UCSB’s Commitment to the Office for Human Research Protections

The University of California Santa Barbara is committed to the ethical principles for the protection of human subjects in research set forth in the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and regulatory protections provided in 45 CFR Part 46.

Operating under our FederalWide Assurance (#FWA00006361) with the Office for Human Research Protections (OHRP), UCSB recognizes and accepts responsibility, which it shares with its investigators and other researchers, for determining that research involving human subjects fulfills these ethical principles and protections.

Our HSC

The UCSB Human Subjects Committee (HSC) is an independent ethics committee mandated by the Department of Health and Human Services and responsible to OHRP. The HSC is composed of UCSB faculty, staff, and graduate students, and local community members who are appointed by the Vice Chancellor for Research.

The HSC is coordinated by the Human Subjects Coordinator in the Office of Research (OR). The HS Coordinator and OR staff serve as liaison between the HSC, various governmental agencies, external researchers and research institutions, and the University community.

The HSC reviews all human subjects research projects to determine whether:

- Risks to subjects are outweighed by the sum of the benefits; and
- The rights and welfare of subjects are adequately protected and that informed consent is obtained as required by the applicable regulations and policies.

Education & Training


Collaborative Institutional Training Initiative (CITI): Mandatory CITI training may be required by collaborating institutions/organizations/agencies. Training modules are available for UCSB investigators at https://www.citiprogram.org/.

Ethics in Research

**NUREMBERG CODE:** Used by the Nuremberg Military Tribunal in the review of human experimentation by the Nazis; defines the ten basic ethical principles for human subjects research.

**DECLARATION OF HELSINKI:** Originally developed by the World Medical Association; provides recommendations similar to those described in the Nuremberg Code and distinguishes between therapeutic and non-therapeutic research.

**BELMONT REPORT:** A statement of basic ethical principles and guidelines for the conduct of research with human subjects:

- **Respect for Persons** (autonomy; persons with diminished autonomy are entitled to protection)
- **Beneficence** (subjects protected from harm; secure well-being)
- **Justice** (burdens and benefits of research should be justly distributed)
Things you need to know when preparing your protocol:

**GENERAL:** The use of headings and paragraphing will improve readability. If modifying an existing submission, note modification date.

The information below pertains to the regular, nonexempt submission application. The exempt application is a shortened form; required discussion is entered in similar fashion into slightly different fields and sections.

**SUBJECTS:** Describe the inclusion/exclusion criteria; if multiple populations will be included, provide clear descriptions of each population. Be aware that some research activities require additional permissions (e.g. UCSB Biosafety).

**LOCATION:** Describe all locations where research activities (recruitment, consent, procedures, data analysis & storage) will take place. If activities will take place in schools, organizations, institutions, workplaces, and/or in international locations, discuss how permissions will be secured. Upload advertising/recruitment materials under the Attachments tabs. Upload external permission confirmations if applicable.

**PROCEDURES:** Describe all research activities (recruitment/invitation to participate, consent, procedures, debriefing if applicable). Include discussion of frequency, duration, and timing of research activities.

Name and provide a brief description of each instrument/tool that will be used in your research. Upload to the Attachments tab. If unable to upload, discuss why (e.g. copyright).

**CONSENT:** Describe the consent process and type of documentation that will be used (e.g. informed consent form, minor assent, parental permission/consent, information sheet, online consent text, etc.). If using an interpreter or will serve as own interpreter, describe. If using translated documents, describe and confirm translation accuracy. Describe where informed consent will take place and how you will ensure that the consent process is free of coercion and that subjects’ questions have been answered.

**CONSENT FORMS:** Create your consent documentation using either a model template or a custom consent. If using a custom consent, be sure to include all required text from the model consent. Clearly describe the purpose, study procedures (type, frequency, duration). Describe all potential or real risks and benefits resulting from participating in your research.

If subjects will be compensated, describe type of compensation, when compensation will be distributed and whether compensation will be prorated accordingly for subjects who withdraw from research.

**ATTACHMENTS:** Upload all documentation (instruments, recruitment/advertising materials/scripts, confidentiality agreements, etc.).

**PROGRESS REPORTS:** Progress reports are required at renewal and are submitted in conjunction with your renewal application. Include number of subjects enrolled and discussion of research to date. Describe any adverse events, unanticipated events or compliance deviations associated with your research.

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**Online Submission Portal**

All requests for review of exempt and nonexempt human subjects research are submitted through the Orahs e-portal [https://orahs.research.ucsb.edu/](https://orahs.research.ucsb.edu/).


- Introduction to ORahs
- Create a Protocol
- Create a Protocol (Page 1 Subjects tab)
- Create a Protocol (Location & Procedures tabs)
- Create a Protocol (Risk & Consent Forms tabs)
- Create a Protocol (Benefits, Ratio, Attachments, Progress, & Submit tabs)
- Queues


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**Investigator Responsibilities**

Investigators are responsible for obtaining HSC approval before beginning human subjects research. During the conduct of an approved study, investigators are responsible for:

- Obtaining and documenting informed consent, unless this requirement has been waived;
- Obtaining prior approval from the HSC for any modifications to the previously approved research;
- Ensuring that progress reports and renewal requests are submitted according to UCSB HSC policy;
- Providing prompt reports of unanticipated problems involving risks to subjects; and
- Retaining records per institutional requirements.