This is my KK notifications test - let me know if you can see this wonderfully descriptive subject line

To respond to this eDoc:
- Go to [https://onestart.iu.edu/kr-prd/ken/DetailView.form?docId=29988582&command=displayActionListView](https://onestart.iu.edu/kr-prd/ken/DetailView.form?docId=29988582&command=displayActionListView)
- Or you may access the eDoc from your Action List:
  - Go to [https://onestart.iu.edu/kr-prd/ken/actionList.do](https://onestart.iu.edu/kr-prd/ken/actionList.do), and then click on the numeric Document ID: 29988582 in the first column of the List.

To view the route log of this document:

To change how these email notifications are sent (daily, weekly or none):
- Go to [https://onestart.iu.edu/kr-prd/ken/preferences.do](https://onestart.iu.edu/kr-prd/ken/preferences.do)

For additional help, email <mailto:workflow@iu.edu>

**Action Item sent to xasc**
IRB Process Workflow

- Staff pre-review sent to study team
  - Return to PI
IRB Process Workflow

- Staff pre-review sent to study team

✓ Return to PI
IRB Process Workflow

• Based on level of review
  ✓ Exempt – HSO staff member
  ✓ Expedited – IRB member (could be a qualified HSO staff member appointed to the IRB)
  ✓ Full Board – IRB Committee
IRB Process Workflow

- Informed consent stamped
- KC IRB updated
- Correspondence generated
- KC notification
IRB Process Workflow

- Approval Correspondence
IRB Process Workflow

- Stamped Consent Document
## Contact Your HSO Team

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Campus</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baker, Senta</td>
<td>Research Compliance Associate</td>
<td>BL</td>
<td>(812) 855-0945</td>
</tr>
<tr>
<td>Benken, Sara</td>
<td>Associate Director</td>
<td>BL</td>
<td>(812) 856-3753</td>
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<tr>
<td>Mills, Adam</td>
<td>Research Compliance Associate</td>
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<td>(812) 856-4687</td>
</tr>
<tr>
<td>Moran, Sharon</td>
<td>Compliance Assistant</td>
<td>BL</td>
<td>(812) 856-7357</td>
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<tr>
<td>Mumaw, Casey</td>
<td>Research Compliance Consultant</td>
<td>BL</td>
<td>(812) 855-1741</td>
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<tr>
<td>Neel, Andrew</td>
<td>Research Compliance Associate</td>
<td>BL</td>
<td>(812) 856-2487</td>
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Questions?