**Clinical study data and biosample request form**

We appreciate your interest in obtaining biosamples and/or one or more dataset(s) for use in your HD research. An overview of available [datasets](https://enroll-hd.org/for-researchers/datasets/) and [biosamples](https://enroll-hd.org/for-researchers/biosamples/) are below (and also on the [Enroll-HD website](https://enroll-hd.org/for-researchers/access-data-biosamples/)).

Bulleted below are the key steps in the request process. For detailed information on the available data and biosamples or the request process, please visit the [Enroll-HD website](https://platform.enroll-hd.org/for-researchers/access-data-biosamples/).

**Key steps/considerations:**

* **Complete this request form.** **You will need to provide a title and a brief description of your project which will be posted on the Enroll-HD website along with your name and affiliation.**
* **If you are requesting a specified Enroll-HD or HDClarity dataset or non-renewable biosamples (see below for types of datasets/biosamples), you will also need to provide a full project description because this request form will in these cases be forwarded to the Enroll-HD Scientific Review Committee (SRC) for merit review and approval. SRC review will increase the time to process your request by approximately 2-6 weeks and it will in addition take 4-6 weeks to prepare a specified dataset.**
* **To fulfil GDPR requirements we must review and approve the data security measures of all organizations requesting data and/or biosamples. Each requesting organization must provide:**
	+ **the completed data security questionnaire that can be downloaded from the** [**Enroll-HD website**](https://enroll-hd.org/for-researchers/access-data-biosamples/)**, and**
	+ **a document describing the “Technical and Operational Data Security Measures (TOMs)” of the organization (contact your IT department for this document).**

**Once your organization’s security measures are approved, it will not be required to provide this documentation again for future data and/or biosample requests, however we will ask you to confirm that the same measures are still in place or report any changes.**

* **Email: 1) the data and biosample request form, 2) the data security questionnaire and 3) TOMs for each organization requesting access to the datasets/biosamples to:** **AccountSetup@enroll-hd.org****. Use of the biosamples and dataset(s) is conditional upon each of the requesting organizations agreeing to the terms and conditions set forth in the Biosample and/or Data Use Agreement(s) (BUAs/DUAs). A copy of the BUA(s)/DUA(s) for the biosample collections or datasets you would like to obtain can be requested early in the process for review.**

After submission of your completed Biosample and Dataset Request Form, you will be contacted within five business days to confirm receipt of your request. Any questions regarding your request will be sent to the email address you provide below.

**PLEASE NOTE: THIS IS NOT A FUNDING APPLICATION**

**Information about Recipient Researchers**

|  |
| --- |
| **RECIPIENTS*** **List all recipients who require access to the data and/or biosamples.**
* **Each dataset recipient needs to sign a Data Use Agreement (DUA) and Biosamples Use Agreement (BUA) as applicable.**
* **If you are a student, your advisor will need to be the Recipient Researcher.**
* **If the biosamples will be sent to a third party for processing, please list the third party as well and include that information in your detailed description of the experiment.**
 |
| *List each collaborator for your research project below along with their contact information. The primary biosample/data recipient should be listed as Recipient Researcher #1. Each collaborator that needs access to the data/biosamples must be listed as a recipient researcher (add additional fields if needed).* *At least one individual per organization needs to sign the data and/or biosample use agreement (DUA/BUA).* **Background questions:**1. Will the research project be a collaboration among multiple researchers (including biostatisticians) **within the same organization**? [YES / NO]*Each collaborator that wishes access to the data must review and agree to the terms of the DUA; one DUA must be signed per institution.* 2. Will the research project be a collaboration among multiple researchers (including biostatisticians) **at different organizations**? [YES / NO]*If you have collaborators outside your organization who will access the biosamples or dataset, their institution must also sign a Biosample Use Agreement (BUA) and a Data Use Agreement (DUA) and they must be listed as Recipient Researchers below. For collaborators who do not require direct access to the data files and biosamples, please provide researchers names and departments here****. Per the BUA and DUA it is not permitted to transfer any of the data to any entity that is not listed in the agreement.***3. Are/were any of the data requesters site staff in Enroll-HD, HDClarity, TRACK or any of the other clinical studies forming the basis of the below datasets? If yes – what study(ies) and at what clinical site(s)? |

|  |
| --- |
| **RECIPIENT RESEARCHER #1 (Primary recipient.** Anyone who uses data and/or biosamples within the organization must be under the direction and supervision of the Recipient Researcher**)****Organization** (proper legal name):**Type of organization** (i.e., nonprofit, academic, public/private company, institution)**:** |
| First name: |  |
| Last name: |  |
| Title/position: |  |
| E-mail address: |  |
| Telephone: |  |
| Department: |  |
| Business address: | Street:  | City: |
|  | State/Province: | Country: | Postal Code: |
| **Need access to requested data?** |  |
| **Need to combine any of the requested datasets? If yes, please describe which datasets?** |  |
| **Need access to requested biosamples?** |  |
| Are you a fee for service provider?   | [YES/NO] |
| If you are a fee for service provider, are you requesting data and/or biosamples to provide services to any third-party?   | [YES/NO]Please detail what third-party(ies) you are providing services to?Full legal name of each third-party:Type of third-party (i.e., client, fee for service provider; other third-party;)Individuals' Name:Address:Phone:Facsimile:Email:Country:The purpose of services and use for such third-party(ies): |
| Are you planning on transferring the data and/or biosamples to any third-party recipient in any of the following categories?1. Any affiliate [YES/NO]2. Any fee for service providers (e.g., CROs) [YES/NO]3. Any other third-party [YES/NO]4. Any third-party hosting providers (e.g., AWS) or managed services providers [YES/NO] | Please provide the following for each of the third-party recipients:Full legal name of each third-party recipient:Type of third-party recipient (i.e., affiliate; fee for service provider; other third-party; third-party hosting providers)Individuals' Name:Address:Phone:Facsimile:Email:Country:The purpose for the transfer and use by such third-party recipient: |
| Have (or will) all listed third-party recipients where the data and/or biosamples are planned to be used/processed, hosted or stored sign an agreement covering such use/processing, hosting and storage of the data? | [YES/NO] |
| **LEGAL CONTACT FOR RECIPIENT** **#1** (For legal/contract/notice purposes)**Name and title of signatory of the agreement(s):**  |
| Name of legal contact: Person handling the agreement(s) on behalf of the organization |  |
| Title/position: |  |
| E-mail address: |  |
| Telephone: |  |
| Department: |  |
| Business address:Address of legal or contracts department. This is where legal letters and notices will be sent. | Street:  | City: |
|  | State/Province: | Country: | Postal Code: |
| **RECIPIENT RESEARCHER #2 (**If different organization than for Recipient Researcher 1 then anyone who uses data and/or biosamples within this organization must be under the direction and supervision of Recipient Researcher 2**)****Organization** (proper legal name):**Type of organization** (i.e., nonprofit, academic, public/private company, institution)**:** |
| First name: |  |
| Last name: |  |
| Title/position: |  |
| E-mail address: |  |
| Telephone: |  |
| Department: |  |
| Business address: | Street:  | City: |
|  | State/Province: | Country: | Postal Code: |
| **Need access to requested data?** |  |
| **Need to combine any of the requested datasets? If yes, please describe which datasets?** |  |
| **Need access to requested biosamples?** |  |
| Are you a fee for service provider?   | [YES/NO] |
| If you are a fee for service provider, are you requesting data and/or biosamples to provide services to any third-party?   | [YES/NO]Please detail what third-party(ies) you are providing services to?Full legal name of each third-party:Type of third-party (i.e., client, fee for service provider; other third-party;)Individuals' Name:Address:Phone:Facsimile:Email:Country:The purpose of services and use for such third-party(ies): |
| Are you planning on transferring the data and/or biosamples to any third-party recipient in any of the following categories?1. Any affiliate [YES/NO]2. Any fee for service providers (e.g., CROs) [YES/NO]3. Any other third-party [YES/NO]4. Any third-party hosting providers (e.g., AWS) or managed services providers [YES/NO] | Please provide the following for each of the third-party recipients:Full legal name of each third-party recipient:Type of third-party recipient (i.e., affiliate; fee for service provider; other third-party; third-party hosting providers)Individuals' Name:Address:Phone:Facsimile:Email:Country:The purpose for the transfer and use by such third-party recipient: |
| Have (or will) all listed third-party recipients where the data and/or biosamples are planned to be used/processed, hosted or stored sign an agreement covering such use/processing, hosting and storage of the data? | [YES/NO] |
| **LEGAL CONTACT FOR RECIPIENT** **#2** (For legal/contract/notice purposes):**Name and title of signatory of the agreement(s):**  |
| Name of legal contact: Person handling the agreement(s) on behalf of the organization): |  |
| Title/position: |  |
| E-mail address: |  |
| Telephone: |  |
| Department: |  |
| Business address:Address of legal or contracts department. This is where legal letters and notices will be sent | Street:  | City: |
|  | State/Province: | Country: | Postal Code: |

***Add additional recipient researchers as needed***

**Project title and summary (required for ALL requests)**

|  |
| --- |
| **PROJECT DESCRIPTION (Needed for all dataset requests)** |
| **Project title:** |  |
| **Summary** (50-200 words) of the research project.***This summary will be posted on the Enroll-HD.org webpage – do not include confidential information.***  |  |

**I agree with having the Project Description Summary above posted on the** [**https://enroll-hd.org/**](https://enroll-hd.org/) **webpage:**

**Yes** [ ]

**No** [ ]

**Request datasets**

**Please indicate in the ‘Request’ column in the tables below which of the datasets you want to access.** You will need to sign a separate Data Use Agreement (DUA) for each of the requested datasets.

**Clinical Assessment Datasets:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Request** | **Study**  | **Dataset Name** | **Data Category** | **Dataset N** |
|  | **Enroll-HD** | **Enroll-HD PDS6-R1** *(Periodic dataset)* | Clinical Assessment | 25,550 |
|  | **Enroll-HD**  | **Enroll-HD Specified Dataset\***  | Clinical Assessment |  |
|  | **Enroll-HD** | **Enroll-HD My Site Data** *(Enroll-HD PIs asking for permission to use data collected in own clinic)* | Clinical Assessment |  |
|  | **HDClarity, HD-CSF**  | **HDClarity PDS2-R2** *(Periodic dataset)* | Clinical Assessment | 457 |
|  | **HDClarity, HD-CSF**  | **HDClarity Specified Dataset\*** | Clinical Assessment |   |
|  | **HD-YAS** | **HD-YAS**  | Clinical Assessment | 120 |
|  | **PREDICT HD** | **Predict-HD**  | Clinical Assessment | 1485 |
|  | **2CARE** | **2CARE**  | Clinical Assessment | 609 |
|  | **CAB Beta** | **CAB-Beta**  | Clinical Assessment | 267 |
|  | **CARE-HD** | **CARE-HD**  | Clinical Assessment | 347 |
|  | **CREST-E** | **CREST-E** | Clinical Assessment | 650 |

**Imaging Datasets:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Request** | **Study**  | **Dataset Name** | **Data Category** | **Dataset N** |
|  | **PREDICT HD** | Predict-HD BIDS Neuroimaging Data | Imaging | 1485 |

**\*Specified dataset requests (SPS) are requests for an Enroll-HD or HDClarity dataset that includes data that is not already included in the Periodic Datasets. These datasets can either include restricted access variables (marked in orange in data dictionaries), include aggregate data or data prepared in a non-PDS format. SPS requests require completion of the detailed project description at the end of this form and will be reviewed by the Scientific Review Committee (SRC) if release of the requested data increases the risk for identification of participants.**

**Data from Human samples:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Request** | **Study**  | **Dataset Name** | **Data Category** | **Dataset N** | **Sample Type** | **Analyte** |
|  | **HDClarity**  | **HDClarity Interim Assay Results** | Data from biosamples |  220 | CSF | NFL, hHb, totProt, mHTT, totHTT |
|  | **TRACK HD** | **Track-HD NFL Assay Publication Datasets** | Data from biosamples |  298 | Plasma | NFL |
|  | **TRACK HD, Track-ON** | **GWAS-Track Rawdata** | Data from biosamples |  395 |  |  |
|  | **TRACK HD, Track-ON** | **GWAS-Track Imputed SNP Call Results** | Data from biosamples |  395 |  |  |
|  | **TRACK HD, Track-ON, Registry, Enroll-HD**  | **GWAS12345 Publication Dataset** | Data from biosamples |  9064 |  |  |
|  | **HD-YAS** | **HD-YAS Assay Results** | Data from biosamples |  109 | CSF, Plasma | GFAP, hHb, IL6, IL8, mHTT, Neurogranin, NFL, TAU, totHTT, UCHL1, YKL40 |
|  | **Registry** | **GWAS3 Rawdata** | Data from biosamples |  3447 |  |  |
|  | **Registry** | **GWAS3 Imputed SNP Call Results** | Data from biosamples |  2131 |  |  |
|  | **Registry** | **GWAS4 Rawdata** | Data from biosamples |  4022 |  |  |
|  | **Registry** | **GWAS4 Imputed SNP Call Results** | Data from biosamples |  TBD |  |  |
|  |  | **GWAS-VZ2018 Publication Dataset** | Data from biosamples |  374 |  |  |

**Biosamples**

**Available biosamples and prices per study (***excludes handling and shipping costs. Shipping and handling fees are direct pass-throughs of project-specific costs and will be added***).**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study** | **Class** | **Type** | **Unit** | **Cost per sample € (Academic)** | **Cost per sample € (Industry)** |
| **Enroll-HD** | Non-Renewable Biosamples | EDTA plasma | 250-300 µl | 20 | 24 |
| Non-Renewable Biosamples | PBMCs |   | 64 | 77 |
| Non-Renewable Biosamples | Whole blood DNA | Vial (5 µg) | 83 | 99 |
| Renewable Biosamples | DNA from LBCs, in vials | Vial (5 µg) | 61 | 73 |
| Renewable Biosamples | Lymphoblastoid cell lines (LCLs) | ~Vial 1×106 cells | 38 | 46 |
| **HDClarity** | Non-Renewable Biosamples | Cells from CSF |   | Please inquire | Please inquire |
| Non-Renewable Biosamples | CSF | 250-300 µl | 36 | 44 |
| Non-Renewable Biosamples | LiHep plasma | 250-300 µl | 20 | 24 |
| Non-Renewable Biosamples | Serum | ~300 µl | 26 | 31 |
| **Track-HD** | Non-Renewable Biosamples | Buffy coat |   | 64 | 77 |
| Non-Renewable Biosamples | EDTA plasma | 450-500 µl | 30 | 36 |
| Non-Renewable Biosamples | RNA PaxGene |   | 83 | 99 |
| Non-Renewable Biosamples | Whole blood DNA | Vial (5 µg) | 83 | 99 |
| Renewable Biosamples | DNA from LBCs | Vial (5 µg) | 61 | 73 |
| Renewable Biosamples | LCLs | ~Vial 1×106 cells | 38 | 46 |
| **Track-ON** | Non-Renewable Biosamples | Buccal swabs |   | 19 | 22 |
| Non-Renewable Biosamples | CPT plasma | 450-500 µl | 30 | 36 |
| Non-Renewable Biosamples | EDTA plasma | 450-500 µl | 30 | 36 |
| Non-Renewable Biosamples | PBMCs |   | 64 | 77 |
| Non-Renewable Biosamples | Whole blood DNA | Vial (5 ug) | 83 | 99 |

**Request biosamples**

Describe how many biosamples you need (number of participants, number of vials), the type of biosample you need from what study and any other sample selection criteria that should be considered during sample selection.

You can either select the specific participants and visits you want samples from based on the Enroll-HD or HDClarity periodic datasets and provide a list of the participant recoded ids – OR you can provide us the selection criteria that should be applied, and we will do the sample selection for you.

|  |
| --- |
| **Request by clinical/sample characteristics:*****Please indicate the quantity and type of samples needed below and what sample selection criteria should be considered - for example:**** *What participant categories do you want to include (premanifest, manifest, controls)?*
* *What disease categories (early HD, moderate HD, advanced HD)?*
* *Would you prefer the CAG of HD patients to be as similar as possible or would you like to include as broad a CAG range as possible?*
* *What gender distribution do you prefer?*
* *How should the controls be matched to the patient groups (age, gender etc.)?*
* *Include other appropriate information to allow proper sample selection.*

*Please remember the more criteria applied, the more difficult it will be to find the required number of samples.*  |
| **OR** |
| **Participant Specific Request (you may submit excel list if that is easier):** |
| **Recoded ID** | **Type of sample requested, quantity** |
|  |  |

**Sample shipping and handling information**

|  |
| --- |
| **Sample shipping information****Organization** (proper legal name):**Type of organization** (i.e., nonprofit, academic, public/private company, institution)**:** |
| **Shipping address:**  | Street:  | City: |
|  | State/Province: | Country: | Postal Code: |
| **Name of contact person for shipping arrangements:** |  |
| **E-mail of contact person for shipping arrangements:** |  |
| **Telephone of contact person for shipping arrangements:** |  |
| **Do you want to analyze the samples blinded?** (This impacts the way we provide information to you) |  |
| **Do you have a barcode reader?** (This impacts the way we provide information to you) |  |

|  |
| --- |
| **Sample payment information****Organization** (proper legal name): |
| **Invoice address:**  | Street:  | City: |
|  | State/Province: | Country: | Postal Code: |
| **Name of contact person to receive invoice:** |  |
| **E-mail of contact person to receive invoice:** |  |
| **Telephone of contact person to receive invoice:** |  |
| **VAT number** (European requesters) |  |
| **SDI code** (CUU Codice Univovo Ufficio. Only Italian requesters need to provide in addition to VAT) |  |

**ONLY COMPLETE THIS SECTION IF YOU ARE REQUESTING A SPECIFIED DATASET FROM ENROLL-HD OR HDClarity OR NON-RENEWABLE BIOSAMPLES**

|  |
| --- |
| **Detailed Project Description** *Describe in detail your proposed research project using the outline below (i.e., the project description must be divided into sections using the outline headings below as distinct section headings).***Overview***Provide an overview of your proposed research project, why you consider it important and how it will advance the field.* **Specific Aims/Goals***What are the specific aims/goals to be achieved in the proposed research project?**Specific Aim 1*: *Specific Aim 2*: **Background and Preliminary Data***Provide any relevant background information regarding the proposed research project, including any data justifying the hypothesis under test. For sample requests: If no pilot data is available, justify why the requested samples should be used to generate it.***Description of Research Project Activities***Describe (a) the research activities that will be conducted to achieve the specific aims/goals of the proposed research project and how the requested specified dataset and/or biosamples will enable your project, (b) the scientific rationale for the proposed approach, and (c) your statistical analysis plan.***Assay characteristics (for biosample requests)***Provide details on the assay for the biosample types you are requesting including how much biomaterial is needed for each assay.* *Please provide data from prior assay validation. Please note that we normally do not release non-renewable samples for assay validation studies***Collaborators***List each collaborator who will work on the proposed research project and the activities that each will conduct. If no collaborators state "none".***References***List relevant references that will enable review of your proposed project.***Requested data variables (specified dataset)***Provide a detailed description of the specified dataset you are requesting for your research project. Wherever possible, name the specific variables required; these names can be found in the Data Dictionaries located on the* [*Enroll-HD website*](https://enroll-hd.org/for-researchers/data-support-documentation/)*.*  |