[*Study Name/ID pre-filled*]   Site Name: _____

Subject ID: _____

Date Medical History Taken: * ____/_____/20_____
                                 mm   dd   yyyy

Does the participant/subject have a history of any medical problems/conditions in the following body systems?
☐ No (leave rest of form blank)   ☐ Yes

Enter all significant medical history items, including surgeries, EXCEPT the problem/condition that is the focus of this study. Use only one line per description.

§ Use BODY SYSTEM categories for medical history:
• Constitutional symptoms (e.g., fever, weight loss)   • Respiratory   • Neurological • Eyes   • Gastrointestinal   • Psychiatric • Ears, Nose, Mouth, Throat   • Genitourinary   • Endocrine • Cardiovascular   • Musculoskeletal   • Hematologic/Lymphatic • Integumentary (skin and/or breast)   • Allergic/Immunologic

Body System §	Medical History Term * (one item per line)	Start Date * (mm/dd/yyyy)	Ongoing?	End Date (mm/dd/yyyy)
Cardiovascular	Example: Hypertension	03/99/2009	☒Yes ☐No	___/____ /20____
		___/____ /20____	☐ Yes ☐ No	___/____ /20____
		___/____ /20____	☐ Yes ☐ No	___/____ /20____
		___/____ /20____	☐ Yes ☐ No	___/____ /20____
		___/____ /20____	☐ Yes ☐ No	___/____ /20____
		___/____ /20____	☐ Yes ☐ No	___/____ /20____
		___/____ /20____	☐ Yes ☐ No	___/____ /20____
		___/____ /20____	☐ Yes ☐ No	___/____ /20____

GENERAL INSTRUCTIONS

Medical History data are collected to verify the inclusion and exclusion criteria (e.g., no history of cognitive disabilities) and to describe the study population. Typically, the Medical History Form captures conditions that EVER occurred at some point in time within a protocol-defined period (e.g., the last 12 months).

The form should focus on significant medical history of all problems or conditions other than those related to the focus of the study and are presented in the order typically used during a patient visit. If the participant/ subject reports more than one medical condition per system, record each condition on a separate line.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- **Date Medical History Taken** -- Record the date (and time) the medical history was taken. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.

- **Does this participant/subject have**…? – Choose one. If this question is answered NO then the rest of the form is blank. If the question is answered YES then the medical history for at least one body system should be recorded.

- **Body System** – Record the appropriate body system for each line of medical history.

- **Condition/Disease -** Record one Medical History term per line. See the data dictionary for additional information on coding the condition using SNOMED CT.

- **Start Date** –Record the date the medical condition/disease started. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.

- **Ongoing?** – Check Yes or No to indicate if the medical condition/disease is still present.

- **End Date** – If the condition is not ongoing, record the date (and time) the medical condition/disease stopped. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.