

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

SIHSC Approval number:

Date received:

Date approved:

If the proposal is a continuation of a previously IRB reviewed study, the original approval date was:
(If yes, your proposal will go through expedited review, but you still must complete all forms)

Title of project:

Name of principal investigator:

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 of faculty sponsor:

Telephone number of faculty sponsor:

Email address of faculty sponsor:

Attached:

- 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 subject's 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 'yes' to any of the above questions, your research does not qualify as Exempt from review. Please continue to Part B to determine whether the research qualifies for expedited or full review. If you answered no to all the questions, please continue.

6. 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'T** be identified, directly or indirectly through identifiers linked to the subject, **AND** any disclosure of the human participants' responses outside the research would **NOT** reasonably place the participant at risk of criminal or civil liability, or be damaging to the participants' financial standing, employability or reputation?

Yes No

7. Does the research involve the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens in such a manner that participants **CAN'T** be identified, directly or indirectly **AND** any disclosure of the human participants' responses outside the research would **NOT** reasonably place the participant at risk of criminal or civil liability, or be damaging to the participants' financial standing, employability or reputation?

Yes No

If you answered 'yes' to Questions 6 or 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. If your research is a clinical study of drugs or medical devices, is it the case that a) the research on drugs does not require an investigational new drug application, or b) where the research on devices either does not require an investigational device exemption application or the device has already been cleared for marketing and the device is being used in accordance with its cleared/approved labeling?

Yes No N/A

2. If your study requires the collection of blood samples (by finger stick, heel stick, ear stick, or venipuncture), is it the case that those samples are from a) healthy non-pregnant adults who weigh at least 110 pounds and for these participants, the amounts drawn do not exceed 550 ml in an 8 week period and collection does not occur more frequently than 2 times per week; or b) from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected, where for these participants, the amount drawn do not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection does not occur more frequently than 2 times per week?

Yes No N/A

3. If your study requires the collection of biological specimens for research purposes, is it the case that the collection is by noninvasive means? See IRB Policy (Research Categories #3) for examples.

Yes No N/A

4. If your study involves data from clinical/medical procedures, is it the case that the collection of data is through noninvasive procedures (not involving general anesthesia or sedation) that are routinely employed in clinical practice, excluding procedures involving x-rays or microwaves? Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the 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 N/A

5. If your study involves materials (data, documents, records, and specimens) that were previously collected, is it the case that those materials were collected solely for non-research purposes (such as medical treatment or diagnosis)?

Yes No N/A

6. If your study involves the collection of data from voice, video, digital, or image recordings, were those recordings made for research purposes?

Yes No N/A

7. If your study involves individual or group characteristics/behavior, is it the case that your methodology does NOT intervene or manipulate 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 N/A

8. Does your research present no more than minimal risk to human participants (not above what would be expected in everyday activities)?

Yes No

If you answered 'yes' to any of the items in Part B, your research may qualify for Expedited review. If you answered "Not Applicable" to any of Questions 1-7, your research may qualify for Expedited Review. If you answered 'no' to any of the items in Part B, your research does not qualify for Expedited 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:

Participants will be (check all that apply):

- Whitman College Students
- Students at another college (Please specify)
- Community members (not enrolled in school)

Participants will be (check all that apply):

- Adults (at least 18 years of age)
- Children under 18 years of age (please specify the age range; note that some college students may be under 18 years of age, and that they must be treated as children, with parents signing consent forms; see also the policy on age in international contexts)

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
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 SIHSC. Attach additional pages as needed.

**Whitman College Institutional Review Board
Research Proposal 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 attached to this application. It should be simply written 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, and explanation of the purposes of the research, the expected duration of the subject'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 subject.
3. A description of any benefits that may reasonably be expected from the research.
4. A description of how the subject's privacy will be protected. Will the data be kept anonymous? Confidential?
5. A statement that participation is voluntary, that the subject may refuse to participate, and that either the subject or the researchers may discontinue the study at any time with no adverse consequences.
6. A statement advising subjects 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 subject, the subject's parent or guardian if the subject is under 18 years of age or otherwise incompetent, and a line for the date.

**Whitman College Institutional Review Board
Signatures**

I have read and agreed 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 Advisors 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 advisors. Please sign below and check a box to help us evaluate the merit of the student application.

Adviser signature: _____

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 participants.

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 participants.