

Final Protocol Instructions

Deadline: 5:00 PM, Friday in Week 4 of each track

For Track 1, this is August 20; for Track 2, this is September 3

This is the day that your complete concise protocol is due. Please note the following things:

1. **Please indicate in the UPPER RIGHT CORNER your NAME, SECTION LEADER,** and whether you want to receive written feedback on your final protocol (and give written feedback to another student). If you opt in for protocol feedback, you will receive written comments on your protocol from a new section leader and student who is not in your section. However, you will also be asked to provide written comments to another student, by the Wednesday after the protocol submission deadline.
2. We have a recommended length of 5 pages, and an absolute limit of 6 pages of text, single spaced and 12 point font (not narrow!). You are also allowed an additional 5 pages of references and appendices. The reason for these constraints is not so much to reduce the size of your creative task (although our students' welfare is always a priority) as it is to make the task of critiquing one another's protocols a manageable one. The 6-page limit is similar to that of an NIH small grant submission or a small intramural grant. The need to be concise will discipline your approach to describing your study. If necessary you can summarize the ways you would flesh some parts of the text out in a longer version.
3. We cannot make exceptions to the due date. The logistics of sending out the protocols in time for them to be read and critiqued mean that we have no flexibility on this one. Just give us whatever you have by the deadline, even if you still plan further improvements.
4. Upload your protocol onto the website. DO NOT e-mail your final protocol to your section leader. Instead, please post your protocol document as a forum attachment on the course website. First, go to the protocol critique section of the website ("Final Protocol Submission and Review"). Below the protocol preparation instructions, you will see a link labeled:
 **UPLOAD YOUR FINAL PROTOCOL HERE!**
4. The next page provides you with a suggested outline indicating a good way to allocate the 5-6 pages (to help avoid such things as spending too much space on the significance and then neglecting key nitty-gritty aspects of the methods). However, you are not required to follow this outline. We've also posted example protocols from students who have taken this course previously. Note that the protocol does not have to be perfect!

5 Page Protocol

Suggested Outline

STUDENT NAME
SECTION LEADER

Participate in Protocol Critique?
Yes/No

- Title and Investigators
- Abstract (~200 words)
- Research question (1 sentence)
- Specific aims (1 sentence each)
- Significance (½ page)
- Methods (3-4 pages)
 - o Overview of design
 - Type of study
 - Time frame
 - Nature of control
 - o Study subjects
 - Target and accessible populations
 - Selection criteria
 - Plans for sampling, recruiting and retaining subjects
 - o Measurements
 - Predictor variables (intervention, if a clinical trial)
 - Outcome variables
 - Discussion of a particularly important questionnaire to be used in the research (if applicable)

- Potential confounders
- o For clinical trial only
 - Plans for randomization, blinding, run-in period as needed
- Statistical issues (1 page)
 - o Hypotheses
 - o Analysis plan
 - o Sample size estimates
- Ethical considerations (½ page, if applicable)
 - o Describe potential harm to your participants or ethical issues posted by your study
 - o Describe ways that you have attempted to mitigate ethical issues using inclusion/exclusion criteria, study design, measurements or other approaches.

References & Appendices (5-page limit, not counted in protocol page limit)