

**From:** [EnrollHD](#)  
**To:** [EnrollHD](#)  
**Subject:** Enroll-HD: May 2013 Monthly News Bulletin  
**Date:** Wednesday, May 08, 2013 10:02:24 AM  
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## May 2013 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

An Enroll-HD progress update over the past month:

- As of May 3<sup>rd</sup>, a total of **514 participants** have been enrolled at the following sites:
    - Albany Medical College (New York, USA)
    - Baylor College of Medicine (Houston, Texas, USA)
    - The Centre for Movement Disorders (Markham, Ontario, Canada)
    - CHUM Hospital Notre Dame (Montreal, Quebec, Canada)
    - Colorado Neurological Institute (Englewood, Colorado, USA)
    - Columbia University (New York City, USA)
    - Duke University (Durham, North Carolina, USA)
    - Emory University (Atlanta, Georgia, USA)
    - Hennepin County Medical Center (Minneapolis, Minnesota, USA)
    - Hereditary Neurological Disease Center (Wichita, Kansas, USA)
    - Johns Hopkins University (Baltimore, Maryland, USA)
    - The Ohio State University (Columbus, Ohio, USA)
    - The University of Alabama at Birmingham (USA)
    - The University of British Columbia (Vancouver, British Columbia, Canada)
    - The University of California, Davis (Sacramento, California, USA)
    - The University of California, Los Angeles (USA)
    - The University of California, San Francisco (USA)
    - The University of Illinois College of Medicine at Rockford (Illinois, USA)
    - The University of Rochester (New York, USA)
    - The University of South Florida (Tampa, Florida, USA)
    - The University of Tennessee Health Science Center (Memphis, Tennessee, USA)
    - The University of Utah (Salt Lake City, Utah, USA)
    - Wake Forest University School of Medicine (Winston-Salem, North Carolina, USA)
- Top enrolling site is Columbia University (New York City, NY, USA)

with 79 participants enrolled!

- The following sites have completed their two-part site initiation:
  - Boston University (Massachusetts, USA)
  - Cleveland Clinic (Cleveland, Ohio, USA)
  - Cleveland Clinic – Lou Ruvo Center for Brain Health (Las Vegas, Nevada, USA)
  - Kansas University Medical Center (Kansas City, Kansas, USA)
  - Rush University (Chicago, Illinois, USA)
  - The University of Alberta (Edmonton, Alberta, Canada)
  - The University of Alberta Hospital In Edmonton (Canada)
  - The University of California, San Diego (USA)
  - The University of Maryland (Baltimore, Maryland, USA)
  - The University of Vermont (Burlington, Vermont, USA)
  
- The following sites are scheduled for initiation:
  - Booth Gardner Parkinson’s Care Center (Kirkland, Washington, USA)
  - University of Calgary (Alberta, Canada)

## Process Reminders and Updates

- All Enroll-HD assessments and forms have been updated to version 1.1 and all documents have been uploaded to the Study Documents folder in the Electronic Data Capture (EDC) system. Please begin to use the most up to date versions of each form for study visits.
- **Bio-Samples:**
  - A new version of the proforma invoice (with updated language) to be used for shipping biosamples has been sent to all sites. Please ensure you are using the correct version of the proforma invoice for all biosample shipments from now on.
  - Currently, biosample kit re-ordering is still being processed offline. Please continue to monitor the number of biokits your site has and contact your Quintiles Outcome Site Management Associate to order additional kits. As a reminder, it takes approximately 10 business days for the shipment to arrive at your site.
- The Columbia Suicide Severity Rating Scale Baseline Form **must** be completed for any participant who answers “Yes” to previous or current suicidal ideation. The form should **not** be filled out if the participant does not have a current or past suicidal ideation.
- When adding a Family Control to a participant’s Family History tree, it is important to answer “No” or “Unknown” to the question asking whether they are participating in Enroll-HD. By default, a Family Control should answer “No” to the question about participating in the Family History, which is found on their ICF and on the Enrollment form in the EDC.
- Please remember to include the Research Participant ID in the Greenphire ClinCard system and **never** use the HDID. The Research Participant ID is assigned by the Electronic Data Capture system in numerical sequence after a participant is created. The Research Participant ID should also be included in sequence on your Research Participant ID paper

log.

## Regional Updates

### NORTH AMERICA:

- The following sites have enrolled the most participants to date:
  - Columbia University (New York City, USA) with 79 participants
  - The Centre for Movement Disorders (Markham, Ontario, Canada) with 73 participants
  - Hereditary Neurological Disease Center (Wichita, Kansas, USA) with 52 participants
  
- As previously reported, the NIH has issued Enroll-HD a Certificate of Confidentiality (CoC). All informed consent forms (ICFs) for North American sites must be updated to include NIH-specified CoC language. If your ICFs are approved without CoC language, they must be amended to reflect this change. Amanda Klock at CHDI ([Amanda.klock@chdifoundation.org](mailto:Amanda.klock@chdifoundation.org)) will help facilitate this process. Please note, the CoC language is required by the NIH and cannot be changed.

### AUSTRALIA & NEW ZEALAND:

- Three of the five sites in Australia have submitted the study protocol and informed consents to their Ethics Committee with two additional submissions expected to occur in May. Some centers are requiring that the government template contract be used – we are exploring whether this will affect timelines and appreciate all the work site personnel are doing to move the submissions along.
- The study protocol is anticipated to be submitted to the Ethics Committee in New Zealand in May.

### LATIN AMERICA:

- Ethics approval has been received in Argentina, and the first participant is expected to be enrolled in the next few weeks.
- Regulatory submissions for Chile, Peru and Brazil are expected to occur in May.

### EUROPE:

- The Enroll-HD Team continues to prepare for the REGISTRY to Enroll-HD transition.
- The vast majority of starter packs and site contracts have been sent to the sites in the countries that began regulatory submissions in Q1 (Belgium, Denmark, Germany, Ireland, Italy, Netherlands and the United Kingdom).
- The sites in France, Spain and Poland, scheduled for regulatory submission in Q2, can expect their starter packs and contracts in the next few weeks.

Thank you for your support in helping Enroll-HD achieve its goals

**The Enroll-HD Study Team**

