

From: [EnrollHD](#)
To: [EnrollHD](#)
Subject: Enroll-HD Monthly News Bulletin
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April 2013 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

An Enroll-HD progress update over the past month:

- As of April 9th, a total of **433 participants** have been enrolled at the following sites:
 - Albany Medical College (Albany, New York, USA)
 - Baylor College of Medicine (Houston, Texas, USA)
 - Boston University (Boston, Massachusetts, USA)
 - The Centre for Movement Disorders (Markham, Ontario, Canada)
 - Cleveland Clinic (Cleveland, Ohio, USA)
 - Cleveland Clinic – Lou Ruvo Center for Brain Health (Las Vegas, Nevada, USA)
 - 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 (Birmingham, Alabama, USA)
 - The University of Alberta (Edmonton, Alberta, Canada)
 - The University of Alberta Hospital In Edmonton (Canada)
 - The University of British Columbia (Vancouver, British Columbia, Canada)
 - The University of California, Davis (USA)
 - The University of California, Los Angeles (USA)
 - The University of California, San Francisco (USA)
 - The University of Illinois College of Medicine at Rockford (Rockford, Illinois, USA)
 - The University of Maryland (Baltimore, Maryland, 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 76 participants enrolled!
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- The following sites have completed their two-part site initiation:
 - The University of California, San Diego (USA)
 - Kansas University Medical Center (Kansas City, Kansas, USA)
 - Rush University (Chicago, Illinois, USA)
 - The University of Vermont (Burlington, Vermont, USA)
 - The following site is scheduled for initiation:
 - Booth Gardner Parkinson's Care Center (Kirkland, Washington, USA)
 - The Steering Committee met in San Diego, California on March 15th to review the Publication Policy, Data Access Proposal and Scientific Strategy Plan and has made recommendations for revision. The Steering Committee also approved Dr. Joel Perlmutter, Washington University, USA as the Chair and Dr. Ralf Reilmann, University of Munster, Germany as the vice chair of the Scientific Publication Review Committee. The Data Safety and Monitoring Committee Charter is approved pending recommended revisions.

Training

- The Steering Committee confirmed that there are no restrictions regarding participants taking part in other HD studies simultaneously with Enroll-HD. Other studies may have restrictions regarding simultaneous enrollment and site staff should consult the appropriate study teams on this issue.
- A one-page Quick Reference Guide has been circulated to all active sites to answer frequently asked questions, including ICD-10 coding, the Columbia Suicide Severity Rating Scale form, as well as the Caregiver Quality of Life log and sign-off procedures for all forms and visits. Please consult this FAQ document to ensure you are following the correct procedures.
- **A reminder to all sites:** Please only use the 3 test tubes included in each lab kit for each participant's blood draw and do not use local laboratory supplies if spare test tubes are needed. If additional test tubes are needed (e.g. due to breakage), use the spare test tubes provided in the box of kits. Spare test tubes do not include a barcode. Please label the spare test tube with the Participant's LAB ID (found at the top of the participant's Sample Form). **Do not use any barcoded test tubes from another Enroll-HD lab kit. This is because each barcoded test tube within a kit is linked to a specific participant and can ONLY be used for that participant.** If you have questions during the collection of blood or

in shipping the samples, please contact Quintiles/Outcome promptly to ensure the proper procedures and protocols are followed.

Regional Updates

NORTH AMERICA:

- The following sites have enrolled the most participants to date:
 - Columbia University (New York City, USA) with 76 participants
 - The Centre for Movement Disorders (Markham, Ontario, Canada) with 70 participants
 - Hereditary Neurological Disease Center (Wichita, Kansas, USA) with 44 participants

- As previously reported, the NIH has issued Enroll-HD a Certificate of Confidentiality (CoC). All informed consent forms (ICFs) 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) will help facilitate this process. Please note, the CoC language is required by the NIH and cannot be changed.

AUSTRALIA & NEW ZEALAND:

- Two of the five sites in Australia have submitted to their Ethics Committee with two additional submissions expected to occur this month.
- The study protocol is anticipated to be submitted to the Ethics Committee in New Zealand this month.
- There is an Investigator Meeting for Investigators and Study Coordinators scheduled for 13-14 June 2013 in Melbourne. Please stay tuned for more details.

LATIN AMERICA:

- Ethics approvals are pending in Argentina and once approval is obtained. We expect the first participant in Latin America will be enrolled soon after – truly an historic milestone.
- Regulatory submissions for Chile and Peru are scheduled to occur within the next two weeks and Brazil will be close behind.

EUROPE:

- The Enroll-HD Team continues to prepare intensely 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 2013 (Belgium, Denmark, Germany, Ireland, Italy, Netherlands and the United Kingdom).
- The sites residing in countries scheduled for regulatory submission in Q2 2013 can expect their starter packs and contracts by the end of April (France, Spain and Poland).

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

The Enroll-HD Study Team

