



FORM: Faculty Advisor Scholarly/Scientific Review of Research

NUMBER	FORM VERSION DATE	PAGE
HRP-251	1/31/2023	1 of 2

Faculty who supervise graduate student research are called Faculty Advisors (FAs). FAs play an important role in human subjects protections. The FA bears ultimate responsibility for the ethical conduct of research carried out by the student. The time and effort FAs dedicate to their students has a considerable impact on student projects, quality of data, and the time required for IRB approval.

The purpose of this form is to document faculty advisor approval and screening of submission materials for student-led research. This document is to be completed by the advisor and submitted by the student PI in section 6 of the study submission SmartForm in the IRB system. The second purpose of this form is to provide support for individuals responsible for the scientific review of research.

Title of Study:

Principal Investigator (PI):

Faculty Advisor/Chair:

1 QUALIFICATIONS OF THE STUDENT INVESTIGATOR (all items must be checked and described in the in the Protocol, Section 25.0 Resources)

- ☐ The investigator has the qualifications to conduct the study
- ☐ The investigator has the resources to conduct the study (i.e. funding, time, access)
- ☐ The investigator has completed the required Human Subjects Protections training (i.e. CITI) (☐ Check N/A if Not Human Subjects Research)

2 GENERAL SUBMISSION REQUIREMENTS (check each item that has been reviewed and meets expectations of the advisor)

- ☐ This submission includes a Not Human Subjects Research determination request using the HRP-250 (if checked, skip to section 5). (☐ Check if N/A)
- ☐ All documents have been reviewed for clarity, consistency, and completion.
- ☐ Protocol and overall study design are appropriate and hold merit.
 - o The protocol accurately describes the research in a clear, consistent manner
 - o Where applicable, a distinction is made between procedures that are taking place solely for study purposes versus those procedures that are taking place regardless of the study.
 - o The appropriate Protocol document is used: HRP-503 Protocol for Expedited/Full Board studies, HRP-255 or HRP-255SR Request for Exempt Determination for Exempt Studies, or HRP-250 Request for Not Human Subjects Determination
- ☐ The consent process is adequate (☐ Check if N/A)
 - o The consent process is clearly stated in the appropriate Protocol document
 - o If elements of consent are withheld, a debriefing statement is included as part of the consent process
 - o A description of what types of personally identifiable information data is being collected and used for research along with how long the identifiers are maintained is listed
 - o If the research study involves children, there is a child assent process clearly stated in HRP-503 Protocol
- ☐ The consent document(s) or script(s) are complete and written according to current UCF templates (HRP-254 for Exempt Studies, HRP-502/502b for Expedited/Full Board studies) (☐ Check if N/A)
 - o Informed consent begins with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent is presented in a way that facilitates comprehension.
 - o The study purpose and procedures are presented in a clear, concise manner. Information in the consent document is consistent with what is listed in the Protocol.
 - o Signature blocks are removed for minimal risk studies or, only the appropriate signature block is retained. Parental Consent for Child is used where appropriate
- ☐ Recruitment method and materials are consistent with that is described in the appropriate Protocol document and are uploaded for review (☐ Check if N/A)
- ☐ Data collection instruments are listed in the protocol and are uploaded for review



FORM: Faculty Advisor Scholarly/Scientific Review of Research

NUMBER	FORM VERSION DATE	PAGE
HRP-251	1/31/2023	2 of 2

- ☐ Written material to be seen or heard by subjects (including screenshots of any simulations), if any, are uploaded for review
- ☐ Provisions for vulnerable subject populations (e.g. prisoners, children, pregnant women), if any, are described in the appropriate Protocol document
(☐ Check if N/A)

- ☐ Provisions for privacy and confidentiality are adequate

Data management listed in HRP-503 Protocol section 17 or HRP-255 section 3.2 fully describes how and for how long the data will be stored, distinguishing identifiable data management from de-identified data. *Note: storage length of all research data is a minimum of 5 years after study closure per Florida law. The protocol should include provisions for data retention at UCF after the student graduates. If the study design warrants longer storage time periods, protocol specific justification is provided.

- ☐ Other:

3 OVERALL SCIENTIFIC AND SCHOLARLY VALIDITY ((Check if "Yes" or "N/A." All must be checked)

- ☐ Does the protocol accurately describe the study in a clear, detailed protocol in terms of?

- Objectives
- Background
- Setting
- Procedures
- Data and safety monitoring plan
- Risks
- Potential benefits
- Alternatives to participation

- ☐ Is there another way to do this research that would reduce risks to subjects and still answer the scientific question? (☐ Check if N/A)

- ☐ Are there any monitoring procedures that would reduce risks to subjects and not affect the science? (☐ Check if N/A)

- ☐ Is the research likely to answer its proposed question?

- ☐ Does the protocol fairly portray the knowledge expected to result?

4 CLINICAL TRIALS (Check if "Yes" or "N/A." All must be checked if the research is a Clinical Trial.)

- ☐ The available nonclinical and clinical information on an investigational product is adequate to support the proposed clinical trial.

- ☐ The investigator has demonstrated (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

- ☐ The investigator has sufficient time to properly conduct and complete the trial within the agreed trial period.

- ☐ The investigator has available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

- ☐ The investigator will ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

- ☐ A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, will be responsible for all trial-related medical (or dental) decisions.

5 REVIEW COMMENTARY (provide any additional information regarding this submission that may be pertinent to IRB review)

By signing* this document, the faculty advisor is attesting to having conducted adequate review of submission materials and finds them to be complete and accurate. Permission is granted to the investigator to submit to the IRB.

Faculty Advisor/Chair Signature:

Date:

*digital signature with encryption or physical signature is required.