***University of Lynchburg Reviewer Guidelines for New IRB Proposals***

***These guidelines contain HHS basic human subjects protections requirements***

Title of Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PI(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewer(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **1. PURPOSE** | **Yes** | **No** | **Needs**  **Work** |
| Are the aims and underlying hypotheses of the research stated clearly? |  |  |  |
| Are variables clearly stated/described? |  |  |  |
| Is there an adequate explanation of the rationale for the research? |  |  |  |
| **2. PARTICIPANTS** |  |  |  |
| Does the nature of the research justify using the proposed participant population? |  |  |  |
| Are the criteria for inclusion/exclusion clearly presented and reasonable? |  |  |  |
| Is maximum number of participants included, and reasonable? |  |  |  |
| Is the description of potential circumstances that would lead to ending a participant’s participation included and sufficient? |  |  |  |
| **3. RECRUITMENT** |  |  |  |
| Is recruitment process described in sufficient detail (who, how, etc.)? |  |  |  |
| Is recruitment process reasonable and acceptable? |  |  |  |
| Is a copy of recruitment email/letter included, when appropriate? |  |  |  |
| **4. PROCEDURE** |  |  |  |
| Is there sufficient detail in the description of the data collection process? |  |  |  |
| Have the data collection instruments (questionnaires, interview tools, etc.) been provided? |  |  |  |
|  | **Yes** | **No** | **Needs**  **Work** |
| Are the proposed data collection instruments acceptable for use in the study? |  |  |  |
| Is specific information about duration included and reasonable? |  |  |  |
| Is it clear where data collection will take place (in person, online, specific room, etc.)? |  |  |  |
| **5. COMPENSATION/REMUNERATION (if no compensation offered, write N/A)** |  |  |  |
| Are the incentives offered reasonable, based upon the complexities and inconveniences of the study and the participant population? |  |  |  |
| Is information included about notifying the Business Office of personal information for those being compensated? |  |  |  |
| **6. VULNERABLE POPULATIONS (if no vulnerable populations included, write N/A)** |  |  |  |
| Has there been appropriate consideration of any special physiological, psychological, or social characteristics of the participant group that would pose special risks? |  |  |  |
| Are some or all of the subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, and cognitively, economically, or educationally disadvantaged persons? |  |  |  |
| If there is a special population (children, prisoners, pregnant women, etc.), has the appropriate justification been provided? |  |  |  |
| Have additional safeguards been included in the study to protect the rights and welfare of vulnerable participants? |  |  |  |
| **7. MINORS (if no minors included, write N/A)** |  |  |  |
| Is the process of obtaining consent from the parent/guardian described sufficiently and is it a reasonable process? |  |  |  |
| Is a copy of the parental consent form included and sufficient? |  |  |  |
| Is a copy of the assent form included and is it developmentally appropriate? |  |  |  |
|  | **Yes** | **No** | **Needs**  **Work** |
| **8. CONSENT PROCESS AND CONTENT** |  |  |  |
| Is a copy of the consent form and/or oral presentation of consent provided, using the standard University of Lynchburg consent form? |  |  |  |
| Are the timing of and setting for the explanation of the research and obtaining informed consent conducive to good decision making? |  |  |  |
| Will the circumstances of the consent process minimize the possibility of coercion or undue influence? |  |  |  |
| Is the language and presentation of the information conveyed about the study appropriate to the participant population? |  |  |  |
| Do the proposed explanations of the research provide an accurate assessment of its risks and anticipated benefits? Is the possibility (or improbability) of direct benefit to the subjects fairly and clearly described? |  |  |  |
| Does the consent form sufficiently describe: 1) the purpose of the research, 2) duration of participation, and 3) procedures to be followed? |  |  |  |
| Does the consent form include a statement clearly describing the extent to which confidentiality of records identifying the participant will be maintained? |  |  |  |
| Does the consent form include a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and that the participant may withdraw anytime? |  |  |  |
| Does the consent form adequately explain whom to contact for answers to questions about the research and rights of the participant? |  |  |  |
| **9. DATA SAFETY** |  |  |  |
| Is it clear where the data will be stored and who will have access? |  |  |  |
| Is the plan sufficient for protecting the data (ie maintains confidentiality of participant information)? |  |  |  |
| If this is a student project, is it clear how PI affiliated with Lynchburg would have access to the data for the required minimum of 3 years? |  |  |  |
|  | **Yes** | **No** | **Needs**  **Work** |
| **10. RISKS AND BENEFITS** |  |  |  |
| Are the risks (physical, psychological, legal, economic, and social) to participants minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk? |  |  |  |
| Are the risks to subjects reasonable in relation to anticipated benefits? |  |  |  |
| Are potential benefits (direct and indirect) described and reasonable? |  |  |  |
| Are both risks and anticipated benefits accurately identified, evaluated, and described? |  |  |  |
| Do the risks and benefits described here match the risks and benefits described in the consent form? |  |  |  |
| **11. ADDITIONAL CONSIDERATIONS** |  |  |  |
| Are all items completed in the proposal form? |  |  |  |
| Is the appropriate regulatory category (or categories) selected? |  |  |  |
| Are all additional materials in a readable format which allows for review? |  |  |  |
| Are NIH certificates for all research team members included? |  |  |  |

**COMMENTS/CONCERNS:**