

Research Plan/Project Summary Instructions

A complete Research Plan/Project Summary is required for ALL projects and must accompany Student Checklist (1A)

1. All projects must have a Research Plan/Project Summary written prior to experimentation following the instructions below to detail the rational, research question(s) methodology, and risk assessment of the proposed research. For all projects requiring preapproval, this document must be reviewed and approved by the appropriate approval committee(s) (e.g. IRB, IACUC, SRC) before experimentation.
 - a. If changes are made during the research, such changes can be added to the original Research Plan as an addendum, recognizing that some changes may require returning to the IRB and/or the SRC for appropriate review and approvals. If no additional approvals are required, this addendum serves as a Project Summary to explain research that was conducted.
 - b. If no changes are made from the original Research Plan, no Project Summary is required.

The Research Plan/Project Summary should include the following:

- a. **RATIONALE:** Include a brief synopsis of the background that supports your research problem and explain why this research is important and if applicable, explain any societal impact of your research.
- b. **HYPOTHESIS(ES), RESEARCH QUESTION(S), ENGINEERING GOAL(S), EXPECTED OUTCOMES:** How is this based on the rationale described above?
- c. Describe the following in detail:
 - **Procedures:** Detail all procedures and experimental design including methods for data collection. Describe only your project. Do not include work done by mentor or others.
 - **Risk and Safety:** Identify any potential risks and safety precautions needed.
 - **Data Analysis:** Describe the procedures you will use to analyze the data/results.
 - **Discussion of Results and Conclusions:** Discuss the data/results and the conclusions that can be drawn.
- d. **Bibliography:** List at least five (5) major references (e.g. science journal articles, books, Internet sites) from your literature review. *APA format is recommended.* If you plan to use vertebrate animals, one of these references must be an animal care reference.

Items 1–4 below are subject-specific guidelines for additional items to be included in your research plan/project summary as applicable.

1. Human participants research:

- a. **Participants.** Describe who will participate in your study (age range, gender, racial/ethnic composition). Identify any vulnerable populations (minors, pregnant women, prisoners, mentally disabled or economically disadvantaged).
- b. **Recruitment.** Where will you find your participants? How will they be invited to participate?
- c. **Methods.** What will participants be asked to do? Will you use any surveys, questionnaires or tests? What is the frequency and length of time involved for each subject?
- d. **Risk Assessment.**
 - Risks. What are the risks or potential discomforts (physical, psychological, time involved, social, legal, etc.) to participants? How will you minimize the risks?
 - Benefits. List any benefits to society or each participant.
- e. **Protection of Privacy.** Will any identifiable information (e.g., names, telephone numbers, birth dates, email addresses) be collected? Will data be confidential or anonymous? If anonymous, describe how the data will be collected anonymously. If not anonymous, what procedures are in place for safeguarding confidentiality? Where will the data be stored? Who will have access to the data? What will you do with the data at the end of the study?
- f. **Informed Consent Process.** Describe how you will inform participants about the purpose of the study, what they will be asked to do, that their participation is voluntary and they have the right to stop at any time.

2. Vertebrate animal research:

- a. Discuss potential **ALTERNATIVES** to vertebrate animal use and present a justification for use of vertebrates.
- b. Explain potential impact or contribution this research may have
- c. Detail all procedures to be used
 - Include methods used to minimize potential discomfort, distress, pain and injury to the animals during the course of experiment. *Under Massachusetts Law, an animal cannot be put under duress/stress. This greatly limits what can be done in a vertebrate animal project.*
 - Detailed chemical concentrations and drug dosages. *Very strict rules apply. No animal's normal diet can be interrupted, etc. See rules.*
- d. Detail animal numbers, species, strain, sex, age, source, etc. Include justification for the numbers planned.
- e. Describe housing and oversight of daily care
- f. Discuss disposition of the animals at the termination of the study.

3. Potentially hazardous biological agents research:

- a. Give source of the organism and describe the BSL assessment process and BSL determination.
- b. Detail safety precautions and discuss methods of disposal

4. Hazardous chemicals, activities & devices:

- a. Describe Risk Assessment process and results
- b. Detail chemical concentrations and drug dosages
- c. Describe safety precautions and procedures to minimize risk
- d. Discuss methods of disposal