Submission Requirements	
HSC SOP No:	013
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1. PURPOSE

1.1. Investigators are required to submit protocol applications, or requests for IRB determinations of non-human subjects research to the IRB for review before initiating any research involving human subjects.

2. POLICY and PROCEDURE

2.1. **Applicability**

IRB members rely on the documentation submitted by investigators for review of non-exempt protocol applications. This material must provide the IRB members with sufficient detail about a study to assess whether the project qualifies for IRB approval. Additionally, IRB staff need adequate information included in the protocol application to determine whether a project qualifies for exemption, or should be set-up for non-exempt review.

2.2. **Submission Requirements**

The Human Subjects Office, under the Research Integrity Department within the Office of Research has an electronic web-based IRB protocol document submission system for distribution, review, and approval for human subjects research projects. This software system is named ORahs (Office of Research Application for the use of Human Subjects). All applications for research involving human subjects must be submitted using the ORahs application system. ORahs protocol submissions must include any of the following items that are related to the project:

i. Recruitment materials (fliers, emails, etc.)
ii. Informed consent documents
iii. Research instruments (surveys, questionnaires, interview guides, videos, pictures, other stimuli, etc.)
iv. Site-specific permissions (schools, local ethical reviews, host country permissions, etc.)
v. Data use agreements
vi. Other pertinent study materials

2.3. **Action if Protocol Information is Inadequate**

If the IRB staff or committee member reviewers find there is not sufficient detail in the online application to conduct a thorough protocol review and risk-assessment, then the investigator will be required to submit or resubmit additional information, and/or their presence may be requested at a convened meeting to answer any questions regarding the protocol or to explain any details of the study more in-depth.

3. SCOPE

These policies and procedure apply to all human subjects' research.

4. TRAINING

Training on the procedures set forth in this document and any SOPS will be provided to the existing IRB staff and new staff members. Training to investigators is provided through seminars, workshops, one-on-one consultations, and the Office of Research website.

Investigators may request training sessions with the IRB staff and/or IRB Chair/Designee. Training may include a variety of techniques such as seminars covering multiple topics, topic-specific training, lab meetings, or one-on-one meetings.

ORahs training is provided as needed to staff and investigators, via online tutorials, training manuals, or in-person training.

5. RESPONSIBILITY

The faculty advisor or lead investigator (i.e., the individual who is responsible for the overall project) is responsible for ensuring and attesting to the accuracy of the information provided in the online ORahs protocol application. They are also responsible for ensuring the procedures set forth in the approved protocol are followed accurately and a timely reporting of any adverse events, unanticipated problems, non-compliances, or requests for modifications to the protocol has after the protocol has been approved.

The Research Integrity Director in conjunction with the IRB staff within the Research Integrity Department under the Office of Research are responsible for ensuring adequate IRB documentation of compliance for human subjects activities at UCSB and working with the IT staff to maintain the systems used to support the IRB.

IRB staff are responsible for facilitating the review of exempt and non-exempt applications, pre-reviewing submissions, determining non-human subjects research activities, documentation and management of IRB records, such as meeting minutes and protocol files.

IRB members are responsible for reviewing protocols and ensuring that protocols contain sufficient detail for final approval. IRB members are responsible for working with the IRB staff, as required, to review adverse events, unanticipated problems, and resolve incidents of serious non-compliances.

6. PROCESS OVERVIEW

Investigators are responsible for assembling and submitting research application materials. Application materials must be submitted to the IRB for review using ORahs. Investigators may use the Office of Research website for FAQs, guidance, current requirements, or contact

the IRB staff regarding questions surrounding their online application. Investigators are also responsible for contacting the IRB staff for requests of non-human subjects determinations.

Research applications are checked for completeness by the IRB staff before being assigned to a protocol review type (Exempt, Expedited, or Full Board) based on the level of risk. Incomplete applications are returned to the investigator and may cause delays in the research being reviewed and/or research approval.

References:

45 CFR 46 Regulations