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**IRB eForm Protocol**

**LU IRB – Protocol**

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Application Number: \_\_\_\_\_\_\_\_\_\_\_

* **Use the section headings to complete the IRB eForm, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.**
* **When submitting the IRB eForm (new or revised), enter the date submitted to the field at the top of IRB Form.**

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1. **Objectives** (include all primary and secondary objectives)
2. **Background** (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)
3. **Study Procedures**
4. Study design, including the sequence and timing of study procedures

(distinguish research procedures from those that are part of routine care).

1. Study duration and number of study visits required of research participants.
2. Blinding, including justification for blinding or not blinding the trial, if applicable.
3. Justification of why participants will not receive routine care or will have current therapy stopped.
4. Justification for inclusion of a placebo or non-treatment group.
5. Definition of treatment failure or participant removal criteria.
6. Description of what happens to participants receiving therapy when study ends or if a participant’s participation in the study ends prematurely.
7. **Inclusion/Exclusion Criteria**
8. **Drugs/ Substances/ Devices**
9. The rationale for choosing the drug and dose or for choosing the device to be used.
10. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.
11. Justification and safety information if non-FDA approved drugs without an IND will be administered.

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Application Number: \_\_\_\_\_\_\_\_\_\_\_

1. **Study Statistics**
2. Primary outcome variable.
3. Secondary outcome variables.
4. Statistical plan including sample size justification and interim data analysis.
5. Early stopping rules.
6. **Risks**
7. Risks, listing all procedures, their major and minor risks and expected frequency.
8. Steps taken to minimize the risks.
9. Plan for reporting unanticipated problems or study deviations.
10. Legal risks such as the risks that would be associated with breach of confidentiality.
11. Financial risks to the participants.
12. **Benefits**
13. Description of the probable benefits for the participant and for society.
14. **Payment and Remuneration**
15. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.
16. **Costs**
17. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.