INSTRUCTIONS FOR COVID IMPACT QUESTIONNAIRE (COVX)

I. General Instructions

This form is completed during all ACHIEVE ancillary study visits. The form is a simpler version of the ACHIEVE COV form. The COVX interview follows the normal annual or semi-annual follow-up interview and is designed to collect data on testing, diagnosis, and hospitalizations associated with COVID-19 caused by infection with the SARS-CoV-2 virus. This form should be administered to the participant only. Site staff will coordinate which interviewer should collect this form. The questions for each administration of this form should ask the participant to consider the time since the last time the COV or COVX had been collected.

II. Detailed Instructions for each Item.

0a. Enter the date on which the form was administered.

0b. Enter the 3-digit staff ID for the person who administered the form.

0c. This question was asked on the ACHIEVE COV form but is no longer collected.

0d. Read the script: 'I would like to ask you a few questions to understand if the coronavirus pandemic, or COVID-19, has affected you. Would it be okay to ask you questions about the effects of COVID-19?'

If the participant answers 'no' to item 0d, save and close the form. If the participant answers 'yes' to question 0d, proceed to item 1.

1. Since the last time the participant was asked, if they had a negative test result or has no reason to believe that they have had COVID-19, record 'No' and proceed to item 3. If the participant had a positive test result or was presumed to have had COVID-19, record 'Yes' and proceed to 1a. Choose 'Decline to answer' if the participant declines to answer and proceed to item 3. If they have not been tested or have not yet received test results, or the HCP was unsure, record 'Unsure/unknown' and proceed to item 3.

1a. If the participant had a positive test for acute infection, record 'Positive test for acute infection.' If the participant was not tested but presumed to be COVID-19 positive by healthcare provider, record 'Presumed COVID-19 by healthcare provider but not tested.' Record 'Decline to answer' if the participant does not answer. If the participant is unsure or does not know how they were diagnosed, record 'Unsure/unknown.'

2. Since the last time the participant was asked, if they were not admitted to a hospital for treatment of COVID-19, then record 'No' and proceed to item 3. If the participant was hospitalized for treatment of COVID-19, then record 'Yes' and proceed to 2a. Record 'Decline to answer' if the participant does not answer and proceed to item 3. If the participant is unsure or does not know if they were hospitalized for treatment of COVID-19, record ‘Unsure/unknown’, and proceed to item 3.

2a. Record to which area of the hospital the participant was admitted for treatment of COVID-19.
Breathing support refers to a breathing tube in the throat, it does not include receiving oxygen through a nasal cannula (a device used to deliver supplemental oxygen or increased airflow to a patient in need of respiratory help). If the participant only receives nasal cannula outside of an ICU then record 'Regular room with no breathing support.' If the participant declines to answer record 'Decline to answer' and proceed to item 3. If the participant is unsure or does not know what part of the hospital they were admitted to, record 'Unsure/unknown' and proceed to item 3.

3. Since the last time the participant was asked, record if they had received the COVID-19 vaccine or boosters. If the participant received at least one dose of the vaccine since the last time asked, record item as 'Yes.'