

Research Plan Template

Human Subjects Project

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

**A. Exempt from IRB**

- a.** Student designed invention, prototype or computer application
  - i. Student is the only person testing
  - ii. Testing does not pose a health or safety risk
- b.** Data/record review studies
  - i. Data taken from preexisting data sets
  - ii. Publically available and/or published
  - iii. Does not involve interaction with humans
  - iv. Does not involve collection of data with human participants.
- c.** Behavioral observations of unrestricted public settings
  - i. Student has no interactions with the individuals being observed
  - ii. Student does not manipulate the environment in any way
  - iii. Student does not record any personally identifiable data
- d.** Pre-existing/retrospective data in a de-identified/anonymous format
  - i. Professional providing the data certifies in writing that the data have been appropriately de-identified previously and is in compliance with all privacy and HIPAA laws.
  - ii. The affiliated fair SRC ensures the above by review of the provided written documentation.

**B. Full IRB Required**

- a.** Any other 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?

### **Hypothesis/es**

What is being tested.

(Suggestion: If, then format. If something is done, then something will result.)

### **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 experimentation, data analysis, disposal, etc.

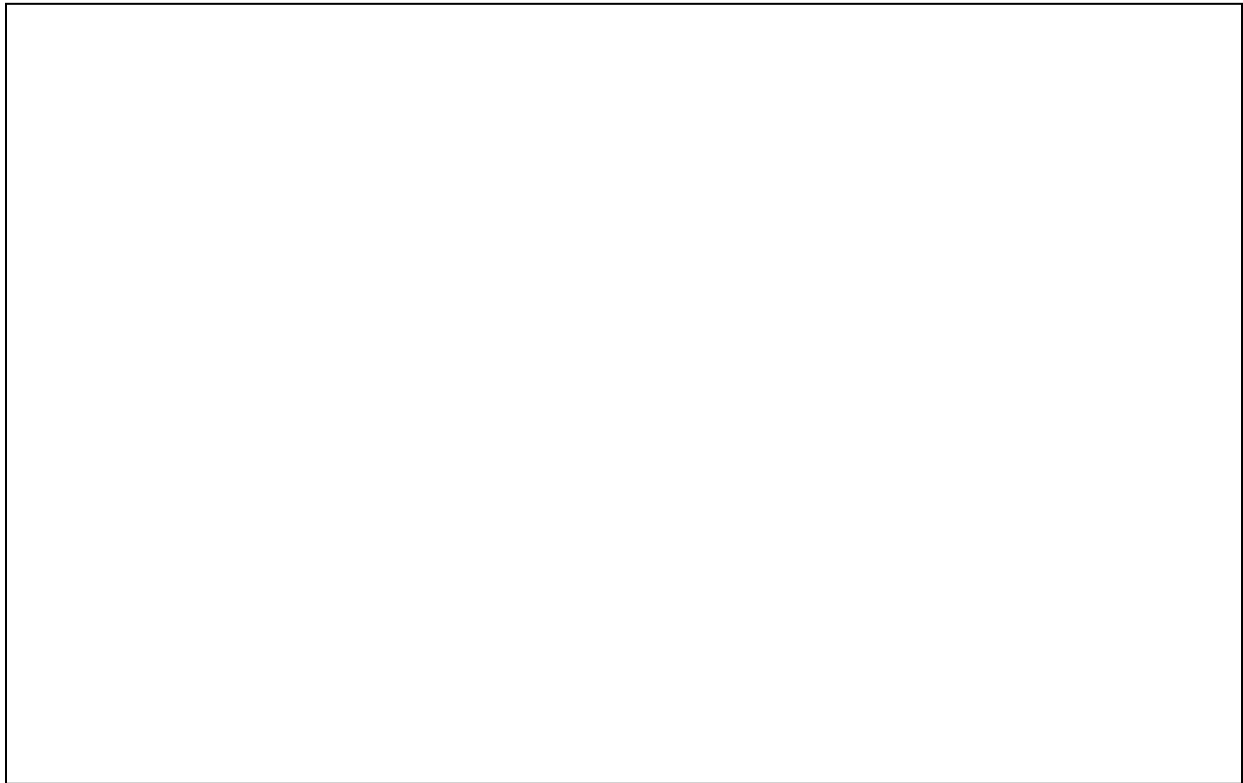
#### **Experimentation:**

These sequential, numbered steps 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? If 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.



**Data Analysis:**

Include a description of the techniques or statistical tests that will be employed to analyze the results of the experimentation.

**Disposal**

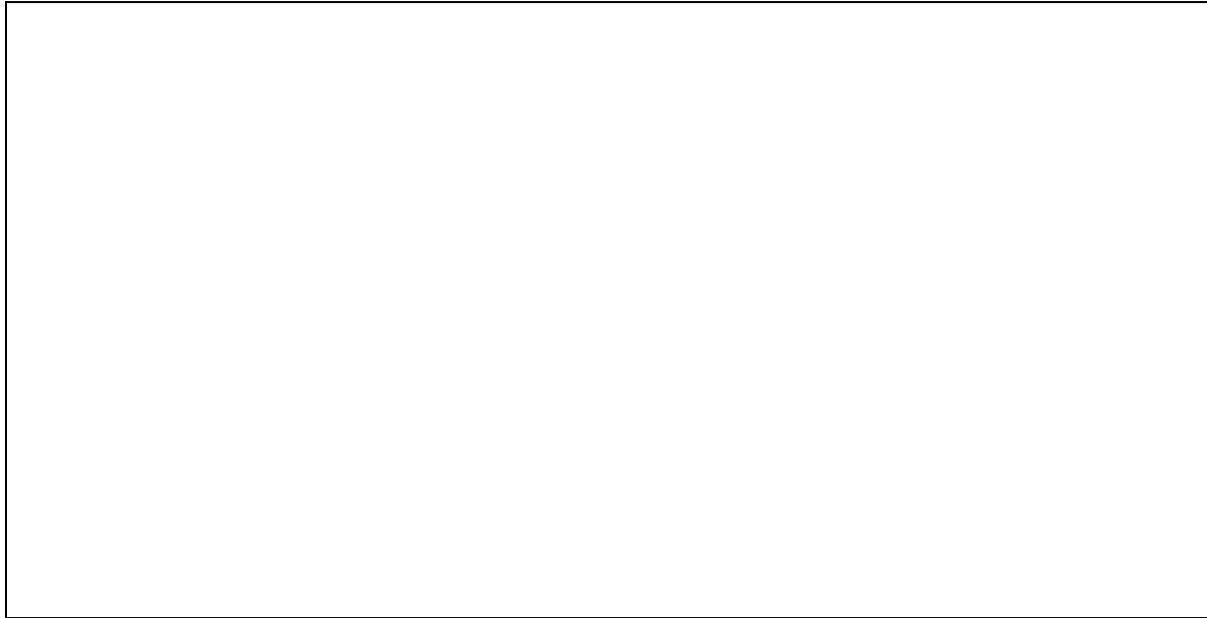
This is necessary for PHBAs, chemicals or materials that require special handling for disposals.

**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. Must include a Reference for Human Subjects Research.

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