**ROWAN UNIVERSITY**

**SOCIAL, BEHAVIORAL AND EDUCATIONAL RESEARCH PROTOCOL TEMPLATE**

**INSTRUCTIONS AND EXAMPLES FOR COMPLETING A ROWAN RESEARCH PROTOCOL**

**WHEN SUBMITTING THE PROTOCOL, PLEASE DELETE ITEMS LABELED AS GUIDANCE (IN BLUE) AND EXAMPLES (IN GREEN). ONLY PROVIDE INFORMATION REGADING YOUR STUDY UNDER EACH OF THE TITLES.**

**TRY TO LIMIT THE PROTOCOL LENGTH TO NO MORE THAN THREE PAGES BY PROVIDING PERTINENT INFORMATION.**

The following template provides three examples (color coded) of developing a research protocol for social, behavioral and educational 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:

* Background significance
* A research design or methodology
* How subjects are recruited
* How participant’s records are obtained and used
* Study description of what will happen in the study whether the study involve prospective interviews or anonymous surveys or analyzing existing data and what data will be collected and analyzed
* Risks and benefits
* How subjects consented
* Statistical Considerations
* Reporting results

Before you start completing an IRB application you should write the protocol for your study using the following official Rowan protocol template. You can obtain this template from the following web-link:[**https://research.rowan.edu/officeofresearch/compliance/irb/submissions/initialsubmissions/index.html**](https://research.rowan.edu/officeofresearch/compliance/irb/submissions/initialsubmissions/index.html)**.**

You must upload the protocol into CAYUSE IRB. Instructions to upload the protocol are posted on Rowan IRB website:

[**https://research.rowan.edu/officeofresearch/compliance/irb/submissions/initialsubmissions/index.html#A1**](https://research.rowan.edu/officeofresearch/compliance/irb/submissions/initialsubmissions/index.html#A1)

The next few pages show the protocol document with examples on how to respond to the questions. Please submit the protocol in WORD format.

**Upon completion of your protocol, please remove all instructions, guidance, and examples text before attaching to your Cayuse IRB submission.**

**ROWAN UNIVERSITY**

**PROTOCOL TEMPLATE**

**Title of Project:** Click or tap here to enter text.

**Short Title:** Click or tap here to enter text.

**\*Principal Investigator:** Click or tap here to enter text.

**College/School and Department:** Click or tap here to enter text.

**Co-Investigators:** Click or tap here to enter text.

**\*\*Funding Source(s):** Click or tap here to enter text.

**Protocol Version Number and date:** Click or tap here to enter text.

\*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 the IRB 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 AND RATIONALE**

GUIDANCE: Clearly state the overall purpose and rationale behind the study. [Note: IRB reviewers come from a diversity of backgrounds. Avoid the use of acronyms and highly technical language. Also state the rationale behind the study making it specific to the study. In general, rationale corresponds to closing the gap or solve a specific problem or advance knowledge in the specific area of research.

EXAMPLES

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

Specific aims of the study are:

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

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

The rationale behind the study is to study the impact of virtual classroom learning in education.

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

The rationale behind the study is to demonstrate that virtual learning is a revolutionary approach to early learning.

**2. BACKGROUND AND SIGNIFICANCE**

GUIDANCE: 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 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., behavior, social, educational, chart review, etc.) and to society in general (e.g. increased understanding of pertinent to objectives and rationale).

For clinical chart reviews, provide the background and explain why you are conducting the chart review and the significance. For social, behavioral and educational 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.

EXAMPLES:

**Social, Behavioral and Educational Example:** Provide description and references (in the Bibliography Section) of previous studies pertinent to your study and justify the proposed study.

**Exempt Review Study Example:** 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. STUDY OBJECTIVES**

GUIDANCE: Primary Objective: Outline specifically what will be achieved by the study that derive directly from the overall purpose. List the primary objective and secondary objectives in bullets. Objectives can be described in the form of a question.

EXAMPLES:

**Social, Behavioral and Educational Example:**

* Primary: Can internet-based training promote student learning compared to face-to-face classroom training?
* Secondary: 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.

**Exempt Review Study Example:**

* **Primary:** The overall objective is to evaluate how race, ethnicity and age affect certain early educational interventions.
	+ **Secondary:** Is the distribution of race/ethnicity among early intervention (EI) participants consistent with what would be expected in the general population?
	+ What is the relationship between race/ethnicity, age of entry into program; and disability category among EI participants?
	+ 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).

**4. HYPOTHESES**

GUIDANCE**:** State 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).

EXAMPLES:

**Social, Behavioral and Educational Example:** 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.

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

**5. RESEARCH DESIGN AND METHODS**

GUIDANCE: Provide a brief overview of the entire study design including various phases of the study (if more than one). Describe if randomization or blinding is used.

Describe your design specific to your study and how you will be interpreting results. Provide or upload all study instruments such as questionnaires, behavioral measures, etc., that are being performed specifically for the purpose of the research. Include copies of all tests and questionnaires. For study specific measurements or data points, list them individually and give a brief justification of why each one is needed. Describe how your research methods that are specific to the study affect research risks, harms and benefit to subjects. 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.

For chart reviews, clearly define the information you will be extracting from the chart with justification for the information collected.

**6. STUDY DURATION, ENROLLMENT AND SITES**

GUIDANCE: It is important that you describe how long the study may take. Estimate the duration as closely as possible. Duration includes the specific length of time to complete the study as well as length of time subjects are expected to complete the given task. Do not include the estimated time for the data analysis phase since data analysis time is no longer an IRB requirement. If there are multiple tasks in a study, provide the time complete each task. Please make sure that fatigue factor is included if the tasks longer time.

* 1. **Duration**

**Social, Behavioral and Educational Example:** 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. **It will take approximately ……..minutes/hours for subjects to complete the task.**

**Exempt Review Study Example**: 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.

**6.2. Enrollment**

GUIDANCE: Describe total sample size (including gender and minority considerations), expected accrual rates and sampling strategy (justified for testing the primary and/or secondary hypothesis). Accrual rates mean expected enrollment of subjects in a period of time. For example, how many subjects will be enrolled in a specific period of time, week, month or year to complete enrollment. Justify the proposed sample size. (Example: Power calculations, expected response rates, etc.). For instance, power calculations, common with experimental designs, are not always used in all research methods. (Example: The quality of research, using secondary data, or extremely large samples).

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, Behavioral and Educational Example**: In this study we plan to approach 100 students ages above 18 irrespective of their gender. 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.

**Exempt Review Study Example:** Data will be retrieved from general census information (NJ counties) freely available on public source 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. Sample Size Justification

**6.3 Study Location/Sites**

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

**Social, Behavioral and Education Example:** This study will be conducted in the College of Education at Rowan University. The address is follows: …………………..

**Exempt Review Study Example:** 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.

**7. STUDY SUBJECT RECRUITMENT**

**7.1 Population**

GUIDANCE:Identify study populations (including age range, gender, and ethnic background), the inclusion and exclusion criteria. In addition, justify the inclusion of targeted persons (e.g., healthy participants, employees, students or participants with certain medical conditions). In determining if the selection and recruitment of participants is equitable, the IRB takes into account the purpose of the research, the setting in which the research will be conducted, whether prospective participants will be vulnerable to coercion or undue influence, the selection (inclusion/exclusion) criteria, participant recruitment and enrollment procedures, and the influence of payments to participants. The IRB also evaluates whether the study imposes fair and equitable burdens and benefits - such that one group of persons does not disproportionately receive the benefits compared to another group assuming only the risks.

EXAMPLES:

**Social, Behavioral and Educational Example:** Our study population is primarily consist of students above 18 – 60 years of age and includes all gender and ethnic backgrounds in the specific class. Students are from a class focused on experiential learning and they are undergraduate students.

**Exempt Review Study Example:** In this study we will be using the publicly available data. No specific population is targeted.

**7.2 Recruitment**

GUIDANCE: Please consider the following ethical questions or recruitment strategies: a) Ensure that selection of research participants is equitable and appropriate for the study. b) Make sure that the recruitment strategy respects an individual’s reasonable expectations for privacy.

EXAMPLES

**Social, behavioral and Educational Example:** 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.

**Exempt Review Study Example:** There is no recruitment of subjects. We will be retrieving data from the website and census information. Example, ask recruitment questions in a private setting where others will not overhear the answers. Do not put undue pressure and give ample time to consider and do not promise excessive inducements.

**7.3 Recruitment Methods**

GUIDANCE: While preparing recruitment, consider the purpose of the research, the setting in which the research will be conducted, and be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons or people with intellectual (other) disabilities. The following methods are permissible:

* + 1. Advertisements, flyers, information sheets, notices, internet postings and/or media to recruit subjects such as social media. Use the Rowan template provided in the IRB website.
		2. Direct recruitment of potential study participants. Researchers having direct contact with subjects.
		3. Recruitment letters. The recruitment letter can be brief but it should include information about how the person was identified to be sent the letter, what is involved if the person participates and an overview of any risks or potential benefits. It should also let the person know how to inform someone if he or she wants to participate, not to participate, or where to get answers to additional questions, and, of course, who is doing the study and why.
		4. Participant Pool. These are pools for which potential research participants have given permission for future contact such as student pool or SONA system.

If the study involves chart or records review, describe how they will be accessed, what you will doing with the identifiers, explain whether a consent/HIPAA authorization is needed or a consent/authorization waiver is needed to access records. Provide a data collection instrument even if they are non-clinical chart or data source in the form an Excel spreadsheet to indicate what data is being collected. Collection of social security number is not permitted.

EXAMPLES:

**Social, Behavioral and Educational Example**: 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 flyer 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 materials are uploaded to this application.

**Exempt Review Study Example:** There is no recruitment of subjects. We will be retrieving data from the website and census information and they are publicly available records. A data collection instrument is attached.

**7.4 Inclusion Criteria**

GUIDANCE: You must specify inclusion and exclusion criteria for participation in the study. Inclusion criteria are characteristics that the prospective subjects must have if they are to be included in the study, while exclusion criteria are those characteristics that disqualify prospective subjects from inclusion in the study. In this sense, inclusion and exclusion criteria are usually written in a positive way: if a participant has an inclusion criteria, they are in; if they have an exclusion criteria, they are out. Inclusion and exclusion criteria may include factors such as age, sex, race, ethnicity, type and stage of disease, the subject’s previous treatment history, and the presence or absence of other medical, premorbid, psychosocial, or emotional conditions.

EXAMPLES:

**Social, Behavioral and Educational Example:** Our target population is students. All students in this class are above 18 years. We will include both male and female students irrespective of their ethnic backgrounds.

**Exempt Review Study Example:** We are retrieving existing publicly available data, which includes subjects of all ages, sex and ethnic background.

**7.5 Exclusion Criteria**

Describe who will be excluded from the study, why they will be excluded taking into consideration their demographic, biomedical or behavioral characteristics. You must also provide proper justification so subjects are not categorically excluded from the study

EXAMPLES:

**Social, Behavioral and Educational Example:** The nature of this study is extremely specific to this class. If students are not part of the targeted population or this class, they will be excluded from the study.

**Exempt Review Study Example 3:** We are retrieving existing publicly available data and we will not exclude any part of the available data.

**8. INFORMED CONSENT**

GUIDANCE: Regulations and ethical considerations require obtaining an informed consent from prospective subjects before they include these subjects in research. Informed consent is dynamic interactive and educational process that takes place between the investigator and prospective subject, allowing the investigator and the participant to exchange information and ask questions and subjects to make a voluntary and informed decision whether to participate in the study. In all cases a copy of the informed consent must be provided before consent and adequate time must be provided for the subject to make an informed decision. In most cases, federal regulations require informed consent and documentation of the process. In certain circumstances, the federal regulations allow a waiver of informed consent documentation of the process. Request for waiver must be granted by the IRB.

PLEASE NOTE that the type of consent form used and the consenting may vary depending upon the type of research and risks and benefits associated with a particular research project. The Office of Research has posted several consent form templates that are broken down into adult consent form for high risk (more than minimal risk), parental consent for children in more than minimal risk studies, child’s assent, audiovisual consent, social behavioral research educational research, alternate consent for anonymous surveys, questionnaires, interviews etc. Please use the appropriate consent form for your study.

Minimal risk means, the probability and magnitude of risk is no greater than that experienced during the daily life such as, blood draws, experiments involving dance, music and drawings, collecting biospecimens.

Medical chart reviews with protected health information with identifiers requires HIPAA authorization or HIPAA waiver of authorization when appropriate. RowanSOM Privacy Officer or RowanSOM IRB will make the final determination.

Verbal, phone and electronic consent are permissible. Please check with the IRB office before deciding on the use of verbal, phone or electronic consent. Having a casual conversation with a prospective subject does not meet the criteria for consenting.

EXAMPLES:

**Social, Behavioral and Educational Example:** This study requires proper consenting. Please use the consent form template available on the IRB website that is appropriate for your study. This form can be downloaded from the CIRB site under “Submission and Forms”.

**Exempt Review Study Example**: This is a publicly available data thereby not requiring consent.

**9. RESEARCH COSTS TO SUBJECTS AND COMPENSATING RESEARCH SUBJECTS**

GUIDANCE: Although most research studies do not involve costs to participate in a research study, some studies may incur out of pock expenses. Federal regulations require that, when appropriate prospective research subjects must be informed of any additional costs to the participant. Therefore, list all the costs such as mileage, parking, meals, tolls etc. that the subject may incur and also indicate the amount of compensation (monetary, gift cards, raffles, etc.) in the protocol and on the consent form.

**9.1 Compensation**

GUIDANCE: Federal regulations provide no clear guidance on the level of compensation that should be offered to research subjects. However, the regulations do require that researchers seek consent only under circumstances that minimize the possibility of coercion or undue influence. Payment or non-monetary reward is given to subjects as remuneration for time and inconvenience of participation, as well as an incentive to participate. Compensation can include remuneration that is monetary (cash, gift cards, vouchers, etc.) and/or non-monetary (gifts/promotional items, course credit, extra credit, etc.). Compensation should be appropriate for the time and effort subjects devote to participation. The level of payment should not be high enough to cause subjects to accept risks that they would not otherwise accept or participate in activities to which they would otherwise strongly object based on personal values or beliefs.

**9.2 IRS Reporting and Collection of Social Security Numbers**

It is the responsibility of the PI to maintain accurate payment records according to University accounting standards and sponsor requirements. In addition, the IRS requires that Rowan University Finance Department report payments in excess of $600. If a PI anticipates reaching this threshold with a single subject in a calendar year, s/he should consult his/her department and/or University accounting regarding this to ensure the appropriate paperwork is filed. Historically, the majority of research projects at Rowan do not meet this reporting threshold.

Because of the sensitive data associated with Social Security numbers, these should generally be collected separately (outside of research protocol or consent) for research payment purposes only when necessary to comply with IRS reporting requirements.

EXAMPLES

**Social, Behavioral and Educational Example:** There will not be any cost for participating in this research project. We will not be providing any compensation to you to participate in this study.

**Exempt Review Study Example**: This is a publicly available data thereby not requiring compensation.

**10. STATISTICAL CONSIDERATIONS**

**10.1 Sample size**

GUIDANCE: Sample size refers to how much data is needed to make a correct decision on particular research. When more data are collected, then the decision will be more accurate. There will be less error of the parameter estimate. Provide justification for the sample size, for instance, consider including relevant statistical information (Example: Power calculations, expected affect size, attrition rates, and data from other studies. Include the number that needs to be screened to achieve the desired result. Estimate the number likely to agree to participate and how sample size will be adjusted for potential refusals.

For longitudinal studies, indicate the number of potential drop outs and how sample size is adjusted for potential loss to follow-up.

EXAMPLES:

**Social, Behavioral and Educational Example:** 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.

NOTE: If you have the capability to determine the “n” based on the power analysis you may 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”.

**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.

**10.2 Study Variables and Outcome**

**The following sections 10.3, 10.4, and 10.5 are guidance only. Include appropriate responses based on your study variables.**

GUIDANCE: All research projects are based around variables. A variable is the characteristic or attribute of an individual, group, educational system, or the environment that is of interest in a research study. Variables can be straightforward and easy to measure, such as gender, age, or course of study. Other variables are more complex, such as socioeconomic status, academic achievement, or attitude toward school. Variables may also include an aspect of the educational system, such as a specific teaching method or counseling program. Characteristics of the environment may also be variables, such as the amount of school funding or availability of computers. Therefore, once the general research topic has been identified, the researcher should identify the key variables of interest.

Outcome variables are usually the dependent variables which are observed and measured by changing independent variables. These variables determine the effect of the cause (independent) variables when changed for different values. The dependent variables are the outcomes of the experiments determining what was caused or what changed as a result of the study.

The response variable is also called as the dependent variable because it depends on the causal factor, the independent variable. Depending on the various input values of the experimental variables, the responses are recorded.

**10.3 Independent Variables**

GUIDANCE: Describe any behavioral treatments or interventions to be compared for their effects on participants. If the study is chart reviews, indicate how you will be comparing various factors associated with the research question or previous reviews. NOTE: Some behavioral studies may involve interventions to be compared for their effects on participants.

**10.4 Dependent Variables or Outcome Measures**

GUIDANCE: A Dependent variable is what happens as a result of the independent variable. For example, if you want to explore whether diet impacts on the incidence of kidney diseases, diet is the independent variable while kidney disease is the dependent variable.

**10.5 Confounding Variable**

GUIDANCE: A confounding variable, or confounder, affects the relationship between the independent and dependent variables. A confounding variable in the above example would be differential exposure to other factors that increase kidney disease such as smoking or consuming alcohol.

**10.6 Data Handling and Analysis**

GUIDANCE: Describe how research data is stored, archived or disposed-off in a safe and secure manner during and after the conclusion of a research project. This includes the development of policies and procedures to manage data handled electronically as well as through non-electronic means. Data analysis plan should include data entry and final statistical analysis of data with respect to study endpoints. If data includes protected health information or personal identifiers, provide a plan when the link to data source and data will be destroyed.

GUIDANCE: For greater than minimal risk studies, the following elements should be described when describing data handling:

1. File formats to be used
2. Rowan University directory/server to be used to store identifiers and personal, private identifiable information, including any linking document
3. Will the data be shared? If so, with whom and when?
4. Plan for protecting the data and anonymizing data
5. Archiving, long-term storage, or final disposition/destruction of data, including repositories and/or anonymizing data

EXAMPLE: Data will be analyzed using quantitative methodologies. In most instances, only descriptive statistics will be reported, however, when appropriate more advanced data analysis may take place (t-tests) to determine differences based on student populations. All data will be reported in aggregate and confidentiality will be protected. We will keep all our data in a secure or in an encrypted and password protected environment with access limited to the study team. Or, we will store our data in by keeping the data and signed consent forms in separate cabinets with access only to study team.

**11. RISKS AND POTENTIAL BENEFITS**

**11.1 Risks**

GUIDANCE: In human subject research, research is categorized into two categories: Minimal risk or Greater than minimal risk. Research is considered minimal risk when the risks of the research are not greater than those experienced in regular daily life. Researchers are responsible for identifying any possible risks of the research and minimizing risks to subjects whenever possible. Some common types of risks are: physical, economic risk, social, psychological, legal and loss of confidentiality. Include strategies to eliminate risk by keeping data in secure places, limiting access to data by designating individuals who will have access to data and conducting procedures that are specific to the study. Strategies to minimize risk should include use of existing records or specimens, obtaining a Certificate of Confidentiality to minimize the likelihood of forced disclosure of sensitive materials, coding data and samples to conceal identifiers and limiting access to research data.

EXAMPLES:

**Social, Behavioral and Educational Example**: There may be some psychological/emotional stress by participating in either the internet-based study or face-to-face physical presence in the class. We will either eliminate or decrease risk by doing the following………………………

**Alternate language example:** This is a minimal risk study. There are no physical dangers to respondents. There is the potential for participants to be identified, given our access to their personal identifiers. These risks will be minimized by maintaining identifying information in separate, password-protected files to which only the research team will have access.

**11.2 POTENTIAL BENEFITS**

These are only guidance. Describe the potential benefit with respect to your study using the following guidance (A, B, C below).

GUIDANCE: In the context of research, there may be three types of benefits:

1. Direct Benefit: A benefit arising from receiving the intervention being studied. Any study that involves an intervention could have an anticipated direct benefit. In these studies, participants may receive some intervention (medical, behavioral, or other), that they would not otherwise receive. When describing the anticipated benefits of research in the protocol and consent document, it is important that researchers make subjects aware that the benefits of the intervention are not known, and that the research is being conducted to evaluate the effectiveness of the intervention. Whenever possible, the researcher should provide any known information about the probability and magnitude of the anticipated benefit.
2. Indirect Benefit: This occurs when research does not involve an intervention there is little opportunity for direct benefit. When the risks of the research are no greater than those encountered in the everyday life, there is no requirement for direct benefit. When the research risks are greater than minimal risk, then the researcher must provide justification that explains how the anticipated benefits of the research justify the risks to the subjects. Indirect Benefits such as collateral benefit arising from being a subject, even if one does not receive the experimental intervention (for example, a free physical exam and testing, free medical care and other extras, or the personal gratification of altruism).
3. Aspirational benefit like benefit to society and or future patients, which arises from the results of the study.

EXAMPLE: There may not be any direct benefit. Results of our study may help enhance our ability to develop some guidelines with respect to …………………….that would in general benefit the society.

**12. DATA AND SAFETY MONITORING**

For studies where the risk of harm is greater than minimal risk, a safety monitoring plan must be included to ensure the safety of subjects.

This section is not applicable to minimal risk studies such as chart reviews, questionnaires, surveys that are part of social, behavioral and education research.

**13. PLANS FOR REPORTING OR PUBLISHING RESULTS**

GUIDANCE: **It is a good practice to describe your plan for reporting aggregate of results to research subjects (if promised on the consent from) or in a research or scholarly publication.**

EXAMPLE: We plan to share the aggregate data with our research subjects’ results in accordance with the signed consent form. Or, aggregated data without the identifiers will be used in any publication resulting from this study.

**14. BIBLIOGRAPHY**

Include all references cited in the text. Keep it specific to the study.

**15. APPENDICES**

GUIDANCE: Include here any additional information such as flow charts, diagrams, instruments, etc., that is related to the protocol, but is not applicable or does not appear to fit into one of the sections such as flow charts, diagrams