University of Lynchburg

Institutional Review Board (IRB) for Human Subjects Research

Minimal Risk Research Protocol Proposal Form

This protocol proposal form is for ***minimal risk research*** (inherently minimal risk or risk that has been sufficiently minimized). **Once the document is complete, please share the file with the IRB director, Dr. Alisha Walker Marciano. If a student is completing the protocol proposal, the faculty/staff mentor must share it with the IRB director. No proposals will be accepted from students.** Undergraduate students are not permitted to serve as Principal Investigator (PI) for a research study and must have a faculty/staff mentor as the study PI; graduate students may serve as Co-Principal Investigator (Co-PI) along with a faculty/staff member. Members of the research team are not permitted to recruit or begin data collection until approval has been provided by the Director of the IRB. Incomplete or improperly completed/submitted protocol proposals will experience a delay in the review process.

Proposal Checklist (PRIOR TO SUBMITTING, PLEASE SELECT EACH BOX TO INDICATE COMPLETION; click on box twice to highlight, then right click to add a check):

- ☐ Proposal is filled out completely (thorough responses to ALL questions).
- ☐ NIH Ethics Certificate included at the end of the document for EACH research team member.
- ☐ Data collection instrument(s) or comparable item(s). Include a copy (not an external link) of all materials at the end of the proposal.
- ☐ Invitation to participate in study (e.g. email, oral script, etc.), if applicable. Please include this at the end of the proposal.
- ☐ At least one of the following (include full consent form (not an external link) at the end of the proposal). **Check the box next to the appropriate consent for your study**:
  - ☐ Informed Consent Form (for participants over the age of 18 years old)
  - ☐ Informed Assent Form (for participants under the age of 18 years old) and Informed Parental Consent Form
  - ☐ Description of verbal consent
  - ☐ Explanation of waiver of consent
- ☐ Additional support materials (add as many appendices as necessary at the end of the document- **no external links to materials**, please).
- ☐ Administration Permission Form if research is being conducted at another organization (educational setting, business, etc.) or a signed letter from an organization leader from each data collection site stating data collection is permissible.

Section One: Basic information about the research study and research team

What is the name of the person completing this protocol proposal? <<name>>

Title of the Research Study: <<title>>

Per the Lynchburg IRB Ethical Research Practices Policy, all members of the research team must complete the online NIH ethics training. Please do not submit this protocol without confirmation of this requirement. *(Please note: NIH ethics certificates for ALL research team members listed in this protocol proposal MUST be included at the end of this document).* For questions about this requirement or to request a potential substitution or waiver, please contact the IRB at irb-hs@lynchburg.edu.

Principal Investigator (PI) or Co-Principal Investigators (Co-PIs): <<pi>>

PI Department or Office (list for Co-PIs, if applicable): <<pidept>>

PI Email Address (list for Co-PIs, if applicable): <<piemail>>

Additional research team members and their roles:

Name of researcher and Role of researcher

<<name research 1>> <<role research 1>> <<affiliation 1>> <<student researcher1>>

<<name research 2>> <<role research 2>> <<affiliation 2>> <<student researcher2>>

<<name research 3>> <<role research 3>> <<affiliation 3>> <<student researcher3>>

<<name research 4>> <<role research 4>> <<affiliation 4>> <<student researcher4>>

Is this an undergraduate student research project?

<<ungrad>>

Is this a graduate student research project?

<<grad>>

Research category/categories selected (by number) for project:

<<category1>>

<<category2>>

<<category3>>

<<category4>>

<<category5>>

<<category6>>

<<category7>>

<<category8>>

<<category9>>

<<category10>>

<<category11>>

<<category12>>

<<category13>>

Explanation of how project fits with research category selected:

<<explanation>>

Section Two: Background information on the proposed research study

Please respond to all items below. Researchers are encouraged to provide as much detail as they would provide in describing to a faculty member or other academic professional who is not in their discipline/profession. The reviewer may not necessarily be familiar with technical jargon, acronyms, or devices.

1. **Purpose**. Provide a description of the purpose of your study, including the rationale/background for the study. What are the goals and hypotheses of the research? This statement should describe the variables being studied and explain why this topic is important to study.

Please insert response here in red text.

2. **Participants**. Briefly describe the study population (e.g., college students, adults, etc.) and specify the maximum number of participants in your study. Include inclusion and/or exclusion criteria (e.g., age restrictions, health restrictions, etc). Describe any circumstances under which a participant's participation may be ended by the researcher.

Please insert response here in red text.

3. **Recruitment**. Recruitment is the responsibility of the PI and research team. Explain how you will recruit participants (who will be recruited, how will they be recruited, how they sign up, etc.). If procedures include recruitment via email, specify who will send the recruitment email and to whom it will be sent. Include a copy of the recruitment email at the end of this proposal.

Please insert response here in red text.

4. **Procedure**. Describe the research methodology and study design (step-by-step details of what will happen to participants in this study), including expected duration (time in a single session, number of sessions, etc.) of participation. Be specific about your procedures for data collection (including whether online or in-person) and describe the data collection materials. Include a copy of all materials (not an external link) at the end of this proposal.

Please insert response here in red text.

5. **Compensation/Remuneration.** Describe whether participants will receive any compensation or remuneration (e.g., $$, gift certificates) or token gifts (e.g. candy, stickers), and how they will obtain the compensation. [Note: If participants are paid, the Business Office will require personal information for participants for tax purposes. Details regarding compensation and release of personal information must be included in the consent form.]

Please insert response here in red text.

6. **Vulnerable populations**. Describe whether your study will involve vulnerable populations such as individuals under the age of 18, prisoners, or cognitively, economically, or educationally disadvantaged participants; and describe safeguards planned to protect the welfare of this population.

Please insert response here in red text.

7. **Minors**. If participants will be minors (under the age of 18) describe the process of obtaining parental/guardian consent and child assent. Include a copy of parental consent form and assent form (not an external link) at the end of the proposal.

Please insert response here in red text.

8. **Consent**. Explain the process (how, when, where) of how consent will be obtained and specify what will be included in the consent form (or verbal consent, when applicable). Explain how you will ensure participants will not feel coerced to participate. If requesting a waiver of documentation of consent, provide a reason for why obtaining signed consent is not appropriate. Include a copy of the consent form (not an external link) at the end of the proposal.

Please insert response here in red text.

9. **Data Safety**. Describe the data storage and protection plan (federal guidelines state that data be kept for at least three years). Explain specifically where data will be stored (hard copies and/or electronic) and how it will be protected. Describe how the researchers will maintain the confidentiality of participants' responses.

Please insert response here in red text.

10. **Risks and Benefits**. Describe any foreseeable risks and/or discomforts to the participants and explain how these risks will be minimized (e.g. referral to professional, removal from study, etc.). Describe potential direct and indirect benefits of the study (how participants, society, science, etc. will potentially benefit from the findings). These risks and benefits should also be described in the consent form.

Please insert response here in red text.

11. **Ethics Certificates.** Please insert an NIH ethics certificate for ALL research team members here. If any research team member does not have an NIH ethics certificate below, the protocol proposal will be returned to the PI and will need to be resubmitted once all certificates have been added.

Please insert all additional documentation below (include text/images, not external links to documents because reviewers have had difficulty accessing information via external links which delays the review process). If the documentation requested does not apply to your study, please type "not applicable" in the space provided.

Insert Recruitment Email/Oral Script (include text, not links to documents):

Insert Data Collection Materials (include text, not links to documents):

Insert Consent Document(s) (include text, not links to documents):

Insert Other Documentation as needed (e.g. recruitment flyer, equipment, etc.):