

Instructions for Completing the Medical History Form

The Medical History form (MHE) is interview based, and must be completed prior to randomization on Visit 0 to rule out any potential exclusion criteria (in conjunction with the physical exam and lab screen). Based on the responses from the Demographics form, inquire about the prospective participant's medical history. Questions should be adapted to the appropriate literacy level of the prospective study participant.

At times, a participant might inform research staff that s/he has a medical condition that was not recorded on the MHE during the screening process. Research staff should relay this information to the Project Coordinator. The Project Coordinator should notify the appropriate medical personnel, who should update the MHE form.

If the MHE form is updated with a major medical disorder, staff should:

- 1) Make a note of the update in the protocol deviation log
- 2) Sign and date the change on the MHE form, and be sure that the change is keyed into the DMS
- 3) Add a note log that includes the date the change was made.