**Proposal Format, Review Process, and Reviewer Guidelines**

**for studies using the Enroll-HD Platform**

Version date March 11, 2021

The aim of this document is to briefly overview the proposal review process and review guidelines to be used for the first year of review activity within the Scientific Oversight Committee. The guidelines are subject to periodic review and revision.

Proposals will be given to the Scientific Oversight Committee after administrative review by the Enroll-HD Operations Committee. Administrative review will be done to ensure that all parts of application have been submitted and are complete. The Enroll-HD Operations Committee will also review proposals for burden on sites and subjects and may reject proposals that are deemed by them to be unreasonable or otherwise inappropriate for inclusion in Enroll HD.

Proposals will be reviewed within one month of receipt by the Scientific Oversight Committee via teleconference, to be set up by administrative support personnel (this would likely work OK if we had a call every two months, more challenging to promise this if we do a call quarterly).

There will be two primary reviewers for each proposal, who will have the major responsibility for understanding the proposal and presenting a short synopsis to the group on a review call. At least one of the primary reviewers will have expertise in the area of the proposal. Investigators will be informed that proposals must be written in general language so that an educated member of the HD research community can read and understand them, even if the person does not work in that particular area. It is understood that there may be some technical sections that are less accessible to all committee members. CHDI will make a statistical reviewer available on an as needed basis.

The primary reviewers will be asked to provide their ratings of the proposal. The SOC Chair, supported by the administrative assistant of the SOC, will collate, and return comments to the investigator. The comments will be included in a letter sent by an administrative assistant for Enroll HD Scientific Oversight Committee or other Enroll-HD Staff.

**Overall Ratings of Proposals**

Overall ratings are to be done as an overall evaluation. These overall ratings can be guided by the individual criterion ratings from your review, but do not need to be a direct correlation with the total individual rating.

There are four possible outcomes for the overall ratings:

1) Accept without revisions

2) Accept with minor revisions, with expedited approval by SOC chairs and at least one primary reviewer who confirm acceptability of revisions

3) Re-review required following study modification. IMPORTANT: A rating of 3 is not tentative acceptance, but a chance for iterative development with feedback from the SOC review. Re-review will use two reviewers, at least one of whom will have been an original reviewer (where possible).

4) Reject- proposal is inappropriate or not feasible, will not be reviewed again without substantial modification.

Note that we expect most proposals will receive a 1 or 2 rating. A rating of 3 should be used only rarely, and a rating of 4 should be used almost never. The spirit of the Scientific Oversight Committee is explicitly to enable research and to work with investigators to move projects forward.

**REVIEW DATE:**

**REVIEWER NAME:**

**STUDY NAME/ACRONYM:**

|  |  |  |
| --- | --- | --- |
| Criteria | Rating  | CommentsUse scores ranging from 1 (outstanding) to 4 (poor, unacceptable).  |
| INDIVIDUAL CRITERIA |
| Will this study add to significant knowledge about HD? |  |  |
| Are the aims, study design and methods clear and appropriate to achieve the goals of the study  |  |  |
| Is the study feasible within Enroll-HD? |  |  |
| Does the study follow good clinical and ethical guidelines? |  |  |
| Do Investigator and site(s) have adequate HD research experience to do this study? |  |  |
| Overall Assessment (Ratings 1 – 4, whole numbers) and Comments |
| OVERALL ASSESSMENT |  |  |
| Raise issues to be addressed to Enroll-HD Scientific Oversight Committee in this space, if needed |