

COMPLETING A ROWAN PROTOCOL

The following template provides three examples of developing a research protocol for social and behavioral research and biomedical research for medical chart review. These templates are for guidance purposes only to provide a general idea of how a protocol may be written to describe a research design or methodology, how participants are chosen and approached or how participant’s records are obtained and used, a description of what will happen in the study whether the study involve prospective interviews or anonymous surveys or analyzing existing data or biological specimens and what data will be collected and analyzed.

Before you start completing an eIRB application you should write out the protocol for your study. You must use the official Rowan protocol template. You can obtain it either from the appropriate Rowan website (<http://www.rowam.edu/som/hsp/forms/protocol.html>) or from the department of surgery – resident research IRB file.

You will be uploading the protocol into the Rowan-IRB from and copy/pasting various sections from the protocol into the IRB form. The two documents must be consistent with each other.

The next few pages show the protocol document with an outline (in blue) of how to respond to the questions. All ‘Word’ documents uploaded into the eIRB application must contain a version date a pagination in a footer.

 

**Title of Project:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**\*Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**\*\*Funding Source(s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***\*Principal Investigator is the person in-charge of the study or the principal investigator of a funded project. Students, post-docs, clinical fellows and residents cannot be principal investigators; however, they could be co-investigators. Co-investigators can develop and complete eIRB application; however, they must be approved by the principal investigator.***

***\*\*Funding source is the agency that funded the study. For example, National Science Foundation, National Institutes of Health, Nelson Foundation, etc. If your study is not funded by an external agency, mark it as “Internally funded.”***

**Directions on how to use the form**

**Delete all orange and blue text. Blue and orange text is for informational purposes only**

**If the numbered section does not apply to you, then put** Not Applicable**. Do not erase section.**

**Write in or copy into your input where it says** <INSERT HERE>

**1**. **Purpose/Specific Aims**

*Clearly state the overall purpose of the study. [Note: IRB reviewers come from a diversity of backgrounds. Therefore, avoid the use of acronyms and highly technical language.]*

<INSERT HERE>

***1.1 Objectives***

*Create objectives—statements outlining specifically what will be achieved by the study—that derive directly from the overall purpose.*

<INSERT HERE>

***1.2 Hypotheses***

*Express scientific hypotheses—statements about expected relationships between variables— that are testable and that include measureable outcomes/endpoints as described in the Research Design and Methods section of the protocol. Hypotheses correspond directly to the objective(s).*

<INSERT HERE>

**2. Background and Significance**

*Provide a succinct review of the relevant scientific literature to justify the proposed study. Include key references but not a complete literature review. Include relevant preclinical data, such as animal studies or other human studies utilizing similar drugs, devices, procedures, leading up to, and supporting the proposed research, if applicable. Address the importance of the knowledge that may reasonably be expected to result for your discipline (e.g., clinical, diagnostic, etc.) and to society generally (e.g. increased understanding of disease, etc.).*

<INSERT HERE>

3. **Research Design and Methods**

*Describe the design of the study (cross sectional, descriptive, case/control, retrospective chart review). Justify how this design addresses the research objectives and hypotheses. If applicable, describe procedures for randomization of subjects’ care or assignment to interventions.*

*Describe your design specific to your study and how you will be interpreting results. This is where IRB will take a critical look at your research methods, whether proposed procedures in the study are equitable and how your research methods affect research risks, harms and benefit to subjects. Therefore, be specific and describe your methods pertinent to your study.*

<INSERT HERE>

**3.1. Duration of Study**

*It is important that you describe how long the study may take. Estimate the duration as closely as possible. Duration includes the length of time to complete the study as well as length of time subjects are expected to complete the given task. If there multiple tasks, provide the time complete each task. Please make sure that fatigue factor is included if the tasks longer time.*

<INSERT HERE>

***3.2 Study Sites***

*List all of the study sites where studies will be conducted. If the study is outside Rowan campuses provide the location’s name. If the study site is non-Rowan facilities provide the location and also state how or whether you have secured permission to conduct the study at that site. If you have secured permission, you must upload that letter in the eIRB application.*

<INSERT HERE>

***3.3 Sample Size Justification***

*Describe total sample size (including gender and minority considerations), expected accrual rates and sampling strategy (justified for testing the primary and/or secondary hypothesis). Power calculations for proposed sample size and endpoints should also be included. Give references for the pilot data and method of sample size calculation.*

<INSERT HERE>

***3.4 Subject Selection and Enrollment Considerations***

*[****Note:*** *Selection and enrollment design considerations are extremely important for assuring human subjects’ protections, including their voluntary & informed consent, privacy of person and confidentiality of data, and equitable access to research.]*

<INSERT HERE>

***3.5.1 Inclusion Criteria***

*Describe the target subject population. Provide all relevant demographic (e.g., age, ethnicity), biomedical (e.g., disease status, laboratory values, pregnancy) and behavioral characteristics (e.g., cognitive abilities, mood) relevant for inclusion and exclusion. [Note: In order to assure all persons equitably share the burdens and benefits of research, scientific objectives, not membership in a privileged or vulnerable group, must guide the development of inclusion criteria.]*

<INSERT HERE>

**3.5.2 *Exclusion Criteria***

*Describe what relevant demographic, biomedical or behavioral characteristics exclude persons from participating in your research. Provide clear justification(s) for exclusions. No group of persons—women, pregnant women, children, minorities, non-English speaking persons—should be categorically excluded from the study without a scientific or ethical reason to do so. Note any efforts you will take to overcome any anticipated barriers to participation. [****Note:*** *If a study is to offer value to future patients, its results must be generalizable. This means that the sample of subjects selected for the study must be representative of society’s members.]*

<INSERT HERE>

***3.5.3 Subject Recruitment***

*Describe how, when, and by whom individuals will be recruited to participate in the study. Explain how individuals will be approached, what collateral materials will be used to recruit them (e.g., flyers, internet, letters from physicians), and the context of the offer of participation (location, timing of offer, and decision deadline). Provide copies of all recruitment materials in an appendix to the protocol. Indicate the number of subjects to be approached for recruitment, allowing for screen failures and/or drop outs. Carefully consider how/if others (e.g., family members) become secondary subjects as a result of the information provided by the primary subjects and how such persons will be protected if that occurs.*

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*This paragraph encompasses multiple sub-topics. You must address each point in the paragraph individually.*

*Provide copies of all recruitment materials in an appendix to the protocol. Indicate the number of subjects to be approached for recruitment, allowing for screen failures and/or drop outs.*

*Carefully consider how/if others (e.g., family members) become secondary subjects as a result of the information provided by the primary subjects and how such persons will be protected if that occurs.*

*Describe how, when, and by whom individuals will be recruited to participate in the study.*

<INSERT HERE>

***3.5.4 Consent Procedures***

*Describe the consent procedures to be followed, including how, when, where and by whom informed consent will be obtained and documented. [Example: The study will be explained to the potential subject by the Principal Investigator, the consent will be read, and their questions will be answered. If s/he wishes to enroll, the subject will sign the consent form. The study staff obtaining consent will also sign and date the consent form, and a copy will be given to the subject.] Be mindful to create an environment that supports voluntary and informed decision-making and include additional safeguards for persons likely to be vulnerable to coercion or undue influence. Procedures must reflect that informed consent will be sought from each prospective subject or the subject’s representative. A copy of the consent document(s) you will use must accompany your IRB application. Under certain circumstances, a waiver of consent may be necessary. If so, a request for a waiver must be submitted to the IRB for their consideration/approval. [Note: Informed consent is not an event but a process. Study staff should periodically check with subjects to answer any further questions they may have about the study or their rights while participating in it.]*

<INSERT HERE>

***3.5.5 Subject Costs and Compensation***

*List all costs, if any, that subjects will likely incur, such as, parking fees, travel expenses, food, over-the-counter or prescription drug costs. Likewise, list all expenses that will be covered by the research, such as study drugs or tests. Indicate what compensation, if any, will be provided and whether it will be pro-rated depending on what parts of the study the subject completes.*

<INSERT HERE>

**3.6 Chart Review Selection**

*Describe who and how charts will be accessed for retrospective chart review. Explain the parameters you will use to select charts and where will you review these charts to abstract data. Provide a data log or excel spread sheet with the relevant variables you plan to collect. The information collected should be directly relevant to the objectives and hypotheses for the research. Explain when and how identifiers will be removed from the data collected. If a waiver of consent is granted, identifiers should be destroyed with no possibility of linking the data with these identifiers as soon as possible. This affords respect and privacy protections to persons whose data was reviewed/used without their consent.*

<INSERT HERE>

**4. Study Variables**

***4.1 Independent Variables or Interventions***

*Describe any treatments or interventions to be compared for their effects on participants. Clearly differentiate interventions or procedures that are a part of standard of care from those that are experimental. In the case of chart reviews, indicate if you will be comparing specific treatments or other interventions performed in the past. All procedures and interventions must be consistent with sound research design and should not unnecessarily expose subjects to risks of harm.*

<INSERT HERE>

***4.1.1 Drug or Device Interventions***

*Include the regimen (drugs, doses and schedule by which the treatment will be given), and drug administration guidelines (i.e., route of administration, infusion solution, concentration if applicable, rate of infusion and how the drug is packaged). Describe fully and clearly how all study drugs are prepared and administered, including special precautions. Provide FDA investigational new drug (IND) or investigational device (IDE) information as applicable.*

*Not applicable to social and behavioral studies*

<INSERT HERE>

***4.2 Dependent Variables or Outcome Measures***

*Describe all study instruments such as questionnaires, behavioral measures, laboratory tests, or medical evaluations (e.g., history/physical, X-rays) that are not a part of standard clinical practice and are being performed specifically for the purpose of the research. Wherever possible, describe in lay terms the amount of specimen to be taken (e.g., blood in tsp.; tumor tissue). Include copies of all tests and questionnaires. For chart reviews, clearly define the information you will be extracting from the chart with justification for the information collected.*

*If you are giving a questionnaire, briefly describe what you are asking and attach a copy of the questionnaire to the protocol. For study specific measurements or data points, list them individually and give a brief justification of why each one is needed.*

<INSERT HERE>

***4.3 Risk of Harm***

*Fully describe physical, psychological/emotional, social, legal and economic risks of harm that are possible to affect subjects as a result of study interventions and/or outcomes. Do not describe risks and benefits of standard therapies subjects will receive regardless of their participation in the research. Discuss these risks in the context of potential benefits of participation in the research and how reasonable these risks are in relation to benefits.*

<INSERT HERE>

***4.4 Potential for Benefit***

*State potential benefits for the individual and/or society, being careful not to overstate benefits. Almost all research studies—even those with minimal risk—have the risk of loss of subjects’ privacy and confidentiality of data collected or produced. In addition, the research may involve a risk to certain communities or groups of individuals. Determine if any data collected are sensitive (e.g., alcohol, drug use, sexual) and whether a Certificate of Confidentiality will be requested. For all risks of harm listed, address how these risks will be minimized (e.g., whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes) and how they are justified.*

*For all studies, state that “there may not be any direct benefit”. However, you can state if there are any anticipated direct benefit or benefit to the society.*

<INSERT HERE>

**5. Data Handling and Statistical Analysis**

*Provide a data analysis plan that is logical and appropriate for endpoints selected. The plan should not introduce bias through exclusion of subjects from analysis. Describe data entry, editing and methods for quality assurance. Indicate how information will be recorded (e.g., electronically, audio, paper), where data will be stored, who will have access, and how subject’s privacy and confidentiality of health information will be protected during collection, storage, use, or transmission (e.g., flash drives, internet) of data. Document when the link between personal health identifiers and data will be destroyed, if ever. Consider, particularly for chart review, destroying the link as soon as possible. Document how long the investigator will keep the data [should be a minimum of 6 years]. Describe the statistical methods to be employed. Clinical relevance of the results as well as statistical significance should be discussed. Describe and justify any interim analyses.*

*This is self-explanatory except for the part about statistical analysis. However, provide an outline of how you are going to analyze your data. Example, if your intent is to compare two or more groups, state the statistical method you will be using to analyze the data.*

<INSERT HERE>

**6. Data and Safety Monitoring**

*For all studies of greater than minimal risk, a safety monitoring plan must be included to ensure the safety of subjects. This plan should include procedures for monitoring the safety of the study, procedures for the sponsor and the IRB, and plans for interim safety reviews. Adverse events need to be defined with information on how they will be managed and reported. Provide a plan for emergency care and/or clinical management of adverse events as needed (e.g., uncovering of suicide risk). Explain how you will know if the study is causing undue burdens or harms to subjects. Include the frequency and type of assessments you will use to determine safety of subjects throughout the study.*

*If the study is greater than minimal risk, you may consider or be required to create an independent Data and Safety Monitoring Board (DSMB). If such a board is planned or required, the IRB will need information on the composition and credentials of the monitoring group, their frequency of meetings and reporting procedures.*

*This section is not applicable to many clinical chart review studies, questionnaires, surveys etc. This section is NOT applicable to social and behavioral studies. This section is only applicable to clinical and psychological studies where the risk of harm is high requiring an external committee to evaluate adverse reactions or adverse events.*

<INSERT HERE>

**7. Reporting Results**

 ***7.1 Individual Results***

*Describe your plan for notifying subjects of study or individual test results that have clinical importance (e.g., abnormal lab values on screening). If providing individual results, provide evidence of appropriate lab certifications (e.g., CLIA) and the qualification(s) of the study staff who will return such results.*

*This section is not applicable for many social and behavioral studies. For clinical studies, please follow instructions under 7.1.*

<INSERT HERE>

**7.2 Aggregate Results**

*Describe your plan for notifying subjects of aggregate research results, as applicable. (Note: Studies show that a primary reason persons enroll in research is to make a meaningful contribution to future health of others. Returning aggregate results to subjects respects and recognizes their contributions to research.)*

*This is optional based on the design of your study.*

<INSERT HERE>

**7*.3 Professional Reporting***

*Describe your plan to share the results of your research with the scientific community.*

*Indicate whether you will be publishing your report and how you will accomplish that. Also indicate that you will be publishing the aggregate without the use of participant’s identifiers****.***

<INSERT HERE>

**8. Bibliography**

 *Include all references cited in the text.*

<INSERT HERE>

**APPENDICES**

*After you have completed this form (the ‘PROTOCOL’), attach any additional information that is related to the protocol, but is not applicable or does not appear to fit into one of the sections above.*

*Note: All surveys, observational data collection sheets, and other research instruments should be uploaded as separate documents in eIRB.*

*Note: Recruitment documentation should be uploaded in section 11 of the eIRB application.*

*Note: Consent documents should be uploaded in section 13.2 of the eIRB application. The only exception to this is if the study submitted is exempt. In that case, then the consent document would be included in section 7 as a separate document*

*Note: For a chart review project you will also have to upload a copy of your data collection sheet. The sheet must state on the bottom the version # and the page number.*

<INSERT HERE>