

**Whitman College Institutional Review Board
Research Proposal Cover Sheet**

Office Use Only		
IRB approval number:	Date received:	Date approved:

If this proposal is to continue a previously IRB-reviewed study, the original approval date was: _____
(If yes, your proposal will go through expedited review, but you must still complete all forms.)

Title of project:

Name of principal investigator (PI):

Whitman College ___ Faculty ___ Staff ___ Student ___ Other (please describe)

Campus address:

Telephone number:

Email address:

Name of faculty sponsor (if PI is a student):

Department affiliation:

Telephone number of faculty:

Email address of faculty sponsor:

Checklist:

Category of Review

Research Proposal Summary

Potential Risks and Benefits

Background Information

Proposed Methods

Informed Consent Form (or explanation)

Signatures

Whitman College Institutional Review Board
Category of Review

Part A – Questions to determine exemptions

1. Does the research involve as subjects: prisoners, fetuses, minors (under 18 years of age), pregnant women, the seriously ill, or mentally or cognitively compromised adults?

___ Yes ___ No

2. Does the research involve the collection or recording of behavior or information which, if known outside the research, could reasonably place subjects at risk of criminal or civil liability, OR be damaging to the subjects' financial standing, employability, or reputation?

___ Yes ___ No

3. Does the research involve the collection of information regarding sensitive aspects of subjects' behavior (e.g. drug or alcohol use, illegal conduct, sexual behavior)?

___ Yes ___ No

4. Does the research involve deception?

___ Yes ___ No

5. Do the procedures of this research place the subject at any foreseeable risk above what would be expected in everyday activities?

___ Yes ___ No

- **If you answered 'No' to all of the above questions, your research may qualify as exempt from review. Please answer questions 6 and 7, and then proceed to Part B.**
- **If you answered 'Yes' to any of the above questions, please go directly to Part B to determine whether the research requires expedited or full review.**

6. a. Does the proposed research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, where human subjects can be identified, directly or indirectly, through identifiers linked to the subjects?

___ Yes ___ No

- b. Could any disclosure of the human participants' responses reasonably place the participants at risk of criminal or civil liability, or be damaging to the participants' financial standing, employability, or reputation?

___ Yes ___ No

7. a. Does the research involve the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens in such a manner that participants could be identified, directly or indirectly?

Yes No

- b. Could any disclosure of the human participants' responses outside the research place the participants at risk of criminal or civil liability, or be damaging to the participants' financial standing, employability, or reputation?

Yes No

- **If you answered 'No' to questions 6 and 7, your research may qualify as exempt from review. Please complete all remaining forms and submit this application to the IRB. You may not begin data collection until the IRB officially confirms the exempt status of this project.**

Part B – Questions to determine expedited reviews

1. a. Is your research a clinical study of drugs or medical devices?

Drugs: Yes No

Medical Devices: Yes No

- **If 'Yes' (drugs), answer 1.b. If 'Yes' (devices), answer 1.c. and 1.d. If 'No,' move to question 2.**

b. Does the research on drugs require an investigational new drug application?

Yes No

c. Does the research on devices require an investigational device exemption application?

Yes No

d. Has the device already been cleared for marketing and is the device being used in accordance with its cleared/approved labeling?

Yes No

2. a. Does your study require the collection of blood samples (by finger stick, heel stick, ear stick or venipuncture)?

Yes No

- **If 'Yes,' answer 2.b. and 2.c. If 'No,' move to question 3.**

b. Is it the case that: the samples will be from healthy, non-pregnant adults who weigh at least 110 pounds, and the amounts drawn will not exceed 550 ml in an 8 week period, and collection will not occur more frequently than 2 times per week?

Yes No

c. Is it the case that samples will be drawn from compromised (e.g. ill or pregnant) adults, and/or children, and that the amounts drawn will not exceed the lesser of 50 ml or 3 ml per kg body weight in an 8 week period, and that collection will not occur more frequently than 2 times per week?

Yes No

3. a. Does your study require the collection of biological specimens?

Yes No

- **If 'Yes,' answer 3.b. If 'No,' move to question 4.**

b. Is it the case that the collection is by non-invasive means? See IRB Policy (Research Categories #3) for examples.

Yes No

4. a. Does your study involve data from clinical/medical procedures?

Yes No

- **If 'Yes,' answer question 4.b. If 'No,' move to question 5.**

b. Is it the case that the collection of data is through noninvasive procedures (those not involving general anesthesia or sedation) that are routinely employed in clinical practice (excluding x-rays or microwaves)? Note that where medical devices are employed, they must be cleared/approved for marketing. (Studies to evaluate the safety and effectiveness of medical devices are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) See IRB Policy (Research Categories #4) for examples.

Yes No

5. a. Does your study involve material (data, documents, records and specimens) that were previously collected?

Yes No

- **If 'Yes,' answer question 5.b. If 'No,' move to question 6.**

b. Is it the case that those materials were collected solely for non-research purposes (such as medical treatment or diagnosis)?

Yes No

6. a. Does your study involve the collection of data from voice, video, digital, or image recordings?

Yes No

- **If 'Yes,' answer 6.b. If 'No,' move to question 7.**

b. Were those recordings made for research purposes?

Yes No

7. a. Does your study involve individual or group characteristics/behavior?

Yes No

- **If 'Yes,' answer question 7.b. If 'No,' move to question 8.**

b. Does your methodology intervene with the participants or their environment? [The following methodologies generally do not count as interventions or manipulations: surveys, interviews, focus groups, program evaluations, human factors evaluations, or quality assurance methodologies.]

Yes No

8. a. Does your research present more than minimal risk to human participants (above what would be expected in everyday activities)?

Yes No

- **If you answered 'No' to all of the items in Part B, your research may qualify for expedited review.**
- **If you answered 'Yes' to any of the items in Part B, your research may not qualify for expedited review. The IRB committee will determine whether the proposal should receive expedited or full review.**
- **In all cases, please complete all IRB forms and submit them to the Chair of the IRB.**

**Whitman College Institutional Review Board
Research Proposal Summary**

Dates of proposed research:

Estimated number of participants:

Participant profile (check all that apply):

Whitman College students ___

Students at another college ___ (Please specify _____)

Community members ___

Participants will be (check all that apply):

Adults (at least 18 years of age) ___

Minors (under age 18) ___ (Please specify age range _____)

Note that some college students may be under 18 years of age, and if so they must be treated as minors, with parents or guardians signing consent forms; see also the policy on age in international contexts).

Special needs ___ (Please describe under 'special characteristics,' below)

Describe any special characteristics of the participants:

Describe the procedure for recruiting participants:

Describe procedures that will be used to ensure confidentiality of participants.

**Whitman College Institutional Review Board
Summary of Potential Risks and Benefits**

Will participants receive any compensation for participating? Yes No
If yes, describe the compensation.

Will deception be used? Yes No
If yes, describe the nature of the deception and a justification for its use.

Describe any foreseeable risks to participants, and procedures that will be used to minimize those risks.

**Whitman College Institutional Review Board
Research Proposal Background Information**

Describe the background information, including specific aims and hypotheses or research questions. A reference list and copies of pertinent articles can be appended if thought to be of value in the evaluation of the research by the IRB. Attach additional pages as needed.

**Whitman College Institutional Review Board
Research Proposal Materials and Methods**

Provide a detailed description of the research procedure. If applicable, please include a summary of how each variable will be measured, and proposed statistical analyses. Attach additional pages as needed.

**Whitman College Institutional Review Board
Written Consent Document**

If you do not plan to use a consent form, please include an explanation and justification.

The written consent document should be typed on a separate page and then attached to this application. It should be written simply, so that it can be easily understood by the average person. Do not use technical jargon or abbreviations. The following basic elements must be included.

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the participant's involvement in the research, a description of the procedures to be followed, and identification of any procedures that are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the participant.
3. A description of any benefits that may reasonably be expected from the research.
4. A description of how the participant's privacy will be protected. Will the data be kept confidential? Anonymous?
5. A statement that participation is voluntary, that the participant may refuse to participate, and that either the participant or the researchers may discontinue the study at any time with no adverse consequences.
6. A statement advising participants that if they have any questions about the research, or their rights, they may contact you. Your name and telephone number must be included.
7. Signature lines should be included for the participant, the participant's parent or guardian if he/she is a minor or otherwise incompetent, and a line for the date.

**Whitman College Institutional Review Board
Signatures**

I have read and agree to abide by the requirements contained in the statement of principles governing the protections of the rights and welfare of human subjects promulgated by Whitman College.

Researcher signature _____ Date _____

For Faculty Advisers of Student Research

Federal guidelines mandate that research be of sufficient merit to justify the participation of human subjects. The IRB prefers to confer most of the responsibility for determining merit to advisers. Please sign below and check a box to help us evaluate the merit of the student application.

Adviser signature _____ Date _____

I have discussed the proposed research with the student applicant named above and find the research to be of sufficient merit to justify the use of human subjects.

I have discussed the proposed research with the student applicant named above but have made no determination of merit.

I have discussed the proposed research with the student applicant named above and find the research is not of sufficient merit to justify the use of human subjects.