\*Date Medical History Taken (M M/D D/Y Y Y Y):

Does the participant/subject have a history of any medical problems/conditions in the following body systems?

Yes

No (leave rest of form blank)

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 Table:

* Constitutional symptoms (e.g., fever, weight loss)
* Eyes
* Ears, Nose, Mouth, Throat
* Cardiovascular
* Respiratory
* Gastrointestinal
* Genitourinary
* Musculoskeletal
* Integumentary (skin and/or breast)
* Neurological
* sychiatric
* Endocrine
* Hematologic/Lymphatic
* Allergic/Immunologic
* Hepatobiliary

Medical History Table

| \*Body System (Ex. Cardiovascular) | \*Medical History Term  (one item per line) – Ex. Hypertension | \*Start Date  (m m/d d/y y y y) – Ex. 03/99/2009 | \*Ongoing? | \*End Date (m m/d d/y y y y) |
| --- | --- | --- | --- | --- |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | Yes  No | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | Yes  No | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | Yes  No | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | Yes  No | Data to be entered by site |

\*Element is classified as Core

## General Instructions

This case report form (CRF) contains data elements related to prenatal and perinatal history and general medical history.

The General Medical History section of 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/time according to the ISO 8601, the International Standard for the representation of dates and times ([ISO 8601](http://www.iso.org/iso/iso8601)). 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.).
* Does this participant/subject have…? - If this question is answered NO then the rest of the form is blank. If the question is answered YES then fill out the chart with all relevant medical history.
* 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 (and time) 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 – Record the date (and time) 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.