IRB Training Presentation

January 2019

Objectives:

- Readers will be able to:
  - Determine if project is “human subjects research”
  - Determine if a research project is “exempt”
  - Identify requirements for IRB approval
  - Identify characteristics of the Informed Consent process and the elements of informed consent
  - Address HIPAA-related issues in research
  - Identify post-approval requirements

Translation of Selected Objectives:

- Readers will be able to:
  - Avoid IRB Review Whenever Possible
  - Smoothly achieve IRB approval, whenever necessary
  - Otherwise stay out of trouble

Not Objectives:

- To provide required training in human subjects protection
  - www.citiprogram.org for that
- To summarize history of atrocious abuses of human subjects
- To summarize the development of human subjects protection
- To discuss the ethical principles of the *Belmont Report*
- To detail the specific federal regulations

What Is the IRB?

- An independent committee charged with overseeing human subjects research at LECOM Health (all campuses and programs of LECOM along with MCH, Senior Living Center, etc.)
- Authority to approve, require modifications to secure approval, or disapprove research projects
- Maintains continuing oversight of projects after approval

Avoiding IRB Review: Part 1

- Stay outside its jurisdiction

IRB Jurisdiction: Human Subjects Research?

- Are human subjects involved?
  - If not, no IRB review and approval needed
- Is it research?
  - If not, no IRB review and approval needed

Are Human Subjects Involved?

- A “human subject” is a living individual about whom an investigator (1) obtains data through interaction or intervention, or (2) obtains identifiable private information or identifiable biospecimens
  - Cadaver studies do not involve living individuals
  - Studies in which subjects are institutions or geographic areas do not involve human subjects
  - Reviews or meta-analyses of existing published literature do not involve human subjects

Is it Research?

- "Research" is a systematic investigation designed to develop or contribute to generalizable knowledge.
  - Case reports (or very small case series) are not systematic investigations; not research
  - Research-like activity intended for internal purposes are not intended to contribute to generalizable knowledge; not research
    - Rule of thumb, intent to share via publication, poster, or presentation makes it research

Activities Deemed Not to be Research

- Scholarly and journalistic activities focusing on the specific individuals about whom the information is collected
- Public health surveillance activities conducted, required, or authorized by a public health authority
- Collection and analysis of data solely for criminal justice or criminal investigative purposes
- Authorized operational activities in support of homeland security, intelligence, defense, or other national security missions

What If My Project is Not Human Subjects Research?

- No IRB “approval” necessary

But:

- Send brief description to IRB and get formal letter confirming that approval is not needed
- Even if human subjects protection rules do not apply, HIPAA still applies to use of protected health information

Avoiding IRB Review: Part 2

- Conduct “exempt” research

Is my Project Exempt?

- Certain categories of human subjects research are “exempt” from all human subjects protection requirements:
  - No IRB review and approval needed
  - No subject informed consent needed
  - But, HIPAA still applies to use of protected health information
- Eight “exempt categories”, six likely in this setting

Exempt Categories

- Research involving educational tests, survey procedures, interview procedures, or observation of public behavior
  - if data recorded without direct or indirect identifiers **or** disclosure outside the research could not harm subjects
  - if data recorded with identifiers, protocol may still qualify for exemption after limited IRB review
  - this exemption generally not available if subjects are children

Exempt Categories (continued)

- Research involving benign behavioral interventions in conjunction with collection of data if the subject prospectively agrees and at least one of the following is met:
  - Data is recorded without direct or indirect identifiers **or** data disclosed outside of the research will not harm the subjects.
  - Data recorded with identifiers may still qualify for exemption after limited IRB review.

Exempt Categories (continued)

- Secondary research uses of identifiable private information or identifiable biospecimens if at least one of the following is met:
  - Source is publicly available **or**
  - Information is recorded without any identifiers, investigator does not contact subjects, and investigator will not re-identify subjects **or**
  - Research involves only use of identifiable health information regulated under HIPAA **or**
  - Research is conducted by, or on behalf of, a Federal department or agency using information gathered by the government.

Exempt Categories (continued)

- Research on normal educational practices in established or commonly accepted educational settings that are not likely to adversely impact students' opportunity to learn required content or the assessment of educators who provide instruction

Exempt Categories (continued)

- Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if the IRB conducts a limited review and determines:
  - Broad consent is obtained
  - Broad consent is appropriately documented or waiver of documentation is appropriate
  - If there is a change made for research purposes in the way the data is stored or maintained, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

Exempt Categories (continued)

- Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if:
  - Broad consent was obtained
  - Documentation of informed consent or waiver of documentation of consent was obtained
  - The IRB conducts a limited IRB review and determines there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data **and**
  - The investigator does not include returning individual research results to subjects as part of the study plan.

Exemption Following Limited IRB Review

- Some studies using identifiable information still qualify for exemption if the IRB finds that:
  - There are adequate provisions to protect the privacy of subjects **and** to maintain the confidentiality of data.

What If I Think My Project is Exempt?

- Investigators cannot make exemption determinations about their own projects
  - Why?
    - If Investigators could decide their own projects are exempt, then all research would be exempt.

What If I Think My Project is Exempt?

- Process
  - Send email to irblecom@lecom.edu with completed Application for Exemption
  - Describe project in sufficient detail for determination of project's qualification for exempt status
    - Use *magic words* (i.e. "no identifiers will be recorded")
    - Include copy of survey (if applicable)
  - If exempt, will receive "determination" letter that no IRB approval is needed

What are exempt projects exempt from?

- Almost everything – exempt from all regulations on human subjects protection
  - No CITI training required
  - No submission of fully developed research protocol for review
  - No informed consent requirement
  - No continuing oversight
- Not exempt from HIPAA

IRB Approval Needed for:

- All non-exempt projects,
- That are research,
- Involving human subjects.

IRB Approval: What Does it Take?

- IRB Must Find:
  - Risks to subjects are minimized
  - Risks to subjects are reasonable
  - Selection of subjects is equitable
  - Appropriate provisions for recruitment and informed consent

How Does the IRB “Find” Things?

THE INVESTIGATOR LAYS THEM OUT CLEARLY IN THE RESEARCH PROTOCOL

What forms should I Use?

- Protocol Cover Sheet must be submitted
- No specific protocol form, but:
  - Protocol Checklist of what you should include and sample research protocol
- Available at http://lecom.edu/research/human-subjects-research-protection-protocol/

What to Include in a Research Protocol for the IRB:

- Information about Principal Investigator
  - Name, title, institutional affiliation and contact information
  - Qualifications
  - Documentation of CITI training for PIs

  www.citiprogram.org
    - Include Completion Report

What to Include in a Research Protocol for the IRB (continued):

- Co-Investigators/Other Study Personnel
  - Names, affiliations, titles, roles in the research
  - Documentation of CITI training
  - Qualifications (especially if filling a gap in the PI's qualifications)

What to Include in a Research Protocol for the IRB (continued):

- About the project
  - Title
  - Description of research question/hypothesis
  - Methodology:
    - Subject selection and recruitment procedures
    - Potential risks/discomforts and benefits
    - Procedures to minimize risks/discomforts
    - Planned interventions or observations

- Methodology (continued):
  - Instrumentation
  - Plans for data collection and analysis
- Informed Consent
  - Procedures to obtain informed consent
  - Copy of Consent Form (or script)
  - Copy of recruitment materials

Informed Consent Process

- Describe circumstances of seeking consent:
  - Must provide sufficient opportunity for consideration of whether to participate
  - Must be free of coercive influences
- Language must be understandable
- No exculpatory language or waivers of rights or appearance of waivers of rights
- Documented

Elements of Informed Consent

- Begin with concise summary of what participant would want to know prior to agreeing to participate in study
- The consent should also include each of the following elements:
  - This is research
  - Purpose of the research
  - Participation in voluntary
  - Expected duration of participation
  - Procedures (and which are experimental)
  - Description of foreseeable risks
  - Description of anticipated benefits

Elements of Informed Consent (continued):

- Disclosure of alternative procedures (if any)
- Description of extent to which records will be confidential
- If more than minimal risk:
  - Is compensation available?
  - Is medical treatment available?

Elements of Informed Consent (continued):

- Who to contact:
  - With questions about the research
  - If there is a research-related injury

    (The Investigator)

  - With questions about rights as a research subject

    (The Chair of the IRB)

Elements of Informed Consent (continued):

- Statement that:
  - Participation is voluntary
  - Refusal will not result in penalty or loss of benefits
  - May withdraw at any time without penalty or loss of benefits

IRB May Also Require:

- Statement regarding unforeseeable risks if subject pregnant or becomes pregnant
- Anticipated circumstances for termination of participation without subjects' consent
- Any additional costs to subjects
- Consequences of decision to withdraw/orderly procedures for withdrawal
- Communication of new findings
- Approximate number of subjects

Waiver or Alteration of Informed Consent Possible **IF**:

- Study has no more than minimal risk
- Waiver/Alteration will not adversely affect rights and welfare of the subject
- Research could not practicably be carried out without waiver
- Additional information provided after participation (if pertinent)

HIPAA Considerations

- General Rule: Need Patient's Authorization
  - May be on covered entity's specific form
  - For research, may be included in Consent Form
    - Specific wording in IRB procedures
- May be waived by IRB or Privacy Board in very limited circumstances
- No Authorization Needed for:
  - Decedents
  - Work preparatory to research
  - De-identified data

Post-Approval Requirements

- Modifications must be approved by IRB in advance
  - Exception: to avoid imminent harm to subject or others
- Unanticipated or serious adverse events must be reported to IRB
- Continuing review and re-approval each year until research only involves data analysis

Resources on LECOM Website

- Sample Research Protocol
- Protocol cover sheet
- Protocol checklist
- Application for Exemption
- Instructions for Embedding HIPAA authorization into Consent Form
- HIPAA Waiver Request Form

IRB Contact Information:

- Lindsay Ropchock, J.D.
- irblecom@lecom.edu
- 724-552-2889
- Ext. 2889 (from Millcreek or LECOM)