**DEPARTMENT OF PUBLIC HEALTH**

**HUMAN SUBJECTS GUIDELINES**

The Committee on the Protection of Human Subjects has developed the following outline to provide guidance on the submission of materials to the subcommittee by faculty and/or students interested in performing research involving human subjects. These are the procedures that must be followed in order to have your proposal successfully approved by the sub-committee.

1. The Human Subjects forms can be obtained from the Department of Public Health:
	1. Human Subjects Committee Application Form for Review – REQUIRED -top half completed and submitted with proposal.
	2. Reviewer Comments Form – REQUIRED - top half completed and submitted with proposal.
	3. Application Form for Unfunded Research – complete and submit as applicable.
	4. Application Form for Funded Research – complete and submit as applicable.
2. Human Subjects Training Certification from the National Institutes of Health – REQUIRED - (<http://phrp.nihtraining.com/users/login.php>) must be on file with the Human Subjects Committee Chair (Dr. Greg Thatcher).
	1. [Students & Faculty] Training must be completed prior to submission and be considered current (within the past three years).
	2. [Faculty only] In order for you to keep track of your certification dates, a regularly updated excel spreadsheet will be created and kept in the Documents Section of Blackboard for the Department of Public Health. It will be your responsibility to maintain current certification. Applications may be delayed if certification is found to be out-of-date.
	3. [Faculty] Unless submitting to update your profile, it is not necessary to submit documentation more than once.

**CALIFORNIA STATE UNIVERSITY, FRESNO**

**DEPARTMENT OF PUBLIC HEALTH**

## Protocol for Outline of Research Study to Human Subjects Subcommittee

Directions: Submit 1 original (with signatures) and 3 copies of a Research Study Outline which is organized according to the following categories. Use the same headings and numbers system that appear below. Maximum submission is five (5) typewritten pages.

A. Abstract: Attach a one paragraph summary of the proposal. Include purpose, problem statement, setting, subject population, and general design.

B. Protocol:

1. Purpose and Background

a. Brief statement of the problem and justification for the study including relevance to Public Health.

b. Brief summary of current research to indicate the state of knowledge pertaining to the study.

 c. Specific aims of the research.

* + - Hypotheses or questions.
		- Data to be collected.
1. Characteristics of Subjects

a. Number

b. Source of subjects and sampling procedures

c. Inclusion and exclusion criteria

d. Rationale for inclusion of special groups, particularly if they are limited in capacity to give informed consent.

1. Methods

a. Location of study

b. Recruitment methods which ensure voluntary participation. If deception is to be used, explain in detail why it is necessary and provisions for subsequent disclosure.

c. Investigational or experimental, procedures involving subjects (i.e., tests, interviews, examinations)

 d. Special procedures (any intrusive or discomforting procedures)

 e. Frequency and duration of each procedure

f. Projected statistical analysis

1. Potential Benefits and Risks to:

a. Individual subjects

b. Population from which subjects are drawn

c. Science, society, humanity

**GUIDELINES FOR SUBMISSION OF THESIS/PROJECT**

**PROPOSAL TO THE HUMAN SUBJECTS COMMITTEE**

**DEPARTMENT OF PUBLIC HEALTH**

**WHY:**

In order to protect human subjects who are part of a research project. Remember the following groups are considered vulnerable and need “special” protection.

“Special Classes of Human Subjects”

Research involving pregnant women and in utero or ex utero fetuses, including nonviable fetuses, must comply with the provisions of section 46.207ff of the federal regulations. (See appendix 5.12 of the CSUF Policy and Procedures for Research with Human Subjects.)

Research involving prisoners must comply with subpart C section 46.301ff of the federal regulations. (See appendix 5.12 of the CSUF Policy and Procedures for Research with Human Subjects.)

Research involving children must comply with subpart D section 46.401ff of the federal regulations. (See appendix 5.12 of the CSUF Policy and Procedures for Research with Human Subjects.)

These guidelines are viewed by the Department of Public Health to include the following categories of individuals in addition to those noted above.

* Mentally ill/retarded
* Aged who are not mentally competent
* Special populations (students, military)
* Poor who are dependent upon certain facilities involved in research for their medical care
* Dying, sedated or unconscious patients
* People with AIDS

**WHEN:**

The thesis proposal should be submitted for approval to the Human Subjects Committee after your thesis chair and two committee members have reviewed and approved the proposal as your final draft. The Human Subjects Committee assumes that approval by this committee is the final step before you begin data collection. Your chances for approval the first time the proposal is submitted are greater if you follow this recommendation. For those developing a project proposal, the need for approval by the Human Subjects Committee will be determined by the project chair. Any project that involves human subjects must be submitted.

**WHO:**

Submit the Thesis Proposal to Dr. Greg Thatcher, chair of the Human Subjects Committee.

**HOW:**

Before submission of your proposal, all sub-committee members must have signed the Committee on Human Subjects Application form (available in Department of Public Health office), submitted with 3 copies of your proposal. Please include a phone number and email address where you can be reached to receive the sub-committee’s decision.

In the proposal, clearly identify how all rights of human subjects will be protected (see accompanying sheet used by the Human Subjects Committee to judge your proposal). A copy of your informed consent must be included in the proposal and placed in the Appendix.

The Chair will contact your Thesis/Project Committee Chair with the committee’s decision as well as follow up with a letter for your files.

If you have any questions about the procedure please contact Dr. Greg Thatcher at 559-278-8807.

**CALIFORNIA STATE UNIVERSITY, FRESNO**

**DEPARTMENT OF PUBLIC HEALTH**

**HUMAN SUBJECTS COMMITTEE**

Please ensure that the following rights of human subjects have been protected in the thesis proposal. If you have any concerns, please note them in the space provided.

1. Protection from harm (assess risk / benefit ratio)

2. Recognition of right of self-determinism (voluntary consent free from coercion)

3. Right to privacy (thoughts, records, etc.)

4. Right to confidentiality or anonymity

5. Right to maintain self-respect and dignity

6. Right to refuse to participate or withdraw at any time

7. Right to services/treatment if involved in research study

**OTHER ISSUES:**

1. Procedures for obtaining informed consent.

2. Information regarding how the researcher can be contacted/right of subjects to request
 research findings

3. Sound methodology supports research question.

The final recommendation includes the following 3 options:

1. Approve as submitted

2. Approve with suggested changes

3. Reject

**CALIFORNIA STATE UNIVERSITY, FRESNO**

**DEPARTMENT OF PUBLIC HEALTH**

**Human Subjects Committee Application Form for Review**

Name Signature Phone

(Thesis Comm. Chair)

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_

Collaborator/Student: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_

Is this a Graduate Thesis? \_\_\_\_\_ Research being submitted to a funding source? \_\_\_\_\_\_\_\_

If yes, give name of agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Submission \_\_\_\_\_\_\_\_\_ Date you intended to begin data collection \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Indicate your judgment as Principal Investigator as to the risk category of the study:

Exempt \_\_\_\_\_\_\_\_\_\_\_ Minimal risk \_\_\_\_\_\_\_\_\_\_\_ At Risk \_\_\_\_\_\_\_\_\_\_\_

To be completed by Chair of Human Subjects Committee

Judgment as to risk category: Exempt: \_\_\_\_\_ Minimal risk: \_\_\_\_\_ At Risk: \_\_\_\_\_

Approval Status: Approved: \_\_\_\_\_ Approved w/ Modifications: \_\_\_\_\_ Disapprove: \_\_\_\_\_

**Modifications (if applicable):**

Forward to the University Human Subjects Committee: Yes / No

If yes, with a recommendation to: Approve: \_\_\_\_\_ Disapprove: \_\_\_\_\_

**Rationale:**

Human Subjects Chair: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**DEPARTMENTAL (UNIT) REVIEW FORM**

**COMMITTEE ON THE PROTECTION OF HUMAN SUBJECTS**

**CALIFORNIA STATE UNIVERSITY, FRESNO**

***Please type***

|  |  |  |  |
| --- | --- | --- | --- |
| PRINCIPAL INVESTIGATOR |  |  |  |
|  | Name | Department | Mail Stop |
|  |  |  |  |
| If student or collaborative research | Telephone Number | Dept. Telephone Number |  |
|  | Name | Affiliation |  |
|  |  |  |  |
|  | Telephone Number | Telephone Number |  |

**TITLE OF STUDY**

If funding is sought, from what agency?

How did the Principal Investigator designate the research? Minimal risk 🞎 At risk 🞎

|  |  |  |  |
| --- | --- | --- | --- |
| REVIEWER 1 |  |  | Place your signature in the category of your judgment |
| NameAt risk 🞎 Minimal Risk 🞎 |  | 🞎 APPROVED |
| COMMENTS: |  |  |  |
|  |  | 🞎 DISAPPROVED |
| REVIEWER 2 |  |  | Place your signature in the category of your judgment |
| NameAt risk 🞎 Minimal Risk 🞎 |  | 🞎 APPROVED |
| COMMENTS: |  |  |  |
|  |  | 🞎 DISAPPROVED |
| REVIEWER 3 |  |  | Place your signature in the category of your judgment |
| NameAt risk 🞎 Minimal Risk 🞎 |  | 🞎 APPROVED |
| COMMENTS: |  |  |  |
|  |  | 🞎 DISAPPROVED |

The department may wish to route this form to the 3 reviewers or send each reviewer a form. If the review is done on three separate forms, the Chair ought to give each reviewer the comments of the other reviewers as well as the Principal Investigator. If all three reviewers judge the proposal as “minimal risk,” the Department Chair notifies the Principal Investigator and keeps the form(s) for 5 years. If funding is sought for this study or it is “at risk,” two (2) copies of the protocol and this form are forwarded to the university CPHS, Thomas Administration, Room 130, M/S TA 54, with one additional copy to the dean’s office. (See sections 3.7 or 3.8.)

**Application Form for Unfunded Research**

**CALIFORNIA STATE UNIVERSITY, FRESNO**

**COMMITTEE ON THE PROTECTION OF HUMAN SUBJECTS**

***Please type***

|  |  |  |  |
| --- | --- | --- | --- |
| PRINCIPAL INVESTIGATOR |       |       |       |
|  | Name | Department (unit) | Mail Stop |
|  |       |       |  |
|  | Telephone Number | Dept. Telephone Number |  |

Student’s name or collaborator(s)
 (if applicable) (if a graduate school thesis, so indicate) (affiliation if collaborative research)

|  |  |  |  |
| --- | --- | --- | --- |
|  |       |       |  |
|  | Telephone Number | Telephone Number |  |

**TITLE**

The Principal Investigator is responsible for fully understanding the **Policy and Procedures**  of the CPHS. Below indicate your judgment as Principal Investigator as to the RISK category of the present study. (See definitions on the reverse of this sheet.) (If exempt see 3.52)

Minimal Risk [ ]

**PROCEDURES**

 1. Attach your protocol and submit to your department chair for review by your human subjects committee.

 2. Your departmental committee will review the protocol status and if it agrees with the determination of “minimal risk” status (see Appendix 5.3), then

 3. Your department chair will keep the forms for 5 years.

 4. Your responsibilities have been satisfied.

 HOWEVER,

(If the departmental review changes the determination to “At Risk,” follow the procedure to the right of this page.)

At Risk [ ]

**PROCEDURES**

1. Attach your protocol and submit to your department chair for review by your human subjects committee. (A sample informed consent must be included.)
2. Submit the department review form(s) with this form to the CPHS.
3. Transmit all reviews and two (2) copies of the protocol to the CPHS for review. Send one additional copy to the Dean.
4. Allow two weeks during the school year for your response from the CPHS.

**Application Form for Funded Research**

**CALIFORNIA STATE UNIVERSITY, FRESNO**

**COMMITTEE ON THE PROTECTION OF HUMAN SUBJECTS**

***Please type***

|  |  |  |  |
| --- | --- | --- | --- |
| PRINCIPAL INVESTIGATOR |       |       |       |
|  | Name | Department (unit) | Mail Stop |
|  |       |       |  |
|  | Telephone Number | Dept. Telephone Number |  |

Student’s name or collaborator(s)
 (if applicable) (if a graduate school thesis, so indicate) (affiliation if collaborative research)

|  |  |  |  |
| --- | --- | --- | --- |
|  |       |       |  |
|  | Telephone Number | Telephone Number |  |

**FUNDING SOURCE**

Is the California State University, Fresno Grants Office forwarding the request for funding? No [ ]  Yes [ ]

**TITLE**

The Principal Investigator is responsible for fully understanding the **Policy and Procedures**  of the CPHS. Below indicate your judgment as Principal Investigator as to the RISK category of the present study. (See definitions on the reverse of this sheet.) (If exempt see 3.52)

Minimal Risk [ ]

**PROCEDURES**

 1. Attach your protocol and submit to your department chair for review by your human subjects committee.

 2. Your departmental committee concurs with the Principal Investigator that the study is “minimal risk” (see Appendix 5.3), then

 3. The department chair should forward the packet of materials with this form and the departmental review forms to the University CPHS, Thomas Administration, Room 130, M/S TA54, for expeditious review and “certification to the funding source.”

 4. The researcher will receive notice of “certification” usually within 72 hours.

 HOWEVER,

(If the departmental review changes the determination to “At Risk,” follow the procedure to the right of this page.)

At Risk [ ]

**PROCEDURES**

1. Attach your protocol and submit to your department chair for review by your human subjects committee. (A sample informed consent must be included.)
2. Submit the department review form(s) with this form to the CPHS.
3. Transmit all reviews and two (2) copies of the protocol to the CPHS for review. Send one additional copy to the Dean.
4. Allow two weeks during the school year for your response from the CPH