BIOMEDICAL RESEARCH PROTOCOL

University of Missouri­­­–St. Louis

*Remove the light blue instructions before submitting and fix any formatting issues.*

Project Title:

IRB Number:

Version Number: 1

Version Date:

Principal Investigator:

Funding Source:

Clinical Trial Phase: *Delete if NA.*

Clinicaltrials.gov Number: *Delete if NA.*

Study Drug/Study Device: *Delete if NA.*

IND/IDE Number: *Delete if NA.*

IND/IDE Holder Name: *Delete if NA.*

*Instructions: Use the section headings to write the protocol, inserting appropriate material in each. If a section is not applicable, remove heading or insert NA. If an Amendment is submitted to the IRB and those changes will require modifications to this protocol, the protocol will need to be re-uploaded with an Amendment. Upload two copies, a track changes and clean copy.*

1. **Research Objectives/Background**
2. Include primary, secondary, and exploratory objectives.
3. Include background and rationale for initiating the study. Includes pre-clinical and clinical data, current experiences with procedures, drug, or device, and any other relevant information to justify the research.
4. **Drugs/Biologics/Devices**
   1. Include the product, dose, route, and regimen.
   2. Include the rationale for choosing the drug/biologic and dose, or for choosing the device to be used.
   3. Include the standard reference therapy against which the study product is being compared, or if the reference is a placebo. Include justification for inclusion of a placebo or non-treatment group.
   4. Include justification and safety information.
   5. If an IDE (for investigational devices) or IND (for investigational drugs) is not necessary, provide justification.
5. **Recruitment Process**
6. Describe the recruitment process; including how and where recruitment will take place.
7. Describe any screening/baseline procedures.
8. **Consent Process**
9. Describe the consent process; including who will be approached for consent and what type of consent will be obtained from each subject population, if there is more than one.
10. **Inclusion/Exclusion Criteria**
11. List the inclusion and exclusion criteria.
12. Describe restrictions on participation and appropriate screening procedures to ensure that the restrictions are maintained, including pregnancy testing.
13. **Number of Subjects**
14. Include anticipated enrollment number in this study. Include a break-down in numbers if there is more than one subject population.
15. Include statistical analysis or other justification for the number of subjects enrolled.
16. **Study Procedures/ Design/Treatment Plan**
17. Include study procedures/design/plan; include the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care). Include study duration and number of study visits required.
18. Blinding, including justification for blinding or not blinding the trial. Describe un-blinding procedures.
19. Justification of why participants will not receive routine care or will have current therapy stopped.
20. Definition of treatment failure or participant removal criteria.
21. Description of what happens to participants receiving therapy when study ends or if participation in the study ends prematurely.
22. Include sub-studies or banking information (correlative/special studies)
23. **Potential Risks/Adverse Events**
24. Describe reasonably foreseeable risks or discomforts to the subjects and steps to minimize risks.
25. Describe any stopping rules.
26. Include the plan for reporting unanticipated problems or deviations. This plan must include a five-day reporting requirement to the IRB once becoming aware of an event.
27. **Anticipated Benefits**
28. Include both direct and indirect benefits for either the individual or society.
29. **Compensation**
30. Describe the amount, method, and timing of disbursement. Compensation can include checks, cash, gifts, extra/course credit, etc.
31. **Costs**
32. Detail costs of study procedures, drugs, biologics, or devices and identify who will cover the cost.
33. **Data Safety Monitoring Plan**

Describe the plan to monitor the data, if necessary. A plan is required for treatment and/or intervention studies, sensitive data are being collected, there is a possibility for subjects to experience adverse events, etc.

1. The plan should include when something needs to be reported
2. The frequency of the monitoring, such as points in time or after a specific number of participants are enrolled
3. Who will conduct the monitoring, such as a data board, medical monitor, investigator, independent physician; the specific data to be monitored
4. Procedures for analysis and interpretation of the data
5. Actions to be taken upon specific events or end points
6. Procedures for communication from the data monitor to this site.
7. **Multiple Sites**
8. Specify who is the lead site and describe the roles of each site in the study.
9. Indicate that all required approvals are already in place or will be in place at each site prior to project implementation. If the study will utilize a reliance agreement or a single IRB, please describe which institution(s) will be relying on another IRB for review, and which institution will be responsible for the IRB oversight of the relying IRB(s).
10. Describe the plan that is in place to manage information obtained from multiple sites that may be relevant to the protection of human subjects such as reporting unanticipated problems, protocol modifications, and interim results.
11. **References/Appendices**
12. Include findings from a literature search or pilot study must be outlined including appropriate detailed references to earlier studies and data.
13. Additional references to supporting data or additional information may be included in an appendix.