Departmental Review for Clinical Research
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 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, especially for investigator initiated research.
- Assessing the feasibility of proposed protocol:
  - 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 the 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.

Please Note: This form must be completed by the department reviewer.

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?

5.a. Is this comparative effectiveness research? CER research involves generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care.

☐ Yes, if yes, please go to Question 5.b

☐ No. If No, please go to Question 6.

PS: CER research will be reviewed at the IRB Panel 3 meeting (meets on the second Friday of each month)

5.b. Comparative Effectiveness Research: Are all the interventions being studied part of usual care? What are some of the reasonably foreseeable risks for the interventions being evaluated?

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.

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