FLORIDA STATE UNIVERSITY
COLLEGE OF MEDICINE

Research Workshop Series #8
Institutional Review Boards (IRBs)

What is an IRB?

- Committee comprised of scientists and laypersons who review all proposed human subjects research
- Mission is to ensure and safeguard the safety and welfare of human subjects in research by compliance with the federal regulations

The Belmont Report

- Written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1976)
- Identified basic ethical principles for the conduct of biomedical and behavioral research involving human subjects
- Developed guidelines to assure that such research is conducted in accordance with those principles
- https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

The Belmont Report

Guiding ethical principles are:

- **Respect** for persons
  - Treated as autonomous agents
  - Persons with diminished autonomy are entitled to protection
  - Requirement of voluntary informed consent process
- **Beneficence**
  - Obligation to protect persons from harm by minimizing risks & maximizing benefits
- **Justice**
  - Selection of subjects is fair & equitable
  - Care taken when working with vulnerable populations

Determination or Review?

- QI or non-human subjects research
- Exempt
- Expedited
- Full Board

Exempt Review

Know what "exempt" really means

- It **does not** mean you do not need to submit an application
- It **does not mean exempt from any review**
  - Protocol is reviewed using a faster process
- IRB, not investigators, determine exempt status
  - You must submit your research plans for review
- If exempt, there are no annual review requirements
- Six exemption categories (handout)
  - Must fit into one of these categories

Expedited Review

- No more than minimal risk
- Cannot be used where identification of the subjects and/or their responses places them at risk of criminal or civil liability or be damaging, unless protections in place
- Privacy risks are no greater than minimal
- Does not mean faster or less rigorous review
- Most retrospective chart reviews fall in this category

Expedited Categories

- **Clinical studies of drugs if**
  - An investigational new drug (IND) application is not required
- **Clinical studies of devices**
  - An investigational device exemption application is not required or the device is approved for marketing and the device is being used with its approved labeling

Expedited Categories

- **Collection of blood samples**
  - Healthy non pregnant adults at least 100 lbs.
    - No more than 550 ml in 8 weeks
    - Not more than 2x per week
  - Other adults & children with consideration of age, weight, health, & frequency
    - No more than 50 ml or 3 ml per kg in 8 weeks
    - Not more than 2x per week
- **Prospective collection of biological specimens for research purposes by noninvasive means**
  - Hair/nail clippings, baby teeth at time of exfoliation or extraction, cells collected by swab

Expedited Categories

- **Collection of data through noninvasive procedures**
  - Not involving general anesthesia or sedation
  - Routinely employed in clinical practice, excluding procedures involving x-rays or microwaves
- **Research involving materials (data documents, records, or specimens) collected (or will be collected) solely for non-research purposes**
  - Such as medical treatment or diagnosis
- **Collection of data from voice, video, digital, or image recordings made for research purposes**

Expedited Categories

- **Research on individual or group characteristics or behavior**
  - Perception cognition
  - Cultural beliefs or practices
  - Social behavior

- **Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies**

Full Board Review

- All other research that does not qualify for exempt or expedited review
- Greater than minimal risk
- May include vulnerable subjects
  - Children, pregnant women, fetuses, neonates, prisoners, decisionally impaired
  - May require additional protections
  - Vulnerable subjects alone does not necessarily mean full board review

IRB Approval

- **Conditional Approval**
  - Approved under the condition that clarifications, form revisions, and protocol modifications requested by the IRB are submitted
  - Responses, revisions are reviewed
  - Must be approved for conditional approval to become final approval
- **Final Approval**
  - Usually approved for one year but have to consider renewal timelines
  - Renewal may be short for high-risk studies

Amendments

- **ANY** change to protocol, study procedures, consent forms, and data collection forms
  - Must be submitted and approved by the IRB before any of the changes are implemented
  - Documents
    - Submit track changes and clean copies
  - Minor changes undergo expedited review
    - Does not change risk/benefit ratio
    - Does not significantly change the study design
  - Major changes may undergo full board review

Continuing Review/Renewal

- IRB approval is for one year
- Must renew projects annually or close study
- Typically 90d, 60d, 30d notifications of expiration
- Study will expire if not renewed
  - Research must stop until reapproved (no recruitment, data collection, data analysis, or writing)
  - Does not mean your study is over, you just have to halt processes until it is reapproved

Special Considerations

- **Case reports**
  - Not research if ≤ 3 subjects (de-identified)
- **Quality improvement (QI)**
  - Typically does not meet definition of research since not designed to be generalizable
  - "Intent" of QI is to improve a practice or process within an institution to benefit that institution
  - Publishing/presenting does not automatically change QI into research
  - Case by case basis – can be gray
  - Check local policy for determining requirements
  - Some journals require QI confirmation from an IRB

Special Considerations

- **Pilot studies and pre-testing materials**
  - May be considered research that requires IRB approval
  - FSU IRB: not research if only testing instrument and not using the pilot data

Avoid problems by consulting with your IRB first!

Writing Your IRB Application

- **Use submission date as your deadline**
- **Become fully versed on the application process for every IRB**
  - Check your local IRB policies
- **Be complete, clear, explicit**
  - Make it easy for reviewer to understand your application
  - But…at times less is more
    - Strike a balance between specific enough to be approvable & general enough to be workable
    - Use (insert name) or (insert phone number) in letters to avoid a revision if staff change
- **Contact the IRB for any specific questions before acting**
  - Don't assume you know the answers

Writing Your IRB Application

- **There is no such thing as "no risk"**
  - Common error on applications & consent forms
- **Types of risks**
  - Invasion of privacy (participant observation)
  - Breach of confidentiality (of data)
  - Physical
  - Psychological
    - From mild (e.g., embarrassment) to severe (PTSD flashbacks)
  - Social
    - Change how one is viewed by others
  - Legal
    - For illegal activities, consider a Certificate of Confidentiality
  - Economic
    - Present or future employment
    - Eligibility for insurance

IRB Research Documents

- Study protocol
- Consent/assent forms
- Data collection instruments (CRFs, surveys)
- Scripts (recruiting, screening)
- Key personnel materials
  - Proof of human subjects training
  - CVs or resumes
- Recruitment tools
  - Letters, flyers, posters, brochures
- Any other documents that are patient-facing

Informed Consent

- Information
- Comprehension
- Voluntariness
- Assessment of Risks and Benefits

Required Elements of Consent

- A statement that the study involves **research**
- **Purposes** of the research
- **Expected duration** of participation
- A **description of the procedures** to be followed
- Identification of any procedures which are **experimental**
- Reasonably foreseeable **risks or discomforts**
- Any **potential benefits** to the subject or to others

Required Elements of Consent

- Alternative procedures or courses of treatment
- Confidentiality of records
- Compensation
- Explanation as to whether any medical treatments are available
- If injury occurs and, if so, what they consist of, and where further information may be obtained
- Whom to contact for answers to pertinent questions
- Participation is voluntary
- Refusal to participate or discontinue will not penalize subject

The Consent Process

- Manner and location to ensure participant privacy
- Give adequate information
- Use easy to understand language
- Respond to the participant's questions
- Ensure participant understanding of information
- Provide adequate opportunity for the participant to consider all options
- Obtain the participant's voluntary agreement to participate
- Continue to provide information as the participant or research requires

Minors as Subjects

- **Parental/guardian consent & minor assent**
  - Waiver of parental consent is possible
  - One or both parents depending on risks and benefits
- **Emancipated minors may consent for themselves**
- **Separate consent and assent forms?**
  - Yes, for younger than 12 years
    - Simpler form for children, more detailed for parents
  - Variable for 13-17 years
    - One form with multiple signature lines OR
    - Separate consent and assent forms

Writing Consent Forms

- 5th grade reading level – simplify!
- Avoid jargon
- State realistic risks and benefits
- Make procedures/tasks clear
  - Bullet point or number subjects tasks
  - Think chronologically
  - Link compensation and tasks

Consent Waivers

- **Waiver of consent (no document)**
  - Research designs require that no subjects be left unaware of the purpose of the research – responses may be biased if they know in advance what the investigators are seeking
- **Waiver of documentation of consent (no signature)**
  - Research involves no more than minimal risk to the subjects;
  - Waiver or alteration will not adversely affect the rights and welfare or the subjects;
  - Research could not practicably be carried out without the waiver or alteration; and
  - Only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality
- **Whenever appropriate, subjects should be provided with additional pertinent information**

Working with your IRB

Build a positive working relationship with your IRB

- Work together as research partners
  - Mutual goal of good research that protects subjects
- Promote open & transparent communication
- Focus on building a long-term relationship
- IRB processes are part of the research process, not a separate burden, so "just do it"
- When in doubt or have questions, consult with your IRB
- Get discussion outcomes & answers in writing for your records

Training in the Protection of Human Subjects in Research

- Required training for all CoM-affiliated faculty, staff and students conducting human subjects research
- Online, free training through Collaborative Institutional Training Initiative (CITI) https://www.citiprogram.org/
- Two courses:
  - Basic Course – Biomedical/Clinical or Social/Behavioral
  - Health Information and Privacy Course (HIPS)
- Completion reports included in RAC & IRB submissions

TMH IRB

- Electronic process
- iRIS - https://tmh.imedris.net/
  - New researcher or new to iRIS?
    - Contact TMH IRB office for access (850) 431-2522 or
    - Office of Research (850) 431-4947
- Training requirements
  - Used to be CITI or NIH
    - NIH suspending its training course
    - TMH acquiring CITI training

TMH IRB Contacts

- **Website**:
  - https://www.tmh.org/for-healthcare-professionals/irb
- **General Phone**: (850) 431-2522
- **Karen Pietrodangelo**, MS, MHA, RN, Director, Patient Safety
- **Cynthia Blair**, VP/Chief Organizational Improvement and Planning

  Administrative Liaison
- **Larry C. Deeb**, MD, Chair (until Oct 1)
- **Phillip Treadwell**, PharmD, Vice Chair (Chair as of Oct 1)

FSU IRB

- Electronic submission portal
  - https://humansubjects.research.fsu.edu/applogin.aspx
  - Transitioning to Huron Click next year
- New protocol and consent form templates are forthcoming
- Upload FSU CoM RAC approval letter
  - https://med.fsu.edu/index.cfm?page=rac.home
  - Mandatory process for all CoM involved in human subjects research
  - Application on MedNet (SharePoint)
    - Proposal "Narrative" or protocol
    - Initial CITI training verification

FSU IRB Contacts

- **Website**:
  - https://www.research.fsu.edu/research-offices/human-subjects
- **Stacy Carey, MA, MS**

  Director, Human Subjects Committee

  (850) 644-0284; scarey@fsu.edu
- **Administrative Staff**
  - **Annette Allman** (850) 644-8633; aallman@fsu.edu
  - **Julie Haltiwanger** (850) 645-1685; jhaltiwanger@fsu.edu
  - **Mary Livings** (850) 644-8673; mlivings@fsu.edu
- **General Phone**: (850) 644-7900
- **General Email**: humansubjects@fsu.edu

Protection of Human Subjects Federal Regulations

- **45 CFR 46:**
  - https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML

Thank you!

Questions & Discussion