



Institutional Review Board Research Involving Human Participants Overview of the UCF Human Research Protection Program- CCIE

www.research.ucf.edu/Compliance/irb.html



About the Institutional Review Board (IRB)

- The IRB
 - Chair
 - Board Members
 - Administrative Staff (IRB Office)
 - Purpose is to review research involving human subjects to ensure their rights and welfare are adequately protected.
 - Review protocols— Approve, Require modifications, Table, Disapprove
 - Assist and guide researchers toward a successful review process
 - Not responsible for assisting with study design, but can request changes as part of the “scientific merit” review.
- AAHRPP Accredited—additional standards

I want to do research, where do I start?

- Meet with your Faculty Advisor
- Work to determine if your research qualifies for Human Subjects Research
- Work with your Faculty Advisor to put together all the appropriate forms and submit in the Huron system
- Contact the IRB if you are unsure AFTER you have received guidance from your Faculty Advisor

Study Submissions

- Every day, the UCF Institutional Review Board receives:
 - Initial studies
 - Modification requests
 - Continuing Review or Closures
 - Reportable New Information
- The “Queue”--First in, first out philosophy
 - Turn in your study EARLY
 - Recommend 6 weeks before you plan to start recruitment
 - Researchers can petition the office with extenuating circumstances
- The IRB office is here to help, but your research mentor/faculty advisor will be your primary source of information

Types of IRB Review - Non-Human Subjects Research (NHSR) Determination

- Is not approved, but instead determined to not fall under Human Subjects regulations.
- The IRB makes this determination, NOT the researcher.
- Is it Research?
 - Systematic investigation
 - Designed to develop or contribute to GENERALIZABLE knowledge
- Does the Research involve Living Individuals?
 - Physical procedures to or manipulations of persons or their environment FOR RESEARCH PURPOSES
 - Communication, contact, collection of identifiable data or, interaction (this includes online surveys) FOR RESEARCH PURPOSES

Application + HRP-250

(Recommend emailing details to irb@ucf.edu prior to submitting your application in the online system.)

Types of IRB Review - Exempt Determination

- Is not approved, but instead determined to be exempt from certain parts of Human Subjects regulations.
- The IRB makes this determination, NOT the researcher.
- Includes Several Categories of **Minimal Risk** Research Involving:
 - Commonly accepted educational practices
 - Surveys; interviews; educational, cognitive, aptitude tests (restrictions for persons under age of 18) and observations
 - Brief benign behavioral interventions (One meeting, under 3 hours)
 - Secondary research involving the collection or study of EXISTING data if identifiable information is not recorded

Application + HRP-255 (or HRP-255SR if only secondary research)+ HRP-254 + Other Study Documents

Types of IRB Review - Expedited Review

- These studies are typically approved by one board member
- Includes Several Categories of **Minimal Risk** Research Involving:
 - Research with children
 - Routine noninvasive procedures - i.e. wearing a fitness tracker
 - Surveys, interviews, educational tests, human factors, and tasked based research if they cannot fit into an exempt category (i.e. more than 1 meeting for a task, task extends past 3 hours)

Application + HRP-503 + HRP-502 (adult)/HRP-502b(child) + Other Study Docs

Types of IRB Review - Full Board

- Requires approval by a majority of IRB Members.
- Re-reviewed by the board annually.
- Protocols which meet the definition of more than minimal risk
 - Clinical trials
 - Invasive procedures
 - Extensive blood draws
 - Highly sensitive nature of study or population
- The research team is invited to the IRB meeting to clarify concerns, then the Board votes or formally requests study packet revisions.

Application + HRP-503 + HRP 502/502b + Other Study Documents

Research in K-12 Schools

- Two-part process
- UCF Review is required for many of the school districts before they will review
- Reach out to the school district/teacher/principal FIRST to see if this is something they would be interested in having take place at their school or classroom
- When you don't reach out prior to getting review by the UCF IRB, the process can take much longer, involving multiple revisions after the study is approved and a delay in your research starting

Research in K-12 Schools

- Recruitment cannot be initiated first with the child
- Parents must give consent before a researcher may approach their child with information about a research study
- Parents will consent
- Children will assent

FERPA

- Protecting an educational record
- What is considered FERPA protected information?
 - University ID number, Social Security Number, graded assignments and tests, transcripts, class rosters, financial aid information, notes on conversations with students, emails containing information about students, student writing samples, health data (immunizations)
- What is NOT FERPA protected?
 - Directory information i.e. student name, DOB, telephone number, address.
 - Directory information is defined as would not generally be considered harmful or an invasion of privacy.
- IRB cannot waive FERPA requirements, signatures are usually required

TeachLivE

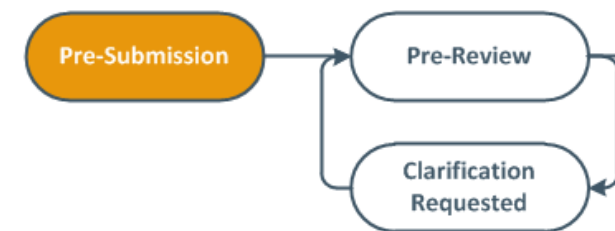
- Mixed reality classroom simulator
- These studies will generally fall under Exempt Category 3 since this is not a fully immersive simulator experience.
 - Sometimes the TeachLivE procedures are happening regardless of research, as part of a class requirement. If you are doing research to test the effectiveness of the assignment, or just planning to use the data collected, then you will also need to upload a class syllabus as part of your study application packet.
- If there are devices involved as part of the research study (i.e., skin conductors, heart rate monitors, etc.) then these studies will be reviewed under an Expedited category.

Compensation- Monetary and Extra Credit

- Equal compensation for equal time and effort
- Minimize the possibility of coercion or undue influence
 - The amount of extra credit or payment should be relatively equal to the amount of time required for the study. For example, you would not compensate a participant \$100 for taking a 15-minute survey. But you might offer a \$5 gift card or a small amount of extra credit points.
 - Consider the amount and method of payment
- If a study requires extended time or multiple interventions, consider prorating the compensation or extra credit for the time of participation in the study.

Common IRB Submission Errors

- Study personnel names; titles, not consistently listed
- Missing CITI training
- External Collaborators
 - UCF affiliated CITI training
 - Individual Investigator Agreements
- Did you move the study from “Pre-Submission” to “pre-Review”? (only PI can “submit”)



A screenshot of the IRB submission interface. The top section has a yellow header labeled 'Pre-Submission'. Below it, text indicates 'Entered IRB:' and 'Last updated: 12/1/2016 1:11 PM'. To the right, the study title 'Zika Vi' is visible, along with fields for 'Principal Investigator', 'Submission type:', 'Primary contact:', and 'IRB coordinator:'. A 'Next Steps' section contains three buttons: 'Edit Study', 'Printer Version', and 'View Differences'. At the bottom, a 'Submit' button is highlighted with a red box and a red arrow points to it from the text in the list. To the right of the 'Submit' button is a 'History' tab and a 'Full' button. A yellow oval labeled 'Pre-Submission' is also visible on the right side of the interface.

Common IRB Submission Errors

- Not clarifying what processes take place regardless of the research and what is being done only for research purposes
- Copying and pasting from previously approved studies
- Writing the documents in past tense
- Incorrect, incomplete or inconsistent information in forms or documents; not uploading documents in the correct area of the online application, not using current templates—**always check for the latest version**
- Spell check, remove comments and redlines, check EVERYWHERE for consistent information, upload in Word document format

Common IRB Submission Errors

- Consent or participant materials are not clearly written in **lay language** or are missing required elements of consent
 - Follow the updated templates located on the IRB website. Only submit the finalized, clean version of the consent
 - Eighth grade reading level, **keep it simple**, but list enough information for someone to make INFORMED CONSENT
 - Most adult studies will not require signatures
 - The consent form/explanation of research is part of your consent process- describe the process in your protocol

Common IRB Submission Errors

Data Confidentiality = about treatment of information

- What identifiers are you recording?
- How are you protecting the identifiers
- How long will you store identifiers
- Include details in both the protocol and consent document

Subject Privacy = about people

- How are you ensuring subjects have a sense of being in control of their personal information and access to their body?

Required Training

- CITI online “human subjects protection training”. The study will not be approved until all Key Study Personnel (KSP) are trained.
- KSP must complete either :
 - Human Subjects Research Group 1. Biomedical Research Investigators and Key Personnel
 - Human Subjects Research Group 2. Social Behavioral Research Investigators and Key Personnel
 - See the UCF IRB website for access
<http://www.research.ucf.edu/Compliance/irb.html>



Thank you!

