

Protocol: CHD Brain and Genes

Visit: ND Protocol Visit

Site ID: |__|__|__| (XXX)

Blind ID: 1 - |__|__|__|__| (1-XXXXX)

Informed Consent Process Note

Check all that apply to indicate you completed the activities.

To be completed by the staff member obtaining consent.

Complete one process note for each person consented

Persons in attendance during the consent process (check all that apply):

Participant Mother Father Legal Guardian

Consent Process

- The participant/LAR was given the opportunity to read the consent document or have it read to them (A translator was provided if needed)
- The consent document was explained in her/his primary language and all pages reviewed
- The participant/LAR was able to ask questions, all were answered in full
- The participant/LAR verbalized understanding of the research
- The participant/LAR was given time to consider consenting
- The participant/LAR signed /dated the consent document
- The assent was signed/dated (per site requirements) as applicable
- The consenting staffer signed/dated the consent and a signed copy was provided to the participant/LAR

Consent Method: In-person consent
 Phone consent

If Phone consent, in addition to the above process:

- The participant/parent/LAR was provided with complete copies of all information related to the consent process (i.e. consent, assent, parent permission as applicable) prior to the phone consent process
- The consent discussion took place directly with the participant/parent/LAR via phone, conference call, video conference, etc.)
- The participant/parent/LAR signed and dated, then returned a copy of the signed and dated document to the research team
- The site staff member authorized to consent signed and dated the consent
- The method/process used to obtain the consent/assent/parental permission is documented on the signature page of the consent form
- A copy of the signed/ dated consent form is returned to the participant/parent/LAR

I attest that the consenting process was conducted as described above

If you **do not** attest, please describe: _____

Name of person obtaining consent: _____

Type of Consent: (check all that apply)

- Consent
 Parent/Legal Guardian Permission
 Assent

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Date Informed Consent Signed

Date Informed Consent signed by participant/parent/LAR:

|_|_| - |_|_| - |_|_|_|_|
M M D D Y Y Y Y

For subjects of assent age, Date Assent signed:

|_|_| - |_|_| - |_|_|_|_| Not Applicable
M M D D Y Y Y Y

Date Staff signed Consent:

|_|_| - |_|_| - |_|_|_|_|
M M D D Y Y Y Y