

Tips for Writing Human Subject Research Protocols

- When defining the ages of your subject population, be sure to define the units of time you are specifying. For example, it cannot be assumed that “subjects ages 18-80” means “subjects’ ages 18-80 *years*”. It is necessary to define the ages in terms of years, days, months, etc. depending on your population.
- Consider the number of subjects you need to *enroll* in order to get your desired number *completed*. For example, if you need 20 subjects to complete the study, your protocol might say: “We plan to enroll 30 subjects to get 20 completed.” This allows some flexibility to account for dropouts.
- Make sure the information in your protocol matches the informed consent and vice versa.
- Be sure to include headers/footers including page numbers, protocol version number, date, protocol title (or descriptive identifier), principal investigator, and sponsor (if applicable).
- If using a protocol template, be sure to delete all sections that are not applicable to your study.
- Be sure to list contraindications to any drugs/products to be used in the study as part of the exclusion criteria.
- When a patient enters a study, they are no longer considered a “patient” as it pertains to the study. Be sure to refer to them as “subjects” or “research participants” throughout the body of your protocol.
- If your protocol requires adhering to a time schedule, consider adding a (\pm) criterion to allow for flexibility should something not go exactly as planned. For example, if you need to draw PK samples every 15 minutes, you may want your protocol to read: “PK samples will be drawn every 15 (\pm 1) minutes.” This will minimize protocol deviations. The exact time that the sample is drawn is recorded on the source documents.
- Consider whether it would be useful to involve a statistician in the development of the study design, research protocol, and data collection plan.
- Double check formatting to make sure it is consistent throughout the document. Also check for spelling and grammatical errors.
- Consider having someone that was not involved in writing the protocol proofread the document. If you are a student, ask your mentor or faculty advisor to read over your study documents prior to submitting them in CRIMSON.
- If you need assistance or have questions concerning the preparation of a clinical research protocol, please contact a member of the Research Support Center (RSC):

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