

INVESTIGATOR'S STATEMENT OF ASSURANCE

(Attach to each copy of your proposal)

The attached investigation involves the use of human subjects. I understand the University policy concerning the use of human subjects and I agree:

1. To obtain informed consent of subjects who are to participate in this project;
2. To report to the human Subjects in Research Committee any unanticipated effects on subjects which become apparent during the course, or as a result, of experimentation and the actions taken as a result;
3. To cooperate with members of the Committee charged with the continuing review of the project;
4. To obtain prior approval from the Committee before altering or amending the scope of the project or implementing changes in the approved consent form; and
5. To maintain documentation of the consent forms and progress reports are required by institutional policy.

PRINCIPAL INVESTIGATOR'S SIGNATURE

SIGNATURE PAGE

(Attach to each copy of your proposal)

Fill in all the blanks.

- Does the subject group include healthy volunteers? Yes No
- Does the subject group include ill persons? Yes No
- Are subject groups excluded for medical reasons? Yes No
- Are there vulnerable subject groups? Yes No
- If yes, is the exclusion criteria for the study specified? Yes No
- Are any subjects under the age of 18? Yes No
- Are any subjects under the age of 12? Yes No
- Are any subjects over the age of 70? Yes No

Principal Investigator's Name Principal Investigator's Signature Date Department

Principal Investigator's email Mailing address/Mail Code/City, State, Zip Telephone

Student Researcher's Name Department

Student Researcher's Name Department

Student Researcher's Name Department

Student Researcher's Name Department

Department Chair's Name Department Chair's Signature Date Telephone

IRB APPLICATION INSTRUCTIONS

(Please print and keep these instructions with your records)

This document contains all forms required for submission of projects involving human subjects to the Institutional Review Board (IRB).

- Page 1 & 2: Investigator's Statement of Assurance & Signature Page. The completed pages including all appropriate signatures should be submitted with the hard copy version of the application.
- Pages 3 & 4: Application instructions and Checklist. Use these pages to ensure the application is complete.
- Pages 5 – 8: Application. These pages comprise the bulk of the application. Each page has a major heading (A-D) and several subheadings (numbered). Each subheading is followed by a short description of what might or must be included in the application. The Principal Investigator should fill out these pages by removing the short descriptions of what might be included and filling in the information as it pertains to their particular project. If you have prior IRB approval from another institution, you do not need to fill out pages 5-8. Complete pages 1&2 and submit the full application, supporting information and approval notification from the sponsoring institution. (Hard copy submissions will be sufficient-see below).
- All application and renewals must include IRB training certificates from the IRB computer-based training course found on the following web site: <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp> Please include only a copy of your certificate, keeping the original for your records.

Supplemental Information:

All applicants should submit a copy of the information letter or signed consent form that will be distributed to each person in the study.

All applications should submit signed waivers or consent forms from groups or institutions who are sponsoring the project (example: a school board, hospital, etc), if appropriate.

If an applicant is submitting a survey-based project, including a copy of the survey instrument may be required by the IRB. It is in your best interest to submit a copy of the survey instrument with the application.

Submission:

Application along with all appropriate forms should be sent to:

Dr. Theresa S. Kay, Chair of the IRB Committee
1202 University Circle
Weber State University
Ogden, Utah 84408-1202

The IRB requests applicants submit their application in two different format; an electronic file on disk and a **regular paper version**. The electronic version is used to

expedite approval of applications requiring a full IRB review and the hard copy, including signed forms, is maintained on file as an archive.

- Electronic Version: Either attach an application document to an e-mail and send it to tkay@weber.edu or include a diskette containing the document with the complete hard copy. The IRB requests you submit your electronic file either in WordPerfect format (8.0 or smaller) or in Word as a .doc file.
- *****Macintosh Users:** Please submit your application using a PC disk and document format; preferably in WordPerfect. Note: We have had mixed results reading WORD files from Macintosh computers. It is in your best interest to ensure we can read your application.

CHECKLIST FOR YOUR APPLICATION PACKAGE

- Investigator's Statement of Assurance with Signatures (Page 1 of this document)
- Signature Page (Page 2 of this document)
- Completed Application
- Informed Consent Form (if applicable)
- Copy of all surveys, interview questions, and instruments to be used for your project.
- Copies of all advertising (fliers, posters, drafts of classified ads, etc.) for research subjects
- Copy of IRB computer-based training course certificate for all Principal Investigator's, Co-Principal Investigators, and Student Researchers
- Electronic file of application (on diskette or by e-mail)
- Documentation of promised access (e.g. from a school board)(if applicable)

A. APPLICATION FORM

The application form must be filled out completely so committee members may have a clear understanding of the nature and human subject implications of the research proposal. A summary paragraph for each section is sufficient. A statement referring to the attached material **is not sufficient** and will **not** be accepted. Applications submitted with incomplete forms will be returned without consideration of the proposal.

1. TITLE

Give the complete title as it appears on the grant proposal.

2. DESCRIPTION OF THE STUDY

Include the nature of the study and how human subjects will be used and indicate any special procedures.

3. DURATION OF THE STUDY

Estimate the length of time it will take to complete the entire project.

4. MULTICENTER STUDY

Indicate whether this is a multicenter study and give the number of institutions outside of the university which will be participating.

5. NUMBERS OF SUBJECTS

Identify the total number of subjects to be used in every center.

6. HEALTH STATUS OF THE SUBJECTS

Include the information regarding the health of the subjects.

7. SUBJECT GROUPS EXCLUDED

Describe any subject groups excluded from medication reasons or vulnerable subject groups. List the specific exclusion criteria for the study. If more explanation is needed, the committee has further information.

8. AGES OF THE SUBJECTS

Include the information regarding the age of the subjects. Please note that participants under the age of 18 must also have parental consent.

9. DESIGN OF THE STUDY

Include a brief statement about the design that will be used.

10. RISKS TO SUBJECTS

Describe all the risks to which the study may expose the subjects, including those which are considered to be of low probability. If the risks to the subjects are substantial, explain how the risks are justified by the expected benefits. Discuss how possible reactions or side effects will be managed.

ANY MODERATE OR HIGH RISK STUDY MUST GO THROUGH A SEPARATE REVIEW PROCEDURE WHICH INCLUDES THE APPROPRIATE ADMINISTRATIVE OFFICER AND THE UNIVERSITY ATTORNEY.

11. BENEFITS TO SUBJECTS AND OTHERS

Include all remuneration to the subjects including the amount given or prorated for those who do not complete the study. List what specific incentives will be offered.

12. COSTS TO BE BORNE BY SUBJECTS

Specify the charges relating to the study, which can include but not limited to: financial, emotional, time, etc, for which the participant will be responsible.

13. IS CONFIDENTIALITY ASSURED

- A.** State how research subjects will be recruited or selected and how their participation will be solicited in the study. State specifically the procedures used to obtain informed consent from each one. Researchers must obtain and document informed consent from each participant or their representative before they participate in the study. See the section on informed consent.
- B.** Describe explicitly how the security and confidentiality of all information received and the privacy of all subjects will be maintained. Explain how data will be collected and stored in detail.

14. CONTRACT OR GRANT NUMBER

Include the contract or grant number, sponsoring agency, and/or granting agency.

15. NAME OF PRINCIPAL INVESTIGATOR AND DEPARTMENT

Include the names of all the investigators, signatures, mailing addresses, telephone numbers, University Department, and Department Chair's name.

B. DESCRIPTION OF THE STUDY

This should be brief (no longer than two pages) and should include:

1. BACKGROUND INFORMATION

This should include literature review, research design detail, etc, as well as supplemental information from Section A, #2 and #9.

2. EXPERIMENTAL METHODS

This should include the description of the study, population, research design, and interpretation of significant results.

3. DESCRIPTION OF RECRUITMENT PROCEDURES

This should include all advertising methods.

4. MODERATE OR HIGH RISK

If the proposal is deemed moderate or high risk, submit ten copies of the complete proposal as well as any other information appropriate to the review of the study. An electronic copy **must** accompany the proposal in this case.

C. INFORMED CONSENT

The IRB with Human Subject Research Committee in conformance with federal guidelines requires documentation of informed consent. The committee may, for some or all subjects, waive the requirement that the subject or the subject's legally authorized representative sign a written consent form. If the committee finds the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. In cases where the documentation requirement is waived, the committee may require the investigator to provide subjects with a written statement regarding the research.

The entire consent form must be written in the second person and in language totally intelligible to an average person who has no background in science or scientific technology.

BASIC ELEMENTS OF INFORMED CONSENT

In seeking informed consent, the following information shall be provided to each subject:

1. A statement that the study involves research, and explanation of the purposes of the research, the expected duration of the studies expected participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any foreseeable risks or discomforts of the subject.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
4. A disclosure of any alternative procedures or courses of treatment, if any, that might be advantages to the subject.
5. A statement describing the extent, if any, to which confidentiality of records is maintained and that notes the possibility that the food and drug administration may inspect the records, if applicable.
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

ADDITIONAL ELEMENTS OF INFORMED CONSENT

When appropriate one or more of the following elements of information shall be provided to each subject:

1. A statement that the particular procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
2. Anticipated circumstances under which the subjects participation may be terminated by the investigator without regard to the subjects consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of the subjects decision to withdraw from the research and procedure for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of the subjects involved.

Except as previously stated, informed consent shall be documented by the use of a written consent form approved by the committee and signed by the subject or the subjects legally authorized representative. A copy shall be given to the person signing the form.

Except as previously stated, the consent form must be either of the following:

1. A written consent form that embodies the elements of informed consent, This form may be read to the subject or legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.
2. A short form written consent stating that the elements of consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the committee shall approve a written summary of what is to be said to the subject or representative. Only the short form itself is to be signed by the subject or legal representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or representative in addition to a copy of the short form.