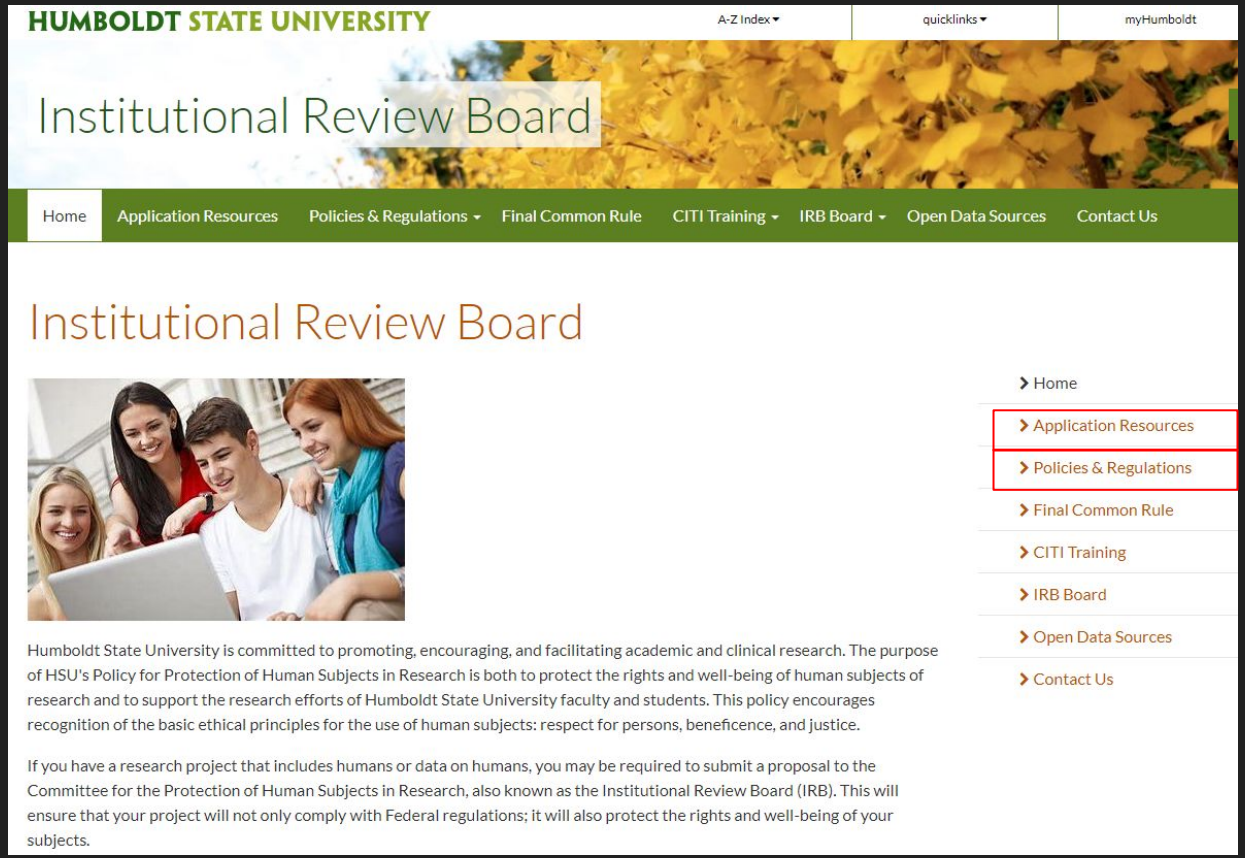
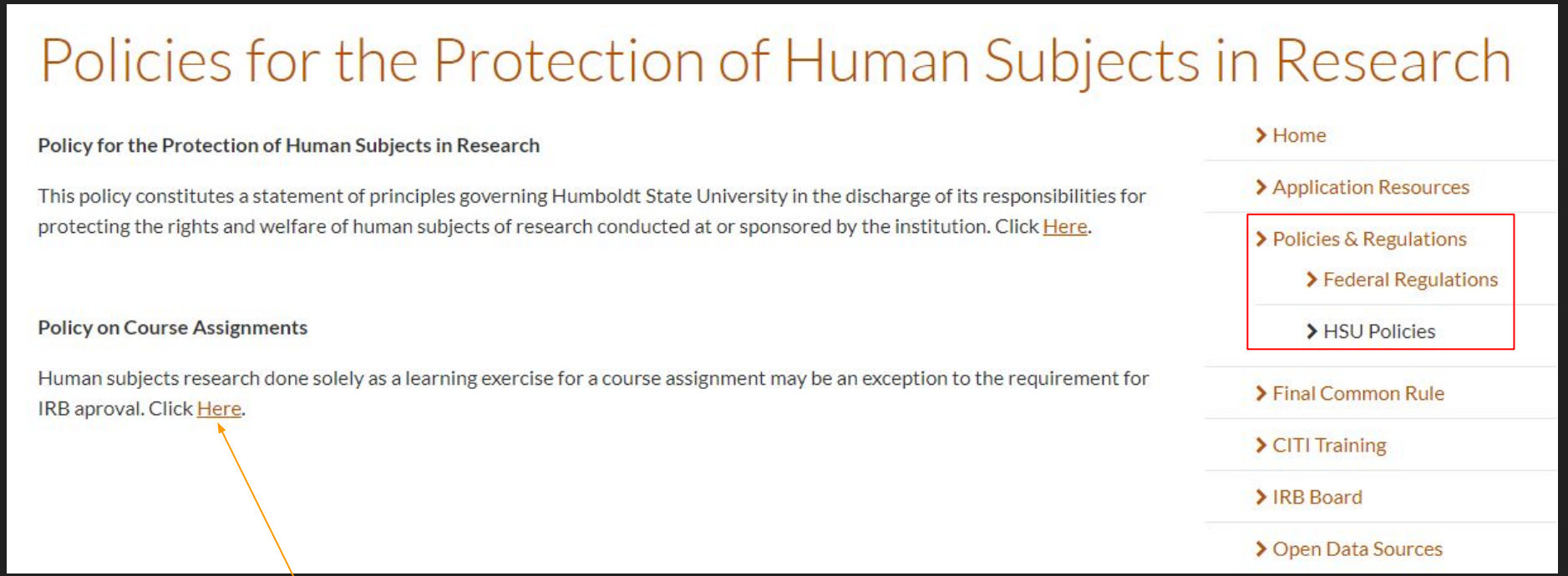
Welcome to HSU's IRB (the *human subjects* review board)



These slides explain our online resources for IRB

- Training
- Applications
- Policies & Procedures

HSU IRB policy: what is covered, what is not.



Course learning activities may not need IRB review
Explained in detail here.

HSU IRB policy

Executive Memorandum

POLICY FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

The Humboldt State University (HSU) Institutional Review Board (IRB) exists to ensure the protection of the rights and welfare of human subjects recruited to participate in research. All individuals listed on an HSU IRB application are required to take an online training that provides essential background information on policies and principles of human subjects protection. HSU is in compliance with California State University Executive Order No. 890 and HSU's Federalwide Assurance (FWA00001093), as approved by the Office of Human Research Protection (OHRP) of the United States Department of Health & Human Services (DHHS). The HSU Institutional Review Board for the Protection of Human Subjects in Research (IRB) has the authority and responsibility to 1) review proposed data collection and research efforts involving human subjects, and 2) maintain records and written procedures in accordance with institutional, local, state, tribal and federal regulations. HSU adheres to local, state and federal regulations governing the protection of human subjects in research.

Activities Covered by This Policy:

This policy applies to data collection and research efforts that contribute to generalizable knowledge and involve human subjects, as defined below.

1. *Data collection* refers to the collection and compilation of information about or from human subjects. Sources of data include existing records, surveys, interviews, websites, databases, focus group discussions, forums, and similar sources of data.
2. *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. *Generalizable knowledge* refers to information or data that are analyzed, from which conclusions are drawn, and then are disseminated outside of a classroom or University unit, for example through publication, presentation, or on the internet.
3. *Human subject* means a living individual about whom an investigator 1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Such research is covered if it is:

- conducted at HSU;
- using HSU facilities;
- by HSU employees (faculty and staff), students, or other persons affiliated with HSU;
- using HSU employees or students as subjects; or
- under the auspices of the HSU Sponsored Programs Foundation or other HSU auxiliaries.

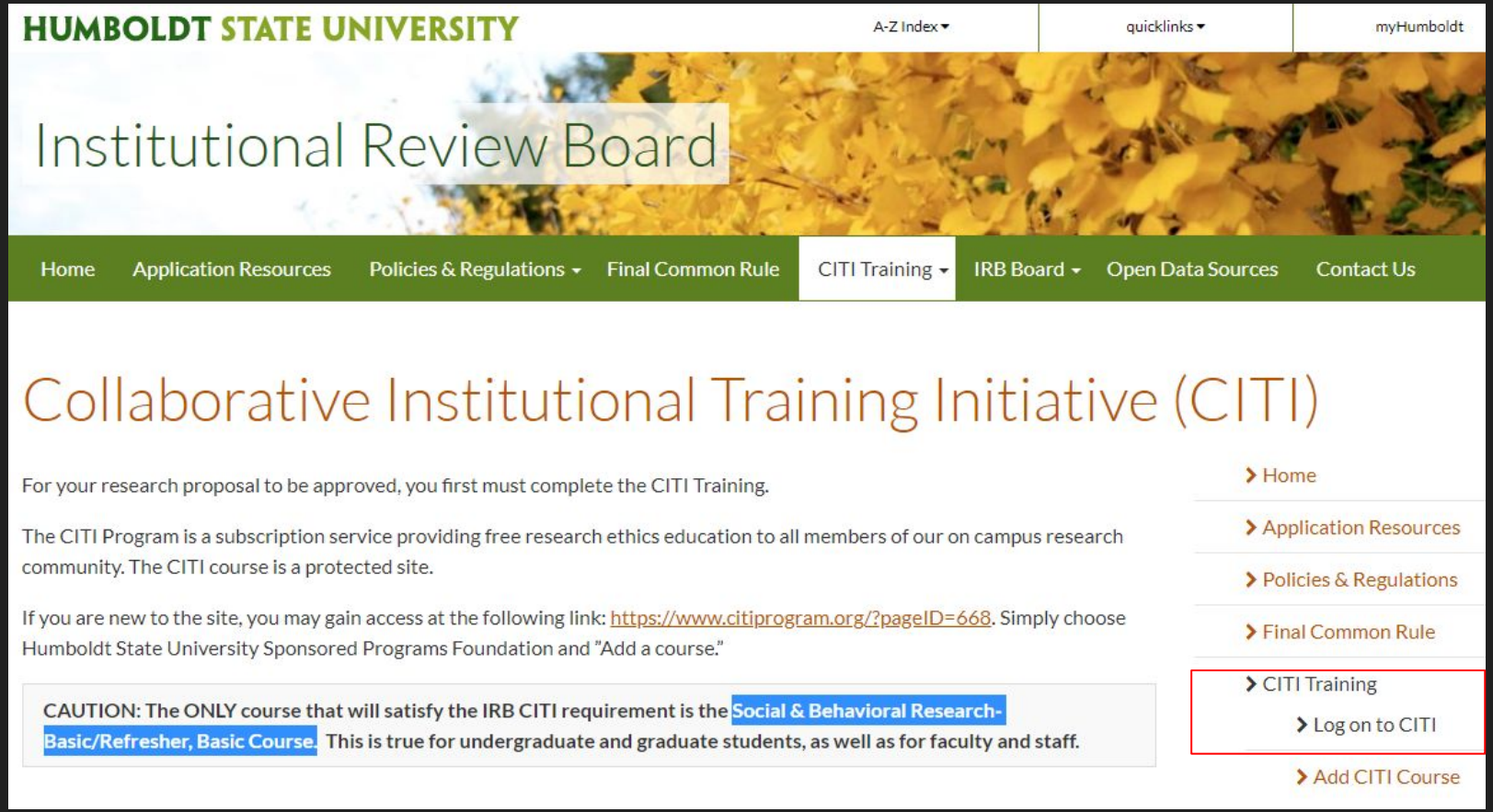
Why the IRB exists & who we are

- Federal law protects specific rights of human research subjects and requires local IRBs to protect those rights
- Laws are based on the Belmont Report principles of Beneficence, Justice, and Respect for Persons
- The IRB at HSU includes staff, faculty, non-scientists, and community members, who review research applications for IRB compliance

What type of research is covered?

Which investigators are covered?

Procedures: IRB CITI training



Complete the required CITI course before writing your application

Certification lasts 3 years

Supplemental online training is available for research involving Native Tribes

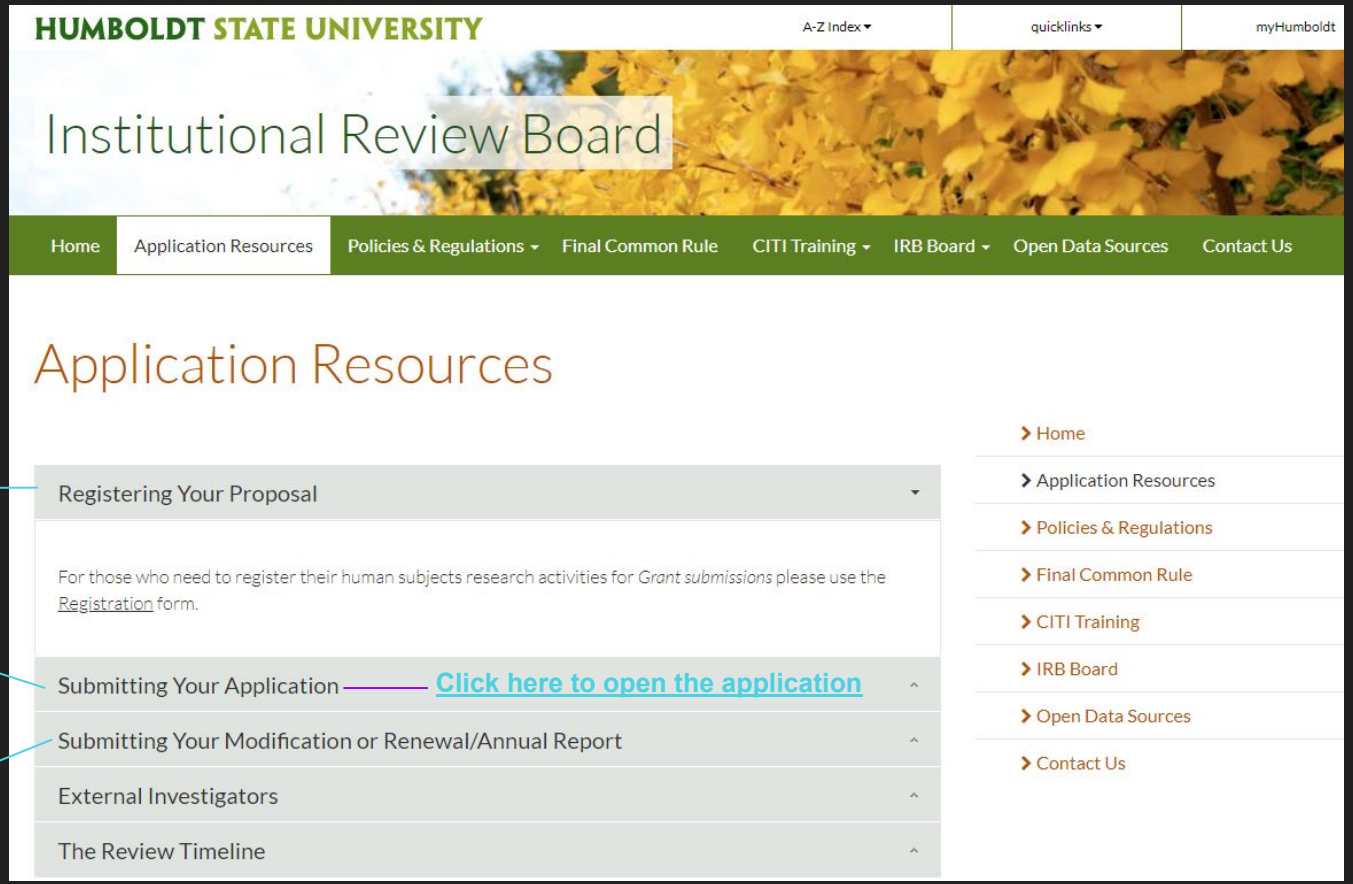
Procedures: Applying for IRB approval

IRB Web Forms

For Grant Submissions

Standard application

Modification and renewal of approved IRBs



Procedures: IRB application web form (link)

Search

Main menu

» IRB Submission Forms
» Required Consent Information
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» IRB Reviewer Help
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» My Registration Forms
» My Applications to Assure
» My Applications, Modifications or Renewals to Review

» Log out

Create Application

Note

Be sure to save your changes before leaving this page or logging out.

Application

Submit this Application for Review, and all following electronic versions of material(s) that will be required to conduct your project by using the "Submit Application" button.

- Recruitment Materials: Posters, flyers, and verbatim text/scripts that will be used to recruit potential participants
- Informed Consent, Parental Permission or Assent Forms
- Surveys, questionnaires, interview questions, measurement instruments, etc.
- CITI Completion report

NOTE: Please Complete all fields under each collapsed heading before Submitting your Application. Incomplete applications will not be reviewed and information you have entered will be lost. To save any information you have entered into the Application, click the "Save Draft" button at the bottom of the Application. Only the "Save Draft" button will save your work. **Don't Forget to Save the Application Before You Log Out! Clicking the "Submit Application" button will begin the IRB review process. Only click the "Submit Application" button if you have completed all sections.** If you are filling out this application, you may want to read the Principal Investigator help page. If you have questions, check the help pages on the left sidebar. If your questions persist, please contact us at: irb@humboldt.edu, or call (707) 826-5165

- Grant Submission Information
- Project Information
- Responsible Faculty or Staff Member
- Student or External Investigator
- Additional Contact Information
- Purpose of Project
- Personnel
- Responsible Faculty or Staff Member Assurances

Section 1
Personnel & Purpose

- Investigators
- Staff / faculty supervisor (required)
- Study purpose

Purpose of Project *

- [ ] Faculty Research
- [ ] Staff Research
- [ ] Graduate Research
- [ ] Undergraduate Research
- [ ] Funded Research

(check all that apply)

Application sections

- 1. Lay Abstract of Proposed Research
- 2. Type of Data to be Collected
- 3. Subjects
- 4. Research Question, Purpose or Hypothesis
- 5. Subject Recruitment and Selection
- 6. Vulnerable Subjects
- 7. Documentation of Consent
- 8. Consent Process
- 9. Methods and procedures involving human subjects
- 10. Benefits
- 11. Potential Risks
- 12. Risk Management Procedures
- 13. Anonymity and Confidentiality
- 14. Data Storage, Security and Destruction
- 15. Informed Consent Storage
- Supplemental Documentation

Section 2
Methods & Subject protections

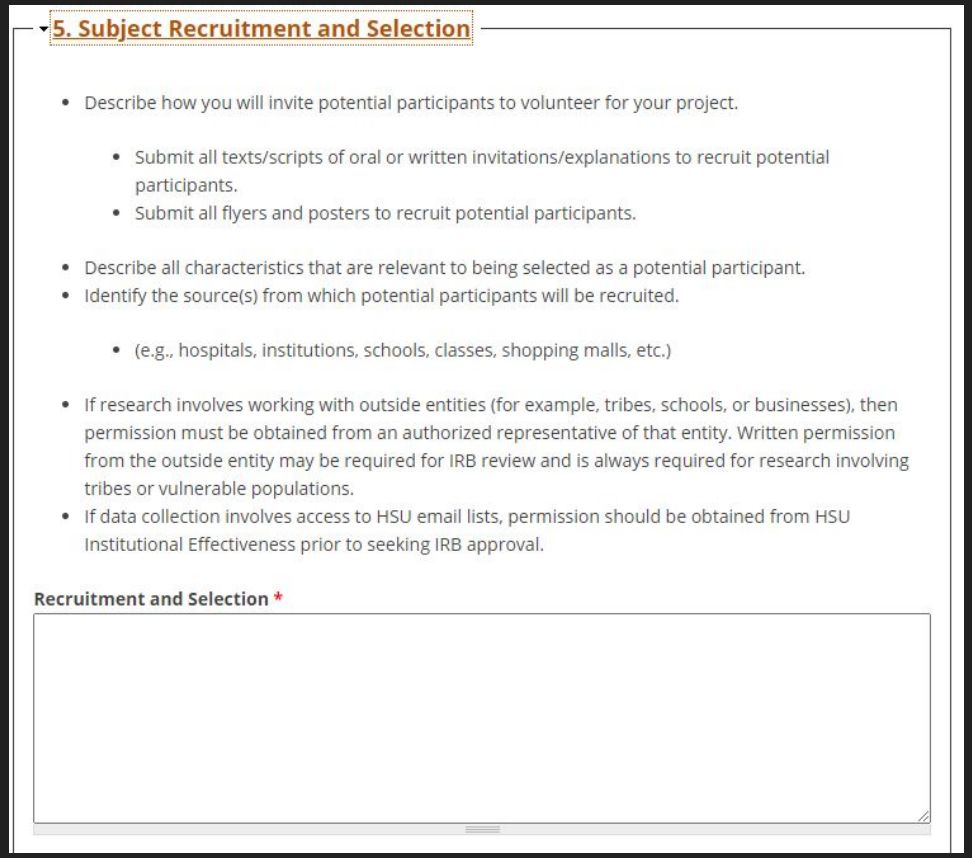
- IRB reviews for required elements of subject protections such as informed consent and data security.
- Basic information about the study rationale is needed for context.

Examples questions

Next page

The application provides guidance for each question.

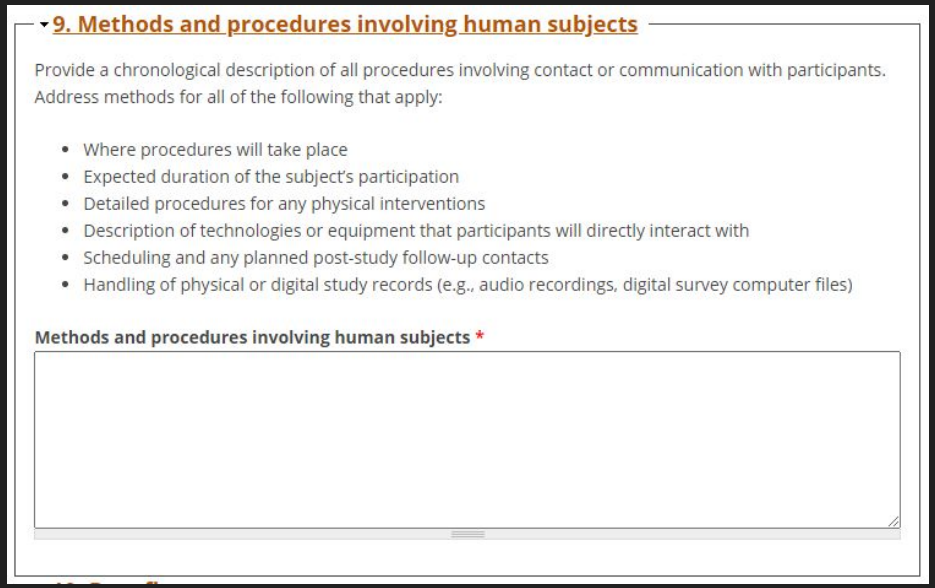
(examples)



5. Subject Recruitment and Selection

- Describe how you will invite potential participants to volunteer for your project.
  - Submit all texts/scripts of oral or written invitations/explanations to recruit potential participants.
  - Submit all flyers and posters to recruit potential participants.
- Describe all characteristics that are relevant to being selected as a potential participant.
- Identify the source(s) from which potential participants will be recruited.
  - (e.g., hospitals, institutions, schools, classes, shopping malls, etc.)
- If research involves working with outside entities (for example, tribes, schools, or businesses), then permission must be obtained from an authorized representative of that entity. Written permission from the outside entity may be required for IRB review and is always required for research involving tribes or vulnerable populations.
- If data collection involves access to HSU email lists, permission should be obtained from HSU Institutional Effectiveness prior to seeking IRB approval.

Recruitment and Selection *



9. Methods and procedures involving human subjects

Provide a chronological description of all procedures involving contact or communication with participants. Address methods for all of the following that apply:

- Where procedures will take place
- Expected duration of the subject's participation
- Detailed procedures for any physical interventions
- Description of technologies or equipment that participants will directly interact with
- Scheduling and any planned post-study follow-up contacts
- Handling of physical or digital study records (e.g., audio recordings, digital survey computer files)

Methods and procedures involving human subjects *

Please address each bullet point

Consent form templates & other resources on the IRB website

Submitting Your Application

The Institutional Review Board (IRB) requires submission of a full protocol for each new study involving human subjects. A protocol includes the application and all other documents.

- Follow the instructions on the Application for the new Drupal submittal process. Email notification will be provided at each step of the process.
- Whenever an informed consent or information sheet is used to provide information to study participants, all relevant information from the IRB Required Consent Information should be included. Please see the second page of the Checklist if your research involves the use of an online survey or questionnaire.
- Below are templates for your use when creating informed consent forms:
  - Regular consent
  - Online consent
  - Anonymous Exempt consent
- Feel free to adapt the language of the Counseling Resources document to meet your specific needs. Please include or remove counseling contacts as appropriate for your specific population of participants.
- If the research involves Protected Health Information (PHI), then Health Insurance Portability and Accountability Act (HIPAA) requirements must be considered. Please see the IRB-HIPAA Privacy Rule Summary for more information.
- If your research involves social media, please see the Guidance on Social Media Research.
- If your research involves children, please see the Research with Children FAQs for direction in obtaining parental consent and child assent.

Templates and detailed guidelines make consent forms easy!

Guidance is provided on using social media or children in research

How long do IRB reviews take?

The Review Timeline

The IRB believes that researchers are entitled to timely review of research proposals:

Proposals submitted during the Academic Year

- The IRB's goal is to contact researchers regarding the status of their application within approximately 10 working days (Green days on the HSU Green & Gold Calendar).
- Due to the work load at certain times, the IRB cannot guarantee any time frame (for example, during holidays).
- Please allow ample time for review, possible modifications and final determination for your proposal prior to your projected start date.

Proposals submitted during the Summer

- Typically, committee members have been willing to volunteer their time over the summer in order for the IRB to continue to review Exempt and Expedited proposals.
- No expectations of review time are associated with proposals submitted during the summer.

For IRB questions or concerns, please email us:

irb@humboldt.edu