

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.”***

**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.]*

***Social and Behavioral Example 1: The purpose of this research study is to evaluate the effectiveness of virtual classroom versus physical classroom training.***

***Specific aims of the study are:***

***1. To compare a classroom-based and internet-based class at Rowan University***

***2. To identify possible reasons why internet-based training is more effective than physical training.***

***Clinical or Basic Science Example-Chart review 2: The purpose of this research study is to evaluate the cumulative survival rate after 10 years of peritoneal dialysis or hemodialysis. This is a retrospective chart review study with the following specific aims:***

1. ***To compare cumulative survival rates after peritoneal dialysis;***
2. ***To determine whether cumulative survival rate after peritoneal dialysis is equivalent or better than hemodialysis based on their residual renal functions and***
3. ***To determine whether age and gender have any effect in cumulative survival in patients on hemodialysis compared to hemodialysis.***

***Exempt Review Study Example 3: The purpose(s) of the present study is to investigate race/ethnicity in relation to early intervention services, establishing a foundation of data that will drive further investigation.***

***1.1 Objectives***

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

**List all of your objectives**

***Social and Behavioral Example 1: Can internet-based training promote student learning compared to face-to-face classroom training? We intend test the efficacy based on the survey responses about their learning experiences at the end of the course. We will also compare the effectiveness of training between the two groups using a training specific questionnaire.***

***Clinical or Basic Science Example-Chart review 2: The overall objective of this study is to determine whether peritoneal dialysis is equivalent to or better than hemodialysis on cumulative survival rates based on their residual renal functions.***

***Exempt Review Study Example 3: The present research study will investigate the following questions: a) Is the distribution of race/ethnicity among early intervention (EI) participants consistent with what would be expected in the general population?; b) What is the relationship between race/ethnicity, age of entry into program; and disability category among EI participants?; c) What is the comparison between race/ethnicity in EI and race/ethnicity factors in special education classification for school age children (as indicated in Pre-School, 4th grade, 8th grade, 11th grade).***

***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).

***Social and Behavioral Example 1: We hypothesize that internet-based training is superior compared to physical classroom-based training because internet based learning provides more flexibility by facilitating thorough discussions and interactions in the virtual environment leading to enhanced learning.***

***Clinical or Basic Science Example-Chart review 2: We hypothesize that peritoneal dialysis yields equal or better cumulative survival compared to hemodialysis irrespective of age and gender***

***Exempt Review Study Example 3: The overall hypothesis is that minorities are underrepresented in early intervention programming.***

**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.).

***For clinical studies, the paragraph above provides the required guidance to complete this section.***

***For social and behavioral studies, provide a succinct review of literature to justify the proposed study including only pertinent references. In general, social and behavioral studies involve generating data by means of questionnaires, observation, studies of existing records and sometimes some types of stimulus or intervention. Address the importance of obtaining such knowledge to your field of science or society in general.***

***Social and Behavioral Example 1:*** ***Provide references of previous studies pertinent to your study and justify the proposed study.***

***Clinical or Basic Science Example-Chart review 2: Provide a literature survey using very pertinent references to justify the proposed study. Include any historical data in support of the proposed study.***

***Exempt Review Study Example 3: Archived data (state of NJ) pertaining to race/ethnicity of children participating in early intervention programs will be analyzed (available on http://www.nj.gov/health/fhs/eis/data.shtml).***

***Although research (Madrigal, 2011; Togut, 2011) indicates that minorities are overrepresented in special education, the current study predicts that minorities are underrepresented in early intervention programming.***

***Try to limit your narration to no more than one page giving pertinent references***.

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.***

***Social and Behavioral Example 1: In this study we plan to approach 100 students. Fifty of those students had previously opted to take the course via internet and the remaining 50 students had chosen to take the same course by physically participating in a class room. We need 30 students in each group to reach statistical significance. Same curriculum was used for both groups and the same teacher was teaching on internet and traditional class room. The course will be divided into four quarters. At the end of each quarter, both groups will be provided with a set of questionnaire to obtain feedback on their learning experiences from each of the groups. Responses will be anonymous. Recruiting material and questionnaires are attached to this application.***

***Clinical or Basic Science Example 2: In this retrospective chart review we will use existing data that have been recorded in the medical chart. We will be reviewing 1000 charts of patients who have undergone either peritoneal or hemodialysis from year 2004- 2014. We will extract clinical information and survival data, age and gender from each patient’s health records. The objectives are to determine the survival rate based on the dialysis procedure and to determine whether there will be differences between the group due to morbidity, age and gender to prove our hypothesis whether peritoneal dialysis is equivalent to or better than hemodialysis on cumulative survival rates based on their residual renal functions.***

***Exempt Review Study Example 3:*** .***Data will be retrieved from archived sources available on the nj.gov public website. In addition to EI data as noted above, data will be collected from general census information (NJ counties) pertaining to***

***race/ethnic distribution and department of education reports pertaining to race/ethnicity in special education. Data will be coded and analyzed via SPSS.***

**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.

***Social and Behavioral Example 1: We anticipate that this study will take approximately eight months to complete. Six of those months are associated with the length of the course and remaining two months will be for data analysis purposes.***

***Clinical or Basic Science Example 2: We will be reviewing approximately 1000 medical charts from January 1, 2014 through July 15, 2014. This study will take approximately 2 years to complete.***

***Exempt Review Study Example 3: It would approximately take six months to retrieve data and we hope to complete the analysis of the study within in one year from the approval date.*** .

***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.

***Social and Behavioral Example 1: This study will be conducted in the College of Education at Rowan University.***

***Clinical or Basic Science Example 2: Medical charts will be obtained from the nephrology clinic at Rowan University School of Osteopathic Medicine.***

***Exempt Review Study Example 3:*** .***We will extract data from archived sources available on the nj.gov public site. In addition to EI data as noted above, data will be collected from general census information (NJ counties) pertaining to***

***race/ethnic distribution and department of education reports pertaining to race/ethnicity in special education.***

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***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.

***Social and Behavioral Example 1: This class has 100 students. In order to obtain statistical significance, we need 30 students in each group. This sample size was determined based on our previous experience with a similar study published in 2013 (Peter Rabbit et al. Internet-based learning. Education 2013; 35:123-234.***

***If you have the capability to determine the “n” based on the power analysis you mays state that based on power analysis, we have determined that sample size we have selected is adequate to prove our hypothesis.***

***As another example, if you are conducting surveys or direct interaction with participants, and if you are not able to provide a power analysis, you may sate that you will be approaching “x” number of subjects to reach a desired number of “n” for your research. In general, it is estimated that approximately 35% of subjects respond to surveys. Therefore, calculate the “x” to reach your “n”.***

***Clinical or Basic Science Example 2: Epidemiologic studies using charts and surveys you may use the following website to select sample size determination.*** [***http://smm.sagepub.com/content/4/4/311***](http://smm.sagepub.com/content/4/4/311)***.***

***Exempt Review Study Example 3:***  ***We are uncertain at the present time what the sample size will be since we will be retrieving the data from the website and census information. We will use all available data pertinent to our research objectives.***

***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.]

***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.]

***Social and Behavioral Example 1: Our target population is students. All students in this class are above 18 years. We will include both male and female students. However, participation is voluntary.***

***Clinical or Basic Science Example 2: We plan to collect data from 100O charts irrespective of the age, gender or ethnicity.***

***Exempt Review Study Example 3:***  ***Our target population is students of all races/ethnicity in special education group of school age children from preschool to 11th grade.***

***If your study falls outside of those examples illustrated here, follow directions provided above under 3.5.1.***

**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.]*

***Social and Behavioral Example 1: Students participating in this study must belong to this class. We will not exclude anyone in this class.***

***Clinical or Basic Science Example 2: We will use all charts without exception or comorbidity.***

***Exempt Review Study Example 3: None of the students in the special educationgroup will be excluded.***

***If your study falls outside of those examples illustrated above, follow directions provided above under 3.5.2.***

***If the population you are studying includes children, but you are excluding them in your study, provide justification.***

***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.

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).

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

***Social and Behavioral Example 1: We will be recruiting students using a handout in the class room. For students participating on the internet, we will send an email and post the handout on the website that is used for the class. In both cases, the researcher will explain to the students the nature of the project as well as soliciting their voluntariness to participate in the study. Copies of the recruitment are uploaded to this application.***

***Clinical or Basic Science Example 2: This is a chart review. We will not be recruiting study subjects rather we will be redacting data from charts.***

***Exempt Review Study Example 3:***  ***There is no recruitment of subjects. We will be retrieving data from the website and census information.***

***If your study involves recruiting participants for a interactive or interventional study, follow directions provided above. If you will be using recruiting material such as emails, bulletin board announcements, news paper advertisements, etc., have the flyer, email, letter to subjects etc. ready to be uploaded into the eIRB application.***

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.

***Follow directions provided above.***

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.

***Follow directions provided above.***

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).

***Follow directions provided above. If above directions are not applicable, it is ok to say “not applicable”.***

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.

***Follow directions provided above.***

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.

***Most often the answer is “not applicable” particularly for Glassboro campus. However, in some genetic studies it is not unusual to ask information about family members or even ask family members if they are interested in participating in your study. If that is the case, sate exactly how you will be reaching out to other family members and how they will be protected.***

***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.]

***Social and Behavioral Example 1: This study requires consenting. Please use the consent form template appropriate for your study. This form can be downloaded from the eIRB site under “Submission and Forms”.***

***Examples 2 and 3 does not require a consent form***

***Consent forms and procedures may vary depending upon the nature and risk to subjects. Minimal risk consent generally apply to blood draws, data collections, use of left over human specimens, interviews and behavioral interventions.***

***More than minimal risk consent form and process apply to studies in which the probability and magnitude of risk is greater than the risk endured during the daily life. Medical consent forms may require HIPAA authorization if participant’s protected health information.***

***There are also nonmedical consents that apply to social and behavioral studies. This may include any one of the following depending upon the type and methods of your study.***

* ***“Interview Consent”***
* ***“Online Consent”***
* ***“Paper Survey Consent”***
* ***“Parent or Guardian Consent”***
* ***“Alternate Consent”***

***The eIRB site provides some sample templates. Please use the appropriate template for your research study.***

***In some cases involving children an assent may be required if children are below 18 years of age. The assent language may vary depending upon the age and maturity of children. In general children above seven years of age require an assent. Adolescents may actually be assented using the adult consent form with some modifications for adolescents to assent .An assent template is also provided in the eIRB site.***

***Some research may involve oral or phone or electronic consent. Please contact the IRB office for further instructions on these forms of consenting procedures.***

***Medical chart reviews without the use of identifiers may not require consent; however, they may require HIPAA waiver of authorization.***

***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.

***In general many studies may not involve any cost to the participants. If it does, clearly describe why and what the cost would be.***

***If you are providing compensation in any form, like gifts, lottery, raffle or money or credit card describe the process. Compensation should commensurate with the task and time, but not look like inducements.***

**3.5 Chart Review Selection**

***Clinical or Basic Science Example 2 is applicable here.***

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.

***Follow the guidance above (3.5))***

**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.

***Follow the guidance above (4.1)***

***Some behavioral studies may involve interventions to be compared for their effects on participants.***

***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***

***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.***

***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.

***Example 1: There may some psychological/emotional stress by participating in either the internet-based study or face-to-face physical presence in the class. Describe if you are anticipating psychological/emotional stress and what would you do to alleviate such stress.***

***Examples 2 and 3: It does not involve physical risk of harm. However, there may be distinct possibility of breach of confidential information that was collected. Describe a procedure by which you will preserve confidentiality. This may involve collection of anonymous data and storing data in a place a place that is secure.***

***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.***

**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.

***Thiis is self-0 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.***

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.***

**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.***

**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.***

**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.***

**8. Bibliography**

 Include all references cited in the text.

**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.***