Enroll-HD Process Reminders and Guidelines

New reminders - September 2015

- 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 in the field to indicate why the assessment was not performed. **This is required to properly process payment for the visit.**
- 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, as it will be reviewed and checked during your next interim monitoring visit.

Biosample reminders

- 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.
- **As a reminder, the Samples CRF in the EDC needs to be completed and submitted before blood samples are shipped.** The notification in the Samples form is required to retrieve the samples from customs in Italy. Failure to submit the Samples form will cause delays and could lead to issues with sample integrity; this may necessitate a sample re-draw at the participant's next Enroll-HD visit.
- When submitting the Samples form in the EDC, site staff are reminded to **press the button <u>only once</u>**. 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.

Data entry reminders

- When contacting IT Support or sending any correspondence regarding a participant, remember to send **only the first four digits of the HDID.**
- If you are unable to create a second Phone Contact visit for a missed follow up visit in the EDC, please send an email to IT Support (ITSupport@Enroll-HD.org) and include the first four digits of the HDID. A second Phone Contact visit will be added for the participant.
- 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. Follow these steps:
    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 display the HDID and you can print this form out for your source files.
    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.
- Please remember to complete ICD-10 coding for all comorbid conditions captured on the Comorbid CRF. A list of common ICD-10 codes can be found in the Enroll-HD Operations Manual. This information is required in order to sign off on the page and the visit.
- 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.
- If a participant has a history of suicidal ideation or attempt, or has mentioned suicidal ideation or attempts during the current visit, the Columbia Suicide Severity Rating Scale (CSSRS) assessment should be completed.
- At each visit please remember to review and discuss with participants whether any reportable events have occurred since their last study visit.
- 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.**
- **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.**
- 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.

IRB/ERB reminders

- If changes are required on your site's informed consent forms, please remember to send **all changes** to Imani Dupree at CHDI (imani.dupree@chdifoundation.org) for approval prior to submitting to your IRB. Once you have received IRB approval, please remember to forward the documentation and approved ICFs to Quintiles (EnrollHD@quintiles.com)
- For sites that are submitting for re-approval, if ICFs do not require changes you still need to send copies of your ICFs to Quintiles (EnrollHD@quintiles.com) after they have been re-approved by your IRB.

Financial reminders
- Prior to enrolling participants, **sites are required to set up their eClinical GPS account in Greenphire 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.
- 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.

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 Shilpa Deshpande (shilpa.deshpande@chdifoundation.org) for English versions in North America/Australasia and Katrin Barth (katrin.barth@uni-ulm.de) for all language versions for active countries in Europe. 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 been met. All local language translations of these materials are currently in process for European and Latin American sites and will be available soon.