**ROWAN UNIVERSITY**

**PROTOCOL TEMPLATE FOR CLINICAL RESEARCH AND CLINICAL INTERVENTIONAL STUDIES**

Clinical Research Protocols (protocols) are research studies conducted by Rowan University faculty, students and staff. The protocol may test something for a specified condition or purpose, e.g., a drug or medical device, or may review previous studies or record the history of a disease or condition. Interventional studies include, industry sponsored research and investigator-initiated clinical research.

**WHEN SUBMITTING THE PROTOCOL, PLEASE DELETE ITEMS LABELED AS ‘GUIDANCE”. ONLY PROVIDE INFORMATION REGADING YOUR STUDY UNDER EACH OF THE TITLES.**

The following template provides guidance and example (color coded) of developing a research protocol for Clinical Research and Clinical Interventional Studies These templates are for guidance purposes only to provide a general idea of how a protocol may be written to describe:

* Background significance
* Study Objectives
* Investigation plan
* Study Procedures
* Study evaluation and measures
* Statistical considerations
* Study medications or Device
* Safety management
* Study administration
* Reporting results (Publication)
* References

This protocol template may be modified depending upon the type of intervention or clinical research. 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 will be uploading the protocol into the Rowan-IRB electronic submission instructions to upload the protocol are posted on Rowan IRB website: [**https://research.rowan.edu/officeofresearch/compliance/irb/index.html**](https://research.rowan.edu/officeofresearch/compliance/irb/index.html)

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

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**CLINICAL AND INTERVENTIONAL RESEARCH PROTOCOL TEMPLATE**

**Note1:** Some of the sections may not be applicable for your research. In such cases, enter “not applicable.” Delete all of green sections when the protocol is complete.

**Note 2**: If this is an Industry-sponsored study, please read the Investigator’s Brochure provided by the sponsor before completing the protocol.

**Note 3:** Investigator-initiated trials are those that are not industry-sponsored clinical trials that are planned by a researcher. The burden of submitting such trial is a bit more cumbersome and the principal investigator bears the ultimate responsibility to conduct such trials.

**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 or Sponsor:** 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 or industry that funded the study. For example, Glaxo-SmithKline, National Institutes of Health, etc. If the study is investigator-initiated clinical research enter “Internally funded” or identify the funding source.

**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. State the specific rationale behind the study. In general, rationale corresponds to closing the gap or solve a specific problem or advance knowledge in the specific area of research.

**2. BACKGROUND AND SIGNIFICANCE**

GUIDANCE: Provide an introduction to the project with relevant literature and available data. Provide references in Section 14 of this template. Describe previous clinical and non-clinical findings. This section must include the description of the investigational product or description or the type of intervention. If it is a product (drugs, biologicals or device) describe how they are selected.

**3. STUDY OBJECTIVES**

Describe the primary and secondary objectives using bullets. It is important to specifically outline what will be achieved in this study. This must be based on the purpose of the study and expected outcomes.

**4. INVESTIGATIONAL PLAN**

The design should include different phases of the study such as:

1. Screening phase (Determining eligibility to the study)
2. Treatment phase
3. Follow up phase (if applicable)
4. Randomization and blinding

Additional guidance is provided in Section 8 below.

**4.1 Study Design:** The design should be specific to the study purpose(s) and objectives. The design in addition to products and interventions, must include questionnaires, diaries, etc. that are being used. Each study must be clearly described.

**4.2 Screening:** Screening is done to determine the eligibility. This could be done verbally or during a screening visit or screening consent using certain parameters for the eligibility of the study.

**4.3. Treatment Phase**: Clearly describe the treatment phase. Often charts or diagrams may be used to describe the treatment procedures.

**4.4 Follow up phase:** Some studies may include a follow up phase after the intervention has been completed, which must be included here. Provide details of what will be done at this phase.

**4.5 End of Study Visit:** Provide detailed description of what will occur at this visit

**4.6 Randomization and blinding**: The design must include the procedures for randomization and blinding. Please keep research subjects in mind while preparing this section.

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

**5.1 Study Duration:** 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. Since studies may involve multiple dosing, visits and procedures, it is highly recommended to the investigator to prepare a study chart or table pertinent to study visits, treatments, intervention and study procedures such as tests, imaging, etc.

**5.2 Study Sites:** If there are multiple visits, take into consideration the burden on the research subject for transportation and companionship. Describe the study location and sites. Take into consideration treatment and intervention site may be different than laboratory tests and imaging.

**5.3 Number of Subjects:** State the number of subjects projected to be enrolled at your site and how many subjects will be actually enrolled at your site as well as other sites nationally or internationally, if this a multi-site study.

**5.4 Study Population:** 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, subjects with certain diseases characteristics or 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.

**6. INCLUSION AND EXCLUSION CRITERIA**

GUIDANCE: You must specify inclusion and exclusion criteria for participation in the study. If this is an industry-sponsored study refer to the investigators brochure.

**6.1 Inclusion criteria**: They 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. If this is an Industry-sponsored study, please read the investigators brochure to determine who may be included in the study and who may not with respect age, sex, ethnic background and medical conditions.

**6.2 Exclusion Criteria:** Protocol must state why certain subjects may be excluded from the study. Describe who will be excluded from the study, why they will be excluded taking into consideration their age, sex, ethnic background, pregnancy, certain co-morbid conditions and certain concomitant medications. Exclusion must provide proper justification so subjects are not categorically excluded from the study

**7. RECRUITMENT STRATEGIES**

**7.1 Recruitment:** While preparing recruitment, consider the purpose of the 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. 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. 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.
4. 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.

**8. STUDY PROCEDURES**

**8.1 Screening procedures:** Identify study populations (including age range, gender, ethnic background, medical condition, and 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.

**8.2 Treatment phases:** This must include number of visits for treatment and testing, expected follow up visits (if any), unscheduled visits, use of concomitant medications, rescue medication, withdraw from the study due to adverse effects or patient’s decision to discontinue or early termination, alternate treatments and rescue medication. Provide detailed description of study visit or visits since there may be more than one visit. Include all procedures in each of the visits. This is usually included as a simple bullet list of all of the interventions, monitoring procedures and measurements such as lab tests, imaging, physical exams, drug dispensing, diary etc., that will take place. This section should be perfectly clear to ensure that the study is executed as planned.

**8.3 Concomitant Medication**: All prior and concomitant medications used prior to treatment with study drug/intervention or XX days prior to the screening visit and through the end of the study must be described including the dates of administration, dosage, and reason for use.

**8.4 Rescue Mediation:** If subjects receive rescue medication for adverse reactions or inadequate response to study medication, include here the options and how the decision will be made to permit such treatment.

**8.5 Withdraw**: Be aware that subjects have the right to withdraw from the study. The Investigator or the Sponsor (if applicable) may also withdraw subjects who are not in compliance with the study plan. Or, withdraw may be because to protect the subject for reasons of safety or for administrative reasons. Describe the process for withdraw including how you record the withdraw.

**8.6 Early Termination**: Describe the procedures that will be performed for each subject that withdraws prior to completing the study.

**9. STUDY EVALUATION MEASURE**

All monitoring procedure, measurement and intervention described in Section 4 must have a corresponding description of exactly how the measurement will be made. Each evaluation, BP, QOL questionnaire, etc. should be listed with a description here. All data collected should be described along with how it will be measured. Standard, validated tests and test instruments do not have to be included in the Appendix but non-standard and non-validated instruments should be included.

**9.1 Screening and baseline measurements**: This consist of information or testing done/gathered for each arm of the study at the beginning of a study from which variations found in the study are measured. A person's health status before he or she begins a clinical trial. Baseline measurements are used as a reference point to determine a participant's response to the experimental treatment. This may include physical exams, laboratory, radiological tests (imaging), diagnostic test, measures, scales, pharmacokinetic evaluation, if any and safety evaluations (risk mitigation). In general, minimum requirements are, age, gender, region of enrollment, ethnicity, relevant demographic characteristics, clinical measures relevant to study, such as clinical characteristics, including baseline values of outcome measures and prior and concurrent treatment characteristics.

Screening may involve medical chart review, routine or specific medical examinations, laboratory tests, pregnancy test, imaging etc. List the screening tests and records to be reviewed including what information may be gathered from medical charts. Please note that HIPAA authorization may be required for collect medical protected health information.

**10. STATISTICAL CONSIDERATIONS**

**10.1 Primary endpoint:** This is the endpoint for which subjects are randomized and for which the trial is powered. The primary endpoint is the variable that relates back to the Primary Objective and serves as the basis for the justification for the Sample Size.

**10.2 Secondary endpoints**: These are endpoints that are analyzed post hoc, for which the trial may not be powered nor randomized yet the treatment or intervention is effective in a subgroup of population. The baseline data also needs rigorous analysis to make a valid comparison or determine a valid outcome. Therefore, describing the comparative analysis to determine the outcome should be described.

**10.3 Efficacy**: Efficacy is "the extent to which a drug has the ability to bring about its intended effect under ideal circumstances, such as in a randomized clinical trial". Effectiveness is "the extent to which a drug achieves its intended effect in the usual clinical setting". The protocol must describe how efficacy analysis is done, what statistical methods are used and who will perform the statistics. It is a good practice to include a statistician in the trial.

**10.4 Pharmacokinetic Analysis:** Provide description of pharmacokinetic parameters to be assessed and methods to be employed to calculate those parameters.

**10.5 Safety analysis:** This requires accurate safety data reviews including adverse events, toxicity and laboratory evaluations. A subject should be included if, and only if, the subject actually received a study treatment (even if it is a placebo). This set of subjects are grouped for analysis according to the treatment they actually received, as opposed to the treatment they were allocated to receive at randomization.

**10.6 Sample size and power:** Every clinical trial should be well planned. The estimation of sample size along with other study related parameters depends on Type I error, Type II error and Power. In any clinical trial, the sample size has to be planned on a justifiable, rational basis. The purpose of sample size calculation is to determine the optimal number of participants (patients) to be included in the trial.

**10.6.1 Sample size**: This refers to how much data is needed to make a correct decision on particular research. When more is data collected, then the decision will be more accurate and there will be less error of the parameter estimate. Provide statistical justification for the sample size (considerations include desired power and, as appropriate, assumed effect sizes for a hypothesis testing study; precision for a study whose objective is to estimate a population parameter.). 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.

**10.7 Interim analysis:** (If applicable)- Interim analysis is one of the reliable rational approaches to clinical trials that incorporate what is learned during the course of a clinical study and how it is completed, without compromising the validity or integrity of the trial. If you are conducting an interim analysis, please describe the method and how the analysis will impact on the study and the decision making for continuance of the trial.

**11. STUDY ADMINISTRATION**

**11.1 Randomization**: Refers to a study in which the participants are divided by chance into separate groups that compare different treatments or other interventions. Using chance to divide people into groups means that the groups will be similar and that the effects of the treatments they receive can be compared more fairly. At the time of the trial, it is not known which treatment is best. In a randomized control trial, the trial uses a control group for comparison or reference. In the control group, the participants do not receive the new treatment but instead receive a placebo or reference treatment. Please describe the randomization process that will be used in the study.

**11.2 Blinding:** Blinding or masking is used to try to eliminate bias. It is a tenet of randomized controlled trials that the treatment allocation for each patient is not revealed until the patient has irrevocably been entered into the trial, to avoid selection bias. Describe how you will be introducing blinding in your study.

**11.3 Un-blinding:** This is disclosure to the participant and/or study team of which treatment the participant received during the trial. Un-blinding a trial is a necessary process to protect participants in the event of medical or safety reasons. The process of un-blinding should be planned and must be included in the study protocol.

**11.4 Data collection**: when a clinical trial is being designed, it is important to plan how data will be collected and during the trial. It is important to be cognizant of obtaining clinical trial data from the days of collecting information on a handwritten paper or “Case Report Form” and subsequently double data entering the CRF data into a clinical data management system. These days there are more innovative ways to collect data as close to the source as possible. Your research design should include the data collection methods (paper or electronic) and what data is being collected with sufficient details. Every monitoring procedure, measurement and intervention listed in Section 4 should have a corresponding description of exactly how the measurement will be made. Each evaluation, BP, QOL questionnaire, etc. should be listed with a description here. A copy of any non-standard measurement tool should be attached as an appendix. The IRB website contains a list of validated measurement tools that do not need to be appended to the protocol or application.

**11.5 Regulatory and ethical considerations:** Clinical research and clinical trials primarily involves protection of rights, safety, and well-being of the research participants.

**11.6 Data and Safety Monitoring Plan:** Describe the safety and monitoring plan, which includes the processes and safeguards that will be in place to identify risks to research subjects and to protect subjects during the execution of the trial. The plan should focus on anticipated risks of the trial/intervention and must describe the nature of oversight and who will monitor the study such as a medical monitor associated with the study, a designated independent safety monitor, an internal steering committee or an internal data safety monitoring board (DSMB) that is independent of the study team or the sponsor. Internal DSMB must be approved by the IRB. If a DSMB will be employed, the full details of the composition of the DSMB, how it will operate, and how the interim analyses are to be performed should be provided.

**11.7 Risks:** Identify any possible risks, including the likelihood of such risks. Some common types of risks are harm from drugs and devices, adverse reactions, physical, economic risk, social, psychological, legal and loss of confidentiality. Each intervention, drugs and devices bring their own risk. Describe those risks and strategies to reduce those risks with respect to design and execution of the study. Consider all physical, psychological, economic, or societal harms that might accrue to subjects or others.

Distinguish between risks associated with routine clinical care from those that will occur as a result of research. 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.

**11.8 Potential benefits:** In the context of research, there may be direct, indirect and aspirational benefit. Benefits should be broken down into direct benefits (accrue to the study subject as a result of participation) and indirect benefits (benefits that accrue to the individual or society in the future). Summarize all those benefits as applicable including aspirational/potential benefits, if any from trial participation.

**11.9 Risk-Benefit Assessment:** This should include proper justification bringing a balance between risks and benefits.

**11.10 Informed consent, Assent and HIPAA Authorization**

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 consenting prospective subjects. Provide adequate time 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.

Describe procedures that will be used to obtain informed consent/ HIPAA Authorization and assent. Also describe who will obtain consent and assent, where will consent/assent process take place, how privacy will be assured, how much time will subjects be permitted to make a decision, how the investigators will assure that subjects comprehend the nature of the study, the study procedures and the risks and benefits of participation. Describe steps that will be taken to avoid coercion and documentation of consent. HIPAA authorization is generally a combined document; however, in some cases they could be separate based on sponsor’s requirement such as NIH-sponsored clinical trials.

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.

**11.11 Waiver of Consent**: In most clinical trials consent waiver is not applicable. Check with the Office of Research Compliance in regards to waiver in clinical trials/interventions.

**11.12 Waiver of Assent**: The request to waive assent must be justified and appropriate for the study being proposed.

**11.13 Waiver of HIPAA Authorization:** Waiver of HIPAA authorization is not applicable to Clinical trials and interventions when protected health information is used for the purpose of the trial or intervention.

**11.14 Costs to Participate:** Although most research studies do not involve costs to participate in a research study, some studies may incur out of pocket expenses. Therefore, if there is cost, 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.

**11.15 Payment to subjects/family:**  Describe payment or non-monetary reward given to subjects or guardians as remuneration for time and inconvenience of participation, as well as an incentive to participate. Compensation should be appropriate for the time, inconvenience 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. The amount paid to parent/guardians should be separated from the amount paid to subjects. When determining compensation, investigators must take into account reimbursement for travel, parking and meals, amount per visit, justification and form of reimbursement, payments to parent for time and inconvenience (i.e. compensation), amount per visit, justification and form of payment and payments to subject for time, effort and inconvenience (i.e. compensation) amount per visit, justification and form of payment. Subjects not completing the study, for whatever reason, must be paid on a pro rata basis. The IRB will review both the amount and method of payment to subjects to insure that neither presents an undue influence on the trial subjects.

**11.16 IRS Reporting and Collection of Social Security Numbers – NOTE to investigators. This section is not required to be included in the protocol:** 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.

**11.17 Privacy and Confidentiality:** Privacy is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. For example, persons may not want to be seen entering a place that might stigmatize them, such as a pregnancy counseling center clearly identified by signs on the front of the building. The evaluation of privacy also involves consideration of how the researcher accesses information from or about potential participants (e.g., recruitment process). IRB members consider strategies to protect privacy interests relating to contact with potential participants, and access to private information.

Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure. This is to inform subjects about the precautions that will be taken to protect the confidentiality of the data and be informed of the parties who will or may have access (e.g., research team, FDA, OHRP). This will allow subjects to decide about the adequacy of the protections and the acceptability of the possible release of private information to the interested parties

Include how privacy is maintained during consent and during the screening and study phase. State all data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and that the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study. Describe the safeguards to maintain subject confidentiality. State if or if not identifiable data will be used for future study without first obtaining IRB approval.

**11.18 Data Use Agreement:** Describe whether the investigator will obtain data from another source. This may require a data use agreement between the owner (provider) and the investigator. Please consult the Privacy Officer if a data use agreement is needed to collect or have access to the PHI. Some data use agreements may be limited in nature such as use of dates and zip codes that will require a limited data set agreement.

**12. SAFETY MANAGEMENT**

**12.1 Definition of Adverse Events**: An adverse event is any undesirable experience associated with the use of a medical product in a research subject. Based on this definition, state how you will record this event including the severity and frequency, whether related to the intervention or treatment or not.

**12.2 Definition of a Serious Adverse Event (SAE) and Reporting:** The event is serious and should be reported to FDA through the sponsor directly to FDA if it is investigator-initiated when the subject’s outcome is: death, life threatening, hospitalization, emergency room visit, disability or permanent damage, congenital anomaly or birth defect. Provide a statement regarding how you will record and report to the sponsor and the IRB. Describe any plans or procedures for taking care of medical emergencies that might develop during the course of the study. The investigator must confirm that he/she will confirm that FDA regulations will be followed to report serious adverse events (21 CFR 312.32 and 21 CFR Part 803).

The investigator must confirm that they will follow the FDA-definition of an SAE and also identify which are study/device/product-specific SAEs (e.g. if the product has potential for abuse, dependency would be an SAE that they could list here)

**12.3 Follow up Report:** If an SAE has not resolved at the time of the initial report and new information arises that changes the investigator’s assessment of the event, a follow-up report including all relevant new or reassessed information (e.g., concomitant medication, medical history) should be submitted to the IRB. Follow up must be continued till the SAE is resolved.

**13. STUDY MEDICATION**

**13.1 Labeling and Packaging:** Little guidance exists for investigational drug labeling the study drug and device. Describe how you will follow packaging and labeling instructions to ensure safety of the product. The IRB submission should include a copy of the product labeling for the product under investigation which may include the IB, package insert, device manual or other documentation.

**13.2 Treatment Compliance and adherence**: Compliance with treatment can be an important determinant of the outcome of clinical trials. Methods of measuring compliance and how they will be applied to the trial/intervention should be described. Likewise, poor adherence to treatment is a key determinant to measure the outcome. Describe how you will measure compliance and adherence to the products to be use in the trial/intervention.

**13.3 Drug/device accountability:** Drug and device accountability is more than just counting pills, vials and devices. Describe and identify the study staff involved in the study is consistent with the documentation, records are completed with the drug dose, patient, date, time, and individual removing the drug from the inventory. The purpose of these records is to ensure regulatory authorities and the Sponsor that the investigational new drug will not be distributed to any person who is not a study subject under the terms and conditions set forth in this protocol. Ensure that the study subject receives the study drug, and receives the correct dosage. There should be documentation to support drug administration. If the patient self-administers study drug, often diaries and pill vials are collected to validate the administration of study drug. If the drug is administered at a clinic visit, use a checklist to complete to verify the dosage that was given to a study subject.

**14. PUBLICATION** **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. If you do not have access to the complete trial data, describe how publication will proceed.

**15. REFERENCES**

Include all references in the sequence that is cited on the protocol. Include only those references that are pertinent to the study.

**16. APPENDICES**

Include here any additional information such as flow charts, diagrams, instruments, diaries, 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 used in the study including the investigator’s brochure.