WHAT IS AN IRB?

Introduction to the UofL Institutional Review Boards & Human Subjects Protection Program

March 2015

Presentation Outline

- What is an IRB?
- Does my project require IRB Review?
- Levels of Review
- Informed Consent and HIPAA
- Tips and Training
- Contacts for Questions
Purpose of the IRB

- Provide ethical review of research
- Ensure rights and welfare of human subjects are protected
- 2 Institutional Review Boards at the University of Louisville
  - Biomedical IRB
  - Social Behavioral Education IRB
- Serve as IRBs for UofL faculty research conducted in:
  - University of Louisville
  - University of Louisville Hospital/James Graham Brown Cancer Center
  - KentuckyOne Health (formerly Jewish Hospital & St Mary’s Healthcare)
  - Norton Healthcare

UofL IRB is:

A campus-wide committee composed of faculty, staff and community members.
- The committee is charged with the review of human participants research to assure that the rights and welfare of human participants are adequately protected
- Regulations and IRBs formally defined in 1970s
- Formed because of abuse of research subjects’ rights:
  - Tuskegee Syphilis Trial (1932-1972)

The Belmont Report

- Respect for persons
  - People are autonomous and have the right to self determination
  - Protect those with diminished capacity
  - Comprehend information to make an informed choice
  - Obtain informed consent, protect privacy and confidentiality
- Beneficence
  - Do no harm
  - Limit risks and provide benefit for subjects when possible
- Justice
  - Equitable selection of subjects
  - Equal distribution of risks and benefits
Regulations and Guidelines

Risks if no IRB review?

DOES MY PROJECT NEED IRB REVIEW?
1) Are you conducting research?

- **Research** - a systematic investigation designed to develop or contribute to generalizable knowledge.
  - Involves development, testing and evaluation

2) Does your research involve human subjects?

**Human Subject** - a living individual about whom an investigator conducting research obtains

- data through intervention or interaction with the individual, or
- identifiable private information
Non Human Subjects Research- NHSR

The PI obtains de-identified or coded data or biological samples under these conditions:

1. The research is not regulated by the FDA; and
2. The researchers never obtain identifiable information.

(Confirm this determination by submitting the Non Human Subjects Research Application to the IRB)

Examples of NHSR:
- You obtain de-identified specimens from a tissue bank or biorepository that has approval to collect and distribute tissue.
- You analyze coded data and never see any identifiable information, such as name or date of birth.

LEVELS OF IRB REVIEW

Understanding Risk

Risk to subjects determines the level of review required

“Minimal Risk” = the probability and magnitude of harm or discomfort you think the subject will experience in the research is not greater than the harm or discomfort the subject would normally encounter in daily life or during routine physical or psychological examination or tests.
Exempt Research

- Involves human subjects, but IRB approval is not required.

- However, the IRB must review the application and certify that the research is:
  - Minimal Risk and
  - Fits into one of four federal exemption categories

Exempt Category 1 & 2

- **Category 1**: Established or commonly accepted educational settings, involving normal educational practices or the effectiveness of or the comparison of methods.

- **Category 2**: Educational tests, surveys, interviews, or observations of public behavior, except if you collect identifiers and info that could place the subjects at risk.

Exempt Category 3 & 4

- **Category 3**: Interview/surveys with elected public officials

- **Category 4**: Research involving the collection or study of existing data, documents, records, or specimens, IF:
  - These sources are publicly available OR
  - You record the information in a way that subjects cannot be identified, directly or through links.

**Important**: You cannot collect any identifiers, including dates.
Expedited Review Categories

Allowed for studies that are:
- No more than minimal risk AND
- Fit into one or more federal expedited review categories

Expedited Review Categories

• Category 1: Approved drug or device for its approved indication

• Category 2: Blood sampling
  - Amounts cannot exceed 550 ml in an 8 week period
  - Collection cannot occur more frequently than 2 x/week for healthy adults

Expedited Review Categories

• Category 3: Non-invasive specimen collection, such as cheek swabs, urine, or hair samples

• Category 4: Non-invasive clinical procedures, such as MRI, EKG, ultrasound, moderate exercising testing- (not x-ray)
Expedited Review Categories

- **Category 5**: Use of data or specimens collected for non-research purposes or research purposes (includes medical records review)

- **Category 6**: Collection of data from voice, video, digital, or image recordings

- **Category 7**: Low-risk behavioral research

Full Board Review

- **Required for studies that are**:
  - Greater than minimal risk OR
  - Are minimal risk, but do not fit in an expedited review category

**Examples**:
- Investigational drugs/devices
- X-rays
- Behavioral studies involving risky interventions, observations of illegal behavior, or very sensitive data/questions.

**Note**:
- Biomedical meetings held three times per month
- Social, Education, Behavioral (SBE) meetings held one time per month.

IRB Member Considerations

When reviewing a new study, IRB members consider:

- Risks to subjects are minimized
  - Procedures consistent with sound research design
  - Do not unnecessarily expose subjects to risk
  - Utilize procedures already done for treatment

- Risk/benefit ratio

- Equitable subject selection and fair recruitment

- Consent sought and documented appropriately

- Protection of privacy and confidentiality
Post-Approval IRB Submissions

- Amendments/Modifications
- Continuing Reviews (Generally occur every 12 months or more frequently if required)
- Post Approval Reporting:
  - Adverse events
  - Protocol Violations
  - Acts of Non-Compliance
  - Safety Information
- Study Closeout Report

INFORMED CONSENT & HIPAA

Obtaining Informed Consent

- Subjects must be informed about a study and voluntarily agree to participate
- Initial process of informing subjects of the study, including risks and benefits
- Ongoing process of advising subjects with new information related to the study, including when new risks are identified
Obtaining Signed Informed Consent

- Consent forms, parental consent forms, assent forms
- Required for greater than minimal risk research

- Use the UofL IRB templates
  http://louisville.edu/research/humansubjects/links-to-forms

Confidentiality & Privacy

- Confidentiality = Data
  - Physical security: Locked cabinets/offices/suites, physically secure computers/servers
  - Electronic security: Follow UofL minimal electronic security standards:
    - Encrypt portable devices
    - Do not store identifiers on unencrypted portable devices
    - Use password-protected files and secure networks

- Privacy = Individuals
  - Is there a private area to interview participants?

HIPAA & PHI

- HIPAA = law to protect patients from inappropriate disclosures of their Protected Health Information (PHI) that could harm their insurability, employability, and/or their privacy

- PHI = info in the medical record that can be used to identify an individual and that was created, used, or disclosed when providing a health care service
What Constitutes PHI – 18 Identifiers

- Name
- Address – street address, city, county, zip code (more than three digits) or other geographic codes
- Dates directly related to patient (except year), including DOB, admission or discharge date
- Telephone number
- Driver’s License number
- Email addresses & fax numbers
- Social Security number
- Medical Record number
- Health plan beneficiary number
- Account number
- Certificate/license number
- Any vehicle or device serial number, including license plates
- Web addresses (URLs)
- Internet protocol (IP) address
- Finger or voice prints
- Photographic images
- Any other unique identifying number, characteristic, or code
- Age greater than 89 (as the 90 year old and over population is relatively small)

Viewing and Disclosing PHI

You must obtain approval to use and disclose PHI from research subjects by one of the following:

1. **Research Authorization** – Authorization must be given by the subject for access, use and disclosure of protected health information (Part of the Informed Consent Process)
2. **Partial Waiver of Authorization** – For screening potential subjects to consent to a research study.
3. **Complete Waiver of Authorization** – When the subject will never sign a research authorization (e.g. retrospective chart review)

When do you need a Partial Waiver?

When you **must view, collect, and/or disclose** potential subjects’ PHI for screening purposes before the subjects can give an authorization to do so.
When do you need a Complete Waiver?

- When the Privacy Board determines that no Research Authorization will be required for a covered entity to view, collect, and/or disclose PHI for a particular research project.

Who can serve as a Principal Investigator?

- UofL Faculty & Staff

- Fellows/Residents in a training program require a faculty advisor to serve as principal investigator

- Students (e.g. nursing school) require a faculty advisor to serve as principal investigator.
What does an IRB expect in an application?

- **Consideration** - of how the issues & methods fit with ethical guidelines & IRB requirements
- **Clarity** - in statement of problem, research questions and methods of data collection
- **Consistency** - in content across all documents
- **Completeness** - of all materials
- **Anticipation** - of problems/other risks
- **Balance** - of risks/benefits

Required Training & Conflict of Interest

**Key Study Personnel** contribute in a substantive way to the execution and monitoring of the study, which includes obtaining consent

**Key Study Personnel** are required to take:
- Human Subjects Protection + HIPAA research course through the CITI website.
- Annual Attestation & Disclosure Form (ADF) submitted in iRIS.
- Upload their CV to their profile in iRIS.

Attestation & Disclosure Form

An individual conflict of interest (COI) mean a situation that *compromises* or could compromise an individual’s *professional judgment* in carrying out teaching, research, outreach, or public service activities

COI may be because of an external relationship that *directly or indirectly* affects an external interest of
- the covered individual
- an immediate family member
- or an associated entity
Very Important

- UofL IRB approval is required before initiating, modifying, or extending your research project.

WHO TO CONTACT

Contacts:

Conflict of Interest Questions: COIOFF@louisville.edu

Human Subjects Protection & HIPAA Training (On www.citiprogram.org website): Carla Jones, Research Integrity Program, 852-2454

Obtaining an IRB Sponsored Account:
http://louisville.edu/research/humansubjects/copy_of_forms/SponsoredAccountRequestForm_2142014.pdf
Human Subjects Protection Program
Office

Website:  http://louisville.edu/research/humansubjects
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