INSTITUTIONAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

IRB PRESENTATION

UNIVERSITY OF CENTRAL FLORIDA

OFFICE OF RESEARCH & COMMERCIALIZATION

407-823-2901 OR FAX 407-823-3299

WWW.RESEARCH.UCF.EDU/COMPLIANCE/IRB.HTML

UNIVERSITY OF CENTRAL FLORIDA INSTITUTIONAL REVIEW BOARD OVERVIEW

SOPHIA F. DZIEGIELEWSKI, PH.D., LCSW
IRB CHAIR
MICHAEL G. DEICHEN, MD, MPH
IRB VICE CHAIR

IRB OFFICE STAFF:
JENNIFER NEAL-JIMENEZ, MD,MS,MSB,CCRP
IRB ASSOCIATE DIRECTOR
PATRIA DAVIS, MSP, CIP
KAMILLE CHAPARRO,BS
GILLIAN MORIEN, BA
RENEA CARVER, MA

INSTITUTIONAL REVIEW BOARD

- The Institutional Review Board consists of a committee established to advocate for the protection of the rights and welfare of human participants involved in research.

- Review is required for all research involving human participants conducted by the University of Central Florida (UCF).

- Approval must be obtained prior to initiating research.

IRB FUNCTION

- The purpose of an IRB is to review research involving human subjects to ensure their rights and welfare are adequately protected.

THE ROLE OF THE IRB MEMBERS

- Safeguarding the rights and welfare
- Review protocols
- Assist and guide researchers

IRB RESPONSIBILITIES

The IRB evaluates proposals for new research and conducts review of on-going research

When reviewing research, the IRB considers:

- The process for recruitment
- Selection and informed consent of prospective research participants
- Assessment of the risks and potential benefits
- What additional safeguards are needed if vulnerable populations
- Provision for protecting participants' privacy and maintaining confidentiality.

For on-going research

- Evaluate proposed amendments
- Requests for research continuation

HOW DO I KNOW IF A PROJECT NEEDS IRB REVIEW?

Definition of "research"

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Definition of "human subject(s)"

IRB REVIEW OF RESEARCH

- All research projects are categorized into one of three categories for the IRB review process.
  - Exempt- Explanation of Research
  - Expedited- Adult Consent or Parent for Child Consent
  - Full Board Review

*Level of risk is an important factor in study determination

- Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

LEVELS OF REVIEW- EXEMPT

(REVIEWED BY CHAIR OR OTHER IRB MEMBER)

- Research on commonly accepted educational practices or unidentifiable data Requires Explanation of Research consent
- Document review, educational testing, surveys or observation of public behavior
- Used cautiously with vulnerable populations (seniors, prisoners, children, pregnant women, fetuses)

LEVELS OF REVIEW- EXPEDITED

(REVIEWED BY CHAIR OR IRB DESIGNATED MEMBER)

Minimal risk and fit into an "Expedited" category

- Document review
- Surveys or Interviews
- Collection of specimens
- Routine noninvasive procedures

LEVELS OF REVIEW- FULL BOARD

(REVIEWED BY CHAIR AND IRB MEMBERS)

- Protocols which meet the definition of more than minimal risk
  - Clinical trials

- PI is invited to IRB meeting to clarify concerns

THE IRB HAS THE AUTHORITY TO:

- Approve
- Require modifications
- Table
- Disapprove

KEY TERMS

Anonymous – No one, not even the researcher, is aware of who completed the information

Confidentiality- The research knows who completed the information, but no one else will know

Privacy- Refers to a person's desire to control access of others to themselves. It involves consideration of whether the participants will be comfortable with the Human Research situation

REQUIRED TRAINING

- CITI online human subjects protection training. Study will not be approved until all KSP are trained. Research Personnel must complete either :
  - Group I. Biomedical Research Investigators and Key Personnel
  - Group 2. Social Behavioral Research Investigators and Key Personnel (Basic)
  - https://www.citiprogram.org/

- See the UCF IRB website for access
  - http://www.research.ucf.edu/Compliance/irb.html

QUESTIONS ?