LECOM IRB Process

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Objectives:

- Participants will be able to:
  - Determine whether IRB approval is needed for a particular research project (and what to do when it is not)
  - 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

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.
- Authority to approve, require modifications to secure approval, or disapprove research projects
- Maintains continuing oversight of projects after approval

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
  - 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 intended to contribute to generalizable knowledge; not research
  - Research-like activity intended for internal purposes (i.e. quality assurance); not research
    - Rule of thumb, intent to share via publication, poster, or presentation is a hallmark of research

What If My Project is Not Human Subjects Research?

- No IRB approval necessary
- No contact with IRB necessary

But:

- Contact IRB if in doubt (ifreeman@lecom.edu)
- Confirmation letter available if needed
- Might be HIPAA implications

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, might be HIPAA implications
- Six “exempt categories”, three likely in this setting

Exempt Categories

- Research involving educational tests, survey procedures, interview procedures, or observation of public behavior
  - unless data recorded with identifiers and disclosure outside the research could harm subjects
  - generally not available if subjects are children

Exempt Categories (continued)

- Research involving the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens, **if:**
  - Sources are publicly available, or,
  - Data are recorded without direct or indirect identifiers

Exempt Categories (continued)

- Research on normal educational practices in established or commonly accepted educational settings

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 ifreeman@lecom.edu
  - Describe research plan in sufficient detail for determination if project is exempt
    - Describe anonymous process
    - Include survey (if applicable)
  - If exempt, will receive “confirmation” letter that no IRB approval is needed

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?

- NO FORM
  - But the IRB does publish a list of items to cover

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 print out of training results

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

- 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

- This is research
- Purpose of the research
- 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:

- 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 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
- No Authorization Needed
  - 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
- Continuing review each year

Resources

- LECOM Health Policy on the Protection of Human Subjects in Research
- LECOM IRB Protocol Review Form
- LECOM Instructions for Submitting Protocols
- LECOM Instructions for Embedding HIPAA authorization into Consent Form
- LECOM IRB HIPAA Waiver Request Form
- Federal Office for Human Research Protection
  - www.hhs.gov/ohrp

IRB Chair:

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- Ext. 2870 (from Millcreek Community Hospital or LECOM)