UL-PIRE IRB Submission Form

Name of Project *(Use title submitted to funding source)*		
Principal Investigators (PIs)		E-Mail:
		Phone:
Affiliation		
Address		
Name of person presenting to IRB, if other than PI		E-Mail:
		Phone:
Date of Submission		
Project Code #		Grant #:

Funding Type	☐ Grant ☐ Contract ☐ Subcontract ☐ Other: Pilot study to obtain data for a proposed future R01 grant application	Funding Agency:

Is there an IRB Authorization Agreement in place for this project? ☐ Yes ☐ No
If yes, indicate name of organization:

Type of Review Requested	Initial	☐ Full Submission—all planned research activities are being presented for review ☐ Partial Submission—only some research activities are being presented for review at this time
	Exemption	☐ Exemption of full study is being requested
	Regular Renewal	☐ All research activities are being reviewed (typically annually)
	Interim Modification	☐ Only some research activities are being reviewed at this time (i.e. a modification is being made to something already approved or a new component is being added)
	Final	☐ Study has ended (no more subject enrollment, no intervention, no data collection, and remaining data are either de-identified or maintained with safeguards)

Does this submission request a waiver of informed consent? ☐ Yes ☐ No
☐ Check here if a waiver of informed consent was granted in an earlier submission

Does this protocol involve a clinical trial? *(A prospective study to test the effect of a biomedical or behavioral intervention in human subjects.)* ☐ Yes ☐ No
If yes, what phase? ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV
Has the funding Institute required a DSM plan? ☐ Yes ☐ No
If yes, is a Data and Safety Monitoring Plan attached? ☐ Yes ☐ No

1. Summary—*Give a brief summary (such as the proposal abstract) of the nature of the proposed research and summary of data collection activities. If this project is a collaborative, please indicate collaborators and clarify their role in the project.*

2. Review of Project Activities since Last Regular Renewal Review—*Do NOT complete this section if this is an INITIAL submission. Include the following (for multi-component projects, describe each component separately): a brief description of project activities to date, the number of subjects enrolled, relevant information regarding risks associated with the research, and description of Interim Modification Reviews since the last Regular Renewal Review.*

3. Proposed Changes in Human Subjects Protocols—*Do NOT complete this section if this is an INITIAL submission. Describe any changes and complete Sections 5-9 if new components are being added. If current instruments or consent forms are being revised, attach them with changes clearly indicated.*

4. Description of Any Incidents Involving Human Subjects—*Do NOT complete this section if this is an INITIAL submission. Provide a summary of: any human subjects incidents and/or unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, and complaints about the research since the last IRB review. Alternately, indicate if no incidents have occurred.*

5. Subjects—*Complete this section for INITIAL submissions and as needed for other submissions. Describe the proposed human subjects including: the number to be recruited and their characteristics, how they will be contacted and selected for participation, the local research context, and whether any proposed subjects are members of a vulnerable population (i.e. fetuses, pregnant women, human in vitro fertilization, prisoners, or children).*

Subjects:

Local (In-country) Research Context.

6. Procedures—*Complete this section for INITIAL submissions and as needed for other submissions. Explain how human subjects will be involved, exactly what will be expected of them, the procedures for obtaining informed consent, and how data will be collected and maintained. If requesting a waiver concerning informed consent, complete Section 11.*

Survey

Data Collection Methodology

Data Analysis

7. Risks—*Complete this section for INITIAL submissions and as needed for other submissions. Describe foreseeable physical, psychological, or social risks or discomforts to the subjects.*

Potential Risks.

8. Safeguards—*Complete this section for INITIAL submissions and as needed for other submissions. Explain procedures to be used to minimize each of the potential risks listed in Section 7. Describe procedures for: protecting the participants' privacy; maintaining confidentiality of the data; and monitoring staff compliance to IRB-approved protocol.*

9. Benefits—*Complete this section for INITIAL submissions and as needed for other submissions. Describe benefits to be derived from the proposed research for the human subjects and/or for society.*

10. Request for Exemption—*Refer to 45 CFR 46.101 (b) and indicate the paragraph citation (1-6) that applies to either the full project or specific component(s). Provide specific justification based on project design. Include appendix materials (surveys, interview protocols, focus group guides, recruitment flyers, etc.) related to this study.*

☐ Exemption of Full Project—45 CFR 46.101 (b)(_____)

☐ Exemption of only some project component(s). *List components for which exemptions are being requested, providing exemption citation for each component.*

11. Request for Consent Waiver— *If a waiver of consent is requested, document the appropriate requirements:*

☐ Waiver of Informed Consent—45 CFR 46.116(d)—*address 1 through 4*
(1) 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.

☐ Waiver of ***Documentation*** of Informed Consent—45 CFR 46.117(c)—*address 1 or 2*
(1) 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
(2) 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.

12. Disposition of Project—*Complete this section for Final IRB Review only. For IRB purposes, the project has ended when there is no more subject enrollment, no intervention, no data collection, and remaining data are either de-identified or maintained with safeguards. Describe here the disposition of the project and its data and provide a brief summary of findings.*

13. List of Attachments—*Provide a <u>numbered</u> list of documents attached to this submission (i.e. questionnaires, surveys, interview schedules, recruitment and interview scripts, and recruitment materials). Include the attachment number as part of the electronic file name and on each document.* ***For Initial Review, OHRP requires that the original proposal (Face Sheet, Abstract, and Research Section including the Human Subjects Section) is included for review. Please attach as an appendix****. For Regular Renewal or Interim Modification Reviews, attach current consent document(s) and include instruments ONLY if changes are being proposed.*

Appendix 1: Letter of Application
Appendix 2: Copy of Proposal
Appendix 3: Informed Consent and/or Assent Form
Appendix 4: Sample Questions Survey.
Appendix 5: CVs of Investigators
Appendix 6: Protocol budget
Appendix 7: Copy of IRB Approval from an Institutional Review Board (IRB), if available