



Statistical Center for HIV/AIDS
Research and Prevention

SCHARP
at FRED HUTCH

CRF Completion Guidelines

CoVPN5002

Version 2.0

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CRF Completion Guidelines

The following instructions are study-specific data completion instructions intended to assist site staff when completing electronic case report forms (eCRFs) and paper case report forms (CRFs). Detailed guidance on general data collection, entry, navigation and general use of Medidata Rave is provided in the

Medidata Rave Electronic Data Capture (EDC) Training Manual, which is found on the CoVPN5002 Protocol page: <https://atlas.scharp.org/cpas/project/HPTN/5002/begin.view?>

General Guidelines

- The Participant ID is automatically assigned by Rave EDC as a 9-digit field, starting with the 3-digit site number followed by a randomly assigned 5-digit participant number, and 1-digit check number.
- All data entered in Rave must match the data on any None-CRF source documents.
- Complete all required data fields. Ensure that all entries are in English and are accurate, consistent, complete and medically logical.
- If “Other” is chosen as a response, further details must be provided by responding to the “If ‘Other’, specify” field.
- Text box fields have character limits. Text exceeding the limit will not be saved and a “Non-conformant” icon will appear.
- Visit dates must be complete and in chronological order according to the protocol.
- Most date fields must be entered as Day/Month/Year (dd/mmm/yyyy) (e.g., 01 NOV 2017). Exceptions are detailed in specific form sections where applicable.
- Drop-down menus are available for many fields. Use these menus, when available, to select the appropriate response.
- Avoid using abbreviations, symbols or special characters.
- Avoid hitting the return or enter key in text fields.
- Log forms allow you to make multiple entries over the course of the study. All entries at the same time in ‘Complete View’ and View individual entries in portrait view.
- The following log forms for this study are available in the Ongoing logs folder at the bottom of the sidebar on the Participant’s home page:
 - Protocol Deviations
 - SARS-Cov-2 Test Results
- Correct/update data fields by clicking the pencil icon at the far right of the field, correct/update the value and give the reason for the change, if applicable. Save the form to apply the changes.
- If an incorrect data entry is made, a system query will fire. Correct the error and save the form.
 - System generated queries with no query response will automatically close with a form correction.
 - System generated queries with a query response will change into a manual query that will need to be closed by the data management team.
- All actions performed on a data field are tracked in the audit trail. If data is modified inadvertently, the change is also shown in the audit trail for that field.
- The SCHARP Clinical Data Manager will provide direction for when the Investigator should perform the final review and sign the eCRF pages.

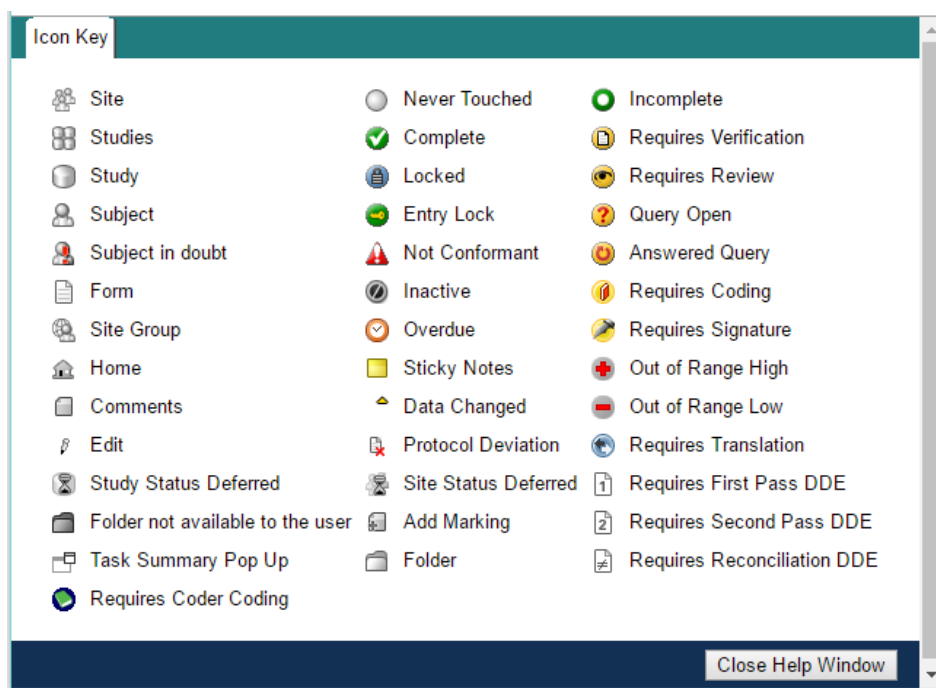
Loading of Forms in Visit Folder

- Medidata Rave will add forms to a visit folder in a participant's casebook based on specified responses on forms. Below are a few key examples.
 - **Example 1: Enrollment and Demographics**
 - If "Population cohort" is marked "Community" on the Enrollment form AND "How old are you?" is 13 or greater on the Demographics form, the Questionnaire-Adult form will be added to the Enrollment folder.
 - **Example 2: Enrollment**
 - If "Population cohort" is marked "Adults residing in nursing homes/assisted living facilities" and "For adults residing in nursing homes/assisted living facilities, is the participant able to complete the questionnaire?" is marked "No", the Medical Record Abstraction form will be added to the Enrollment folder.

Icon Key

A link to an Icon Key is available on the PTID (Subject)-level page. The key contains pictures and descriptions of the icons used in Rave. Below is a screen shot of the Icon Key.

Figure 1. Icon Key

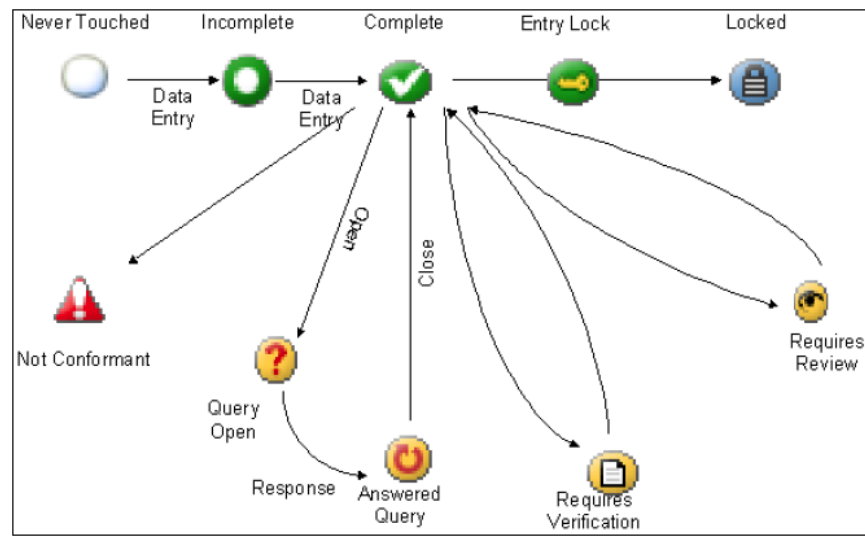


Icon Progression

The life cycle of participants, folders, forms, and fields follows a logical progression starting with “never touched” and moving toward “complete” and “locked”. Graphical icons are used throughout Rave to show status.

The following figure illustrates the status represented by each icon and the progression of icons through the life cycle.

Figure 2. Icon Progression



Task Summary

The Task Summary displays all pending tasks for the study. It displays the number of participants with outstanding tasks that need site review (see Figure 3); for example, open queries. Clicking on the arrow next to the task expands it to show the specific participants with open queries (see Figure 4). Clicking on a PTID will open the participant’s casebook.

Figure 3. Site-Level Task Summary

Task Summary: Site	Subjects
▶ Requiring Signature	18
▶ NonConformant Data	2
▶ Open Queries	6
▶ Overdue Data	0



Figure 4. Site-Level Task Summary

Task Summary: Site	Subjects
▶ Requiring Signature	18
▶ NonConformant Data	2
▼ Open Queries	6
997240800	
997601764	
997669871	
997707873	
997842416	
997880644	
1	
▶ Overdue Data	0

At the Subject level, the Task Summary displays the number of pages for that participant that need site review. In Figure 5 below, there is one open query on the Screening Outcome form at V1.0 – Screening. In the expanded task summary view, clicking on this form link will open the form.

Figure 5. Subject-Level Task Summary

Task Summary: Subject	Pages
▶ Requiring Signature	1
▶ NonConformant Data	0
▼ Open Queries	1
V1.0 - Screening-Screening Outcome	
1	
▶ Overdue Data	0

Recording Dates

- Dates are entered using the “dd MMM yyyy” format, where “dd” represents the two-digit day, “MMM” represents the three-letter abbreviation of the month (in capital letters), and “yyyy” represents the four digits of the year.
- Month abbreviations are shown below. In Rave EDC, these abbreviations are in a drop-down list in the month field.

Month	Abbreviation	Month	Abbreviation
January	JAN	July	JUL
February	FEB	August	AUG
March	MAR	September	SEP
April	APR	October	OCT
May	MAY	November	NOV
June	JUN	December	DEC

For example, record September 20, 2016 as:

20	Sep ▼	2016
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Recording Time

- Use a 24-hour clock (00:00-23:59), where hours are designated from 0–23.
- Midnight is recorded as 00:00, not 24:00.

The following chart shows equivalencies between the 12- and 24-hour clocks:

12-hour clock (a.m.)	24-hour clock	12-hour clock (p.m.)	24-hour clock
Midnight	00:00	Noon	12:00
1:00 a.m.	01:00	1:00 p.m.	13:00
2:00 a.m.	02:00	2:00 p.m.	14:00
3:00 a.m.	03:00	3:00 p.m.	15:00
4:00 a.m.	04:00	4:00 p.m.	16:00
5:00 a.m.	05:00	5:00 p.m.	17:00
6:00 a.m.	06:00	6:00 p.m.	18:00
7:00 a.m.	07:00	7:00 p.m.	19:00
8:00 a.m.	08:00	8:00 p.m.	20:00
9:00 a.m.	09:00	9:00 p.m.	21:00
10:00 a.m.	10:00	10:00 p.m.	22:00

11:00 a.m.	11:00	11:00 p.m.	23:00
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For example, record 2:25 p.m. as: 24-hour clock

Data Corrections and Additions - Rave Form and/or Paper CRF

- Data fields may need to be updated or corrected, such as in response to a query or after site review.
- If the source document is non-CRF in nature (i.e., data entry from medical record), it is sufficient to make data updates in the study database itself.

Unknown and Imputed Dates

- In Rave, where the data are missing or unknown, enter “UN” for the day and/or select ‘UNK’ from the drop-down list for the month.

UN	Jul	▼	2017
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UN	UNK	▼	2015
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Form-Specific Instructions

Demographics

Purpose:

This form documents a participant's demographic and socioeconomic information.

General Instructions:

Complete and submit this form for participants who have signed a study-specific consent form and have been enrolled in the study. This form is located in the Enrollment folder and completed at the Enrollment visit. If the participant does not understand the question, read the categories to the participant. Responses should reflect the participant's status and should not be changed unless correction is needed. All responses must be self-reported by the participant unless they are a child being assisted by their parent or the form is being completed by a legally authorized representative. For participant's that are children completing the form with their parent's assistance, please be aware of questions labeled "(13 and older)". Some questions regarding household data i.e. living situation or income should be answered regardless of age.

Field-specific Instructions:

Field	Instructions
Interviewer please check one of the following:	This field must be completed to determine if the responses were self-reported by the participant or completed by a legally authorized representative.
How old are you?	Enter the participant's age in years. If the participant is less than 1 year old, enter "0" and then enter the infant's age in months in the next field.
Infant age in months	If the participant is less than 1 year old, enter the infant's age in months.
Ethnicity Race	Record the participant's ethnicity and race based on self-definition.
Are you currently a full time or part time student? (13 and older only)	Only for participant's 13 years and older. Record the participant's student status as they report.
What is the highest level of education you have completed?	Record the participant's reported highest-level of education.
What is your marital status (13 and older only)	Only for participant's 13 years and older. Record the participant's reported marital status.
What is the zip code of your primary residence?	Record the reported zip code of the participant's primary residence.

Field	Instructions
<p>What best describes your current primary residence?</p> <p>How many bedrooms are in the residence?</p> <p>Do you live alone, with a group, family, or multiple families in your primary residence?</p> <p>How many people are currently living in your household, including yourself? A household is defined as all the people that occupy a single housing unit such as house, apartment, group of rooms, or single room.</p>	<p>Record the responses best describes the participant's living situation.</p>
<p>Are you a caregiver to anyone in your household? (13 and older only)</p>	<p>Only for participant's 13 years and older. If the participant answers with the response "part-time" or indicates they share the responsibility with someone else in their household, mark "Yes".</p>
<p>What best describes your current employment status? (13 and older only)</p>	<p>Only for participant's 13 years and older. Record the participant's self-reported employment status.</p>
<p>Are you an essential worker (Essential workers are exempt from stay at home and shelter in place orders and must report to their place of work Essential workers include but are not limited to those working in public health/health care, law enforcement, public safety, first responders, food and agriculture, energy and electricity, petroleum, water and wastewater, transportation, public works, communications and IT, and others.)? (13 and older only)</p>	<p>Only for participant's 13 years and older. The definition of an essential worker will vary from region to region. The participant's occupation may not be listed in the description but can still self-report as an essential worker.</p>

Field	Instructions
<p>Since March 2020, have you experienced any discrimination (such as being treated badly, harassed, threatened, isolated) from anyone because you are an essential worker? (13 and older only)</p>	<p>Only for participant's 13 years and older.</p>
<p>Is a member of your household an essential worker? Essential workers are exempt from stay at home and shelter in place orders and must report to their place of work. Essential workers include but are not limited to those working in public health/health care, law enforcement, public safety, first responders, food and agriculture, energy and electricity, petroleum, water and wastewater, transportation, public works, communications and IT, and others.</p>	<p>The definition of an essential worker will vary from region to region. The household member's occupation may not be listed in the description but can still be reported by the participant as an essential worker.</p>
<p>What was your sex assigned at birth?</p>	<p>This is the sex that the participant was assigned at birth.</p>

Field	Instructions
<p>What is your current gender identity?</p>	<ul style="list-style-type: none"> • This response must be self-reported by the participant. • Site staff are encouraged to document in chart notes if the participant, during study participation, prefers to be referred to by a specific pronoun or gender. • Gender is the social part of being male or female and related to self-identity. Below are descriptions of each gender category: <ul style="list-style-type: none"> ○ Male: Any person who identifies their gender as male. ○ Female: Any person who identifies their gender as female. ○ Gender nonconforming: A person whose gender expression is different than gender norms and does “fit” the male/female categories, regardless of their gender identity or sexual orientation. ○ Transgender male (also known as trans male) refers to a person assigned female at birth, but whose gender identity is male or trans-male. ○ Transgender female (also known as trans female) refers to a person assigned male at birth, but whose gender identity is female or trans-female. ○ Additional category, specify: Any other gender reported by the participant. Record what the participant reports in the “If ‘Additional category, specify:’ field.
<p>What is your sexual orientation? (13 years and older)</p>	<p>Only for participant’s 13 years and older. Below are descriptions of each sexual orientation:</p> <ul style="list-style-type: none"> • Straight/Heterosexual: Attracted to a different sex than yourself • Gay/Lesbian/Homosexual: Attracted to the same sex as yourself • Bisexual: Attracted to both the same and different sex than yourself • Queer • Two spirit • Additional category: Any other sexual orientation reported by the participant. Record what the participant reports in the “If ‘Additional category’, specify:” field. • Don’t Know/Not sure • Prefer not to answer
<p>What was your total household income in the past 12 months?</p>	<p>If a person lives with multiple people (e.g. roommate(s)) and does not know the income of everyone else, instruct them to respond with their total personal income. For participants that are children, please ask their parents to respond with their household income.</p>

Enrollment

Purpose:

This form documents the enrollment status of the participant. This form also functions as a Date of Visit CRF for the study. This CRF must be completed for every participant that has screened for the study regardless if they enroll or not.

General Instructions:

Complete this form at the time of enrollment or if the participant is ineligible.

Field-specific Instructions:

Field	Instructions
Was the participant enrolled in the study?	Select "Yes" or "No". If "No", end form.
Date of Enrollment	A complete date is required.
Recruitment date	A complete date is required. If the participant was recruited at a date prior to the enrollment date, please enter the recruitment date from the participant's recruitment card.
Recruitment time slot	Choose the appropriate 4-hour time slot. For participants in the outpatient clinic and community venue cohorts, this time slot should match the time slot assigned on the clinic or venue schedule prepared by SCHARP. If the participant was recruited at a date prior to the enrollment date, please enter the recruitment time slot from the participant's recruitment card
Population cohort	Choose the correct population cohort for the participant. This should directly reflect the type of venue where the participant was recruited.
Venue code	This is the unique three-digit code assigned to the recruitment location in the random sampling worksheet. Nursing home codes range from 100-199, outpatient clinic codes range from 200-299, and community venue codes range from 300-399.
For adults residing in nursing homes/assisted living facilities, is the participant able to complete the questionnaire?	For participant whose Population cohort is "Adults residing in nursing homes/assisted living facilities" please select "Yes" is able to answer the questions of the adult questionnaire or "No" if they are unable. Skip if Population cohort is "Adults from outpatient healthcare facilities" or "Community".
Did the participant complete all study procedures at the enrollment visit?	Select "Yes" or "No". The participant must have completed all study procedures at the Enrollment visit for "Yes".
If "No", at what date did the participant complete all study procedures?	A complete date is required. If participant did not complete all study procedures leave blank.
Specimen ID	Scan or enter the first specimen ID label here.
Will the participant be submitting an oral/saliva specimen sample?	Complete this to populate the Specimen Collection-Saliva CRF if the participant is participating in the sub-study. This will populate the Specimen Collection-Saliva CRF.

Inclusion/Exclusion Criteria

Purpose:

This form documents a participant’s eligibility status at the enrollment Visit.

General Instructions:

Complete this form for each participant screened in CoVPN5002. Complete this form when it is determined whether the participant will enroll in the study.

Field-specific Instructions:

Field	Instructions
Did the participant meet all eligibility criteria?	Select ‘Yes’ or “No’ to indicate if the participant met all eligibility criteria.
Eligibility status	Record the applicable eligibility status by selecting from the drop-down menu. If participant met all eligibility criteria, and Eligibility status is ‘Eligible and enrolled’ OR if Eligibility status is “Incomplete screening”, end form.
Select reason(s) why participant is ineligible	If participant is deemed ineligible per inclusion or exclusion criteria, use the drop-down menu to select a reason and save. Note that it may be necessary to scroll to the right to access drop down menu. Alternatively, the first few characters of each criterion can be keyed in to bring up a more selective list. If there is more than one reason for ineligibility per inclusion or exclusion criteria, click on the “Add a new Log line” and select another reason. Add all applicable reasons as appropriate.
If "E3. Any condition that, in the opinion of the study staff, would make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives", specify (max. 200 characters):	If “E3. Any condition that, in the opinion of the study staff, would make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives” was selected, record reason in the specify text box. If any other response was selected, leave this field blank.
If eligible but participant declined enrollment, specify reason.	Record the reason an eligible participant did not enroll. This text field should only be completed if “Eligibility status” is ‘Eligible, but participant did not enroll’.

Informed Consent

Purpose: This form is used to document the administrative details of the participant’s informed consent.

General Information/Instructions

Complete this form when the participants completes a consent form .Add additional log lines as appropriate. This form is located in the Screening folder.

Field-specific instructions:

Field	Instructions
Informed consent date	Record the date that the participant or guardian signed the informed consent form. A complete date is required.
Consent obtained for additional nasal swab for viral DNA sequencing If the participant has already consented to providing a saliva sample and additional nasal swab, mark "N/A".	Complete the consent for the additional viral sequencing nasal swab or "N/A" if the participant is participating in the sub-study.
Consent obtained for extra samples to be used in other studies	Complete consent for samples to be used in other studies.

Medical Record Abstraction

Purpose:

Medical record abstraction will occur for consenting participants who are residents of nursing and healthcare facilities that are unable to answer the adult questionnaire. Questionnaire domains will include history of chronic illnesses (e.g. diabetes, hypertension, asthma, etc.), smoking history, and prior SARS-CoV-2 diagnosis and will be comparable (when possible) to domains in the questionnaire surveys.

General Instructions:

- Record all information from the medical records that can be entered into the form.
- Not all of the questions may be answered from the information in the medical record. Any question that cannot be answered from the medical records, leave blank.

Section-specific Instructions:

Field	Instructions
Medical History Questions 1-19	These are questions asking about any COVID-19 related and past medical history of the participant that can be gleaned from the medical records. Includes questions pertaining to current medical conditions, past COVID-19 tests, treatments sought, any recent COVID-19 symptoms and travel while symptomatic. Not all of the questions may be answered from the information in the medical record.
Covid contact Question 20	This question is regarding any possible contact the participant may have had with someone tested positive for COVID-19 or was symptomatic
COVID-19 Impact	This section is meant to record any substance use of the participant.

Field-specific Instructions:

Participant Identifier

Purpose:

This form generates a PTID for the participant. Complete this form first for each participant.

Field-specific Instructions:

Field	Instructions
Participant ID	<ul style="list-style-type: none"> To add a participant to the study database, select the 'Add Subject' link on the study home page. The Participant Identifier form will load. No data are required from the site on this form. Click the "Save" button at the bottom of the form. A pop-up box will appear to indicate that a participant has been added to the database. The participant's home page will appear. The link for the Participant Identifier form is at the top of each participant's home page. PTID will appear on each form in participant's casebook. The PTID must be written at the top of each CRF PDF completed for a participant. The first three digits of each PTID is the Rave site ID number.

Protocol Deviation Log

Purpose

This form documents reportable protocol deviations identified for study participants during the implementation of CoVPN5002.

General Information/Instructions

Complete this form each time a reportable protocol deviation is identified. Complete one page per protocol deviation when entering in the study database. If a deviation applies to more than one PTID

complete a Protocol Deviation Log for each PTID that is affected; each PTID needs to have a record of the Protocol Deviation on their own Deviation Log. To add an additional deviation within Medidata Rave, click “Add a new Log line” to add an additional log line.

Reportable protocol deviations are defined by the HPTN (HPTN MOP Section 12) as individual incidents, trends or omissions that result in:

- Significant added risk to the participant
- Non-adherence to significant protocol requirements
- Significant non-adherence to GCP

Item-specific Instructions

Field	Instructions
<p style="text-align: center;">Site awareness date</p>	<ul style="list-style-type: none"> • Record the date the site became aware of the deviation. • A complete date is required.
<p style="text-align: center;">Deviation date</p>	<ul style="list-style-type: none"> • Record the date the deviation occurred (start date). • A complete date is required.
<p style="text-align: center;">Has or will this deviation be reported to local IRB/EC?</p>	<ul style="list-style-type: none"> • Select “Yes” or “No”.

Field	Instructions
Has or will this deviation be reported to DAIDS as a critical event?	<ul style="list-style-type: none"> Select “Yes” or “No”.
Type of deviation	<ul style="list-style-type: none"> Select the applicable deviation from the search list or select “Other” and specify the deviation in the “Description of deviation” field. <i>See table below for the types of deviations.</i>
Description of deviation	<ul style="list-style-type: none"> Use text field to briefly describe specific details of deviation. This must be completed for any deviation selected.
Plans and/or action taken to address the deviation	<ul style="list-style-type: none"> Use text field to provide a brief description of plans to address deviation.
Plans and/or action taken to prevent future occurrences of the deviation	<ul style="list-style-type: none"> Use text field to provide a brief description of plans to prevent similar deviations in the future.
Deviation reported by (staff name):	<ul style="list-style-type: none"> Enter name of staff member that reported the deviation.

PROTOCOL DEVIATION CODE LIST
Description
Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met.
Conduct of non-protocol procedure: A clinical or administrative procedure was performed that was not specified in the protocol and was not covered under local standard of care practice.
Breach of confidentiality: Include potential and actual cases where participant confidentiality is breached. For example, a staff member put a participant's name on a case report form or in an email to protocol leadership.
Mishandled lab specimen: Include any cases where the specimen collected could not be submitted due to error or any case where all requirements of the SSP were not met.
Staff performing duties they are not qualified to perform: Include any cases where staff completed a procedure or task they were not qualified for e.g. drew blood when they were not qualified to perform blood draws.
Questionnaire administration deviation: Examples include completing a questionnaire with a child without an adult present, completing questions the participant cannot answer, and letting the participant complete the questionnaire without an interviewer.
Informed assent/consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process.
Visit completed outside visit window: Completing a split visit outside of the 10-day window.
Other

Protocol Deviation Y/N

Purpose:

This form is used to document if a protocol deviation has occurred.

Generation Instructions

This form is present within the “Ongoing Logs” folder and needs to be marked only once.

Item-specific Instructions

Field	Instructions
Have any protocol deviations occurred?	If “Yes” is selected, the Protocol Deviation Log will appear in the Ongoing Logs folder and can then be completed.

Questionnaires: Adult, 10-12 years, 2 months to 9 years

Purpose:

Adults who reside in each community, have the capacity for consent and are willing and able to answer a brief survey and provide a blood sample and nasal mid-turbinate swab, will be included in the study. Children aged 2 months - 17 years will be included, with consent/assent of their parent or legal guardian; the parent/guardian will complete the questionnaire for those under age 10 years and will assist those ages 11-15.

Generation Instructions

All three questionnaires contain similar questions with the two child questionnaires omitting questions that do not pertain to their age group. Some sections may not appear in the questionnaire given the age group as well with questions from included sections. The adult questionnaire has the most questions. The 10-12 year old’s questionnaire has a subset of questions from the adult questionnaire. The 2 month to 9 year old’s questionnaire has a subset of questions from the 10-12 year old questionnaire. Each questionnaire phrases the question to the particular age group but capture the same information for questions asked across the age groups.

Section-specific Instructions

Field	Instructions
Medical History	These are questions asking about any COVID-19 related and past medical history of the participant. Includes questions pertaining to current medical conditions, past COVID-19 tests, treatments sought, any recent COVID-19 symptoms and travel while symptomatic.
COVID-19 Infection History, Risk, and Exposure	Includes questions pertaining to current medical conditions, past COVID-19 tests, treatments sought, any recent COVID-19 symptoms, any travel while symptomatic, and contact with anyone who has been diagnosed with COVID-19 or was symptomatic. <ul style="list-style-type: none"> Date of diagnostic and antibody test does not need to be exact. If the participant cannot remember the exact date an imputed date can be entered with just month and year. <p>Example: <input type="text" value="UN"/> <input type="text" value="Jul"/> <input type="text" value="2017"/></p>

Knowledge, Attitudes, and Behavior About COVID-19	These are questions about how COVID-19 has affected the participant’s routine behavior and activities and what measures, if any, they have taken up since COVID-19 for prevention of infection.
Violence During COVID-19	These are sensitive questions only appear in the adult questionnaire. Skip this section for participants who live alone, are under 18 years old, over 65 years old or who have a mental disability.
COVID-19 Impact	These are questions about the impact of COVID-19 on the participant’s daily life. These questions are sensitive and personal in nature. Some of these experiences may not apply to the participant.
Willingness to Participate in COVID-19 Vaccine Trial	This section ask questions about the participant’s experience and willingness to participate in a vaccine trial and get a COVID-19 vaccine in the future.

SARS-Cov-2 Test Results

General Instructions:

This form is used to collect PCR/Nasal Swab results for the study.

Item Specific Instructions

Field	Instructions
Specimen ID	<ul style="list-style-type: none"> Enter the specimen ID number for the sample
Specimen collection date	<ul style="list-style-type: none"> Enter the date on which the specimen was collected. A complete date is required.
Test result	<ul style="list-style-type: none"> Select the test result from the dropdown menu

Specimen Collection - Blood

General Instructions:

Refer to the SSP for the number and type of tube(s) required for the specimens. Used to document the collection of research blood specimens that will be sent to the site processing lab.

The Specimen Collection – Blood form is a log form. Should there be a need to collect an additional sample, save the form then click “Add new log line” and new form will appear.

Field-specific Instructions:

Field	Instructions
Specimen type	<ul style="list-style-type: none"> Select specimen type

Field	Instructions
Was specimen collected?	<ul style="list-style-type: none"> Select “Yes” or “No” If “Yes” record collection date and time.
Primary reason specimen was not collected	<ul style="list-style-type: none"> If no specimen was collected, select the reason from the dropdown list or other and specify, and then end the form
Specimen ID	<ul style="list-style-type: none"> Enter the specimen ID number for the sample
Specimen collection date	<ul style="list-style-type: none"> A complete date is required
Specimen collection time	<ul style="list-style-type: none"> Use a 24-hour clock (00:00-23:59)
Was sample stored? If “No”, record why sample was not stored	<ul style="list-style-type: none"> Select “Yes” or “No” If a sample was not stored, record the reason.

Specimen Collection – Nasal Swab

General Instructions

Refer to the SSP for the procedures for collecting the specimens. Used to document the collection of research nasal swab specimens that will be sent to the site processing lab.

Item-specific Instructions

Field	Instructions
Was specimen collected?	<ul style="list-style-type: none"> Select “Yes” or “No” If “Yes” record collection date and time.
Primary reason specimen was not collected	<ul style="list-style-type: none"> If no specimen was collected, select the reason from the dropdown list or other and specify, and then end the form
Specimen ID	<ul style="list-style-type: none"> Enter the specimen ID number for the sample
Specimen collection date	<ul style="list-style-type: none"> A complete date is required
Specimen collection time	<ul style="list-style-type: none"> Use a 24-hour clock (00:00-23:59)

Field	Instructions
Were all requirements of the specimen collection met per the SSP?	<ul style="list-style-type: none"> • Select “Yes” or “No” • If all requirements were not followed, record the reason.

Specimen Collection – Saliva

General Instructions

Oral saliva samples will be collected from only a subset of participants from sites designated by the laboratory and protocol teams.

Refer to the SSP for the procedures for collecting the specimens. Used to document the collection of research oral saliva specimens that will be sent to the site processing lab.

Item-specific Instructions

Field	Instructions
Was specimen collected?	<ul style="list-style-type: none"> • Select “Yes” or “No” • If “Yes” record collection date and time.
Primary reason specimen was not collected	<ul style="list-style-type: none"> • If no specimen was collected, select the reason from the dropdown list or other and specify, and then end the form
Specimen ID	<ul style="list-style-type: none"> • Enter the specimen ID number for the sample
Specimen collection date	<ul style="list-style-type: none"> • A complete date is required
Specimen collection time	<ul style="list-style-type: none"> • Use a 24-hour clock (00:00-23:59)
Were all requirements of the specimen collection met per the SSP?	<ul style="list-style-type: none"> • Select “Yes” or “No” • If all requirements were not followed, record the reason.

Study Termination

Purpose:

This form documents participant’s termination from the study.

General Instructions:

Complete this form for each enrolled participant when all study procedures have been completed or when the participant is confirmed to be unable or unwilling to complete study procedures within the visit window. This form is in the Discontinuations folder.

Field-specific Instructions:

Field	Instructions
Date of Study Exit	A complete date is required.
Primary reason for completion/ discontinuation	Select one reason for study termination from the drop-down menu.
If “Other”, specify	If the primary reason is Other’, then provide additional details in the text field provided.

Change History

Summary of Changes to Study CRF Completion Guidelines

Version		Affected Section(s) or Form(s)	Summary of Revisions
Number	Date		
1.0	13DEC2020	All sections	Original Document
2.0	22DEC2020	Enrollment	<p>Purpose:</p> <p>“This form documents the enrollment status of the participant. This CRF must be completed for every participant that has screened for the study regardless if they enroll or not.”</p> <p>Changed to:</p> <p>“This form documents the enrollment status of the participant. This form also functions as a Date of Visit CRF for the study. This CRF must be completed for every participant that has screened for the study regardless if they enroll or not.”</p>

2.0	22DEC2020	SARS_Cov-2 Test Results	<p>General Instructions: "This form is used to collect the serology results for the study."</p> <p>Changed to: "This form is used to collect PCR/Nasal Swab results for the study."</p>
2.0	28MAR2021	Informed Consent	CRF instructions added for additional nasal swab consent and other studies testing.
2.0	28MAR2021	Enrollment	CRF instructions added for oral/saliva sub-study participant
2.0	28MAR2021	Medical Record Abstraction	<p>"Medical History" questions number "1-24" changed to "1-19"</p> <p>"Covid contact" questions number "25-26" changed to "20".</p>