Research Plan Template

Engineering Project with Human Involvement

Determining the level of Human Involvement and the Need for an IRB:

- A. No IRB Needed
 - **a.** Student designed invention, prototype or computer application
 - **b.** Student is the only person testing
 - **c.** Testing does not pose a health or safety risk

B. Full IRB Required

a. Any other engineering project involving the use of human subjects requires a full IRB Review before experimentation.

Title

Rationale (Problem)

A few sentences explaining the global or societal need for this research. Why would anyone be willing to fund this research in the real world of science?

Engineering Goal

Described what is that you hope to develop. Be specific. Describe simply the hoped-for outcome.

Procedure

Sequentially numbered steps that cover the procedure from beginning to end. The steps should be detailed enough for someone else to be able to replicate the study from your steps. This section can be sub-divided by different sections of the procedure such as safety, experimentation, data analysis, disposal, etc.

Safety: These steps will vary according to the types of projects. These steps must be a part of the research plan as well as being on the Form 3. Some examples are:

Hazardous chemicals or devices: Safety equipment used, including, but not limited to, (goggles, gloves, closed toe shoes), working conditions (fume hood, etc), fire extinguisher if combustion is possible.

Experimentation:

These sequential, numbered steps should continue from safety. This must thoroughly cover the entire study. Make sure to include the experimental design and data collection procedures.

Human Participants:

- a. Describe age range, gender, racial/ethnic composition
- b. Identify vulnerable populations (minors, pregnant women, prisoners, mentally disabled, or economically disadvantaged)
- c. How will you recruit your participants?
- d. Methodology surveys, questionnaires, tests. Frequency and length of time involved per participant.

- e. Risk assessment Are there any risks to the participants (physical, psychological, time involvement, social, legal, etc.)? How will you minimize risk? Are there any benefits to the participants or to society?
- f. Protection of Privacy Will identifiable information be collected? Will data be anonymous and how will anonymity be protected? It not anonymous, will data be confidential and how will confidentiality be safeguarded?
- g. Where will data be stored? Who will have access to the data and what will happen to the data after the study?
- h. Informed Consent Process Describe how you will inform participants about the following four areas: 1) purpose of the study; 2) What they will be asked to do; 3) their participation is voluntary; and 4) they have the right to stop at any time. Where will informed consents be stored, by whom and for how long.

Engineering Design and Construction:

Describe the process. Include only the parts of the project that you specifically did. Do not include parts that were completed by your mentor.

Data Analysis:

Include a description of the techniques or statistical tests that will be employed to analyze the results of the experimentation to determine if you were successful

Disposal

This is necessary for PHBAs, chemicals or materials that require special handling for disposals.

Summary or addendum

Necessary if experimentation changed through the course of the research. If additional SRC or IRB approval was needed, you must also provide a letter from the SRC, explaining the changes which is signed and dated. If new IRB approval was necessary, the new Form 4 and informed consents must be included with the paperwork.

Bibliography

Current journal sources on your topic from your literature review. Also include a Human subjects reference.