Departmental Research Review Form
For Committee for the Protection of Human Subjects

Introduction: The objective of initial departmental review is to assess scientific validity and feasibility of successful completion of the study. Ongoing departmental oversight will help to ensure that the research is progressing well and troubleshoot when there are unanticipated problems. The department review mechanism will achieve its objectives by:

- Facilitating conduct of research protocols which meet the department research goals.
- Advising on the scientific validity of proposed protocols.
- Assessing the feasibility of proposed protocol:
  - Whether the protocol would answer the research question,
  - Whether investigators are qualified by experience, education and training to conduct the research,
  - Whether the investigator has access to adequate resources including facilities and research staff,
  - Whether there are recruitment plan will be able to meet target accrual.
- Establishing prioritization for recruitment when there are multiple open protocols with similar eligibility criteria.
- Assist researchers to conduct research according to the good clinical practice guidelines.
- Oversee the progress of various projects in the department's research program.

Study Title:

PI:

1. Background: Has an adequate review of relevant literature and prior studies been performed? Is it accurately reflected in the submitted materials?

☐ Yes ☐ No ☐ N/A

2. Hypothesis: Does the study address a meaningful scientific question? Is it clearly stated?

☐ Yes ☐ No ☐ N/A

3. Methodology: Is the methodology appropriate to address the hypothesis? Are subject and control/ comparator populations constituted appropriately to address the stated hypothesis? Are the subject inclusion and exclusion criteria appropriate to optimize benefit and risk? Is the study powered sufficiently to provide a meaningful outcome? Is the statistical analysis plan appropriate?

4. Feasibility: Is the research feasible as designed at this site? Is the PI likely to meet enrollment goals? Are stated recruitment methods appropriate for this population?

☐ Yes ☐ No ☐ N/A

5. Comparison to routine clinical care: What is the routine clinical care for the condition being studied? Are any subjects denied access to routine clinical care at any time in the course of the study? How does the risk of the study intervention compare to that of the routine care?

6. Risk to participants: Are study risks accurately described? Could modifications to the protocol improve the benefit to participants or reduce risks? Is the data safety monitoring plan appropriate for the study?

7. Resources: Do the investigators have the qualifications (education, experience and expertise) and resources to carry out the protocol?

☐ Yes ☐ No ☐ N/A

8. Comments : Please use this space to elaborate on any concerns, issues or problems with your review of this study.

Recommendation:

☐ Continue with CPHS submission

☐ Minor revisions recommended.

☐ Major issues identified for revision.

☐ Scientific pre-review not necessary.

If you have a digital signature, please apply below, then click, "Return to PI" to send the form back to the Principal Investigator via email. If you do not have a digital ID, please print the form, sign and return to the Principal Investigator.

Signature Printed Name Date

Return to PI