**Proposal submission instructions for studies supported by the Enroll-HD Platform**

Version 1.3, date Oct 3 2022

The purpose of this document is to provide you with submission guidelines to be used for proposals to the Enroll HD Scientific Oversight Committee (SOC). To facilitate consideration of your proposal, materials must be presented in a simple format that will be understandable to any Huntington’s Disease Investigator regardless of their area of expertise or field of training. Lack of compliance with the submission guidelines may delay review or lead to a request for a revised submission. Please use SINGLE-SPACED 12 point font, Times New Roman.

Please return this form along with the current version of the study synopsis/protocol and a 2-page biosketch of the PI by email to the Enroll-HD Global Platform Manager (olivia.handley@enroll-hd.org).

**Date submitted (MON/DD/YYYY):**

**Is the protocol finalized? Yes/No**

**If no, please enter the estimated time for completion (MON/DD/YYYY):**

**PART I: Scientific Review**

Please provide detail to each section below, referring to the relevant section of the study protocol as necessary.

**1: Introduction, specific aims, and hypotheses-** (up to ½ page)

**2. Background/Justification** (up to one page)

**3. Methods** (up to three pages)

**Briefly outline:**

1. Study design, including how data collection would link with the default Enroll-HD annual study visits
2. Outline all proposed assessments including an estimate of time required and a consideration of participant burden
3. Specify inclusion/exclusion criteria (including clinical and demographic characteristics) of the sample
4. Indicate sample size required, including a consideration of power or a power analysis if applicable. If available, please attach a copy of the power analysis report to your submission.
5. Provide a statistical analysis plan clearly linking analyses to aims/hypotheses
6. What factors if any may impede data collection and if possible, what strategies may be used to increase probability of study enrollment and completion? If available, please attach a preliminary recruitment/retention plan to your submission.
7. Considerations for generalizability of the outcomes of the study: to whom will the results generalize, and what are the limits of generalizability?
8. Please describe how you will ensure you meet relevant data protection requirements and what steps you will take to protect confidentiality.
9. Planned project timelines and expected completion month/year

**4. Significance for HD, impact on future research** (up to ½ page)

1. What is the significance of the proposed study for the field of HD?
2. How will this study will the study influence or provide a foundation for future work?

**5. 2-page PI Biosketch/CV attached: Yes/No**

**6. Informed Consent form template (draft or final version) attached: Yes/No**

**7. References** (up to one page permitted)

**PART II: Platform resource requirements**

|  |  |
| --- | --- |
| 1. Does your study require feasibility analysis? |  |
| 2. How many study sites will be included? |  |
| 3. How many of these sites will be Enroll-HD study sites? | \*[*enter N*] |
| 4a. Will your study recruit any Enroll-HD study participants? |  |
| 4b. Will your study recruit any HDClarity study participants? |  |
| 4c. If yes to 4a or 4b, is participation in Enroll-HD/HDClarity an inclusion criterion for your study participants? |  |
| 5. Are you considering requesting support from the platform monitoring team to complete onsite monitoring of your study specific data/ICFs?: |  |
| 6. Are you considering requesting that your study is hosted on the Enroll-HD EDC? |  |
| 6a. How would you intend to use the Enroll-HD EDC for your study? |  |
| 7.Will your study collect biosamples? |  |
| 8. Will the biosamples be stored for future research? |  |
| 9. Are you considering requesting access to any of the following existing datasets for your study?  |   |
| *Enroll-HD data* |  |
| *HDClarity data* |  |
| *Enroll-HD biosamples* |  |
| *HDClarity biosamples* |  |
| 10. Is your study funded by CHDI? |  |
| 11. Upon completion of your study, would you consider sharing the final study dataset with CHDI? |  |
| 12. If applicable, please give the name of your main point of contact at CHDI and/or within the platform |  |

\*Please list potential Enroll-HD sites (if known)