SOPHIA F. DZIEGIELEWSKI, PH.D., LCSW
IRB CHAIR

MICHAEL G. DEICHEN, MD, MPH
IRB VICE CHAIR

IRB OFFICE STAFF:

JOANNE MURATORI, MA, CIP, CIM
PATRIA DAVIS, MSP, CIP
KAMILLE CHAPARRO, BS
GILLIAN MORIEN, BA
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 and approval is required for all research involving human participants conducted by the University of Central Florida (UCF).

• Approval must be obtained prior to including human participants in an investigation. IRB Policy defines in detail the operations of the Institutional Review Board, its scope of authority, and the requirements for human subjects research conducted by or in collaboration with the UCF.
IRB RESPONSIBILITIES

The IRB evaluates proposals for new research and conducts review of on-going research to ensure that the Guiding Ethical Principles for human subject protection are met.

When reviewing research, the IRB considers issues such as:

- The process for recruitment
- Selection and informed consent of prospective research participants
- Assessment of the risks and potential benefits to participants and the measures for participant safety
- What additional safeguards are needed if vulnerable populations are included
- What methods are provided for protecting participants’ privacy and maintaining confidentiality.

For on-going research, the IRB also evaluates proposed amendments to modify research, safety reports, periodic reports on the progress of research and requests for re-approval to continue research.
OUR TEAM

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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

• Charged with safeguarding the rights and welfare of human subjects.
• Duties include reviewing protocols that involve the use of human subjects.
• Assist and guide researchers to help protect the rights of human subjects.
RESEARCH ETHICS

• Do we have a right to use information gathered unethically?

• Why Do Human Research Subjects Need Protection?
  
  • Prisoner of War camps in Asia and Europe: practiced mutilation surgery, tested antibiotics, affects of cold, injured people to study the healing process.
TRIGGER EVENTS
“WHAT WE’VE LEARNED FROM HISTORY...”

• The Nazi Experiments
• Tuskegee Syphilis Study
• Milgram’s Studies
ETHICAL MILESTONES

• Nuremberg Code 1947 (*Human consent is essential.*)

• National Commission for the Protection of Human Subjects Biomedical & Behavioral 1974 (*First bioethical commission to shape Human Subjects Research.*)

• Belmont Report 1978

• Common Rule 1991
Respect for Persons (“Be courteous”)
- People should be autonomous and not used as a means to an end.
- Allow informed choice where participants can choose for themselves.
- Provide additional protections for those who need it.
- Derived concepts: Informed consent, Respect for privacy

Beneficence (“Do good”)
- We are obligated to protect persons from harm by clearly identifying and maximizing anticipated benefits while minimizing possible risks of harm.
- Derived concepts: Good research design, Competent investigators, Favorable risk/benefit analysis.

Justice (“Be fair.”)
- Requires that the benefits and burdens of research be distributed fairly.
- Derived concepts: Equitable selection of subjects.
COMMON RULE

• A federal policy regarding Human Subjects Protection that applies to 17 Federal agencies and offices.
• Applies to agencies that have signed an agreement to uphold.
• Outlines the requirements for assuring compliance by research institutions.
• Outlines the requirements for researchers' obtaining and documenting informed consent.
• Requirements for Institutional Review Board (IRB) membership, function, operations, review of research, and record keeping.
• Outlines protections for vulnerable populations (Subparts B-D).
  • Research, Development and Related Activities Involving Fetuses, Pregnant Woman, and Human In Vitro Fertilization
  • Biomedical and Behavioral Research Involving Prisoners as Subjects
  • Children Involved as Subjects in Research
SUMMARY: PROTECTIVE MECHANISMS
ESTABLISHED BY “THE COMMON RULE”

- Institutional assurances of compliance
- Review of research by an IRB
- Informed consent of subjects
WHY IS COMPLIANCE IMPORTANT?

- Professional ethics
- Statute compliance
- Publication
- Individual grant funding
- University grant funding
- University research
- Liability
UCF HAS RECEIVED ACCREDITATION OF ITS HUMAN RESEARCH PROTECTION PROGRAM

• Accreditation by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) is the “gold standard” that signifies that UCF is in full compliance with regulatory requirements as well as industry best-practices.
  • Analogous to Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) accreditation for animal research.
  • Demonstrates commitment to human subject protections
WHAT YOU NEED TO KNOW!
HOW DO I KNOW IF A PROJECT NEEDS IRB REVIEW?

Meets federal definition of “research”
Systematic investigation designed to develop or contribute to generalizable knowledge

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Meets definition of “human subject(s)”
The investigator will gather data about living individuals through intervention or interaction OR The investigator will gather data about living individuals that is private AND identifiable.
FEDERAL DEFINITIONS

• Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information provided for specific purposes and the individual does not expect the information to be made public
  • Data from interacting or intervening with subjects (surveys, interviews, focus groups, or
  • Identifiable data such as records (school, medical, etc.) or human specimens (blood, tissue, etc)
• Identifiable – Names, Social Security Numbers, Addresses, or specific information that could identify a person if the population is small
• Identifiers for protected health information (PHI) are defined in detail
CRITERIA FOR IRB APPROVAL

• Risks are Minimized (Consistent with a sound research design and does not unnecessarily expose subjects to risk)
• Risks are Reasonable in Relation to Benefits
• Selection of Subjects is Equitable
• Informed Consent will be Sought for Each Prospective Subject
• Informed Consent will Be Documented
• Research Plan Adequately Provides for Monitoring the Data Collected to Ensure Safety of the Subjects
• Research Plan Adequately Protects the Privacy of Subjects and Maintains Confidentiality
• When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards need to be included in the protocol to protect the rights and welfare of these subjects.
IRB REVIEW OF RESEARCH

• All research projects are categorized into one of three categories for the IRB review process. Each category is different in the level of scrutiny and submission procedures. The IRB is responsible for making the final decision of which category a research project falls under.
  • Exempt
  • Expedited
  • 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
- Document review, educational testing, surveys or observation of public behavior
- Used cautiously with vulnerable populations (seniors, prisoners, children, pregnant women, fetuses)
- Only the institution, not the investigator, can determine exempt status
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 meeting to clarify IRB concerns

• UCF IRB meets once a month
THE IRB HAS THE AUTHORITY TO:

• Approve

• **Require modifications** prior to approval

• **Table** until major issues are clarified

• **Disapprove all research activities including proposed changes in previously approved human subject research.**
REQUIRED TRAINING

• CITI online human subjects protection training is required every 3 years. Study will not be approved until all KSP are trained.
  • [https://www.citiprogram.org/](https://www.citiprogram.org/)

• See the UCF IRB website for access
QUESTIONS ?