

**Finlandia University
Institutional Review Board
Protocol Application Form**

Submit a signed copy of this form, along with supporting material, such as NIH Training certificates and the research proposal, to the IRB Chair. During the academic year, expect Exempt protocols to require one week, and Expedited- and Full-reviewed protocols to require one month, for review. Outside the academic year, contact the IRB Chair (irb@finlandia.edu) for a review timeline.

Submission Date: _____

Study Title: _____

Research Personnel

Principal Investigator (P.I.): _____ **Phone:** _____

Email: _____ **Date of NIH Training:** _____

If the P.I. is a student or someone from outside the University, designate a Finlandia Sponsor/Advisor:

Sponsor/Advisor: _____ **Phone:** _____

Email: _____ **Date of NIH Training:** _____

Co-Investigator (if applicable): _____ **Phone:** _____

Email: _____ **Date of NIH Training:** _____

Additional Personnel (Attach an additional sheet if needed.):

Name	Role	Date of NIH Training

Research Proposal

Attach a brief proposal of the project that explicitly states the purpose, methods, and data collection. Explain how the data will be utilized and published, and how confidentiality of subjects/data will be maintained. Also attach any relevant documents (e.g., informed consent form, survey form, interview protocols, etc.).

Category for Review

Check one level of review (Exempt, Expedited, or Full) for which you believe the project qualifies and check each criterion that applies to your project.

☐ **Exempt from review (minimal risks, or already approved by another IRB)**

- ☐ Research involves ONLY investigation into or comparison of normal instructional strategies.
- ☐ Tests, interviews, and surveys are unlikely to elicit emotion or place subjects at risk of civil/criminal liability or damage to their reputation, financial standing, employability etc. AND information will not be recorded in such a way that subjects can be identified.
- ☐ Research involves only the study or analysis of existing data, documents, records, or specimens that are publicly available or recorded in such a way that subjects cannot be identified.
- ☐ If the study involves ingestion of food: only wholesome food without additives in excess of USDA recommended levels is consumed.
- ☐ Brief informed consent will be done (except in the case of existing data etc).
- ☐ No use of vulnerable subjects will be done (except in the case of existing data, etc.)
- ☐ Has already been approved by IRB at _____
Include a copy of signed IRB approval form.

☐ **Expedited review (minor risk study)**

- ☐ Research and data collection methods are unlikely to elicit strong emotion and deception is not involved.
- ☐ Research involves only noninvasive, painless, and non-disfiguring collection of physical samples, such as hair, sweat, excreta.
- ☐ No use of vulnerable subjects (children, prisoners, pregnant women, mentally ill, disabled, etc.)
- ☐ Data are recorded using noninvasive, painless, and non-disfiguring sensors or equipment, such as EKG, weighing scales, voice/video recording.
- ☐ Research involves only moderate levels of exercise in healthy volunteers.
- ☐ Research does not involve ingestion of drugs or use of hazardous devices.
- ☐ In using existing data, documents, records, or specimens with identifiers, procedures are in place to ensure confidentiality.
- ☐ Informed consent process will be done (attach copy of informed consent form).
- ☐ Data will be kept confidential and not reported in identifiable fashion.

☐ **Full review required (more than minor risk)**

Attach a statement that describe the use of vulnerable participants of the study procedures that and conditions that place subjects at risk. Describe the precautions that will be taken to minimize these risks. Attach a copy of the informed consent form that will be used.

Informed Consent

Indicate if you will collect a signed informed consent form, request a waiver of informed consent, or a waiver of documentation of informed consent. Also, check all criteria for waivers that apply to your research project.

☐ **Signed informed consent forms will be collected.**

☐ **A waiver of informed consent is requested because:**

- ☐ The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and (2) The research could not practicably be carried out without the waiver or alteration.
- ☐ The research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

☐ **A waiver of informed consent documentation is requested because:**

- ☐ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- ☐ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Certification

Principal Investigator: The information I have provided represents a fair estimate of risks to human subjects.

P.I. Signature

Date

IRB Chair: I have read this application and believe that it is:

____ Exempt from IRB Review

____ Appropriate for expedited review, and:

____ Approved

____ Disapproved

____ Appropriate for full review, and:

____ Approved

____ Disapproved

If the proposal is disapproved, the IRB will attach a statement explaining the reasons for not granting approval.

IRB Chair Signature

Date