# Principal Investigator Research Proposal Checklist

| Proposal Contents | | |
|---|---|---|
| Your proposal (Chapter I - Introduction) to the IRB should include the following information. Please indicate what page the below information can be found in your proposal. | | **Page #** |
| A. | **A review of the relevant literature.** | |
| B. | **Research Question or Hypothesis**: List the primary research questions, hypotheses, and / or objectives guiding this study. | |
| C. | **Research Study:** experimental or research design which will answer the research question hypothesis. Provide a step-by-step description of study procedures, including what data will be collected, when, where, and how. List all research locations (attach site permission letters as needed). | |
| D. | **Explanation of the method used for determining the sample size.** Provide the number of subjects (not a range), you intend to enroll over the course of the study**.** | |
| E. | **Explanation of how the data will be used** to answer the research question or hypothesis**.** | |
| F. | **Research Benefits:** List of any direct benefits to be gained from the research and/or to participants from their involvement in the study**.** | |
| G. | **Anticipated Risks:** A statement of anticipated risks to the physical and mental health, comfort and privacy of experimental subjects. | |
| H. | **Strategies to Minimize Risks:** Statement describing the measures that will be implemented to reduce or mitigate potential risks. | |
| I. | **Privacy/Confidentiality:** A description of the measures that will be taken to minimize risks and to ensure confidentiality of sensitive personal data during and after the research**.** | |
| J. | **Data Security:** Data Security for each phase of data's life cycle, including collection, transmission, accessing, collaboration, storage, analysis, reporting, and disposition. Who will be responsible for storage and disposition? **Record Retention Period:** 3 years after the closure of the protocol. | |
| K. | **Explicit information about the recruiting, selection and compensation of subjects.**<br>**Recruitment:** Explain how participants will be identified and contacted, who provides access to contact information, and include permission letters/emails if needed. List all recruitment sources.<br>**Materials:** Provide exact wording of recruitment materials (letters, emails, flyers, phone scripts, social media posts, etc.) and attach copies.<br>**Compensation:** Describe compensation (e.g., cash, gift cards, course credit, raffle prizes), including type, timing, method of distribution, and confidentiality protections. | |
| L. | **Finalized versions of the following documents as applicable to your study:** Surveys / Questionnaires / Psychological & educational tests, Demographics surveys, Focus group instructions/questions, Observation data collection sheets, Educational materials**.** | |
| M. | **Informed Consent & Assent**: Describe the informed consent process, including when, where, and how subjects will be consented. Finalized copy of consent form to be signed by each subject before participation**.** | |
| N. | **Funding:** A statement of whether federal monies will be used in connection with the proposed project. Indicate existing, potential, or pending sources of funding **Costs:** List any participant costs or expenses associated with study participation. | |
| O. | **Population(s):** Describe the target population(s) of the study, for example: TCCD students, competent or healthy adults, vulnerable populations: children (Under 18), prisoners (Individuals involuntarily detained), pregnant women*.<br>**Inclusion Criteria:** List all criteria for including subjects and explain the methods you will use to determine whether a subject is eligible based on your criteria.<br>**Exclusion Criteria:** Explain any specific factors or contraindications that would make a subject ineligible to participate in this study.<br>* If participants are or may become pregnant, describe potential risks to the fetus. Because a fetus cannot consent, special caution is required for research involving more than minimal risk. | |
| | **Note:** If vulnerable populations are used, additional paperwork is necessary. Attach appropriate form as required. | |