

**From:** [EnrollHD](#)  
**To:** [EnrollHD](#)  
**Subject:** Enroll-HD March Bulletin  
**Date:** Wednesday, March 13, 2013 11:09:58 AM  
**Attachments:** [image002.png](#)  
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## March 2013 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

An Enroll-HD progress update over the past month:

- × As of March 12th, a total of **375 participants** have been enrolled at the following sites:
  - The University of Tennessee Health Science Center (Memphis, Tennessee, USA)
  - Albany Medical College (Albany, New York, USA)
  - The University of California, Davis (USA)
  - The Centre for Movement Disorders (Markham, Ontario, Canada)
  - CHUM Hospital Notre Dame (Montreal, Canada)
  - Colorado Neurological Institute (Englewood, Colorado, USA)
  - Emory University (Atlanta, Georgia, 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 British Columbia (Vancouver, British Columbia, Canada)
  - The University of California, Los Angeles (Los Angeles, California, USA)
  - The University of California, San Francisco (San Francisco, California, USA)
  - The University of Illinois College of Medicine at Rockford (Rockford, Illinois, USA)
  - The University of Rochester (Rochester, New York, USA)
  - The University of South Florida (Tampa, Florida, 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 67 participants enrolled!
  
- × The following sites have completed their two-part site initiation:

- The University of California, San Diego (USA)
  - Hennepin County Medical Center (Minneapolis, Minnesota, USA)
  - The University of Alberta (Edmonton, Canada)
  - The University of Alberta Hospital In Edmonton (Edmonton, Canada)
  - The University of Maryland (Baltimore, Maryland, USA)
  - Kansas University Medical Center (Kansas City, Kansas, USA)
  - Rush University (Chicago, Illinois, USA)
- × The following sites are scheduled for initiation:
    - Boston University (Boston, Massachusetts, USA)
    - Cleveland Clinic (Cleveland, Ohio, USA)
    - Cleveland Clinic Lou Ruvo Center for Brain Health (Las Vegas, Nevada, USA)
    - Duke University (Durham, North Carolina, USA)
    - University of Vermont (Burlington, Vermont, USA)

## Training

- × All sites were recently sent a Caregiver Log to include in their investigator site file. As a reminder, the Caregiver ID is unique to each caregiver-participant (to complete the Caregiver Quality of Life Questionnaire). The first caregiver for each participant will be entered in to the Electronic Data Capture (EDC) system as “01” and should also be recorded in the paper version of the log. Please remember that a caregiver-participant can also participate in Enroll-HD as a full-participant (e.g. a “Family Control”)
- × If you encounter screen failures do not enter data into the EDC system; this should be very rare since Enroll-HD has liberal inclusion/exclusion criteria.
- × As a reminder, the Columbia Suicide Severity Rating Scale (C-SSRS) Baseline form should only be completed if the participant in question has experienced suicidal ideations or suicide attempts in the past. This question is asked on the Huntington’s Disease Clinical Characteristics (HDCC) form.
- × Additionally, the Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI-SHP), an extended assessment form, should only be entered for participants who are HD gene mutation carriers.

## Regional Updates

### NORTH AMERICA:

- × The following sites have enrolled the most participants to date:
  - Columbia University (New York City, New York, USA) with 67 participants
  - The Centre for Movement Disorders (Markham, Ontario, Canada) with 66 participants
  - Hereditary Neurological Disease Center (Wichita, Kansas, USA) with 35 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 CoC language. If your ICFs are

already approved, 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:

- Two of the five sites in Australia have submitted to their Ethics Committee with the remaining three submissions expected to occur this month.
- The study protocol is anticipated to be submitted to the Ethics Committee in New Zealand this month.

#### LATIN AMERICA:

- The first site in Argentina is expected to be initiated in the next few weeks. We expect that very soon the first participant in Latin America will enroll – truly an historic milestone.
- Regulatory submissions for Chile and Peru are anticipated this month and Brazil will be close behind.

#### EUROPE:

- Regulatory submissions are scheduled to begin this month after the approval of the Informed Consent Form (ICF) template in the following countries: Belgium, Denmark, Germany, Ireland, Italy, Netherlands and the United Kingdom.
- The distribution of starter packs and site contracts has begun for countries scheduled for regulatory submission in Q1 2013.
- The Enroll-HD Team is preparing intensely for the REGISTRY to Enroll-HD transition.

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

#### **The Enroll-HD Study Team**

