Human Subjects Research Proposal Form

Western Seminary Institutional Review Board Overview:

In keeping with the mission and values of the school, Western Seminary seeks to safeguard the rights and welfare of persons who agree to be participants in research activities. All persons have the right of self-determination and the rights of persons who are asked to be participants in projects must be protected. These rights include the right not to be harmed, the right to self-determination, the right to privacy, the right to obtain and maintain services, the right to maintain self-respect and dignity, the right to have confidential material remain confidential and the right to withdraw or refuse to participate without recrimination. Informed consent is necessary to protect persons engaged as participants in a research endeavor.

Research is broadly defined by the Seminary and includes any activity that involves the gathering of data from human participants in any form other than standard accepted education classroom practices. Examples requiring Institutional Review Board (IRB) approval include, but are not limited to, the following: non-exempt questionnaires or surveys, interviews, observations, documents, bodily samples, specimens, procedures involving bodily manipulations, procedures involving experimental intervention, research involving minors, and research involving individuals unable for any reason to give informed consent. The use of human participants is a privilege granted to the investigator rather than a right. It is the responsibility of the Institutional Review Board (IRB) to assure that the research meets minimal criteria established by Federal law and Federal regulations 45CFR 46, revised January 21, 2019.

Certain categories of use of human participants may apply for, and receive, a general approval that would cover repeated data gathering which follow the same guidelines as approved. For example, a class assignment involving the use of human participants which an instructor uses each time the course is taught may request a "standing" or "repeated use" approval for that particular class assignment as long as the same guidelines are followed as approved by the Institutional Review Board (IRB). However, if the instructor of the course changes or if changes are made in the class assignment, the instructor must reapply for approval of the use of human participants. Individual student research projects for class requirements are NOT eligible for approval under this category.

Individual student research projects MUST submit an application for Institutional Review Board (IRB) review and approval. Program or service areas that will make repeated use of the same data collection techniques may also apply for approval one time only for all subsequent data-gathering efforts as long as the guidelines outlined in the application are followed. Any changes in the procedures would require a new application for approval.

**All research involving human participants at Western Seminary or under the Seminary's auspices must be reviewed and approved by the Institutional Review Board (IRB) of Western Seminary.**

I have read the policy described above:

I Agree

I Disagree

1. Date NIH training was completed\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Please attached NIH certificate to the application documents)

1. Name of Applicant or Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Address of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Email of Principal Investigator : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Phone number of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. Protocol Title : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. Name of Dissertation Chair / Faculty Adviser: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
7. Department/degree program with which you are associated (Include school affiliation if you are from another school): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
8. Anticipated Protocol Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
9. Expected Protocol End Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
10. Objectives

* Describe the purpose, specific aims, or objectives of the Human Research.
* State the research question or hypotheses to be tested.
* Describe your plans for data dissemination and usage (Who will have access to the data and how will the data be used.)

1. Resources available to conduct the Research:

* Demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.
* Describe/estimate the time that you will devote to conducting and completing the research within the agreed time period.
* Indicate the number and qualifications of your staff, their experience in conducting research, their knowledge of the local study sites, culture, and society.
* Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the investigatory product(s), and their research-related duties and functions.
* Describe the facilities in which your research will be conducted.
* Where applicable, describe the availability of medical or psychological resources that participants might need as a consequence of the Human Research.

| **Does the research involve any of the following?** | **YES** | **NO** |
| --- | --- | --- |
| 1. Access to subjects through a cooperating institution or agency? Please note: that a letter of cooperation from the agency must be provided to the IRB team |  |  |
| 1. Payment of subjects for participation? |  |  |
| 1. Participants who could be judged to have limited freedom of consent (e.g., minors, developmentally delayed persons, or institutionalized)? A consent form signed by a parent or guardian is required if you answer “yes” to this question. |  |  |
| 1. Any procedures that might place the subject(s) at risk (psychological, physical, social, or economical)? A signed consent form is required if you answer “yes” to this question. |  |  |
| 1. Substances taken internally by or applied externally to the subjects? A signed consent form is required if you answer “yes” to this question. |  |  |
| 1. Fluids (e.g., blood, saliva) or tissue removed from subjects? A signed consent form is required if you answer “yes” to this question. |  |  |
| 1. Deceiving subjects about the purpose of the research? |  |  |

1. If you indicated “Yes” to any of the above, please provide an explanation.
2. Informed Consent Form: Please upload your "Informed Consent" forms in all the languages you will use. Please describe the process(es) of obtaining informed consent.

* Where will the consent process take place?
* Any waiting period available between informing prospective subjects and obtaining consent?
* Any process to ensure ongoing consent?
* Indicate what language(s) other than English are understood by prospective participants or representatives.
* Describe any processes involved if participants do not speak English

1. Setting of the Human Research

Describe the setting and location in which the Human Research will be conducted.

If applicable, describe:

* Site-specific regulations or customs affecting the research.
* Whether you have secured permission to use the site from the appropriate administrator, agency, company, organization or related advisory board

Please have the site complete a site authorization and upload it with your other documents.

1. Study Design. Describe the following where applicable:

* Recruitment methods - Inclusion and exclusion criteria (how will you screen for eligibility?) Describe and explain the study design
* Describe all instruments, i.e.,, surveys, questionnaires, interview guides, etc (Upload a copy of each document as part of the IRB application)
* Describe what data will be collected, including long-term follow-up
* What data management will you use? (How do you intend to keep the information gathered?)
* Withdrawal of participants (describe any procedures for orderly termination, as well as partial withdrawal from procedures with continued data collection)

1. Risk to participants (describe any potential risks, discomforts or inconveniences to participants, as well as resources put in place to reduce or eradicate the risk.
2. Potential direct benefits to participants (What direct benefits will participants experience Indicate if there is no direct benefit.)
3. Privacy and confidentiality of participants (what steps will be taken to protect interests and information of participants, if applicable)
4. When, and to what group(s) will the results of the data be reported?
5. 29.Form Submission Confirmation By submitting this application, you are certifying that you have read, understand, and will comply with the policies and procedures of Western Seminary and the NIH regarding human subjects in research (<http://phrp.nihtraining.com/users/login.php>). You are agreeing that you will notify and receive approval from the Institutional Review Board (IRB) at Western Seminary before making any changes to the project already described in this request. Finally, you are also certifying that all information submitted is accurate.

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Name/Signature Date:

If you have questions, please contact Dr. Karen Hedinger (IRB Committee chair) [khedinger@westernseminary.edu](mailto:khedinger@westernseminary.edu)