Enroll-HD Process Reminders and Guidelines

New reminders, August 2017:
- If any assistance is needed with regard to any of the points listed here then site staff should contact their site manager (North America, Latin America, Australasia) or Language Coordinator (LanCo) (Europe). If you are unsure who your site manager or Language Coordinator is, please contact ITSupport@enroll-hd.org to confirm.

Recruitment materials reminder
- Printed recruitment materials in different languages are now available for use at your site – for further details and/or high-quality print copies please contact your site manager for English versions in North America/Australasia, French versions in Canada, and Spanish versions for Latin America. Please contact Katrin Barth (katrin.barth@uni-ulm.de) for all language versions for active countries in Europe, including German, Italian, Polish, Danish, Dutch, English, French and Spanish. These have been approved by Western IRB for use in the US and Canada and by local ERBs in Europe for all active countries (**you should confirm this with Katrin**), but you should check that all local IRB/ERB requirements have also been met.

Biosample reminders
- When drawing blood from a participant, you **must** complete and submit a Samples CRF into the EDC **before shipping the blood**. The sample notification generated by the EDC is required for the central lab in Italy to retrieve the samples shipment from Italian customs. Failure to submit the Samples form will cause delays and could compromise sample integrity, possibly requiring a blood sample re-draw at the participant's next Enroll-HD visit. If you are unable to enter the visit in the EDC, please contact the IT Support team (ITSupport@Enroll-HD.org) for immediate assistance.
- When communicating with BioRep (enrollhd@biorep.it) regarding biosample questions or issues, please remember to **send only the LabID.** The LabID can be found on the Samples form.
- When submitting the Samples form in the EDC, site staff are reminded to **press the button only once**. It may take up to 30 seconds for the form to refresh after you hit the enter button. Hitting the button multiple times can lead to errors in the interface between the EDC and the central lab in Italy.
- Sites are now able to order either baseline or follow up boxes of kits. Each follow up kit contains 2 test tubes for blood collection, while each baseline kit contains 3 test tubes. Sites should order both types of kits and use the appropriate collection kit depending on the study visit being conducted.

Data entry reminders

- New data entry rules for PharmacoTx – please ensure that you enter ONE time period, ONE medication, on ONE line! Medications taken at various dosages throughout a day should be entered only on one line. For example, if 25 mg tetrabenazine is taken in the morning and 37.5 mg at bedtime, please enter this information in ONE SINGLE line as dose/unit 25 mg tetrabenazine with daily intake 1-0-0-1.5. Do NOT split into two lines of 25 mg (with daily intake 1-

0-0-0) and 37.5 mg (with daily intake 0-0-0-1). The one-line entry will make your update of the data easier and will facilitate data analysis.

- In addition, please remember to enter the relevant indication for the drug, meaning for which symptom or disease a drug is taken. Do not enter the drug category or drug description (such as antidepressant, blood thinner or antibiotic) and do not enter the aim of the drug therapy (such as "weight loss", if the drug is taken for obesity).

- If a participant does not come for their annual visit, it is important that this visit is cancelled in the EDC. You will not be able to create the participant's next follow up until the previous year's missed visit is cancelled. Please go to the participant's visit overview to cancel a missed study visit.

- The Enroll-HD Coding Team raises the following important points to remember when entering conditions and medications:
    - When entering indications on the PharmacoTx, remember to identify the indication that is being treated. Refrain from entering very general conditions such as "HD" - be as specific as possible.
    - Only one indication should be entered per medication line on the PharmacoTx form.
    - Make sure you closely review each entry and clarify the indication – e.g. "weight loss" is not indicative of whether the drug was given to prevent an underweight condition or to help a participant lose weight.
    - Whenever possible indicate the illness or disease that is being treated by the medication, not the symptom – e.g. enter "schizophrenia" instead of "psychosis".
    - When creating an Event form related to a hospitalization for a mental health event, remember to include a descriptive reason for the hospitalization in the Event Term field – e.g. psychosis, hallucination, depression, etc.

- The Clinical Trials CRF is now available for completion in the EDC - all sites are encouraged to complete when applicable since it captures both past and current participation in a variety of studies and trials. Detailed guidance has been provided to all sites via email, but if you did not receive the guidance please contact the IT Support team (ITSupport@Enroll-HD.org) for a copy.

- The HDID Creation Page is required for source data verification for **all participants**. Please remember to print the page after creating the HDID and store it in your files – this will be reviewed and checked during your next interim monitoring visit.

- When creating an HDID for a participant, please remember to use the 3 letter abbreviation for the month when entering the participant's date of birth.

- If you are unsure whether an HDID was created properly, remember to use the Verify HDID tool to check, as follows:
    1. Enter all of the **correct** information into the fields, then click the "yes" bubble indicating that the HDID already exists.
    2. If the HDID was properly created it will be shown and you can print this form out for your records.
    3. If the HDID is not found, it means the original HDID was created incorrectly. You should change the bubble asking whether the HDID exists from yes to no. You will then receive a new HDID.
    4. Please send this HDID, along with the incorrect HDID that already exists in the EDC, to IT Support (ITSupport@Enroll-HD.org).

- If a participant at your site misses their annual follow-up visit, please remember to create the Phone Contact visit in the EDC and fill out the Missed Visit form. Detailed instructions have been sent to all sites regarding the process for creating this special visit - if you need further assistance, please contact IT Support (ITSupport@Enroll-HD.org). Follow-up and documentation of an out of window participant visit provides the Data Safety Monitoring Committee and the Medical Monitor additional information about these participants who are not returning and ensures due diligence from you at the site.

- If a participant is not able to come for a Follow Up visit, make sure that you cancel the visit in the EDC under the participant's visit overview. Participants with overdue follow up visits show up in red text on your Participant Grid in the EDC.

- On the Cognitive CRF, if you answer "no" to one of the 4 required core cognitive assessments (SDMT, Stroop Color, Stroop Word, Category Fluency) please remember to leave a text comment for each assessment to indicate why the test was not performed. **This is required to process payment for the visit.**

- When contacting IT Support or sending any correspondence regarding a participant, remember to send **only the first four digits of the HDID.**

- Sites are reminded to complete the coding for all participant occupations captured on the Variable form using the SNOMED dictionary. If you are unsure of the process for coding occupation, please contact IT Support.
- Proof of date of birth is required in the source files kept at your site - this can include current medical records or any proof of identification showing date of birth.
- At each visit remember to review and discuss with participants whether any reportable events have occurred since their last study visit.
- [The Operations Manual](#) provides detailed instructions on all aspects of the study, including biosampling, data entry, the informed consent process and Greenphire payments; it is important to familiarize yourself with these processes to ensure data and biosample integrity.
- A reminder to all sites regarding the sign-off of CRFs in the EDC system - all individual CRFs must be signed by a site user after data entry is complete, and the visit itself (Baseline, Annual Follow-Up, General, Family History) must also be signed by a site user before the visit can be flagged as ready for monitoring and then subsequently approved for payment.

IRB/ERB reminders

- For sites that are submitting for re-approval, even if ICFs do not require changes you still need to send copies of your ICFs to your site manager and copy Quintiles (EnrollHD@quintiles.com) after they have been re-approved by your IRB.
- If changes are required on your site's ICFs, please remember to send **all changes** to your site manager for review prior to submitting to your IRB. Once you have received IRB approval, please remember to forward the documentation and approved ICFs to your site manager and copy Quintiles (EnrollHD@quintiles.com).

Financial reminders

- Prior to enrolling participants, **sites are required to set up their bank account in the Greenphire eClinicalGPS system to enable payment**. If your financial information is not entered into the eClinical GPS system, payment cannot be made to your site for data entry, start-up and IRB costs. Therefore, this information must be entered prior to the start-up of a site.
- All fees outlined in your site's contract, including start-up and IRB approval fees, must be requested through the Greenphire eClinical GPS system. **CHDI cannot process payments for any paper copy invoices submitted.** Please review the [eClinical GPS training materials](#) if you are unsure of the process for submitting an invoice for fees.
- It can take up to 8 weeks to receive payment after you have submitted your forms for remote data review and queries have been answered – please be sure to check your dashboard and query inbox often to ensure all queries have been answered.
- It can also take up to 8 weeks to receive participant travel support funds once requested; please keep this in mind and request additional travel support funds promptly when your site's fund balance is at 50% of the original.

Safety reminders

- If a participant has either a history of suicidal ideation or attempt, **a PBA score >2 in the PBAs assessment**, or mentioned suicidal ideation or attempts during the current visit, the Columbia Suicide Severity Rating Scale (CSSRS) assessment must be completed. CSSRS assessments can be completed for as many participants as a clinical site considers necessary.