Navigating the Institutional Review Board Process

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 an IRB and What Does it Do?

- An independent committee charged with overseeing human subjects research.
- Authority to approve, require modifications to secure approval, or disapprove research projects
- Maintains continuing oversight of projects after approval

Is a Project Human Subjects Research?

- Are human subjects involved?
  - If not, IRB review and approval is not needed
- Is it research?
  - If not, IRB review and approval is not needed

What are “Human Subjects”?

- A “human subject” is a living individual about whom an investigator (1) obtains data through interaction or intervention, or (2) obtains identifiable private information
  - NOTE: The definition does not say “patient”, any living individual can be a human subject of research
  - NOTE: There does not need to be an “intervention”, data collection alone is enough

What Research is Not “Human Subjects Research”?

- Cadaver studies: Not “living individuals”
- Studies for which subjects are not human: institutions, geographic areas, time periods, etc.
- Reviews or meta-analyses of existing published literature: no interaction, no intervention, no collection of identifiable data about individuals

What Is Research?

- “Research” is a systematic investigation designed to develop or contribute to generalizable knowledge.
  - Case reports (or very small case series): not systematic investigations, so not research
  - QA/QI for internal use only: not intended to contribute to generalizable knowledge, so not research

If a 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

Exempt Research

- Certain categories of human subjects' research are "exempt" from the requirement for IRB review and approval

- Eight "exempt categories," six likely in this setting

Exempt Category #1

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

Exempt Category #2

- Research involving educational tests, survey procedures, interview procedures, or observation of public behavior
  - unless data recorded with identifiers **and** disclosure could harm subjects
  - If data will be recorded with identifiers, project may still be exempt following limited IRB review
- This exemption generally not available if subjects are children

Exempt Category #3

- Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording, if the subject prospectively agrees (and if there is no deception) and **if one of the following apply:**
  - data are recorded without identifiers, or,
  - disclosure outside the research would not harm subjects.
  - If data will be recorded with identifiers, project may still be exempt following limited IRB review

Exempt Category #4

- Research involving secondary uses of identifiable private information or identifiable biospecimens, if one of the following applies:
  - Data are publicly available;
  - Data are recorded without identifiers, the investigator does not contact subjects, and the investigator will not try to re-identify subjects;
  - **Research only involves data collection and analysis of private information from medical records covered by HIPAA**; or
  - the research is conducted by or on behalf of a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities in certain circumstances.

Exempt Categories #7

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

Exempt Categories #8

- Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if:
  - Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or biospecimens was obtained;
  - Documentation of informed consent or waiver of documentation of consent was appropriate;
  - An IRB conducts a limited IRB review; AND
  - The investigator does not include returning individual research results to subjects as part of the study plan.

Who Decides if a 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.
- At LECOM, the IRB Chair makes the determination

Process for Requesting Exemption

- Complete “Application for Exemption” at https://lecom.edu/research/irb/ /
  - Use *magic words* (i.e. “no identifiers will be recorded”)
  - Include copy of survey or data collection forms (if applicable)
- Submit via email to IRBLECOM@lecom.edu
- 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 by IRB
- Not exempt from HIPAA

IRB Approval Needed for:

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

Criteria for IRB Approval

- 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 publishes two helpful documents:
  - The review form that IRB members use to analyze proposals for approval
  - A sample research protocol
  - https://lecom.edu/research/irb/

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

- 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

- Brief Overview as beginning
- 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 at irblecom@lecom.edu or 724-552-2889)

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

Resources on LECOM Website

- Sample Research Protocol
- Instructions for Submitting Protocols
- Instructions for Embedding HIPAA authorization into Consent Form
- HIPAA Waiver Request Form
- LECOM IRB Protocol Review Form
- Federal “Decision Trees”

Contact Info for IRB

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