



Enroll-HD – Clinical Data and Biosample Access Policy

The overarching goal of Enroll-HD is to accelerate the development of therapeutics that will benefit HD-affected individuals. As a cornerstone of that goal, Enroll-HD was designed by CHDI Foundation to ensure that as many researchers as possible worldwide could access the de-identified study data and renewable biosamples in a rapid, transparent, straightforward manner, lowering barriers to entry into HD research while safeguarding the identity of research participants. The Enroll-HD website will host various datasets that will be made available to any interested researcher from academia, government institutions, nonprofit organizations, and public and private companies.

There will be no merit review of project proposals related to requests for access to **periodic datasets** or **renewable biosamples**. Any researcher who wants to access the de-identified Enroll-HD clinical data or biosamples will create an Enroll-HD Clinical Data and Biosamples Access Account on the Enroll-HD website; checks will be made to verify that the applicant is indeed employed by the stated, recognized research organization. Any questions arising from applications will be referred to the Scientific Publication Review Committee (SPRC).

Requests for **non-renewable biosamples** or **specified datasets** will be referred to the SPRC for merit review of the proposed research or prioritization according to available resources, respectively.

Researchers will be required to sign a clinical [data use agreement](#) and/or a [biosamples use agreement](#) for biosamples, as applicable (click the link to view the form of these agreements). Any future modifications to these agreements will be electronically agreed to by each data user on first login after any new agreement is adopted.

Active communication regarding planned and ongoing data analyses is encouraged to provide opportunity for collaborative work. Researchers accessing the Enroll-HD data are required, as part of the application process, to submit a brief, broad outline (50-200 words) of their proposed research study; this will be posted on the Enroll-HD website along with the researchers contact details. Other researchers interested in a particular research project are encouraged to contact the data/biosample recipient to discuss areas of mutual interest with a view to potential collaboration.



Enroll-HD – Publication Policy

1. Enroll-HD and CHDI Foundation respect the freedom of investigators to pursue their research interests, including independent unrestricted publication of their analyses and findings.
2. Researchers using data or biomaterials generated within Enroll-HD are committed to:
 - a. prompt publication of all valid data, outcomes, and other results derived using data or biological materials collected within Enroll-HD;
 - b. acknowledgment of the role played by all individuals contributing to a publication, as authors or otherwise;
 - c. acknowledgment (in the Methods section when appropriate) of the Enroll-HD data-gathering methods with the following language – “Enroll-HD is a global clinical research platform designed to facilitate clinical research in Huntington’s disease. Core datasets are collected annually from all research participants as part of this multi-center longitudinal observational study. Data are monitored for quality and accuracy using a risk-based monitoring approach. All sites are required to obtain and maintain local ethical approval”;
 - d. acknowledgment of the support of CHDI Foundation as the sponsor of Enroll-HD and, as a group, the Enroll-HD research participants with the following language - “Enroll-HD is a clinical research platform and longitudinal observational study for Huntington’s disease families intended to accelerate progress towards therapeutics; it is sponsored by CHDI Foundation, a nonprofit biomedical research organization exclusively dedicated to collaboratively developing therapeutics for HD. Enroll-HD would not be possible without the vital contribution of the research participants and their families”. Other entities providing support (financial or otherwise) should also be acknowledged as appropriate; and
 - e. acknowledgment of the individuals who contributed to the collection of the Enroll-HD data by including the URL (<https://www.enroll-hd.org/acknowledgments/>) that lists those individuals.
3. **Authorship.** Eligibility for authorship, the order of authors, the acknowledgment of persons whose contribution does not warrant authorship but does merit recognition and, to the extent addressed therein, other matters related to authorship should be determined by the publication committee (see below) in accordance with the [Guidelines for Responsible Conduct Regarding Scientific Communication](#) set forth by the Society for Neuroscience (SfN) from time to time. In particular, Enroll-HD will adhere to the [authorship criteria defined by the International Committee of Medical Journal Editors](#) that are already adopted by the SfN, *The British Medical Journal*, *The Journal of the American Medical Association*, *The Lancet*, *The New England Journal of Medicine*, and the Public Library of Science, among many others.
4. **Publication Committee.** If one or more individuals propose to base a scientific publication on the analysis of data or biological materials obtained from Enroll-HD and the data or biological materials were not generated solely by such individual(s), a publication committee will be formed to address publication issues (including authorship) relating to the publication.



A publication committee should consist of (1) all authors who were involved in the design of the scientific work using such data or biological materials, or the analysis of the data resulting from such scientific work (or those who would qualify as an author were they offered a role in manuscript preparation; see ICMJE criteria above), and (2) persons who collected a substantial part of the data or biosamples used in the scientific work.

5. Open Access. Scientific publications resulting from the data or biosamples provided by Enroll-HD should be disseminated as widely as possible. Authors are encouraged to submit publications to fully open-access journals; publications in such journals may qualify for publication cost reimbursement from CHDI (see [policy for reimbursement of publication costs](#)).
6. Archiving. Researchers using Enroll-HD study data and/or biosamples are encouraged to send a copy of each published manuscript to the info@enroll-hd.org upon publication. If permitted by the journal, a version of the article (or link to it) will be made available on the Enroll-HD website.