



Enroll-HD – Publication Policy

Introduction

Sharing of data and bio-specimens with the scientific community is a major objective of the Enroll-HD study. The Scientific Publication Review Committee (SPRC) has been charged with the task of overseeing data sharing and ensuring implementation of the publication policy.

Policy

The SPRC will not evaluate the scientific merits of proposed analyses that utilize clinical data and renewable bio-specimens, nor evaluate proposed manuscripts. The SPRC will focus on the implementation of the publication policy of Enroll-HD and on an administrative review of manuscripts as described below; these activities will be supported by the Enroll-HD Operations Team.

The following publication policies will be included in the data use and material transfer agreements covering data and sample sharing in Enroll-HD.

1. Named authors will have to meet authorship criteria as set out by International Committee of Medical Journal Editors (http://www.icmje.org/ethical_1author.html). For many journals, contribution of data is not, by itself, an adequate criterion for authorship, but qualifies Enroll-HD investigators and other key center staff that participated in the collection of the data and specimens for acknowledgement by name as Co-Investigators/Collaborators or as Contributor (see below for definitions).
2. Researchers who propose to use the data and/or bio-specimens which have been collected from Enroll-HD collaborators will post a broad outline of the study/data mining proposal on the Enroll-HD website as part of the permissions process. At the same time, the Enroll-HD Operations team will distribute notifications of projects using Enroll-HD data and samples along with contact details of the lead proposer(s). Active communication within Enroll-HD regarding planned and on-going analyses is encouraged, as well as active collaboration between site investigators and other researchers as Enroll-HD-related papers are developed. Notifications will reiterate the definitions of a collaborator and author.
3. Site Investigators and others participating and contributing to the Enroll-HD collaboration who have a specific interest in the topic may contact the research team in order to express an interest in active involvement in the study/data mining project. With agreement, they would work with the research team on the study/data mining project and be involved in the writing and reviewing of the manuscript and thereby qualify for named authorship. Declaration of interest should be received within 4 weeks of the announcement.

In the event of a large number of expressions of interest relative to the size of the study/data mining project the lead research team may limit the number of Enroll-HD collaborators for



active involvement to a workable number at an early stage in the process and post a further message on the website that a sufficient number of expressions of interest have been received.

In the event of a disagreement, a mediation process would be put into effect by the SPRC.

4. All manuscripts will acknowledge the methods of Enroll-HD data gathering using language that is recommended by the Enroll-HD Steering Committee and found in the data use agreement.
5. All manuscripts will acknowledge the support of the CHDI Foundation Inc for Enroll-HD as well as other entities providing financial support if appropriate.
6. In addition to the named authors, all manuscripts will be submitted with (1) an acknowledgement of Enroll-HD using a corporate acknowledgement phrase followed by an asterisk, (2) a list of Co-Investigators/Collaborators and Contributors (if appropriate) for indexing in PubMed and listing as part of the publication (in print or as an e-content) and (3) as a class, the research participants in the study. The following definitions will be used to assign appropriate acknowledgement:

Co-Investigator/Collaborator: A person who does not meet the criteria for authorship of the study, but who acted as an investigator or study coordinator for Enroll-HD. Co-Investigators may be listed in the appendix (or online – depending on the journal) and are indexed in PubMed. This will include a listing of Co-Investigators/Collaborators under the name “The Enroll-HD Study Group”; this name will be included on the authorship line. The number of individuals each site is permitted to include on the list for “The Enroll-HD Study Group” will be proportionate to the number of subjects recruited at their site. This number will be determined and approved by the Enroll-HD Steering Committee. The list of collaborators will be maintained by the Enroll-HD Operations Team and distributed to the lead author.

Contributor: A person who does not meet the criteria for authorship, but has contributed in other ways, including collection of data; technical help; acquisition of funding; supervision of key personnel; contribution of drugs, reagents, equipment or patients; or editing the manuscript for non-intellectual content. Contributors are listed in the Acknowledgement section of the manuscript. The list of contributors will be maintained by the Enroll-HD Operations Team and distributed to the lead author.

To the extent possible, names and centers should be listed for online review and appropriate indexing. “The Enroll-HD Study Group” listing may be obtained from the Enroll-HD Steering Committee or from the Enroll-HD website (www.enroll-hd.org); the Steering Committee delegates responsibility for maintaining the Investigator List to the SPRC which will be supported by the Enroll-HD Operations Team and will periodically review the listing for accuracy. If there are any disputes in respect to authorship of a publication or the Investigator Listing the SPRC is responsible for conducting a mediation process and for referring the issues to the Steering Committee if a dispute resolution cannot be achieved by the mediation process conducted by the SPRC.



7. Manuscripts will be submitted to the Enroll-HD SPRC for administrative review prior to submission. The purpose of the review will be to ensure that all of the above requirements are met.
8. A full citation of every published manuscript will be provided by the corresponding author to the Enroll-HD SPRC upon acceptance of the manuscripts.
9. A copy of every manuscript will be provided to the Enroll-HD SPRC upon publication. If permitted by the journal, a version of the article or link to the article will be available online at the Enroll-HD website.

Checklist

If Enroll-HD data and/or specimens are used in a publication please ensure the following:

- ✓ Posting of the outline of the proposal on the Enroll-HD website
- ✓ Add the Enroll-HD acknowledgement
- ✓ Add full listing of Enroll-HD Contributors as provided by the Enroll-HD Operations Team
- ✓ Include any recommended language that describes the Enroll-HD data and specimen collection methods
- ✓ Cite CHDI Foundation, Inc. as the source of support for Enroll-HD as well as other entities providing financial support if appropriate
- ✓ Provide a copy of the manuscript to the SPRC for review 2 weeks before planned submission
- ✓ After submission, keep Enroll-HD SPRC apprised of acceptance or rejection
- ✓ After acceptance, provide Enroll-HD SPRC with the manuscript citation
- ✓ If possible, provide a copy of the manuscript or URL for the website

Sub-studies and Ancillary Studies

For sub-studies and ancillary studies, members of the sub-study/ancillary study PI and team will be given one year after the end of the study to submit for publication the major conclusions; after this period, the data will be released for data sharing under the Enroll-HD Data Sharing Guidelines. The Enroll-HD publication policies described above apply to all sub-studies and ancillary studies that use Enroll-HD data. The one exception is that only the Enroll-HD recruitment sites that participate in the specific sub-study or ancillary study will be cited.