**Date Medical History Taken** (MM/DD/YYYY):

**Intended respondent for the COVID-19 questions is the participant/subject.**

1. **Do you think that you have or have had COVID-19?**

[ ]  Yes, confirmed by a positive test

[ ]  Yes, suspected by a doctor but not tested

[ ]  Yes, my own suspicions

[ ]  No

1. **If YES, when were you told/when did you think you first had COVID-19?**

\_ \_ / \_ \_ / \_ \_ \_ \_ (DD/MM/YYYY) [ ]  N/A

1. **Have you ever been given a vaccine for COVID-19 or enrolled in the COVID-19 clinical vaccine trials?**

[ ]  Yes

[ ]  No

[ ]  Don’t know

[ ]  Refuse to answer

Additional standardized COVID-19 questions are available from other resources. Please see list on instructions page.

**The information in the following sections should be obtained through interview and/or medical record data abstraction.**

**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.

**Table 1: Body System**

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

**Table 2: Example Medical History**

| **Body System** | **Medical History Term** (one item per line) | **Start Date** (mm/dd/yyyy) | **Ongoing?** | **End Date** (mm/dd/yyyy) |
| --- | --- | --- | --- | --- |
| **Example:** Cardiovascular | **Example:** Hypertension | **Example:** 03**/**11**/**2009 | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |

**Table 3: Medical History**

| **Body System §** | **Medical History Term** (one item per line) | **Start Date** (mm/dd/yyyy) | **Ongoing?** | **End Date** (mm/dd/yyyy) |
| --- | --- | --- | --- | --- |
|  |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  |

## Additional Pediatric-specific Elements

*These elements are recommended for pediatric studies.*

1. Birth Weight:

(kg):

1. Gestational Age:

(weeks): And (days):

1. Post Natal Age (PNA):

(weeks): And (days):

1. Post Conceptional Age (PCA) Can be calculated/derived from #2 and #3:

(weeks): And (days):

1. 5 minute APGAR score:
2. 10 minute APGAR score:

Recorder Signature: Date: \_ \_ / \_ \_ / \_ \_ \_ \_

## 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.

Important note: The medical history term data elements included on this CRF Module are classified as Core (i.e., strongly recommended for all studies to collect) and are part of the General Core CDEs. The remaining data elements are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.

Please see the Data Dictionary for element classifications.

## 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.
* **Do you think that you have or have had COVID-19?** – If YES, choose all positive response options that apply.
* **If YES, when were you told/when did you think you first had COVID-19?** – Record the date that you first thought you had or were told you had COVID-19. The date should be recorded to the level of granularity known (e.g., year, year and month, etc.) and in the format acceptable to the study database. If you never thought you had or were never told you had COVID-19, choose N/A.
* **Have you ever been given a vaccine for COVID-19 or enrolled in the COVID-19 clinical vaccine trials?** – Choose one.
* **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.
* **Birth Weight** – Record the birth weight of the participant/ subject in kilograms (kg). This element is intended for pediatric clinical studies.
* **Gestational Age** – Record the gestational age of the participant/subject in weeks and days. This element is intended for pediatric clinical studies.
* **Post Natal Age (PNA)** –Record the gestational age of the participant/subject in weeks and days. This element is intended for pediatric clinical studies.
* **Post Conceptional Age (PCA)** – Record the post conceptional age of the participant/subject in weeks and days. This element is intended for pediatric clinical studies. This field is not needed if Gestational Age and Post Natal Age are captured since it can be derived from those data.
* **5 minute APGAR score** –Record the APGAR score (0 - 10 points, inclusive) assessed at 5 minutes.
* **10 minute APGAR score** – Record the APGAR score (0 - 10 points, inclusive) assessed at 10 minutes.

## References

COVID-19 Related Health Questions, <https://www.phenxtoolkit.org/protocols/view/940101>

COVID-19 Vaccination – Adult, <https://www.phenxtoolkit.org/protocols/view/940401>

Additional standardized COVID question are available from:

* NIH CDE Repository: <https://cde.nlm.nih.gov/home>
* PhenX Toolkit: <https://www.phenxtoolkit.org/collections/view/8>
* RECOVER Research Protocols: <https://recovercovid.org/protocols>