**Lab 9: Working with human subjects**

# Part I: IRB Application

When you choose to do research on humans, you must apply for permission for the Institutional Review Board (IRB) at your college/university/hospital/etc. The IRB application process requires that you describe your study in detail, including descriptions of what interventions or treatments you are testing, how you are gathering results, and how you are getting informed consent from your participants. The goals of the Lab are (1) to learn about the basic pieces of an IRB application and (2) to design a small statistical study.

Before you get started, spend a few minutes thinking about a research study that you would be interested in conducting, perhaps as part of a senior project in your major. For this lab, the study must involve humans and it must be a **randomized controlled experiment**, not an observation study. Plan to have a treatment and control group, or multiple treatment groups.

This lab is an abbreviated version of an IRB application. It should give you sense of what the IRB process includes.

Group Members

|  |  |
| --- | --- |
| Full Names | Contact Information |
|  |  |
|  |  |
| Faculty Sponsor | (Professor’s name here) |

**Title of Study:**

Use complete sentences and appropriate grammar as you answer each of the following questions.

# Brief Summary:

Provide a brief non-technical description of the study. Typical summaries are around 100 words. A reader of your summary should be able to tell that it is a randomized controlled experiment.

# Purpose: (Read only)

Provide a summary of the background information (citing at least 3 prior studies related to yours, found via Google Scholar or other scholarly resources), clearly state the research question(s), and tell why the study is needed or interesting. This section must include a brief review of properly cited related literature.

[We will skip this step, but if you were conducting a study, you would want to become an expert on the area by reading about what other researchers have done before you get started.]

# Participants

Provide a short description of who will be participating in the study. Are there certain types of people that will be specifically excluded or included in the study? List required characteristics of potential subjects. Justify exclusion of any group, especially by criteria based on gender, ethnicity, race, and age. Indicate how many participants you would plan to include.

# Full description of the study design, methods and procedures

Describe the research study. Discuss the study design and study procedures. Include a description of what the subjects will be asked to do. Address what the treatment groups will be and how you will assign subjects to different groups. How is data to be collected (e.g. questionnaire, interview, blood draw, or other specific procedure)?

(This should be several hundred words in length.)

# Description of the statistical tests you will employ

Which type(s) of hypothesis test(s) will you conduct? What will your null and alternative hypotheses be? Be specific about whether you are comparing means, proportions, or working with linear regression.

# Description of Risks and Measures to Minimize Risks (read only)

Include risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality), social harm (e.g. disruption of a group), economic harm (e.g., loss of employment or insurability, loss of professional standing or reputation, loss of standing within the community) and legal jeopardy (e.g., disclosure of illegal activity or negligence), and risk of pain and physical injury. Describe what will be done to minimize these risks. If there is no direct interaction with subjects, and risk is limited to breach of confidentiality (e.g., for existing data), state this.

[We will skip this step, but if you were conducting a study, you would want to be specific about risks, including physical risks and risks to privacy.]

# An Example Script (read only)

Some IRB applications require the researcher to include a script which provides a clear example of how the research will take place and how the participants will interact with the researcher.

The reasons for this script are so that the IRB reviewers have a very clear idea of what you plan to do and to ensure that you as a researcher have really thought through your experiment and your interactions with human participants.

[We will skip this step, but if you were conducting a study, you might be asked to write a script (like a play) which includes (1) how participants will be recruited and how the study will be explained to the participants, (2) what the participants in the treatment group(s) will experience as they interact with the researcher.]

# A Consent Form

The study of humans requires the consent of humans, with usually involves signing a consent form. Find a template consent form on MyCarroll at the following address:

https://my.carroll.edu/campusresources/academics/IRB%20Documents/Forms/AllItems.aspx

Modify the consent form to fulfill the needs of your study.

Copy your modified consent form here. It is likely 1 to 2 pages.

Once you complete an official IRB application, you would submit it to the IRB committee and wait for several weeks (or longer) to receive permission to conduct your experiment. The IRB committee may contact you for additional information or clarification before granting permission. Or they may decide that your study is too dangerous or ill-defined to proceed. Make sure to submit your IRB application well in advance of when you need to begin your study. Some larger universities or institutions may take several months to grant IRB requests.

# Part II: Human subjects data

On Wednesday we collected data during a randomized controlled study on vision and balance. The data is available on Moodle. Conduct a hypothesis test on this data, state your hypotheses clearly, and include a table that shows all of your calculations from Excel. Make sure this is well labeled.

Then write up the results of your study, as if for a news article. Describe what your research question was, what experiment you performed, and what your results and conclusions were. This should be about two paragraphs and should use common English. The reader should be able to tell your study was a randomized controlled study, not an observational study.