

Subject Case Report Forms

CoV5001_Version_3.0_PROD_BK_19OCT2020 - ALL

Signature Prompt: I certify that I have ensured the accuracy and completeness of the data reported in the Case Report Forms.

Did the participant complete this visit?

Yes 1
No

If "Yes", enter visit date:

_____ 2

If "No", select reason visit was missed:

Unable to contact participant 3
Participant unable to schedule visit within window
Participant refused visit
Participant incarcerated
Participant admitted to non-participating healthcare facility
Participant withdrew from study
Participant deceased
Participant unable to travel and no capacity for home visit
Participant unable to provide consent for visit
Other

If "Other", specify (max. 200 characters):

_____ 4

Did the participant exit/terminate the study at this visit?

Yes 5
No

If "Yes", complete Study Termination form.

ADDITIONAL PROCEDURES/FORMS

Hematology 7

Participant Transfer 8

Participant Receipt 9

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
Form: Date of Visit
Generated On: 20 Oct 2020 15:49:41

Pregnancy Test Results



CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL

Form: Date of Visit

Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-------------------|-------------|--|-------|--|----------------------|
| ① SVYN | \$1 | Did the participant complete this visit? | | Y = Yes N = No | SVYN |
| ② SVSTDTC | dd MMM yyyy | Visit date | | | SVSTDTC |
| ③ SVRSNMSD | 2 | Reason Visit Missed | | 1 = Unable to contact participant 2 = Participant unable to schedule visit within window 3 = Participant refused visit 4 = Participant incarcerated 5 = Participant admitted to non-participating healthcare facility 6 = Participant withdrew from study 7 = Participant deceased 8 = Participant unable to travel and no capacity for home visit 9 = Participant unable to provide consent for visit 99 = Other | SVRSNMSD |
| ④ SVRSNMSDOS P | \$200 | Reason Visit Missed Other Specify | | | SVRSNMSDOS P |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL

Form: Date of Visit

Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-------------------|-----------|---|-------|-------------------|----------------------|
| 5 SUPPTER | \$1 | Did the participant exit/terminate the study at this visit? | | Y = Yes N = No | SUPPTER |
| 7 LBHEM | 1 | Hematology | | | LBHEM |
| 8 TRANSFER | 1 | Participant Transfer | | | TRANSFER |
| 9 RECEIPT | 1 | Participant Receipt | | | RECEIPT |
| 10 LBPREG | 1 | Pregnancy Test Results | | | LBPREG |

Interim visit code _____ **1**

Date of visit _____ **2**

What is/are the reason(s) for this interim visit?

Mark all that apply.

Participant missing part or all of a scheduled study visit and is outside of visit window. **4**

Participant contacted site to report updated Medical History. **5**

Update Medical History log.

Participant contacted site to report updated Concomitant Medications. **6**

Update Concomitant Medication log.

Repeat specimen collection **7**

Other reason **8**

If "Other reason", specify (max. 200 characters): _____ **9**

Did the participant exit/terminate the study at this visit? Yes **10**

If "Yes", complete Termination form. No

FORMS COMPLETED AT INTERIM VISIT:

Hematology **12**

Participant Transfer 13

Participant Receipt 14

Pregnancy Test Results 15

Specimen Collection - Blood 16

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Interim Visit
 Generated On: 20 Oct 2020 15:49:41

| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---|------------|-------------|---|-------|--------|----------------------|
| ① | INTVSTCDE | 3.1 | Interim visit code | | | INTVSTCDE |
| ② | SVSTDTC1 | dd MMM yyyy | Date of visit | | | SVSTDTC1 |
| ④ | INTMSD | 1 | Participant missed or will miss all or part of a regularly scheduled study visit and is outside of visit window. | | | INTMSD |
| ⑤ | INTMH | 1 | Participant contacted site to report updated medical history. | | | INTMH |
| ⑥ | INTCM | 1 | Participant contacted site to report updated concomitant medications. | | | INTCM |
| ⑦ | INTSPEC | 1 | Repeat specimen collection | | | INTSPEC |
| ⑧ | INTOTH | 1 | Other reason | | | INTOTH |
| ⑨ | INTOSP | \$200 | If "Other reason", specify | | | INTOSP |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Interim Visit
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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-------------|-----------|---|-------|-------------------|----------------------|
| 10 SUPPTER1 | \$1 | Did the participant exit/terminate the study at this visit? | | Y = Yes N = No | SUPPTER1 |
| 12 LBHEM | 1 | Hematology | | | LBHEM |
| 13 TRANSFER | 1 | Participant Transfer | | | TRANSFER |
| 14 RECEIPT | 1 | Participant Receipt | | | RECEIPT |
| 15 LBPREG | 1 | Pregnancy Test Results | | | LBPREG |
| 16 BSBLD | 1 | Specimen Collection - Blood | | | BSBLD |

Medication name _____ **1**

Indication _____ **2**

Date started _____ **3**

Date stopped _____ **4**

Or _____

Continuing at final clinic visit **5**

Route

- Oral **6**
- Intramuscular
- Intravenous
- Topical
- Inhalation
- Vaginal
- Rectal
- Subcutaneous
- Subdermal
- Sublingual
- Intrauterine
- Nasal
- Intraocular
- Other

If "Other", specify: _____ **7**

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Concomitant Medications
 Generated On: 20 Oct 2020 15:49:41

| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---|------------|------------------|--|-------|--|----------------------|
| ① | CMTRT | \$200 | Concomitant Medication Name | | | CMTRT |
| ② | CMINDC | \$100 | Concomitant Meds Indication | | | CMINDC |
| ③ | CMSTDAT | dd- MMM- yyyy | Concomitant Meds Start Date | | | CMSTDAT |
| ④ | CMENDAT | dd- MMM- yyyy | Concomitant Meds End Date | | | CMENDAT |
| ⑤ | CMONGO | 1 | Concomitant Meds Ongoing | | | CMONGO |
| ⑥ | CMROUTE | \$5 | Concomitant Meds Route of Administration | | PO = Oral IM = Intramuscular IV = Intravenous TOP = Topical IHL = Inhalation VAG = Vaginal REC = Rectal SC = Subcutaneous SD = Subdermal SL = Sublingual IU = Intrauterine IHN = Nasal IOC = Intraocular OTHER = Other | CMROUTE |

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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-------------------|-----------|---|-------|--------|----------------------|
| ⑦ OSP_CMROUT E | \$200 | Concomitant Meds Route of Administration Other Specify | | | OSP_CMROUT E |

Did the participant experience any COVID-19 symptoms prior to or at enrollment?

Yes **1**
No

If "No", end of form.

Fever

Yes **3**
No

If "No", go to Fatigue/Malaise

Onset date

_____ **4**

Maximum temperature

Fixed Unit: C **5**

Overall

Fatigue/Malaise

Yes **7**
No

If "No", go to Myalgia

Onset date

_____ **8**

Maximum severity

Mild **9**
Moderate
Severe

Myalgia

Yes **10**
No

If "No", go to Chills

Onset date

_____ **11**

Maximum severity

Mild **12**

Moderate
Severe

Chills

Yes 13
No

If "No", go to Headache

Onset date _____

14

Maximum severity

Mild 15
Moderate
Severe

Head

Headache

Yes 17
No

If "No", go to Nausea/Vomiting

Onset date _____

18

Maximum severity

Mild 19
Moderate
Severe

Gastrointestinal

Nausea/Vomiting

Yes 21
No

If "No", go to Diarrhea/Abdominal pain

Onset date _____

22

Maximum severity Mild **23**
Moderate
Severe

Diarrhea/Abdominal pain Yes **24**
If "No", go to Cough No

Onset date _____ **25**

Maximum severity Mild **26**
Moderate
Severe

Lungs

Cough Yes **28**
If "No", go to Chest congestion/Shortness of breath No

Onset date _____ **29**

Maximum severity Mild **30**
Moderate
Severe

Chest congestion/Shortness of breath Yes **31**
If "No", go to Pharyngitis/Rhinorrhea No

Onset date _____ **32**

Maximum severity Mild 33
Moderate
Severe

ENT

Pharyngitis/Rhinorrhea Yes 35
If "No", go to Anosmia/Ageusia No

Onset date _____ 36

Maximum severity Mild 37
Moderate
Severe

Anosmia/Ageusia Yes 38
If "No", end of form. No

Onset date _____ 39

Maximum severity Mild 40
Moderate
Severe

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
Form: COVID-19 Symptoms - Enrollment
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| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----|---------------------|--------------|---|-------|--|----------------------|
| 1 | MHCVYN | \$1 | Any COVID-19 Symptoms | | Y = Yes N = No | MHCVYN |
| 3 | FEVER_MHYN | \$1 | Fever Occurrence | | Y = Yes N = No | FEVER_MHYN |
| 4 | FEVER_MHSTD AT | dd- MMM yyyy | Fever Onset Date | | | FEVER_MHSTD AT |
| 5 | FEVER_VSORR ES | 3.1+ | Maximum Temperature | | | FEVER_VSORR ES |
| 7 | FATIGUE_MHY N | \$1 | Fatigue/Malais e Occurrence | | Y = Yes N = No | FATIGUE_MHY N |
| 8 | FATIGUE_MHS TDAT | dd- MMM yyyy | Fatigue/Malais e Onset Date | | | FATIGUE_MHS TDAT |
| 9 | FATIGUE_MHS EV | 1 | Fatigue/Malais e Maximum Severity | | 1 = Mild 2 = Moderate 3 = Severe | FATIGUE_MHS EV |
| 10 | MYALGIA_MHY N | \$1 | Myalgia Occurrence | | Y = Yes N = No | MYALGIA_MHY N |
| 11 | MYALGIA_MHS TDAT | dd- MMM yyyy | Myalgia Onset Date | | | MYALGIA_MHS TDAT |
| 12 | MYALGIA_MHS EV | 1 | Myalgia Maximum Severity | | 1 = Mild 2 = Moderate 3 = Severe | MYALGIA_MHS EV |
| 13 | CHILL_MHYN | \$1 | Chills Occurrence | | Y = Yes N = No | CHILL_MHYN |

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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-----------------------|--------------|---|-------|--|----------------------|
| 14 CHILL_MHSTD AT | dd- MMM yyyy | Chills Onset Date | | | CHILL_MHSTD AT |
| 15 CHILL_MHSEV | 1 | Chills Maximum Severity | | 1 = Mild 2 = Moderate 3 = Severe | CHILL_MHSEV |
| 17 HEAD_MHYN | \$1 | Headache Occurrence | | Y = Yes N = No | HEAD_MHYN |
| 18 HEAD_MHSTD AT | dd- MMM yyyy | Headache Onset Date | | | HEAD_MHSTD AT |
| 19 HEAD_MHSEV | 1 | Headache Maximum Severity | | 1 = Mild 2 = Moderate 3 = Severe | HEAD_MHSEV |
| 21 NAUSEA_MHY N | \$1 | Nausea/Vomiti ng Occurrence | | Y = Yes N = No | NAUSEA_MHY N |
| 22 NAUSEA_MHS TDAT | dd- MMM yyyy | Nausea/Vomiti ng Onset Date | | | NAUSEA_MHS TDAT |
| 23 NAUSEA_MHS EV | 1 | Nausea/Vomiti ng Maximum Severity | | 1 = Mild 2 = Moderate 3 = Severe | NAUSEA_MHS EV |
| 24 ABD_MHYN | \$1 | Diarrhea/Abdo minal Pain Occurrence | | Y = Yes N = No | ABD_MHYN |
| 25 ABD_MHSTDA T | dd- MMM yyyy | Diarrhea/Abdo minal Pain Onset Date | | | ABD_MHSTDA T |

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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----------------------|---------------------|---|-------|--|----------------------|
| 26 ABD_MHSEV | 1 | Diarrhea/Abdominal Pain Maximum Severity | | 1 = Mild 2 = Moderate 3 = Severe | ABD_MHSEV |
| 28 COUGH_MHYN | \$1 | Cough Occurrence | | Y = Yes N = No | COUGH_MHYN |
| 29 COUGH_MHST DAT | dd- MMM yyyy DAT | Cough Onset Date | | | COUGH_MHST DAT |
| 30 COUGH_MHSE V | 1 V | Cough Maximum Severity | | 1 = Mild 2 = Moderate 3 = Severe | COUGH_MHSE V |
| 31 SOB_MHYN | \$1 | Chest Congestion/Shortness of Breath Occurrence | | Y = Yes N = No | SOB_MHYN |
| 32 SOB_MHSTDA T | dd- MMM yyyy T | Chest Congestion/Shortness of Breath Onset Date | | | SOB_MHSTDA T |
| 33 SOB_MHSEV | 1 | Chest Congestion/Shortness of Breath Maximum Severity | | 1 = Mild 2 = Moderate 3 = Severe | SOB_MHSEV |
| 35 SORET_MHYN | \$1 | Pharyngitis/Rhinorrhea Occurrence | | Y = Yes N = No | SORET_MHYN |

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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|------------------------|--------------|---|-------|--|----------------------|
| 36 SORET_MHST DAT | dd- MMM yyyy | Pharyngitis/Rhi norrhea Onset Date | | | SORET_MHST DAT |
| 37 SORET_MHSEV1 | | Pharyngitis/Rhi norrhea Maximum Severity | | 1 = Mild 2 = Moderate 3 = Severe | SORET_MHSEV |
| 38 ANOSMIA_MH YN | \$1 | Anosmia/Ageu sia Occurrence | | Y = Yes N = No | ANOSMIA_MH YN |
| 39 ANOSMIA_MH STDAT | dd- MMM yyyy | Anosmia/Ageu sia Onset Date | | | ANOSMIA_MH STDAT |
| 40 ANOSMIA_MH SEV | 1 | Anosmia/Ageu sia Maximum Severity | | 1 = Mild 2 = Moderate 3 = Severe | ANOSMIA_MH SEV |

Was the participant hospitalized? Yes 1
No

If "No", end of form.

Baseline independence with activities of daily living Requires no assistance 2
Some assistance needed
Complete assistance needed

Date of admission _____ 3

Did the participant receive intensive care? Yes 4
No

If "No", go to "Did the participant receive supplemental oxygen?"

ICU start date _____ 5

Number of days in ICU _____ Fixed Unit: # days 6

Did the participant receive supplemental oxygen? Yes 7
No

If "Yes", mark all that apply.

If "No", go to "Did the participant experience hypotension requiring vasopressors?"

High-flow oxygen (e.g., >15L/min) 8

Non-invasive ventilation (e.g., CPAP, BiPAP) 9

Invasive ventilation 10

ECMO **11**

Any other oxygen (e.g., 2L/min nasal cannula) **12**

Days of invasive ventilation (including ECMO) Fixed Unit: # days **13**

Did the participant experience hypotension requiring vasopressors? Yes **14**
No

Did the participant experience kidney injury? Yes **15**
No

If "Yes", did the participant receive renal replacement therapy (e.g., dialysis)? Yes **16**
No

Did the participant experience thrombosis or other vascular event, including stroke? Yes **17**
No

Did the participant experience myocarditis or pericarditis? Yes **18**
No

Did the participant have pneumonia on radiologic imaging (e.g., chest x-ray or CT scan)? Yes **19**
No
Unknown, chest imaging not performed

Was the participant enrolled in any experimental treatment trials? Yes **20**
No

If "Yes", specify treatment (max. 200 characters):

21

Record any medications on the Concomitant Medications log. _____

Did the participant receive any of the following medications?

Complete below AND record on the Concomitant Medications log.

Remdesivir

Yes 23
No

Chloroquine/hydroxychloroquine +/- azithromycin

Yes 24
No

Tocilizumab or other IL-6 pathway inhibitors

Yes 25
No

Anti-SARS-CoV-2 monoclonal antibody

Yes 26
No

Convalescent plasma

Yes 27
No

Corticosteroids

Yes 28
No

Off-label immunomodulatory therapy (not in the context of a clinical trial)

Yes 29
No

If "Yes", specify (max. 200 characters): _____

30

Off-label antiviral therapy (not in the context of a clinical trial) Yes **31**
No

If "Yes", specify (max. 200 characters): _____ **32**

Other COVID-19 specific therapy Yes **33**
No

If "Yes", specify (max. 200 characters): _____ **34**

Discharge Information

Has the participant been discharged? Yes **36**
No

If "No", end of form.

Date of discharge _____ **37**

What is the participant's vital status? Alive **38**
Deceased

If "Deceased", complete Study Termination CRF and end of form.

Discharge independence with activities of daily living Requires no assistance **39**
Some assistance needed
Complete assistance needed

Was the participant discharged on supplemental oxygen? Yes **40**
No

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: COVID-19 Hospitalization
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| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----|---------------------|-------------|--|-------|---|----------------------|
| 1 | HOSP_MHYN | \$1 | Hospitalized | | Y = Yes N = No | HOSP_MHYN |
| 2 | BASEADL_SSO RRES | | Baseline Independence with Activities of Daily Living | | 1 = Requires no assistance 2 = Some assistance needed 3 = Complete assistance needed | BASEADL_SSO RRES |
| 3 | ADMDAT | dd MMM yyyy | Admission Date | | | ADMDAT |
| 4 | ICU_MHYN | \$1 | Intensive Care | | Y = Yes N = No | ICU_MHYN |
| 5 | ICU_MHSTDAT | dd MMM yyyy | ICU Start Date | | | ICU_MHSTDAT |
| 6 | ICU_MHDUR | 2 | ICU Days | | | ICU_MHDUR |
| 7 | OXY_MHYN | \$1 | Supplemental Oxygen | | Y = Yes N = No | OXY_MHYN |
| 8 | HIOXY_MHYN | 1 | High-flow oxygen | | | HIOXY_MHYN |
| 9 | NINV_MHYN | 1 | Non-invasive ventilation | | | NINV_MHYN |
| 10 | INV_MHYN | 1 | Invasive ventilation | | | INV_MHYN |

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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|--------------------|-----------|--|-------|---|----------------------|
| 11 ECMO_MHYN | 1 | ECMO | | | ECMO_MHYN |
| 12 OTHOXY_MHY N | 1 | Any other oxygen | | | OTHOXY_MHY N |
| 13 INV_MHDUR | 2 | Invasive Ventilation Days | | | INV_MHDUR |
| 14 HYPO_MHYN | \$1 | Hypotension Requiring Vasopressors | | Y = Yes N = No | HYPO_MHYN |
| 15 KIDN_MHYN | \$1 | Kidney Injury | | Y = Yes N = No | KIDN_MHYN |
| 16 DIAL_MHYN | \$1 | Renal Replacement Therapy | | Y = Yes N = No | DIAL_MHYN |
| 17 VASC_MHYN | \$1 | Thrombosis/Va scular Event | | Y = Yes N = No | VASC_MHYN |
| 18 MYO_MHYN | \$1 | Myocarditis/Pe ricarditis | | Y = Yes N = No | MYO_MHYN |
| 19 PNEU_MHYN | \$1 | Pneumonia On Imaging | | Y = Yes N = No U = Unknown, chest imaging not performed | PNEU_MHYN |
| 20 TRIALS_MHYN | \$1 | Experimental Treatment Trial | | Y = Yes N = No | TRIALS_MHYN |

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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|--------------------|-----------|--|-------|-------------------|----------------------|
| 21 MHOSP | \$200 | Experimental Treatment Trial Specify | | | MHOSP |
| 23 REMD_CMYN | \$1 | Remdesivir | | Y = Yes N = No | REMD_CMYN |
| 24 HCQAZ_CMYN | \$1 | Chloroquine Hydroxychloro quine Or Azithromycin | | Y = Yes N = No | HCQAZ_CMYN |
| 25 TOCILI_CMYN | \$1 | Tocilizumab Or IL-6 Pathway Inhibitor | | Y = Yes N = No | TOCILI_CMYN |
| 26 ANSARS_CMY N | \$1 | Anti-SARS-CoV -2 Monoclonal Antibody | | Y = Yes N = No | ANSARS_CMY N |
| 27 CONVAL_CMY N | \$1 | Convalescent Plasma | | Y = Yes N = No | CONVAL_CMY N |
| 28 CORT_CMYN | \$1 | Corticosteroids | | Y = Yes N = No | CORT_CMYN |
| 29 IMM_CMYN | \$1 | Off-Label Immunomodul ar Therapy | | Y = Yes N = No | IMM_CMYN |
| 30 IMM_CMDESC | \$200 | Off-Label Immunomodul ar Therapy Specify | | | IMM_CMDESC |

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| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----|---------------------|-------------|---|-------|---|----------------------|
| 31 | ANTV_CMYN | \$1 | Off-Label Antiviral Therapy | | Y = Yes N = No | ANTV_CMYN |
| 32 | ANTV_CMDES C | \$200 | Off-Label Antiviral Therapy Specify | | | ANTV_CMDES C |
| 33 | OTH_CMYN | \$1 | Other COVID-19 Specific Therapy | | Y = Yes N = No | OTH_CMYN |
| 34 | OTH_CMDESC | \$200 | Other COVID-19 Specific Therapy Specify | | | OTH_CMDESC |
| 36 | DIS_MHYN | \$1 | Discharged | | Y = Yes N = No | DIS_MHYN |
| 37 | DISDAT | dd MMM yyyy | Discharge Date | | | DISDAT |
| 38 | VS_DSDECOD | 1 | Discharge Vital Status | | 1 = Alive 2 = Deceased | VS_DSDECOD |
| 39 | DISCADL_SSO RRES | 1 | Discharge Independence with Activities of Daily Living | | 1 = Requires no assistance 2 = Some assistance needed 3 = Complete assistance needed | DISCADL_SSO RRES |

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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-------------------|-----------|--|-------|-------------------|----------------------|
| 40 DISOXY_MHYN\$1 | | Supplemental Oxygen On Discharge | | Y = Yes N = No | DISOXY_MHYN |

HEMOGRAM

Was a hematology sample collected?

Yes **2**
No

Hematology collection date

_____ **3**

Hemoglobin

Fixed Unit: g/dL **4**

Hematocrit

Fixed Unit: % **5**

MCV

Fixed Unit: fL **6**

Platelets

Fixed Unit: cells/mm³ **7**

WBC

Fixed Unit: cells/mm³ **8**

DIFFERENTIAL

Was a differential done?

Yes **10**
No

Differential collection date

_____ **11**

Neutrophils

Fixed Unit: cells/mm³ **12**

Lymphocytes Fixed Unit: cells/mm³ **13**

Monocytes Fixed Unit: cells/mm³ **14**

Eosinophils Fixed Unit: cells/mm³ **15**

Basophils Fixed Unit: cells/mm³ **16**

Atypical lymphocytes Fixed Unit: cells/mm³ **17**

Comments (max. 450 characters): **18**

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| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----|------------------|-------------|--|-------|-------------------|----------------------|
| 2 | HEM_LBPERF | \$1 | Hematology Sample Collected | | Y = Yes N = No | HEM_LBPERF |
| 3 | HEM_LBDAT | dd MMM yyyy | Hematology Collection Date | | | HEM_LBDAT |
| 4 | HBG_LBORRES | 8.5 | Hemoglobin Result | | | HBG_LBORRES |
| 5 | HCT_LBORRES | 7.5 | Hematocrit Result | | | HCT_LBORRES |
| 6 | MCV_LBORRES | 8.5 | Ery. Mean Corpuscular Hemoglobin Result | | | MCV_LBORRES |
| 7 | PLAT_LBORRE S | 7 | Platelets Result | | | PLAT_LBORRE S |
| 8 | WBC_LBORRE S | 7.2 | WBC Result | | | WBC_LBORRE S |
| 10 | DIFF_LBPERF | \$1 | Differential Performed | | Y = Yes N = No | DIFF_LBPERF |
| 11 | DIFF_LBDAT | dd MMM yyyy | Differential Collection Date | | | DIFF_LBDAT |
| 12 | NEUT_LBORRE S | 7 | Neutrophils Result | | | NEUT_LBORRE S |

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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----------------------|-----------|--------------------------------|-------|--------|----------------------|
| 13 LYM_LBORRES | 6 | Lymphocytes Results | | | LYM_LBORRES |
| 14 MONO_LBORR ES | 6 | Monocytes Result | | | MONO_LBORR ES |
| 15 EOS_LBORRES | 4 | Eosinophils Result | | | EOS_LBORRES |
| 16 BASO_LBORRE S | 4 | Basophils Result | | | BASO_LBORRE S |
| 17 LYMAT_LBORR ES | 4 | Lymphocytes Atypical Result | | | LYMAT_LBORR ES |
| 18 COVAL | \$450 | Comments | | | COVAL |

Thank you for being a part of our research. As you know, the virus SARS-CoV-2 and the disease it can cause, COVID-19, affect many people. People live in different places, with different customs, cultures, sexual practices, and beliefs. We hope to include people from different communities in our research. We respect all people. Not all questions we ask in our research will apply to you. Because we do not want to make assumptions, we ask the same questions of everyone. We want you to be comfortable in speaking with us. You do not have to answer any question that makes you uncomfortable.

Now I am going to ask you some questions about yourself. The answers to these questions will tell us more about who you are, such as your age and race. I will also ask you about your sex and gender. Please feel free to ask any questions about things that you don't understand. All of your answers will be kept private.

Region Americas **2**
 Africa (South Africa)
 Africa (other African countries)

Date of birth. _____ **3**

Age. _____ Fixed Unit: yrs **4**

The next question is about your sex. When I ask about your sex, I am asking about what sex you were determined to be at birth, which is generally done by looking at a baby's genitals (sex organs).

Sex assigned at birth Male **6**
 Female

Ethnicity. Hispanic or Latino. **7**
 Not Hispanic or Latino.

Race

Mark all that apply.

American Indian or Alaska Native. **9**

Asian. **10**

Black or African American. **11**

Native Hawaiian or other Pacific Islander. **12**

White. **13**

Other. **14**

.If "Other", specify: _____ **15**

.Do you currently have health insurance/coverage or medical aid? Yes. **16**
No.
Don't know.
Prefer not to answer.

.If Region is "Americas", what is the highest level of formal schooling you have completed? **17**
No formal education.
Did not graduate from high school.
High school graduate or GED.
Some college/AA degree/technical school training.
Undergraduate college degree (BS/BA).
Some graduate school.
Master's degree.
Doctorate/medical degree/law degree.
Don't know.
Prefer not to answer.

.If Region is "Africa (South Africa)" or "Africa (other African countries)", what is the highest level of formal schooling you have completed?

- No formal education. 18
- Some primary school.
- Completed primary school.
- Some secondary/high school.
- Completed secondary/high school.
- Some university/technical education (associates/bachelors/technical degree).
- Completed university/technical education (associates/bachelors/technical degree).
- National certificate/trade diploma/occupational certificate.
- Some graduate school (doctorate/masters/honours/higher education degree).
- Completed graduate school (doctorate/masters/honours/higher education degree).
- Prefer not to answer.

.If Region is "Africa (other African countries)", end of form.

Gender.

Mark all that apply.

Gender is the social part of being male or female, and relates to your self-identity. I am asking whether you consider yourself to be transgender male, transgender female, gender queer, gender variant or gender non-conforming, female, or male or if you identify yourself in an additional category. How do you identify your gender?

Male. 21

Female. 22

Transgender Male. 23

Transgender Female. **24**

Gender Nonconforming/Gender Variant. **25**

Gender Queer. **26**

Self-identify. **27**

.If "Self-identify", specify: _____ **28**

Prefer not to answer. **29**

The next question asks about your sexual orientation. By sexual orientation, I mean who are you sexually attracted to.

.How do you identify your sexual orientation? Gay/Lesbian/Homosexual. **31**
Bisexual.
Queer.
Two Spirit.
Straight/Heterosexual.
Additional category.
Not sure.
Prefer not to answer.

.If "Additional category", specify: _____ **32**

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 Form: Demographics
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---------------|------------------|--|-------|--|----------------------|
| 2 REGION | 1 | Region | | 1 = Americas 2 = Africa (South Africa) 3 = Africa (other African countries) | REGION |
| 3 BRTHDAT | dd- MMM- YYYY | Date of Birth | | | BRTHDAT |
| 4 AGE | 3 | Age at Informed Consent | | | AGE |
| 6 SEX | \$1 | Sex at Birth | | M = Male F = Female | SEX |
| 7 ETHNIC | 1 | Ethnicity | | 1 = Hispanic or Latino. 2 = Not Hispanic or Latino. | ETHNIC |
| 9 RACEAMIND | 1 | American Indian or Alaska Native | | | RACEAMIND |
| 10 RACEASIAN | 1 | Asian | | | RACEASIAN |
| 11 RACEAFRAM | 1 | Black or African American | | | RACEAFRAM |
| 12 RACEHAWAII | 1 | Native Hawaiian or other Pacific Islander | | | RACEHAWAII |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Demographics
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|------------------------|-----------|--------------------------------------|-------|--|----------------------|
| 13 RACECAUC | 1 | White | | | RACECAUC |
| 14 RACEOTH | 1 | Race Other | | | RACEOTH |
| 15 RACEOSP | \$200 | Race Other Specify | | | RACEOSP |
| 16 MEDAID_SCOR RES | | Currently Have Medical Aid | | 1 = Yes. 2 = No. 3 = Don't know. 4 = Prefer not to answer. | MEDAID_SCOR RES |
| 17 EDLEVEL_SCO RRES | 2 | Highest Level Formal Education | | 1 = No formal education. 2 = Did not graduate from high school. 3 = High school graduate or GED. 4 = Some college/AA degree/technic al school training. 5 = Undergraduate college degree (BS/BA). 6 = Some graduate school. 7 = Master's degree. 8 = Doctorate/med ical degree/law degree. | EDLEVEL_SCO RRES |

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-----------------------------------|-----------|--------------------------------|-------|--|-----------------------|
| | | | | 9 = Don't know. 10 = Prefer not to answer. | |
| 18 EDLEVELAF_S 2 CORRES | | Highest Level Formal Education | | 1 = No formal education. 2 = Some primary school. 3 = Completed primary school. 4 = Some secondary/high school. 5 = Completed secondary/high school. 6 = Some university/technical education (associates/bachelors/technical degree). 7 = Completed university/technical education (associates/bachelors/technical degree). 8 = National certificate/trade certificate/national diploma/occupational certificate. | EDLEVELAF_S CORRES |

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 Form: Demographics
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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---------------------|-----------|--------------------------------------|-------|--|----------------------|
| | | | | 9 = Some graduate school (doctorate/ma sters/honours/ higher education degree). 10 = Completed graduate school (doctorate/ma sters/honours/ higher education degree). 11 = Prefer not to answer. | |
| 21 SCORRES_GN DRM | 1 | Gender Male | | | SCORRES_GN DRM |
| 22 SCORRES_GN DRF | 1 | Gender Female | | | SCORRES_GN DRF |
| 23 SCORRES_GN DRTGM | 1 | Gender Transgender Male | | | SCORRES_GN DRTGM |
| 24 SCORRES_GN DRTGF | 1 | Gender Transgender Female | | | SCORRES_GN DRTGF |
| 25 SCORRES_GN DRGV | 1 | Gender Nonconforming /Gender Variant | | | SCORRES_GN DRGV |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL

Form: Demographics

Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----------------------------|-----------|--|-------|---|-------------------------|
| 26 SCORRES_GN DRQR | 1 | Gender Queer | | | SCORRES_GN DRQR |
| 27 SCORRES_GN DRSI | 1 | Gender Self-identify | | | SCORRES_GN DRSI |
| 28 SCORRES_GN DRSIOSP | \$200 | Gender Self-identify Other Specify | | | SCORRES_GN DRSIOSP |
| 29 SCORRES_GN DRNA | 1 | Gender Prefer not to answer | | | SCORRES_GN DRNA |
| 31 SCORRES_SEX ORIEN | 1 | Sexual Orientation | | 1 = Gay/Lesbian/Homosexual. 2 = Bisexual. 3 = Queer. 4 = Two Spirit. 5 = Straight/Heterosexual. 6 = Additional category. 7 = Not sure. 8 = Prefer not to answer. | SCORRES_SEX ORIEN |
| 32 SCORRES_SEX ORIENOSP | \$200 | Sexual Orientation Other Specify | | | SCORRES_SEX ORIENOSP |

This form should only be completed for participants who provide a stool sample.

In the last 6 months, did the participant follow a special diet?

Yes **2**

No

If "No", go to "Does the participant limit or avoid any food or food groups (such as meat, dairy, carbs)?"

What kind of special diet did the participant follow? Specify: _____

3

Does the participant limit or avoid any food or food groups (such as meat, dairy, carbs)?

Yes **4**

No

If "No", go to "Did the participant eat fermented milk products...in the last 24 hours prior to sample collection?"

What food groups does the participant limit or avoid?

Mark all that apply.

Meat

6

Wheat/Grains

7

Fish

8

Carbohydrates

9

Dairy

10

Other

11

If "Other", specify (max. 200 characters): _____

12

Did the participant eat fermented milk products (such as yogurt, amahewu if made with milk, etc.) in the last 24 hours prior to sample collection?

Yes **13**
No

Did the participant eat fermented milk products (such as yogurt, amahewu if made with milk, etc.) in the last 6 months prior to day of sample collection?

Yes **14**
No

Did the participant take any probiotic supplements in the last 24 hours prior to sample collection?

Yes **15**
No

Did the participant take any probiotic supplements in the last 6 months prior to day of sample collection?

Yes **16**
No

Did the participant take any antibiotics in the last 24 hours prior to sample collection?

Yes **17**
No

If "Yes", record on the Concomitant Medications log.

Did the participant take any antibiotics in the last 6 months prior to day of sample collection?

Yes **18**
No

If "Yes", record on the Concomitant Medications log.

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 Form: Dietary Information
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| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----|-------------------|-----------|---|-------|-------------------|----------------------|
| 2 | DIET_MHYN | \$1 | Special Diet Last 6 Months | | Y = Yes N = No | DIET_MHYN |
| 3 | OSP_MHDESC | \$200 | Special Diet Specify | | | OSP_MHDESC |
| 4 | LIMIT_MHYN | \$1 | Limit or Avoid Food Groups | | Y = Yes N = No | LIMIT_MHYN |
| 6 | MEAT_MHYN | 1 | Meat | | | MEAT_MHYN |
| 7 | WHGR_MHYN | 1 | Wheat/Grains | | | WHGR_MHYN |
| 8 | FISH_MHYN | 1 | Fish | | | FISH_MHYN |
| 9 | CARB_MHYN | 1 | Carbohydrates | | | CARB_MHYN |
| 10 | DAIR_MHYN | 1 | Dairy | | | DAIR_MHYN |
| 11 | LIMITOTH_MH YN | 1 | Other | | | LIMITOTH_MH YN |
| 12 | LIMITOTHSP | \$200 | Other Specify | | | LIMITOTHSP |
| 13 | FERM24H_MH YN | \$1 | Fermented Milk Products Last 24 Hours | | Y = Yes N = No | FERM24H_MH YN |
| 14 | FERM6M_MHY N | \$1 | Fermented Milk Products Last 6 Months | | Y = Yes N = No | FERM6M_MHY N |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Dietary Information
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---------------------------------|-----------|---|-------|-------------------|----------------------|
| 15 PROB24H_CMY\$1 N | | Probiotic Supplements Last 24 Hours | | Y = Yes N = No | PROB24H_CMY N |
| 16 PROB6M_CMY \$1 N | | Probiotic Supplements Last 6 Months | | Y = Yes N = No | PROB6M_CMY N |
| 17 ANTIB24H_CM \$1 YN | | Antibiotics Last 24 Hours | | Y = Yes N = No | ANTIB24H_CM YN |
| 18 ANTIB6M_CMY \$1 N | | Antibiotics Last 6 Months | | Y = Yes N = No | ANTIB6M_CMY N |

Was the health contact completed? Yes 1
If "No", end of form. No

Contact date _____ 2

What is the participant's vital status? Alive 3
If "Deceased", complete Study Termination CRF and end of form. Deceased

What is the participant's current independence with activities of daily living? Requires no assistance 4
Some assistance needed
Complete assistance needed

Does the participant require supplemental oxygen? Yes 5
No

Does the participant require dialysis? Yes 6
No

Since the study began, did the participant ever develop blood clots? Yes 7
No

Does the participant consider themselves to be recovered? Yes 8
If "Yes", end of form. No

Symptom Assessment

Mark all ongoing symptoms.

Fever 10

Fatigue/Malaise 11

Myalgia 12

Chills 13

Headache 14

Nausea/Vomiting 15

Diarrhea/Abdominal pain 16

Cough 17

Chest congestion/Shortness of breath 18

Pharyngitis/Rhinorrhea 19

Anosmia/Ageusia 20

Other 21

If "Other", specify up to 3 symptoms below.

Specify (max 200 characters): _____ 23

Specify (max 200 characters): _____ 24

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Form: Health Contact
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Specify (max 200 characters):

25

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 Form: Health Contact
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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-----------------|-------------|--|-------|--|----------------------|
| ① SSYN | \$1 | Visit Complete | | Y = Yes N = No | SSYN |
| ② SSDAT | dd MMM yyyy | Contact Date | | | SSDAT |
| ③ SURV_SSSTAT 1 | | Vital Status | | 1 = Alive 2 = Deceased | SURV_SSSTAT |
| ④ ADL_SSORRES 1 | | Current Independence with Activities of Daily Living | | 1 = Requires no assistance 2 = Some assistance needed 3 = Complete assistance needed | ADL_SSORRES |
| ⑤ OXY_SSYN | \$1 | Supplemental Oxygen | | Y = Yes N = No | OXY_SSYN |
| ⑥ DIAL_SSYN | \$1 | Dialysis | | Y = Yes N = No | DIAL_SSYN |
| ⑦ CLOT_SSYN | \$1 | Blood Clots | | Y = Yes N = No | CLOT_SSYN |
| ⑧ RECV_SSYN | \$1 | Recovered | | Y = Yes N = No | RECV_SSYN |
| ⑩ FEVER_SSYN | 1 | Fever | | | FEVER_SSYN |
| ⑪ FATIGUE_SSYN | 1 N | Fatigue/Malaise | | | FATIGUE_SSYN N |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL

Form: Health Contact

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| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----|-------------------|-----------|--|-------|--------|----------------------|
| 12 | MYALGIA_SSY N | 1 | Myalgia | | | MYALGIA_SSY N |
| 13 | CHILL_SSYN | 1 | Chills | | | CHILL_SSYN |
| 14 | HEAD_SSYN | 1 | Headache | | | HEAD_SSYN |
| 15 | NAUSEA_SSYN | 1 | Nausea/Vomiti ng | | | NAUSEA_SSYN |
| 16 | ABD_SSYN | 1 | Diarrhea/Abdo minal pain | | | ABD_SSYN |
| 17 | COUGH_SSYN | 1 | Cough | | | COUGH_SSYN |
| 18 | SOB_SSYN | 1 | Chest congestion/Sh ortness of breath | | | SOB_SSYN |
| 19 | SORET_SSYN | 1 | Pharyngitis/Rhi norrhea | | | SORET_SSYN |
| 20 | ANOSMIA_SSY N | 1 | Anosmia/Ageu sia | | | ANOSMIA_SSY N |
| 21 | OTH_SSYN | 1 | Other | | | OTH_SSYN |
| 23 | OSP1_SSDESC | \$200 | Other Specify 1 | | | OSP1_SSDESC |
| 24 | SSOSP2_SSDE SC | \$200 | Other Specify 2 | | | SSOSP2_SSDE SC |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
Form: Health Contact
Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----------------------|-----------|--------------------|-------|--------|----------------------|
| 25 SSOSP3_SSDE SC | \$200 | Other Specify 3 | | | SSOSP3_SSDE SC |

Informed consent date

1

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Form: Informed Consent
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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|------------|-------------|--------------------------|-------|--------|----------------------|
| ① RFICDAT | dd MMM yyyy | Informed Consent Date | | | RFICDAT |

Participant Information

Height

Fixed Unit: cm **2**

Weight

Fixed Unit: kg **3**

Targeted Conditions

Does the participant have any of the following conditions?

If "Yes", record details in Medical History log below and/or on Concomitant Medications log, as applicable.

Hypertension

Yes **5**
No

COPD/emphysema/asthma

Yes **6**
No

Congestive heart failure

Yes **7**
No

Diabetes

Yes **8**
No

If "Yes", does the participant have renal disease, eye disease or peripheral neuropathy consistent with diabetic neuropathy?

Yes **9**
No

Record any medication use, including insulin, on the Concomitant Medications log.

Chronic kidney disease Yes **11**
No

If "Yes", does the participant require dialysis? Yes **12**
No

Autoimmune disease (e.g., rheumatoid arthritis, lupus) or immunodeficiency (e.g., low antibody levels, hypogammaglobulinemia) Yes **13**
No

Record any immunosuppressant medications on the Concomitant Medication log.

Has the participant ever smoked cigarettes? Yes **15**
No

If "Yes", does the participant currently smoke cigarettes? Yes **16**
No

Has the participant ever smoked marijuana? Yes **17**
No

If "Yes", does the participant currently smoke marijuana? Yes **18**
No

Medical History

Description of condition/event _____ **20**

Start date of condition/event _____ **21**

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Form: Medical History
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Comments (max. 450 characters):

22

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 Form: Medical History
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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----------------------|-----------|---|-------|-------------------|----------------------|
| ② HEIGHT_VSOR RES | 3 | Height | | | HEIGHT_VSOR RES |
| ③ WEIGHT_VSO RRES | 4.1 | Weight | | | WEIGHT_VSO RRES |
| ⑤ HYPER_MHYN | \$1 | Hypertension | | Y = Yes N = No | HYPER_MHYN |
| ⑥ CEA_MHYN | \$1 | COPD/Emphysema/Asthma | | Y = Yes N = No | CEA_MHYN |
| ⑦ CHF_MHYN | \$1 | Congestive Heart Failure | | Y = Yes N = No | CHF_MHYN |
| ⑧ DIAB_MHYN | \$1 | Diabetes | | Y = Yes N = No | DIAB_MHYN |
| ⑨ DIABDX_MHYN | \$1 | Renal Disease/Eye Disease/Peripheral Neuropathy | | Y = Yes N = No | DIABDX_MHYN |
| ⑪ CKD_MHYN | \$1 | Chronic Kidney Disease | | Y = Yes N = No | CKD_MHYN |
| ⑫ CKD_MHOCCUR | \$1 | Dialysis | | Y = Yes N = No | CKD_MHOCCUR |
| ⑬ AUTOD_MHYN | \$1 | Autoimmune Disease/Immune deficiency | | Y = Yes N = No | AUTOD_MHYN |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Medical History
 Generated On: 20 Oct 2020 15:49:41

| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----|------------|------------------|---|-------|-------------------|----------------------|
| 15 | TOB_SUTRT | \$1 | Cigarettes Ever | | Y = Yes N = No | TOB_SUTRT |
| 16 | TOB_SUNCF | \$1 | Cigarettes Current | | Y = Yes N = No | TOB_SUNCF |
| 17 | MJ_SUTRT | \$1 | Marijuana Ever | | Y = Yes N = No | MJ_SUTRT |
| 18 | MJ_SUNCF | \$1 | Marijuana Current | | Y = Yes N = No | MJ_SUNCF |
| 20 | MHTERM | \$200 | Medical History Event Reported Term | | | MHTERM |
| 21 | MHSTDAT | dd- MMM- yyyy | Start Date of Medical History Event | | | MHSTDAT |
| 22 | COVAL | \$450 | Comments | | | COVAL |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
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Participant ID:

①

NOW

②

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
Form: Participant Identifier
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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|--------------|----------------------|-----------------------|-------|--------|----------------------|
| ① SUBJID | \$9 | Subject Identifier | | | SUBJID |
| ② SUBJID_NOW | dd MMM yyyy HH nn | | | | SUBJID_NOW |

Name of receiving study site

- Atlanta - Hope Clinic 1
- Atlanta - Ponce de Leon Center
- Baltimore - Johns Hopkins University
- Birmingham - Alabama
- Boston - Brigham and Women's Hospital Vaccine
- Boston - Fenway Health
- Chapel Hill
- Cleveland - Case
- Miami - University of Miami IDRU
- New Orleans - Adolescent Trials Unit
- New York - NY Blood Center
- New York - Physicians & Surgeons
- Newark - New Jersey Medical School
- Philadelphia - Penn Prevention
- Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection
- San Francisco - Bridge HIV
- Seattle Vaccine Trials Unit
- Belo Horizonte - FUMG
- Buenos Aires - Almagro
- Buenos Aires - Balvanera, Ramos Mejia
- Iquitos - Asociacion Civil Selva Amazonica
- Lima - Barranco
- Lima - San Marcos/CITBM
- Lima - San Miguel
- Lima - Via Libre
- Merida
- Mexico City
- Rio de Janeiro - IPEC-Fiocruz
- Rosario - Instituto CAICI
- Cape Town - Groote Schuur

- Durban - Botha's Hill
 - Durban - Chatsworth
 - Durban - Isipingo
 - Durban - Tongaat
 - Durban - Verulam
 - Durban-eThekweni
 - Elandsdoorn
 - Gaborone
 - Harare - Parirenyatwa
 - Harare - Seke South
 - Harare - St. Mary's
 - Khayelitsha
 - Kisumu
 - Klerksdorp
 - Ladysmith - QM
 - Lilongwe - Malawi
 - Lusaka - Matero
 - Lusaka - ZEHRP
 - Maputo, Polana Canico Health
Research and Training Center
Network
 - Masiphumelele
 - Mbeya
 - Medunsa
 - Mthatha
 - Ndola
 - Rustenburg
 - Soshanguve - Setshaba RC
 - Soweto - Bara
 - Soweto - Kliptown
 - Tembisa - Clinic 4
 - Vulindlela
-

Name of transferring study site

- Atlanta - Hope Clinic
- Atlanta - Ponce de Leon Center
- Baltimore - Johns Hopkins University
- Birmingham - Alabama
- Boston - Brigham and Women's Hospital Vaccine
- Boston - Fenway Health
- Chapel Hill
- Cleveland - Case
- Miami - University of Miami IDRU
- New Orleans - Adolescent Trials Unit
- New York - NY Blood Center
- New York - Physicians & Surgeons
- Newark - New Jersey Medical School
- Philadelphia - Penn Prevention
- Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection
- San Francisco - Bridge HIV
- Seattle Vaccine Trials Unit
- Belo Horizonte - FUMG
- Buenos Aires - Almagro
- Buenos Aires - Balvanera, Ramos Mejia
- Iquitos - Asociacion Civil Selva Amazonica
- Lima - Barranco
- Lima - San Marcos/CITBM
- Lima - San Miguel
- Lima - Via Libre
- Merida
- Mexico City
- Rio de Janeiro - IPEC-Fiocruz
- Rosario - Instituto CAICI
- Cape Town - Groote Schuur

- Durban - Botha's Hill
 - Durban - Chatsworth
 - Durban - Isipingo
 - Durban - Tongaat
 - Durban - Verulam
 - Durban-eThekweni
 - Elandsdoorn
 - Gaborone
 - Harare - Parirenyatwa
 - Harare - Seke South
 - Harare - St. Mary's
 - Khayelitsha
 - Kisumu
 - Klerksdorp
 - Ladysmith - QM
 - Lilongwe - Malawi
 - Lusaka - Matero
 - Lusaka - ZEHRP
 - Maputo, Polana Canico Health
Research and Training Center
Network
 - Masiphumelele
 - Mbeya
 - Medunsa
 - Mthatha
 - Ndola
 - Rustenburg
 - Soshanguve - Setshaba RC
 - Soweto - Bara
 - Soweto - Kliptown
 - Tembisa - Clinic 4
 - Vulindlela
-

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Date informed consent signed at receiving site

3

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Participant Receipt
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-------------|-----------|------------------------------------|-------|--|----------------------|
| ① RECSITENM | 3 | Name of receiving study site | | 787 = Atlanta - Hope Clinic 709 = Atlanta - Ponce de Leon Center 700 = Baltimore - Johns Hopkins University 821 = Birmingham - Alabama 726 = Boston - Brigham and Women's Hospital Vaccine 819 = Boston - Fenway Health 706 = Chapel Hill 704 = Cleveland - Case 776 = Miami - University of Miami IDRU 855 = New Orleans - Adolescent Trials Unit 825 = New York - NY Blood Center 777 = New York - Physicians & Surgeons 820 = Newark - New Jersey Medical School 863 = Philadelphia - Penn Prevention | RECSITENM |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Participant Receipt
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|------------|-----------|-----------|-------|--|----------------------|
| | | | | 793 = Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection | |
| | | | | 764 = San Francisco - Bridge HIV | |
| | | | | 778 = Seattle Vaccine Trials Unit | |
| | | | | 741 = Belo Horizonte - FUMG | |
| | | | | 850 = Buenos Aires - Almagro | |
| | | | | 852 = Buenos Aires - Balvanera, Ramos Mejia | |
| | | | | 732 = Iquitos - Asociacion Civil Selva Amazonica | |
| | | | | 714 = Lima - Barranco | |
| | | | | 848 = Lima - San Marcos/CITBM | |
| | | | | 715 = Lima - San Miguel | |
| | | | | 831 = Lima - Via Libre | |
| | | | | 883 = Merida | |
| | | | | 884 = Mexico City | |
| | | | | 721 = Rio de Janeiro - IPEC-Fiocruz | |
| | | | | 894 = Rosario - Instituto CAICI | |
| | | | | 816 = Cape Town - Groote Schoor | |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|------------|-----------|-----------|-------|---|----------------------|
| | | | | 789 = Durban - Botha's Hill | |
| | | | | 761 = Durban - Chatsworth | |
| | | | | 803 = Durban - Isipingo | |
| | | | | 807 = Durban - Tongaat | |
| | | | | 548 = Durban - Verulam | |
| | | | | 785 = Durban-eThek wini | |
| | | | | 867 = Elandsdoorn | |
| | | | | 723 = Gaborone | |
| | | | | 770 = Harare - Parirenyatwa | |
| | | | | 754 = Harare - Seke South | |
| | | | | 762 = Harare - St. Mary's | |
| | | | | 835 = Khayelitsha | |
| | | | | 792 = Kisumu | |
| | | | | 775 = Klerksdorp | |
| | | | | 832 = Ladysmith - QM | |
| | | | | 720 = Lilongwe - Malawi | |
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CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Participant Receipt
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| | | | | | |
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| | | | | 816 = Cape Town - Groote Schoor | |
| | | | | 789 = Durban - Botha's Hill | |
| | | | | 761 = Durban - Chatsworth | |
| | | | | 803 = Durban - Isipingo | |
| | | | | 807 = Durban - Tongaat | |
| | | | | 548 = Durban - Verulam | |
| | | | | 785 = Durban-eThek wini | |
| | | | | 867 = Elandsdoorn | |
| | | | | 723 = Gaborone | |
| | | | | 770 = Harare - Parirenyatwa | |
| | | | | 754 = Harare - Seke South | |
| | | | | 762 = Harare - St. Mary's | |
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| | | | | 834 = Soweto - Kliptown | |
| | | | | 874 = Tembisa - Clinic 4 | |
| | | | | 790 = Vulindlela | |

| | | | |
|------------|-------------|---|----------|
| ③ RECICDAT | dd MMM yyyy | Date informed consent signed at receiving site | RECICDAT |
|------------|-------------|---|----------|

Name of transferring study site

- Atlanta - Hope Clinic
- Atlanta - Ponce de Leon Center
- Baltimore - Johns Hopkins University
- Birmingham - Alabama
- Boston - Brigham and Women's Hospital Vaccine
- Boston - Fenway Health
- Chapel Hill
- Cleveland - Case
- Miami - University of Miami IDRU
- New Orleans - Adolescent Trials Unit
- New York - NY Blood Center
- New York - Physicians & Surgeons
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- Iquitos - Asociacion Civil Selva Amazonica
- Lima - Barranco
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- Lima - Via Libre
- Merida
- Mexico City
- Rio de Janeiro - IPEC-Fiocruz
- Rosario - Instituto CAICI
- Cape Town - Groote Schuur

- Durban - Botha's Hill
 - Durban - Chatsworth
 - Durban - Isipingo
 - Durban - Tongaat
 - Durban - Verulam
 - Durban-eThekweni
 - Elandsdoorn
 - Gaborone
 - Harare - Parirenyatwa
 - Harare - Seke South
 - Harare - St. Mary's
 - Khayelitsha
 - Kisumu
 - Klerksdorp
 - Ladysmith - QM
 - Lilongwe - Malawi
 - Lusaka - Matero
 - Lusaka - ZEHRP
 - Maputo, Polana Canico Health
Research and Training Center
Network
 - Masiphumelele
 - Mbeya
 - Medunsa
 - Mthatha
 - Ndola
 - Rustenburg
 - Soshanguve - Setshaba RC
 - Soweto - Bara
 - Soweto - Kliptown
 - Tembisa - Clinic 4
 - Vulindlela
-

Name of receiving study site

- Atlanta - Hope Clinic 2
- Atlanta - Ponce de Leon Center
- Baltimore - Johns Hopkins University
- Birmingham - Alabama
- Boston - Brigham and Women's Hospital Vaccine
- Boston - Fenway Health
- Chapel Hill
- Cleveland - Case
- Miami - University of Miami IDRU
- New Orleans - Adolescent Trials Unit
- New York - NY Blood Center
- New York - Physicians & Surgeons
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-

Visit of last completed contact with participant

- V1.0 - Enrollment 3
 - V2.0 - Follow-up
 - V3.0 - Follow-up
 - V4.0 - Follow-up
 - V5.0 - Follow-up
 - V6.0 - Follow-up
 - V7.0 - Health Contact
 - Interim Visit
-

If "Interim visit", specify Interim visit code

_____ 4

Date participant's records were sent to receiving study site

_____ 5

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 Form: Participant Transfer
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| ③ TRNSFVISIT | 3 | Visit code of last completed contact with participant | | 1 = V1.0 - Enrollment 2 = V2.0 - Follow-up 3 = V3.0 - Follow-up | TRNSFVISIT |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---------------|-------------|---|-------|--|----------------------|
| | | | | 4 = V4.0 - Follow-up 5 = V5.0 - Follow-up 6 = V6.0 - Follow-up 7 = V7.0 - Health Contact 98 = Interim Visit | |
| ④ INTERIMCD | 5.1 | Interim Visit Code | | | INTERIMCD |
| ⑤ RECRDSNTDAT | dd MMM yyyy | Date participant's records were sent to receiving study site | | | RECRDSNTDAT |

Was a pregnancy test done?

Yes ①
No

If no, why?

Not of reproductive potential ②

Add details to Comments.

Participant is pregnant

Other

Collection date

_____ ③

Collection time

_____ ④

Pregnancy test result

Positive ⑤
Negative

Comments (max. 450 characters):

_____ ⑥

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Pregnancy Test Results
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| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---|-----------------|-------------|-----------------------------------|-------|--|----------------------|
| ① | HCG_LBPERF | \$1 | Any Pregnancy Test Done | | Y = Yes N = No | HCG_LBPERF |
| ② | HCG_LBRESN D | | Reason Not Done | | 1 = Not of reproductive potential 2 = Participant is pregnant 3 = Other | HCG_LBRESN D |
| ③ | HCG_LBDAT | dd MMM yyyy | Date of Specimen Collection | | | HCG_LBDAT |
| ④ | HCG_LBTIM | HH:nn | Time of Specimen Collection | | | HCG_LBTIM |
| ⑤ | HCG_LBORRES1 | | Pregnancy Test Result | | 1 = Positive 2 = Negative | HCG_LBORRES |
| ⑥ | COVAL | \$450 | Comments | | | COVAL |

Household Exposure

At the time of, or just before, their positive SARS-CoV-2 test, did the participant live with any other individuals in their household?

Yes **2**
No

If "Yes", please provide the below information for all individuals in the participant's household

Age

Fixed Unit: yrs **4**

Did the household member have confirmed SARS-CoV-2 infection by a laboratory test?

Yes **5**
No

If "Yes", was the laboratory test performed prior to the study participant's symptoms or test results?

Yes **6**
No

Did the household member develop symptoms consistent with COVID-19?

Yes **7**
No

If "Yes", did the symptoms develop before the study participant's symptoms or test results?

Yes **8**
No

Other Exposure

What is the participant's OSHA risk of occupational exposure?

Lower exposure risk **10**
Medium exposure risk
High exposure risk
Very high exposure risk
Not applicable

Does the participant have regular exposure to young children (<5 years old)?

Yes **11**
No

Did the participant have exposure to any other individuals with confirmed SARS-CoV-2 infection or COVID-19 outside the home setting?

Yes **12**
No

If "No", end of form.

Date of last contact with individual

_____ **13**

Exposure description (max. 200 characters):

_____ **14**

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: SARS-CoV-2 Exposure
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| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----|---------------------|-----------|--|-------|--|----------------------|
| 2 | AP_DMYN | \$1 | Any Other Individuals In Participant Household | | Y = Yes N = No | AP_DMYN |
| 4 | AP_AGE | 3 | Age | | | AP_AGE |
| 5 | APCOVID_LBY N | \$1 | Confirmed SARS-CoV-2 Infection | | Y = Yes N = No | APCOVID_LBY N |
| 6 | APCOVID_LBP REYN | \$1 | Lab Test Before Participants Symptoms/Res ults | | Y = Yes N = No | APCOVID_LBP REYN |
| 7 | APSYMP_MHY N | \$1 | COVID-19 Symptoms | | Y = Yes N = No | APSYMP_MHY N |
| 8 | APSYMP_MHPR EYN | \$1 | Symptoms Before Participant Symptoms/Res ults | | Y = Yes N = No | APSYMP_MHPR EYN |
| 10 | OSHA_ERSCAT | \$2 | OSHA Risk Of Occupational Exposure | | 1 = Lower exposure risk 2 = Medium exposure risk 3 = High exposure risk 4 = Very high exposure risk NA = Not applicable | OSHA_ERSCAT |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: SARS-CoV-2 Exposure
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---------------------------|--------------|---|-------|-------------------|----------------------|
| 11 EXPCH_DMYN | \$1 | Regular Exposure To Young Children | | Y = Yes N = No | EXPCH_DMYN |
| 12 EXPOTH_DMY N | \$1 | Exposure To Confirmed SARS-CoV-2 or COVID-19 Outside Home | | Y = Yes N = No | EXPOTH_DMY N |
| 13 EXPOTH_DAT | dd- MMM yyyy | Date Of Last Contact | | | EXPOTH_DAT |
| 14 EXPOTH_DES | \$200 | Exposure Description | | | EXPOTH_DES |

Specimen collection date _____ **1**

Test result
Detected **2**
Not Detected
Indeterminate

Where was the specimen collection done?
Inpatient **3**
Outpatient
Employer
Urgent Care
Emergency Room
Home
Other

If "Other", specify: _____ **4**

Test type
RT-PCR **5**
Antibody/serology
Antigen
Other

If "Other", specify: _____ **6**

Specimen collection type
Nasal or Nasopharyngeal Swab **7**
Nasal Wash
Oropharyngeal Swab
Saliva
Blood
Other

If "Other", specify: _____ **8**

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: SARS-CoV-2 Test Results
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-------------|-------------|------------------------------------|-------|--|----------------------|
| ① LBDAT | dd MMM yyyy | Specimen Collection Date | | | LBDAT |
| ② LBORRES | 1 | Test Result | | 1 = Detected 2 = Not Detected 3 = Indeterminate | LBORRES |
| ③ LBLOC | 1 | Specimen Collection Location | | 1 = Inpatient 2 = Outpatient 3 = Employer 4 = Urgent Care 5 = Emergency Room 7 = Home 6 = Other | LBLOC |
| ④ LBLOCOSP | \$100 | Test Location Other Specify | | | LBLOCOSP |
| ⑤ LBSPEC | 1 | Test Type | | 1 = RT-PCR 2 = Antibody/serol ogy 4 = Antigen 3 = Other | LBSPEC |
| ⑥ LBSPECOSP | \$100 | Test Type Other Specify | | | LBSPECOSP |
| ⑦ LBANTREG | 1 | Specimen Collection Type | | 2 = Nasal or Nasopharynge al Swab 1 = Nasal Wash | LBANTREG |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: SARS-CoV-2 Test Results
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---------------------|-----------|--|-------|--|----------------------|
| | | | | 3 = Oropharyngeal Swab 4 = Saliva 5 = Blood 6 = Other | |
| ⑧ LBANTREGOSP \$100 | | Specimen Collection Type Other Specify | | | LBANTREGOSP |

Is the participant eligible to enroll in the study?

Yes 1

If "No", go to "Eligibility status".

No

Enrollment date _____ 2

Group at Enrollment

Group 1 - asymptomatic 3

Group 2 - mild symptoms, not hospitalized

Group 3 - hospitalized

Eligibility status

Eligible and enrolled 4

Ineligible

Incomplete screening

If "Ineligible", select reason(s) why participant is ineligible.

Inclusion Criterion 1 - Age 18 or older. 5

Inclusion Criterion 2 - Test result indicating presence of SARS-CoV-2 virus.

Inclusion Criterion 3 - Ability and willingness to provide informed consent.

Inclusion Criterion 4 - Willingness to have clinical research staff come to place of residence or hospital if needed.

Inclusion Criterion 5 - Willingness to be followed for the planned duration of the study.

Inclusion Criterion 6 - Assessment of understanding: volunteer demonstrates understanding of this study.

Inclusion Criterion 7 - Agreement to allow access to medical records.

Inclusion Criterion for Group 1 - No current symptoms.

Inclusion Criterion for Group 1 - No symptoms consistent with COVID-19 within 2 weeks prior to positive test.

Inclusion Criterion for Group 1 -
Positive SARS-CoV-2 RNA test or
antigen test within six days prior
to enrollment (target time) up to
10 days prior to enrollment
(upper allowable window).

Inclusion Criterion for Group 2 -
Onset of mild symptoms
consistent with COVID-19 within
six days prior to enrollment
(target time) up to 14 days prior
to enrollment (upper allowable
window).

Inclusion Criterion for Group 2 -
Positive SARS-CoV-2 RNA test or
antigen test within six days prior
to enrollment (target time) up to
10 days prior to enrollment
(upper allowable window).

Inclusion Criterion for Group 3 -
Participant hospitalized for
COVID-19 within 3 days prior to
enrollment.

Exclusion Criterion 1 - Any
medical, psychiatric, occupational,
or other condition that, in the
judgment of the investigator,
would interfere with, or serve as a
contraindication to, protocol
adherence or a volunteer's ability
to give informed consent.

Volunteer inappropriate for
enrollment in investigator's
judgement

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Screening Outcome
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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|------------|-------------|--|-------|--|----------------------|
| ① IEENRYN | \$1 | Is Ppt Eligible to Enroll in Study | | Y = Yes N = No | IEENRYN |
| ② IEENRDAT | dd MMM yyyy | Enrollment date | | | IEENRDAT |
| ③ IEGRP | 1 | Group at Enrollment | | 1 = Group 1 - asymptomatic 2 = Group 2 - mild symptoms, not hospitalized 3 = Group 3 - hospitalized | |
| ④ IESTATUS | 1 | Eligibility Status | | 1 = Eligible and enrolled 3 = Ineligible 4 = Incomplete screening | IESTATUS |

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 Form: Screening Outcome
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| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|------------|-----------|---|-------|--|----------------------|
| ⑤ IETEST | 2 | Inclusion Exclusion Criterion Result | | 1 = Inclusion Criterion 1 - Age 18 or older. 2 = Inclusion Criterion 2 - Test result indicating presence of SARS-CoV-2 virus. 3 = Inclusion Criterion 3 - Ability and willingness to provide informed consent. 4 = Inclusion Criterion 4 - Willingness to have clinical research staff come to place of residence or hospital if needed. 5 = Inclusion Criterion 5 - Willingness to be followed for the planned duration of the study. 6 = Inclusion Criterion 6 - Assessment of understanding: volunteer demonstrates understanding of this study. | IETEST |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Screening Outcome
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|------------|-----------|-----------|-------|--------|----------------------|
|------------|-----------|-----------|-------|--------|----------------------|

7 = Inclusion
 Criterion 7 -
 Agreement to
 allow access to
 medical
 records.
 8 = Inclusion
 Criterion for
 Group 1 - No
 current
 symptoms.
 9 = Inclusion
 Criterion for
 Group 1 - No
 symptoms
 consistent with
 COVID-19
 within 2 weeks
 prior to
 positive test.
 10 = Inclusion
 Criterion for
 Group 1 -
 Positive
 SARS-CoV-2
 RNA test or
 antigen test
 within six days
 prior to
 enrollment
 (target time)
 up to 10 days
 prior to
 enrollment
 (upper
 allowable
 window).

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Screening Outcome
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|------------|-----------|-----------|-------|--------|----------------------|
|------------|-----------|-----------|-------|--------|----------------------|

11 = Inclusion
 Criterion for
 Group 2 -
 Onset of mild
 symptoms
 consistent with
 COVID-19
 within six days
 prior to
 enrollment
 (target time)
 up to 14 days
 prior to
 enrollment
 (upper
 allowable
 window).
 12 = Inclusion
 Criterion for
 Group 2 -
 Positive
 SARS-CoV-2
 RNA test or
 antigen test
 within six days
 prior to
 enrollment
 (target time)
 up to 10 days
 prior to
 enrollment
 (upper
 allowable
 window).

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Screening Outcome
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|------------|-----------|-----------|-------|--------|----------------------|
|------------|-----------|-----------|-------|--------|----------------------|

13 = Inclusion
 Criterion for
 Group 3 -
 Participant
 hospitalized for
 COVID-19
 within 3 days
 prior to
 enrollment.
 14 = Exclusion
 Criterion 1 -
 Any medical,
 psychiatric,
 occupational,
 or other
 condition that,
 in the
 judgment of
 the
 investigator,
 would interfere
 with, or serve
 as a
 contraindicatio
 n to, protocol
 adherence or a
 volunteer's
 ability to give
 informed
 consent.

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
Form: Screening Outcome
Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|------------|-----------|-----------|-------|--|----------------------|
| | | | | 15 = Volunteer inappropriate for enrollment in investigator's judgement | |

Do NOT use this form for any local lab specimens. Use this form ONLY to document the collection of blood specimens that will be sent to the site processing lab.

Was specimen collected? Yes **2**
No

If "No", end of form.

Specimen collection date _____ **4**

Specimen collection time _____ **5**

ACD or NaHep (sodium heparin) Collected **6**
Not collected

SST - room temperature Collected **7**
Not collected

SST - on wet ice for serum cytokines (innate immunity) Collected **8**
Not collected

SST - Clinical SARS-CoV-2 IgG Antibody Results Collected **9**
Not collected

Tempus Collected **10**
Not collected

Mark if a new Specimen Collection form is needed to complete specimen collection requirements for this visit. **11**

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Specimen Collection - Blood
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-------------|-------------|---|-------|---------------------------------------|----------------------|
| 2 BSYN | \$1 | Any Specimen Collected | | Y = Yes N = No | BSYN |
| 4 BSDAT | dd MMM yyyy | Specimen Collection Date | | | BSDAT |
| 5 BSTIM | HH:nn | Specimen Collection Time | | | BSTIM |
| 6 BSACD | 1 | ACD or NaHep Collected/Not Collected | | 1 = Collected 2 = Not collected | BSACD |
| 7 BSSST | 1 | SST Room Temperature Collected/Not Collected | | 1 = Collected 2 = Not collected | BSSST |
| 8 BSSSTICE | 1 | SST Wet Ice Collected/Not Collected | | 1 = Collected 2 = Not collected | BSSSTICE |
| 9 BSSSTAB | 1 | Antibody Results Collected/Not Collected | | 1 = Collected 2 = Not collected | BSSSTAB |
| 10 BSTEMPUS | 1 | Tempus Collected/Not Collected | | 1 = Collected 2 = Not collected | BSTEMPUS |
| 11 ADDSPE | 1 | Add Specimen Collection Form | | | ADDSPE |

Was specimen collected?

Yes 1
No

If "No", provide reason and end of form.

Primary reason specimen was not collected

Participant declined 3
Participant unable to provide sample
Other

If "Other", specify (max. 200 characters):

_____ 4

Specimen collection date

_____ 5

Specimen collection time

_____ 6

Specimen collection location

Clinical research site 7
Elsewhere (e.g. Home)

Was the procedure performed by participant or by staff?

Participant 8
Staff

Swab type

Nasopharyngeal 9
Nasal

Were all requirements of the specimen collection met per the SSP?

Yes 10
No

If "No", provide explanation in Comments. Report any nasal product use on the Concomitant Medications log.

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
Form: Specimen Collection - NP/Nasal Swab
Generated On: 20 Oct 2020 15:49:41

Comments (max. 600 characters):

12

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Specimen Collection - NP/Nasal Swab
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---------------|-------------|--|-------|---|----------------------|
| ① BSYN | \$1 | Any Specimen Collected | | Y = Yes N = No | BSYN |
| ③ BSWHYNO | 2 | Primary Reason Specimen Was Not Collected | | 1 = Participant declined 2 = Participant unable to provide sample 99 = Other | |
| ④ BSOTH | \$200 | Primary Reason Other Specify | | | BSOTH |
| ⑤ BSDAT | dd MMM yyyy | Specimen Collection Date | | | BSDAT |
| ⑥ BSTIM | HH:nn | Specimen Collection Time | | | BSTIM |
| ⑦ BSLOC | 1 | Specimen Collection Location | | 1 = Clinical research site 2 = Elsewhere (e.g. Home) | BSLOC |
| ⑧ BSMETHOD | 1 | Procedure Performed By Participant Or By Staff? | | 1 = Participant 2 = Staff | BSMETHOD |
| ⑨ BSANTREGPCR | 1 | Swab Type | | 1 = Nasopharyngeal 2 = Nasal | BSANTREGPCR |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
Form: Specimen Collection - NP/Nasal Swab
Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-------------------|-----------|--|-------|-------------------|----------------------|
| 10 BSCOND | \$1 | Specimen Collection Requirements Met? | | Y = Yes N = No | BSCOND |
| 12 BSCOVAL | \$600 | Comments | | | BSCOVAL |

Was specimen collected?

Yes 1
No

If "No", provide reason and end of form.

Primary reason specimen was not collected

Participant declined 3
Participant unable to provide sample
Other

If "Other", specify (max. 200 characters):

_____ 4

Specimen collection date

_____ 5

Specimen collection time

_____ 6

Specimen collection location

Clinical research site 7
Elsewhere (e.g. Home)

Was the procedure performed by participant or by staff?

Participant 8
Staff

Has the participant recently experienced nosebleeds?

Yes 9
No

Were all requirements of the specimen collection met per the SSP?

Yes 10
No

If "No", provide explanation in Comments. Report any nasal product use on the Concomitant Medications log.

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
Form: Specimen Collection - Nasal Wash
Generated On: 20 Oct 2020 15:49:41

Comments (max. 600 characters):

12

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Specimen Collection - Nasal Wash
 Generated On: 20 Oct 2020 15:49:41

| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----|---------------------|-------------|--|-------|---|----------------------|
| 1 | BSYN | \$1 | Any Specimen Collected | | Y = Yes N = No | BSYN |
| 3 | BSWHYNO | 2 | Primary Reason Specimen Was Not Collected | | 1 = Participant declined 2 = Participant unable to provide sample 99 = Other | |
| 4 | BSOTH | \$200 | Primary Reason Other Specify | | | BSOTH |
| 5 | BSDAT | dd MMM yyyy | Specimen Collection Date | | | BSDAT |
| 6 | BSTIM | HH:nn | Specimen Collection Time | | | BSTIM |
| 7 | BSLOC | 1 | Specimen Collection Location | | 1 = Clinical research site 2 = Elsewhere (e.g. Home) | BSLOC |
| 8 | BSMETHOD | 1 | Procedure Performed By Participant Or By Staff? | | 1 = Participant 2 = Staff | BSMETHOD |
| 9 | BSNSBLD_MHY\$1 N | | Recent Nosebleeds | | Y = Yes N = No | BSNSBLD_MHY N |
| 10 | BSCOND | \$1 | Specimen Collection Requirements Met? | | Y = Yes N = No | BSCOND |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
Form: Specimen Collection - Nasal Wash
Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-------------------|-----------|-----------|-------|--------|----------------------|
| 12 BSCOVAL | \$600 | Comments | | | BSCOVAL |

Was specimen collected?

Yes 1
No

If "No", provide reason and end of form.

Primary reason specimen was not collected

Participant declined 3
Participant unable to provide sample
Other

If "Other", specify (max. 200 characters):

_____ 4

Specimen collection date

_____ 5

Specimen collection time

_____ 6

Specimen collection location

Clinical research site 7
Elsewhere (e.g. Home)

Does the participant have a mouth injury or infection that might cause there to be blood in the sample?

Yes 8
No

Were all requirements of the specimen collection met per the SSP?

Yes 9
No

If "No", provide explanation in Comments.

Comments (max. 600 characters):

_____ 11

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Specimen Collection - Saliva
 Generated On: 20 Oct 2020 15:49:41

| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----|------------------|-------------|--|-------|---|----------------------|
| 1 | BSYN | \$1 | Any Specimen Collected | | Y = Yes N = No | BSYN |
| 3 | BSWHYNO | 2 | Primary Reason Specimen Was Not Collected | | 1 = Participant BSWHYNO declined 2 = Participant unable to provide sample 99 = Other | |
| 4 | BSOTH | \$200 | Primary Reason Other Specify | | | BSOTH |
| 5 | BSDAT | dd MMM yyyy | Specimen Collection Date | | | BSDAT |
| 6 | BSTIM | HH:nn | Specimen Collection Time | | | BSTIM |
| 7 | BSLOC | 1 | Specimen Collection Location | | 1 = Clinical research site 2 = Elsewhere (e.g. Home) | BSLOC |
| 8 | BSMOUTH_MH YN | \$1 | Mouth Injury or Infection | | Y = Yes N = No | BSMOUTH_MH YN |
| 9 | BSCOND | \$1 | Specimen Collection Requirements Met? | | Y = Yes N = No | BSCOND |
| 11 | BSCOVAL | \$600 | Comments | | | BSCOVAL |

Was a specimen collected? Yes **1**
If "No", provide reason and end of form. No

Primary reason specimen was not collected Participant declined **2**
Participant unable to provide sample
Other

If "Other", specify (max. 200 characters): _____ **3**

Date of stool collection _____ **4**

Time of stool collection _____ **5**

How many swabs were collected? One **6**
Two

Method of swab collection Swabbing the rectum **7**
Swabbing stool
Swabbing used toilet paper

Brand name of saline vial _____ **8**

Lot number of saline vial _____ **9**

Was the stool collected when the participant was in the clinic or elsewhere? Clinical research site **10**
Elsewhere (e.g. Home)

If "Clinical research site", go to "Was the procedure performed by participant or by staff?"

Date swab(s) arrived at clinic _____ **11**

Time swab(s) arrived at clinic _____ **12**

Was the procedure performed by participant or by staff? Participant **13**
Staff

Did the participant use any intrarectal products within 48 hours prior to specimen collection? Yes **14**
No

If "Yes", specify type of intrarectal products (mark all that apply):

Douches **15**

Lubricants **16**

Enemas **17**

Anti-inflammatory creams **18**

Cleaning product **19**

Other **20**

If "Other", specify (max. 200 characters): _____ **21**

For participants assigned female sex at birth, is menstruation occurring? Yes **22**
No
Not applicable

Comments (max. 450 characters): _____ **23**

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Specimen Collection - Stool
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---------------|-------------|--|-------|---|----------------------|
| ① STYN | \$1 | Any Stool Specimen Collected | | Y = Yes N = No | STYN |
| ② STWHYNO | 2 | Primary Reason Stool Specimen Was Not Collected | | 1 = Participant STWHYNO declined 2 = Participant unable to provide sample 99 = Other | |
| ③ STOTH | \$200 | Primary Reason Other Specify | | | STOTH |
| ④ STDAT | dd MMM yyyy | Stool Specimen Collection Date | | | STDAT |
| ⑤ STTIM | HH:nn | Stool Specimen Collection Time | | | STTIM |
| ⑥ STSWAB | 1 | Number of Stool Swabs Collected | | 1 = One 2 = Two | STSWAB |
| ⑦ STSWABMETH | 1 | Method of Stool Swab Collection | | 1 = Swabbing the rectum 2 = Swabbing stool 3 = Swabbing used toilet paper | STSWABMETH |
| ⑧ STVIALBRAND | \$30 | Saline Vial Brand Name | | | STVIALBRAND |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Specimen Collection - Stool
 Generated On: 20 Oct 2020 15:49:41

| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|----|------------------|-------------|--|-------|---|----------------------|
| 9 | STVIALLOT | \$15 | Saline Vial Lot Number | | | STVIALLOT |
| 10 | STCOLL | 1 | Stool Collected Outside or In Clinic? | | 1 = Clinical research site 2 = Elsewhere (e.g. Home) | STCOLL |
| 11 | STDATAR | dd MMM yyyy | Date Stool Swabs Arrived | | | STDATAR |
| 12 | STTIMAR | HH:nn | Time Stool Swabs Arrived | | | STTIMAR |
| 13 | STMETHOD | 1 | Procedure Performed By Participant Or By Staff? | | 1 = Participant 2 = Staff | STMETHOD |
| 14 | INTRAR_STYN | \$1 | Intrarectal Product Use Within 48 Hours | | Y = Yes N = No | INTRAR_STYN |
| 15 | DOUC_STTER M | 1 | Douches | | | DOUC_STTER M |
| 16 | LUB_STTERM | 1 | Lubricants | | | LUB_STTERM |
| 17 | ENEMA_STTER M | 1 | Enemas | | | ENEMA_STTER M |
| 18 | AIC_STTERM | 1 | Anti-inflamat ory creams | | | AIC_STTERM |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Specimen Collection - Stool
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---------------------|-----------|------------------------------------|-------|---|----------------------|
| 19 CLEAN_STTER M | 1 | Cleaning product | | | CLEAN_STTER M |
| 20 OTH_STTERM | 1 | Other Rectal Product | | | OTH_STTERM |
| 21 OPS_STTERM | \$200 | Other Rectal Product Specify | | | OPS_STTERM |
| 22 MENS_RPYN | \$2 | Menstruation Occurring | | Y = Yes N = No NA = Not applicable | MENS_RPYN |
| 23 STCOMM | \$450 | Comments | | | STCOMM |

Date of study exit _____ **1**

Primary reason for completion/discontinuation

Scheduled exit visit/end of study **2**

Death

Participant refused further participation

Participant is unwilling or unable to comply with required study procedures

Investigator decision

Unable to contact participant

Early study closure

Protocol deviation

Study terminated by sponsor

Participant unable to adhere to visit schedule

Participant relocated, no follow-up planned

Other, specify

If "Other", specify (max. 200 characters): _____ **3**

If "Death", enter date of death. _____ **4**

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: Study Termination
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|------------|-------------|---|-------|---|----------------------|
| ① DSSTDAT | dd MMM yyyy | Date of Study Completion or Discontinuation | | | DSSTDAT |
| ② DSTERM | 2 | Study Completion Reported Term | | 1 = Scheduled exit visit/end of study 2 = Death 3 = Participant refused further participation 4 = Participant is unwilling or unable to comply with required study procedures 6 = Investigator decision 8 = Unable to contact participant 10 = Early study closure 11 = Protocol deviation 15 = Study terminated by sponsor 17 = Participant unable to adhere to visit schedule 18 = Participant relocated, no follow-up planned 99 = Other, specify | |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
Form: Study Termination
Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|--------------------|-------------|---|-------|--------|----------------------|
| 3 DSTERMOSP | \$200 | Study Completion Reported Term Other Specify | | | DSTERMOSP |
| 4 DTHDAT | dd MMM yyyy | Date of Death | | | DTHDAT |

Select the date you are taking your temperature _____ ①

Select the time you are taking your temperature _____ ②

Temperature (degrees Celsius) _____ Fixed Unit: C ③

In the past day, have you taken any medication to reduce your fever? Yes ④
No

Medication name(s): _____ ⑤

Form submit timestamp _____ ⑥

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: COVID-19 Temperature Log
 Generated On: 20 Oct 2020 15:49:41

| | Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---|------------------|----------------------|--------------------------------------|-------|-------------------|----------------------|
| ① | CESTDAT | dd MMM yyyy | Date | | | CESTDAT |
| ② | CESTTIM | HH:nn | Time | | | CESTTIM |
| ③ | TEMP_VSORRE S | 3.1+ | Temperature | | | TEMP_VSORRE S |
| ④ | FEVER_CMYN | \$1 | Any Medication To Reduce Fever | | Y = Yes N = No | FEVER_CMYN |
| ⑤ | FEVER_CMTRT | \$200 | Medication(s) | | | FEVER_CMTRT |
| ⑥ | TSTAMP | dd MMM yyyy HH:nn | Form Submit Timestamp | | | TSTAMP |

Are/were you in the hospital today?

Yes 1
No

What is today's date? _____ 2

Do you have any symptoms today?

Yes 3
No

Are you currently feeling more tired than usual, not feeling well?

Yes 4
No

Please rate your tiredness/not feeling well today.

I had the symptom, but I could still do my normal activities. 5
The symptom really bothered me. It was hard to do my normal activities.
The symptom was very bad. I was not able to do activities that I usually do.

Are you currently experiencing all over muscle aches?

Yes 6
No

Please rate your all over muscle aches today.

I had the symptom, but I could still do my normal activities. 7
The symptom really bothered me. It was hard to do my normal activities.
The symptom was very bad. I was not able to do activities that I usually do.

Are you currently experiencing chills?

Yes 8
No

Please rate your chills today.

- I had the symptom, but I could still do my normal activities. 9
 - The symptom really bothered me.
 - It was hard to do my normal activities.
 - The symptom was very bad. I was not able to do activities that I usually do.
-

Are you currently experiencing headache?

- Yes 10
 - No
-

Please rate your headache today.

- I had the symptom, but I could still do my normal activities. 11
 - The symptom really bothered me.
 - It was hard to do my normal activities.
 - The symptom was very bad. I was not able to do activities that I usually do.
-

Are you currently experiencing a sore throat or runny nose?

- Yes 12
 - No
-

Please rate your sore throat or runny nose today.

- I had the symptom, but I could still do my normal activities. 13
 - The symptom really bothered me.
 - It was hard to do my normal activities.
 - The symptom was very bad. I was not able to do activities that I usually do.
-

Has your sense of smell changed or have you experienced a loss or change in taste?

- Yes 14
 - No
-

Please rate your sense of smell and taste today.

- I had the symptom, but I retained some taste/smell. 15
 - My taste/smell was significantly affected.
-

I have no taste or smell.

Are you currently experiencing cough? Yes **16**
No

Please rate your cough today. I had the symptom, but I could still do my normal activities. **17**
The symptom really bothered me. It was hard to do my normal activities.
The symptom was very bad. I was not able to do activities that I usually do.

Are you currently experiencing chest tightness, chest congestion or shortness of breath? Yes **18**
No

Please rate your chest tightness, chest congestion or shortness of breath today. I had the symptom, but I could still do my normal activities. **19**
The symptom really bothered me. It was hard to do my normal activities.
The symptom was very bad. I was not able to do activities that I usually do.

Are you currently experiencing nausea or vomiting? Yes **20**
No

Please rate your nausea or vomiting today. I was able to eat and drink normally. **21**
It bothered me enough that I did not eat or drink normally.
I could not eat or drink.

Are you currently experiencing diarrhea or abdominal pain? Yes **22**
No

Please rate your diarrhea or abdominal pain today.

- I had the symptom, but I could still do my normal activities. **23**
- The symptom really bothered me.
- It was hard to do my normal activities.
- The symptom was very bad. I was not able to do activities that I usually do.

Form availability _____ **24**

Form submit timestamp _____ **25**

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: COVID-19 Daily Symptom Tracker
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---------------------|-------------|-------------------------------|-------|--|----------------------|
| ① HOSP_MHYN | \$1 | In the Hospital Today | | Y = Yes N = No | HOSP_MHYN |
| ② CESTDAT | dd MMM yyyy | Today's Date | | | CESTDAT |
| ③ CEYN | \$1 | Any Symptoms Today | | Y = Yes N = No | CEYN |
| ④ FATIGUE_CEN | \$1 | Fatigue/Malaise Occurrence | | Y = Yes N = No | FATIGUE_CEN |
| ⑤ FATIGUE_CES EV | 1 | Fatigue/Malaise Severity | | 1 = I had the symptom, but I could still do my normal activities. 2 = The symptom really bothered me. It was hard to do my normal activities. 3 = The symptom was very bad. I was not able to do activities that I usually do. | FATIGUE_CES EV |
| ⑥ MYALGIA_CEN | \$1 | Myalgia Occurrence | | Y = Yes N = No | MYALGIA_CEN |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: COVID-19 Daily Symptom Tracker
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---------------------|-----------|----------------------|-------|--|----------------------|
| 7 MYALGIA_CES EV | 1 | Myalgia Severity | | 1 = I had the symptom, but I could still do my normal activities. 2 = The symptom really bothered me. It was hard to do my normal activities. 3 = The symptom was very bad. I was not able to do activities that I usually do. | MYALGIA_CES EV |
| 8 CHILL_CEYN | \$1 | Chills Occurrence | | Y = Yes N = No | CHILL_CEYN |
| 9 CHILL_CESEV | 1 | Chills Severity | | 1 = I had the symptom, but I could still do my normal activities. 2 = The symptom really bothered me. It was hard to do my normal activities. 3 = The symptom was very bad. I was not able to do activities that I usually do. | CHILL_CESEV |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: COVID-19 Daily Symptom Tracker
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|---------------|-----------|--|-------|--|----------------------|
| 10 HEAD_CEYN | \$1 | Headache Occurrence | | Y = Yes N = No | HEAD_CEYN |
| 11 HEAD_CEVN | 1 | Headache Severity | | 1 = I had the symptom, but I could still do my normal activities. 2 = The symptom really bothered me. It was hard to do my normal activities. 3 = The symptom was very bad. I was not able to do activities that I usually do. | HEAD_CEVN |
| 12 SORET_CEYN | \$1 | Pharyngitis/Rhi norrhea Occurrence | | Y = Yes N = No | SORET_CEYN |
| 13 SORET_CEVN | 1 | Pharyngitis/Rhi norrhea Severity | | 1 = I had the symptom, but I could still do my normal activities. 2 = The symptom really bothered me. It was hard to do my normal activities. | SORET_CEVN |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: COVID-19 Daily Symptom Tracker
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-----------------------|-----------|----------------------------|-------|--|----------------------|
| | | | | 3 = The symptom was very bad. I was not able to do activities that I usually do. | |
| 14 ANOSMIA_CERY N | \$1 | Anosmia/Ageusia Occurrence | | Y = Yes N = No | ANOSMIA_CERY N |
| 15 ANOSMIA_CES EV | 1 | Anosmia/Ageusia Severity | | 1 = I had the symptom, but I retained some taste/smell. 2 = My taste/smell was significantly affected. 3 = I have no taste or smell. | ANOSMIA_CES EV |
| 16 COUGH_CERYN \$1 | | Cough Occurrence | | Y = Yes N = No | COUGH_CERYN |
| 17 COUGH_CESEV 1 | | Cough Severity | | 1 = I had the symptom, but I could still do my normal activities. 2 = The symptom really bothered me. It was hard to do my normal activities. | COUGH_CESEV |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: COVID-19 Daily Symptom Tracker
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|-----------------|-----------|---|-------|--|----------------------|
| | | | | 3 = The symptom was very bad. I was not able to do activities that I usually do. | |
| 18 SOB_CEYN | \$1 | Chest Congestion/Shortness of Breath Occurrence | | Y = Yes N = No | SOB_CEYN |
| 19 SOB_CESEV | 1 | Chest Congestion/Shortness of Breath Severity | | 1 = I had the symptom, but I could still do my normal activities. 2 = The symptom really bothered me. It was hard to do my normal activities. 3 = The symptom was very bad. I was not able to do activities that I usually do. | SOB_CESEV |
| 20 NAUSEA_CEYN | \$1 | Nausea/Vomiting Occurrence | | Y = Yes N = No | NAUSEA_CEYN |
| 21 NAUSEA_CESEV | 1 | Nausea/Vomiting Severity | | 1 = I was able to eat and drink normally. | NAUSEA_CESEV |

CoVPN5001_Version_3.0_PROD_BK_19OCT2020: ALL
 Form: COVID-19 Daily Symptom Tracker
 Generated On: 20 Oct 2020 15:49:41

| Field Name | Data Type | SAS Label | Units | Values | Include Field OID |
|--------------|----------------------|------------------------------------|-------|--|----------------------|
| | | | | 2 = It bothered me enough that I did not eat or drink normally. 3 = I could not eat or drink. | |
| 22 ABD_CEYN | \$1 | Diarrhea/Abdominal Pain Occurrence | | Y = Yes N = No | ABD_CEYN |
| 23 ABD_CESEV | 1 | Diarrhea/Abdominal Pain Severity | | 1 = I had the symptom, but I could still do my normal activities. 2 = The symptom really bothered me. It was hard to do my normal activities. 3 = The symptom was very bad. I was not able to do activities that I usually do. | ABD_CESEV |
| 24 FA_DAILY | \$100 | Form Availability | | | FA_DAILY |
| 25 TSTAMP | dd MMM yyyy HH:nn | Form Submit Timestamp | | | TSTAMP |