COVID Evaluation of Risk in Emergency Departments (COVERED) Project

MANUAL OF OPERATING PROCEDURES

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Version 4.0, September 16, 2020

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1.0 Key personnel and contact information

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Project phone number	(731) ID-COVER (432-6837)
Project text number	319-343-5411

2.0 List of abbreviations

Abbreviation	Description
APP	Advanced Practice Provider
CCC	Clinical Coordinating Center
DCC	Data Coordinating Center
ELISA	Enzyme-linked immunosorbent assay
ED	Emergency Department
EMR	Electronic Medical Record
HCP	Healthcare Personnel
IATA	International Air Transport Association
PI	Principal Investigator
PCR	Polymerase Chain Reaction
REDCap	Research Electronic Data Capture

3.0 Screening and enrollment

3.1 Screening

3.1.1 Inclusion criteria

ED HCPs who work regularly at the site, i.e., worked on average 24 hours/week in the site's ED over the last 3 months, and who plan to keep a similar schedule throughout the 12 week* project period, will be recruited.

*Note: After review and discussion of baseline COVID-19 testing results among participants, the CCC, DCC, CDC investigators, and site PIs, made the decision to extend the follow-up period for an additional 8 weeks (i.e., total 20 weeks). This was implemented on July 1, 2020.

Each site should enroll approximately 20 participants in each of the four following groups:

1) Intubating physicians - Emergency physicians will be included who are expected to intubate COVID-19-infected patients and, for the purpose of analysis, have intubated COVID-19 patients (defined as a confirmed positive SARS-CoV-2 PCR test either within the 14 days before or 2 days after intubation) during the project period. Intubating physicians typically are senior residents (including graduating residents) and attendings.

Since attending physicians rarely work 24hours/week on average, if they are the ones mainly intubating at the site, we will allow for some flexibility in the inclusion criteria for this particular group and include attendings working in the 18-20 hours/week range.

2) Non-intubating physicians - Emergency physicians will be included who are not expected to intubate COVID-19-infected patients and, for the purpose of analysis, have not intubated COVID-19 patients either because they do not intubate or because none of the patients whom they intubated were found to be COVID-infected during the project period. For the purpose of analysis, physicians may cross over between groups based on the patients that they treat during the surveillance period. This group will typically include junior residents and some attendings, and advanced practice providers, e.g., nurse practitioners and physician assistants.

Since this group includes junior residents who are rarely scheduled in the ED for 20 weeks at a time (and typically rotate in other departments), we will allow for some flexibility in the inclusion criteria for this particular group and include residents working at least 8 weeks out of the first 12 weeks (weeks 1-12) of the project period, and at least 4 weeks of the final 8 weeks (weeks 13-20) of the project period.

3) Nurses - Emergency department nurses who are expected to treat patients in the ED will be included.

4) Non-clinical care staff will be included. These staff members must work among caregivers, but have a) no routine close patient contact (i.e., they must not be within 6 feet of a patient if the HCP or patient is not wearing a mask or separated by a barrier, e.g., window,

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and b) no prolonged patient contact, i.e., they must interact no more than 10 minutes with a patient per encounter.

Some examples of non-clinical care staff include the following:
1) Unit clerk: answers and places calls, enter data into the computer, file paperwork;
2) Registration/ Financial Clerk: obtains initial information from patients, such as contact information, insurance, and general consent for treatment;
3) Scribe: documents medical care, but does not spend time in close proximity with patients;
4) Technician: stocks the care areas and other work not involving patient contact;
5) Social worker;
6) Pharmacist: verifies orders and communicate with other ED staff without frequent patient contact;
7) Case Manager or Clinical Care Coordinator;
8) Security staff: provides supervision and door access with no significant patient contact; and
9) Other administrative staff meeting the specified requirements for this group.

3.1.2 Exclusion criteria

1) HCPs unable to complete surveillance follow-up visits (e.g., temporary HCPs);
   Note: an exception will be made for graduating senior residents who perform most of or all of the intubations at the site if they are expected to be able to complete at least two consecutive blood draws/swabs;
2) HCPs who have previously been infected with COVID-19; and
3) HCPs who decline to provide informed consent.

3.1.3 Recruitment list

Prior to project launch, Site PIs and project managers will compile a recruitment list (including names and email addresses) of potential participants who would most likely meet the above inclusion criteria. This list should include a minimum of 20 potential recruits in each group (see Section 3.1.1) and if possible, additional HCPs for each group in case a potential recruit does not qualify or is enrolled and later withdrawn (see Section 3.1.4).

Sites will be considered ready to initiate the project by the CCC after completing the following: 1) submitting confirmation that their site IRB deemed the COVERED public surveillance project was non-research; 2) having their Site Readiness Call; 3) obtaining REDCap access for key project staff; 4) executing the subcontract with Olive View-UCLA ERI, 5) setting up processes for tracking intubations and cardiac arrests; 6) setting up processes for scheduling and performing blood draws and nasal swabs per the protocol; 7) setting up processes for specimen handling, processing and shipments; 8) appointing staff to perform all project tasks and tracking data collection; 9) obtaining all necessary institutional and departmental approvals to conduct the project; and 10) receiving all necessary supplies from central laboratory and CCC for data collection.

When the site receives confirmation from the CCC that they are ready to initiate the project, the site PI (or designee) will receive the following materials from the CCC:

1) Project COVERED invitation email template, which will include a site-specific REDCap link to the Screening Form (Appendix A);
2) The participant compensation schedule (Appendix B);
3) Participant letter describing testing and results; and
4) ARUP (central lab) requisition forms (to submit with any shipment of specimens).

The site PI can use the email template and other materials provided to tailor to their own needs and send an invitation to the potential recruits, as well as an email to the project email address (emergencyidnet-covered@uiowa.edu) to notify the CCC and DCC it was sent.

3.1.4 Withdrawals

Reasons for withdrawals include:

1) participant's <u>initial</u> blood (serology) draw (i.e., Abbott IgG test) or nasal swab (PCR) is positive for COVID infection;

The appointed project team member will need to inform the participant of the results and that he/she no longer qualifies to continue participating in the project. The participant will be paid for surveys completed and the initial blood/nasal sample;

2) participant chooses to not continue to participate or has to move on to another job; or

3) participant is noncompliant with returning for their blood draws/swab collections and/or completing their surveys (see Section 4.4); or

4) participant has a medical condition or issue with providing blood for testing such that the phlebotomist is not able to consistently (i.e., 2 or more consecutive blood draws) draw enough blood from them required for testing.

Reasons for withdrawal will be recorded and entered by the project team on the Withdrawal Form in REDCap.

If a participant is withdrawn before the 15th week of data collection, the site team will notify the DCC, who will work with the site team to replace them with another eligible HCP in their same group (see section 3.5). If the participant is withdrawn after the 15th week of data collection, they will not be replaced.

3.1.5 Screening/Participant Interest Form

When a recruited HCP clicks on the link in the invitation email, they will be immediately taken to a Screening/Participant Interest Form on REDCap. The Screening Form should be completed within one week from the date the invitation email was sent. Site coordinators will be able to

view which of their site's potential recruits have completed the screening process through their own REDCap access. Every 2 days, project coordinators should check the REDCap database daily during the first week of project launch and send reminder emails to potential recruits who have not accessed the Screening Form. If a potential recruit has not completed the screening form by 5 days, the project coordinator will notify the site PI and discuss a replacement for this person—**all project participants should be enrolled within 1 week if possible**. If this is not possible, the site should consult the DCC and come up with a plan to enroll their participants as soon as possible and adjust their follow-up period to compensate for their extended enrollment period. If a replacement is decided upon but the replaced potential recruit completes the screening form, the project coordinator should use the directions outlined in the Section 8.2.1 to code them as not eligible for participation.

3.2 Selecting eligible recruits

After potential recruits at sites have completed the Screening Form, the DCC and the site team will have the ability through their REDCap access to invite them to enroll in the project, i.e., send them a link to the electronic consent form (see Section 8.2.1 Eligibility Form).
If a site is unable to recruit 20 participants per project role, they should contact the DCC to set up a meeting to review other potentially eligible recruits that did not meet all project inclusion criteria.

3.3 Informed consent

Informed consent must be obtained prior to obtaining participant's initial blood draw and nasal swab. Informed consent will be completed electronically and maintained within the REDCap database managed centrally at the DCC. This consent form provides information regarding the following:

  1) General project information;
  2) COVERED project goals;
  3) Expected participant obligations;
  4) Participant compensation; and
  5) Participant rights.

Prospective participants will then have the option of selecting a decision to proceed with project participation or not. In order to provide ample time to make a decision, participants can return to the electronic consent form at a later time using the link provided. If the participant has any questions about consent, they should contact their site PI. After confirmation, participants will have the option to download and/or print a copy of the consent script with acknowledgement of participation. This copy can be easily obtained, as indicated by the red arrow seen below:
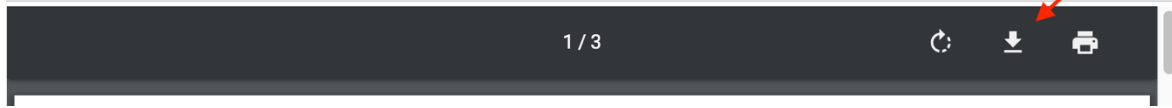
Before final informed consent submission, participants will be asked to certify that all information in the informed consent document is correct. By clicking submit, participants will electronically sign the form and acknowledge this is equivalent of signing a physical document. The electronic informed consent form must be completed and submitted by the participant before participation in any project-related activities.

3.4 Enrollment and project ID assignment

Providing informed consent will enroll the participant in the project and REDCap will automatically assign the participant a project ID.

3.4.1 Baseline survey

After the participant provides consent, REDCap will automatically proceed to the baseline survey. Each project participant must complete this survey within 2 days of consent. Also, since subsequent blood draws and nasal swabs are scheduled based on recorded observations in the 2 weeks following the date of completion of the baseline survey, it is important for participants to complete the baseline survey within 4 days of their initial blood draw and swab collection.

When a participant hits "Submit" at the end of the baseline survey, it is considered complete and they will not be able to change any of their responses. Therefore, if a participant is unsure about specific questions and prefers to answer them later, they must click on "Save and Return Later." However, while the participant is in the survey, they can go back to a previous page to update an answer.

Note: All project surveys can be completed on the participant's own time but within the project specific windows in order to not interfere with clinical care.

3.4.1.1 – Baseline survey characteristics

The Baseline Survey is the longest survey that the participant will need to complete. Baseline Surveys have a different number of questions depending on the participant's job category. However, for all participants, the survey is composed of two parts:

1) Participant Enrollment Form; and
2) Medical History Form.

Participant Enrollment Form

- Personal and emergency contact information – The project team will utilize the personal information to contact participants. For the purposes of the project, the project team needs to be able to reach participants within 24 hours. Emergency contact information will only be used if no project personnel are able to reach a project participant for urgent communications.
- Demographics
- COVID exposures
- COVID infection
  Participants are asked to report any COVID-19 related symptoms that they have experienced. If they were tested for COVID-19 outside of project procedures, they will report results in this section of the survey.
  If a participant reports they have had a positive PCR at baseline, the baseline survey will stop and the DCC will be notified that a participant has reported a positive PCR on the baseline survey. The DCC will alert the site coordinator that this participant will need to be replaced.
- COVID-19-related stress and anxiety
  Participants will be asked about their feelings of stress and anxiety related to COVID-19.
- Current living situation
  Participants will be asked to report their current living situation, including household members who have been infected with COVID-19. Exposures, outside of the ED and household, will also be reported.

Medical History Form

Data entered into the Medical History Form is only available to the DCC and not viewable by site personnel. After the participant submits the Medical History form, the Baseline Survey is considered complete. At the end of the Medical History Form, the section "Serology and COVID-19 PCR testing results password" will ask the participant to set up a password that they will need to use to obtain their test results. The participant should record this password so they can use it to access their test results throughout the project. If a participant forgets their password, they should send an email to the project email address.

After completion of the Medical History Form, the following screen will appear, which contains a Survey Queue link. If the participant is a physician, they will have a link to the intubation/cardiac arrest form. If the participant is not a physician, this screen will have no surveys.

A participant should click on the button "Get link to my survey queue" and save the link that appears as a favorite in their browser or have the link emailed to them through RedCap. The link to this survey queue is included in each weekly participant survey.

3.4.1.2 – After submission of Baseline Survey

After the participant submits the baseline survey, the project coordinator should refer to section 3.4.3 to schedule their initial blood draw and nasal swab collection within 4 days. The initial blood draw and nasal swab should not be completed until after the participant has consented and submits the baseline survey.

3.4.1.3 – Baseline Survey compensation

The DCC will centrally manage the disbursement of all participant project compensation for the duration of the project. When a participant provides all required responses on the Baseline Survey, and marks the survey as "Complete," he/she will receive the following email:

A VISA debit card will be mailed to the participant after submission of the Baseline Survey. The participant should receive the VISA debit card directly from the bank within 7-10 business days. The card will include instructions on how to create a login and password to access the card balance information or how to receive text message updates to be notified that value has been added. The participant must enter their date of birth accurately on their baseline survey for the debit card to work. Also, the debit card cannot be mailed to a P.O. Box, so participants should enter in an alternate mailing address. For additional information regarding compensation, please see Section 7.0.

For questions regarding the Baseline Survey or compensation, project participants can email emergencyidnet-covered@uiowa.edu.

3.4.2 Facility characteristics

The site team should complete a Baseline Facility Characteristic Survey when they start enrolling participants at their site. The Facility Survey will ask information about the site from the prior calendar week.

The Facility Characteristics baseline survey needs to be completed the week that the first participant is enrolled. So, if a site enrolls their first participant, e.g., Monday, May 18, then the facility survey will collect data from the previous calendar week (May 10-17). Each of the surveys asks the coordinator to report on the previous calendar week from midnight Sunday to 23:59 Saturday.

For further instructions on how to access and complete the facility forms, see Section 8.2.3.

3.4.3 Initial blood draw and swabs

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Project coordinators should check the REDCap database daily during the first week of project launch. Once it has been verified that a participant has provided consent and completed and submitted the Baseline Survey, the project team will contact the participant using the contact information gathered in the Participant Enrollment Form of the Baseline Survey. The project team will use all relevant forms of contact listed (i.e., phone numbers, email address, and text messages).

The project team will schedule an appointment for each participant's initial blood draw and nasal swab collection. This should be scheduled within 4 days of participant completing the Baseline Survey. If participant is unable to come for their initial blood draw and swab collection within 4 days of completing the Baseline Survey, the project team should attempt to schedule the blood draw as soon as possible and notify the DCC (by emailing emergencyidnet-covered@uiowa.edu).

Initial blood draws and swabs should not be completed until the participant has consented to participate and completed the Baseline Survey.

3.4.3.1 Baseline serology and nasal swab test results

Results from blood and nasal swab tests will be available within 1-5 days after specimens are received and shipment forms are corrected for errors by the central laboratory (ARUP laboratories, Salt Lake City, UT). Participants will receive an email and text from the DCC when their test results are available. The email will have a password-protected link for the participant to access and view their results (See section 3.4.1.1 "Medical History Form" which describes how the participant sets up this password).

Sites will have access to test results data via REDCap. If a participant's initial/baseline nasal swab PCR test result is positive for SARS-CoV-2 virus, then the reference laboratory will immediately call the CCC to notify them of the result. The CCC will then notify the appointed site team contact, who will notify the participant of their results. For any positive test result, the site appointed project team member will contact the participant via telephone to refer him/her to the local Employee Health Clinic and/or their doctor for evaluation, follow-up testing, and return-to-work recommendations.

Participants who have positive baseline/initial tests will be withdrawn (see Section 3.1.4) and replaced (see section 3.5). If a participant tests positive for COVID-19 at baseline, the DCC will send them a link that will ask them to provide separate consent to complete a survey approximately 2 weeks after their positive test to ask them about their symptoms, exposures to COVID-19 at work or at home, health care evaluation, work history, and changes in practice after December 31, 2019.

3.5 Participant replacement procedures

Participants may be replaced for any of the following reasons:
1) Positive baseline SARS-CoV-2 serology (Abbott IgG test) or nasal PCR;
2) Residency graduation (leaving institution) or schedule change;

3) Voluntary participant withdrawal; and
4) Nonadherence with project procedures (noncompletion of ≥3 consecutive surveys, missing ≥2 consecutive blood draws/swabs, or inability to provide adequate blood specimens for 2 consecutive blood draws).

Before July 15, 2020, sites will attempt to use procedures for planned replacement (see below Section 3.5.1), for graduating residents. After July 15, 2020, sites will use emergency replacement procedures (see Section 3.5.2). Note, if replacements have a positive baseline test, they will also be withdrawn and attempted to be replaced.

3.5.1 Procedures for planned replacement

Planned replacement occurs when the timing of replacement is anticipated (e.g., residency graduation). Planned replacement provides for overlap of project periods to preserve the original project sample size collected.

For graduating residents who will be working in the site hospital until June 30, the withdrawal date will occur on the last scheduled blood draw prior to June 30. For instance, if a participant has a blood draw scheduled for June 25, then a replacement participant will be enrolled to complete the baseline survey on June 11. *Both* participants will have a blood draw performed on June 11 and June 25, with accompanying weekly surveys and intubation forms (if applicable). All replaced participants will use an identical procedure. Sites will use the following timeline to initiate the replacement procedure.

3.5.1.2 Timeline for planned replacement

Figure 1. Planned replacements will occur with 2 weeks of overlap. *A planned withdrawal will always occur on a week with a scheduled blood draw (for the withdrawing participant). The replacing participant should always start 2 weeks before the withdrawal, with the baseline survey completed on the same date as the weekly survey for the withdrawing participant (+/- 2 days).*
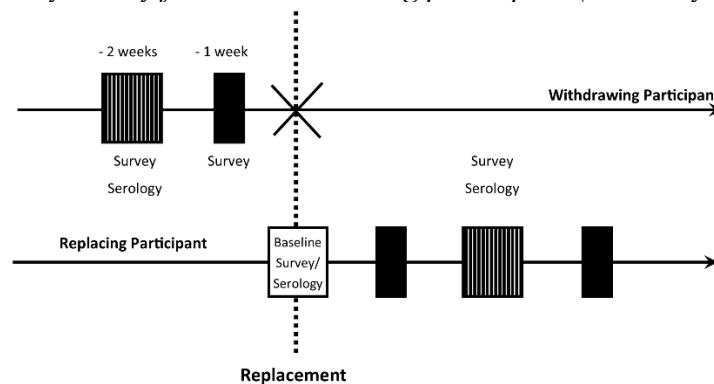
1. 4 weeks prior to Participant Withdrawal (2 weeks prior to the replacing participant starting) an e-mail will be sent to EmergencyIDNet-COVERED@uiowa.edu with the replacement plan:
    a. Subject: <SiteName> Replacement Procedure
    b. Body: We intend to replace the following participants:
        i. Withdraw: <Record ID> <Name>,
        ii. Replacement: <Name>,
        iii. Replacement Date: <Planned date>,
        iv. Reason: Reason
2. 18 days prior to Participant Withdrawal (4 days prior to the replacing participant starting), the participant will be sent a Participant Interest Form link (along with project documentation) to the replacing participant
3. 15 days prior to Participant Withdrawal (1 day prior to the replacing participant starting), the study team will enter the participant into cohort
4. The participant will complete baseline enrollment form, have serology and nasal testing completed, and will start all project procedures.

    Note: All replacements will complete baseline, week 2, and week 4 blood draws/swabs and then complete blood draws/swabs every 4 weeks until the week 20 timepoint of the participant they replaced. It is important for the site to send the replacement plan to the study email so the DCC can keep track of this timepoint and withdraw the participant at that time.

5. The withdrawing participant will complete all procedures for next 2 weeks also.
6. Participant Withdrawal – After the last weekly form and blood draw are completed, the site coordinator will complete the Withdrawal Form for the participant withdrawing from the project.

3.5.2 Procedure for emergency replacement

Emergency replacement occurs when the timing of replacement is unanticipated (e.g., positive SARS-CoV-2 serology on baseline blood draw/PCR, unanticipated job change). Because emergency procedures are used, no overlap will occur. *Note: Noncompletion of project procedures because of COVID-19 infection should NOT trigger withdrawal or replacement procedures after an initial negative baseline.*

3.5.2.1 Timeline for emergency replacement

1. At time of Participant Withdrawal – an e-mail will be sent to EmergencyIDNet-COVERED@uiowa.edu with the replacement plan:
    a. Subject: <SiteName> Replacement Procedure
    b. Body: We intend to replace the following participants:
        i. Withdraw: <Record ID> <Name>,
        ii. Replacement: <Name>,
        iii. Replacement Date: <Planned date>,
        iv. Reason: Reason

2. At time of Participant Withdrawal, the participant will be sent an Interest Form link (along with project documentation) to the replacing participant

3. Immediately upon receipt, confirmation of eligibility, and approval, the study team will – enter the participant into the cohort. The participant will complete baseline enrollment form, have serology and nasal swab testing completed, and will start all project procedures. All replacements will complete baseline, week 2, and week 4 blood draws/swabs and then complete blood draws/swabs every 4 weeks until the week 20 timepoint of the participant they replaced. It is important for the site to send the replacement plan to the study email so the DCC can keep track of this timepoint and withdraw the participant at that time.

4. Participant Withdrawal – At the time of participant withdrawal, the study team will complete the Participant Withdrawal Form.

Note: Emergency participant withdrawal should be rare (except for baseline positive COVID-19 testing). Participation should be encouraged. If sites have an issue that may lead to participant withdrawal, they should contact the coordinating center at EmergencyIDNet-COVERED@uiowa.edu as soon as possible to discuss accommodations and procedures.

3.5.3 Reclassification

Some sites may have graduating residents who will remain at the site hospital in a different capacity (e.g., fellowship in the same emergency department, attending). If the participant still qualifies for project participation, DO NOT initiate replacement procedures. Rather, request reclassification from the DCC:

1. 1 week prior to Reclassification, an e-mail will be sent to EmergencyIDNet-COVERED@uiowa.edu with the reclassification request:
    a. Subject: <SiteName> Reclassification Request
    b. Body: We would like to request reclassification of the following participants:
        i. Participant: <Record ID> <Name>,
        ii. New Role: <Role>,
        iii. Effective Date: <Planned date>

2. The study team will select the new role from the following (in most cases, this will be reclassification of a resident as an Emergency Medicine Attending or Fellow):
    a. Emergency Medicine Attending or Fellow
    b. Emergency Medicine Resident
    c. Advanced Practice Provider (PA, NP, CRNA)
    d. Non-Emergency Medicine Faculty or Fellow
    e. Non-Emergency Medicine Resident
    f. Emergency Department Nurse
    g. Emergency Department Non-Clinical Staff Member (any ED worker with little direct patient contact)

4.0 Follow-up assessments

All participant follow-up assessments will be initiated by an email and text message. The project text message number is 319-343-5411. **This number should be saved in all participant's cell phones as Project COVERED.**

4.1 Weekly participant survey

The DCC will send an email link and a text message to each participant at weekly intervals to access their Weekly Survey on REDCap. The Weekly Survey is composed of the following sections:

1) COVID diagnosis
   a. Participants are asked to report any COVID-19 related symptoms they have experienced in the last week. If a participant was tested for COVID-19 outside of project procedures, they will report results in this section of the survey, and
   b. Other details regarding medications, hospitalizations, and treatment will be reported in this section;
2) COVID exposures
   a. Participants will be asked the amount of exposure they have had to suspected or confirmed COVID-19 patients in the last week, and
   b. Procedures, unprotected exposures, and shifts worked in the ED;
3) Use of PPE
   a. Participants will be asked about changes in PPE usage in the last week, including PPE protocols and shortages at their institutions;
4) Living situation
   a. Participants will be asked to report changes in their current living situation, including household members that have been infected with COVID-19, and
   b. Exposures, outside of the ED and household, will be reported; and
5) Changes to contact information
   a. Any changes in contact information will be recorded.

Information recorded in the survey will include questions relevant to the "past week," i.e., starting from the date the last survey was completed through the date before the new survey link is distributed. These dates will not change if survey completion is delayed. To ensure that the information on the weekly surveys is accurate, the participant should complete the Weekly Survey within 24 hours of receiving the link.

For physician and nurse participants, the sites will send a worksheet to help them keep track of and recall information for some of the variables that are asked on the weekly surveys.

4.1.1 Week 4 stress/anxiety "Post Serologic Testing" survey

Four weeks following a participant's enrollment completion, the participant will be sent an additional link for a survey on COVID-19-related stress and anxiety following knowledge of

their COVID status. This survey is documented in the Record Status Dashboard as, "Post Serologic Testing."

4.2 Blood draws and swabs

Blood and nasal swab collection will occur every 2 weeks for 4 weeks and then every 4 weeks for a total of 20 weeks. The first target date for collection is 14 days +/- 2 days from completion of the baseline survey. The target date will not change every other week even if collection was obtained in either the 2 days before or 2 days after the target date. The window for completion of the baseline and week 2 blood draws/swabs is +/- 2 days to ensure the rapid identification of participants who should be excluded from the project due to baseline positive tests and also to ensure the test results are available prior to the subsequent blood draw/swab. From week 4 onwards, the window for blood draws/swabs will be expanded to +/- 4 days.

Week 0 Baseline Survey completion (+/- 2 days)	Week 2 Target Date (+/- 2 days)	Week 4 Target Date (+/- 4 days)	Week 8 Target Date (+/- 4 days)	Week 12 Target Date (+/- 4 days)	Week 16 Target Date (+/- 4 days)	Week 20 Target Date (+/- 4 days)
Day 1	Day 14	Day 28	Day 56	Day 84	Day 112	Day 140

Project team members will email/text participants 48 hours before the participant's scheduled visit for specimen collection to remind them of his/her visit. If participant is a no-show, then the project coordinator will call participant to attempt to reschedule. If a participant is unable to return for sample collection within the +/- 2 day window for baseline and week 2 blood draws/swabs and within the +/- 4 day window for the week 4-20 blood draw/swabs, then the project team should continue to attempt to schedule the blood draw as close to the window and possible and email the DCC at the email address provided in section 1.0.

For testing following and not including the baseline assessment (e.g., Week 2 or after), if a participant has a positive COVID-19 PCR test or serology the participant will continue in the project and should be reminded to continue completing weekly surveys.

4.2.1 Repeat serology for positive nasal PCR tests after baseline

After baseline, if a participant has a positive nasal PCR test and negative serology, either from the tests performed as part of the project or outside the project (i.e., if participant goes to a clinic or other site to get tested), they will continue in the project. They will be reminded to continue completing weekly surveys, but will not be required to continue with regularly scheduled blood draws/swabs. These participants will be sent an additional consent form by the DCC to provide an additional blood sample after they are cleared to return to work for serologic testing at approximately 21 days after their positive PCR test, and if the serology is negative at 21 days, one more blood sample at 6 weeks after the positive PCR test. If the participant provides consent to provide this additional blood sample, after the participant is cleared to return to work, the

project team will contact them to schedule a repeat blood draw to perform serologic testing to confirm they seroconverted approximately 21 days after their positive PCR test. Site teams should confirm the participant consented to this additional testing before drawing the participant's blood. If the repeat serology test at 21 days has confirmed seroconversion (i.e., is confirmed positive by Abbott and EUROIMMUN tests), then no further testing will be performed. If the repeat serology test at 21 days is negative, the site team will schedule another blood draw for the participant at approximately 6 weeks after their positive PCR test to confirm their seroconversion. Note, if the participant does not seroconvert at 6 weeks after the positive PCR test, no further testing will be done.

4.3 Intubation surveys

Project coordinators will monitor intubations and cardiac arrests at their site. This will require the project coordinator to review the EMR system or generate a report of these procedures at least twice weekly (recommended daily) identified by billing codes, documentation, ventilator usage, pharmacy logs, or some other reliable secondary source. The purpose of secondary screening by the project coordinator is to ensure that no participant-performed intubations are missed.

4.3.1 Intubation/Cardiac Arrest Form

If an intubation(s) was performed or a cardiac arrest was treated by a project participant, they should complete an Intubation/Cardiac Arrest Form. Also, if an attending physician participant was supervising the intubation or a resident was observing the intubation and was within 3 feet of the patient's mouth, he/she should complete an intubation/cardiac arrest form. The participant can access this form in their REDCap "Survey Queue" or by clicking on the link in the welcome or weekly survey e-mail. **Please note that each individual has a separate REDCap link, so this link should not be shared with other project participants.** Once the participant submits the form, he/she will not be able to re-visit the survey, so the participant should ensure that submitted data are accurate.

If a participant does not complete the form within 24 hours, the site project team will notify the participant to remind them to complete the form. All intubation forms should be completed within 24 hours of the event, if possible. If the site is aware that completion is delayed more than 7 days, the site should notify the DCC to discuss further action.

The project team will have access to view which intubation forms are complete in REDCap. Therefore, it is the project team's responsibility to monitor and track when these forms are complete for each participant. If the project team notices an Intubation/Cardiac Arrest Form is incomplete, then they should reach out to the participant and remind them to complete the form as soon as possible.

The participant should only start completing intubations forms after they have completed the baseline survey. They should only complete intubation forms for intubations performed at the site hospital(s).

4.3.2 Patient Information Form (Intubation/CPR)

The Patient Intubation/CPR Information Form will be completed by the site project coordinator. The project team can access this form with the coordinator or site PI's login credentials. Note that for EVERY Intubation/Cardiac Arrest form completed by a participant, the project team should also complete a Patient Intubation/CPR Information Form. **If two or more participants completed a form for intubation or performing CPR on the same patient, only one intubation/CPR patient information form needs to be completed by the site coordinator.** See Section 8.2.4 for instructions on how to access and complete this form.

4.4 Non-compliance and lost to follow-up

Non-compliance and lost to follow-up occurs if a participant misses 3 weekly surveys consecutively, including the intubation/cardiac arrest form. Non-compliance and lost to follow-up also occurs if a participant misses two consecutive blood and nasal swab collection visits. If the non-compliance occurred for reasons other than being symptomatic with COVID-19 infection, then the participant must be withdrawn (see section 3.1.4). Any participant unable to complete weekly forms because of COVID-19 infection should be retained and the DCC should be consulted prior to withdrawing a participant for non-compliance.

4.5 Monitoring follow-up surveys

The DCC will send a link to the participant for the weekly survey in REDCap each week by email and text. In addition, participants will get two additional email reminders, each 2 days apart if the survey was not completed. In order to achieve survey adherence and compliance, the project team will remind participants to complete follow-up surveys if not completed within 2 days of survey window start date. The project team should use the preferred contact methods (e.g., email, text, etc.) from the initial Baseline Survey.

Since participants will receive an email every week for a weekly survey, even if a previous survey was not done, it is important for the project team to consistently check REDCap daily to make sure all surveys have been completed. The DCC will create reports in REDCap with data quality information, which should be checked weekly by site teams. If any information looks incorrect and/or is missing, the project team should contact the participant as soon as possible to capture this data.

All follow-up survey links sent by the DCC will be active for 7 days. After this time period, survey links will expire. Similarly, participants will have 7 days to complete the intubation form. Additionally, participants will receive an email and text message every week with a reminder to complete the Intubation/Cardiac Arrest form when applicable.

If a participant has not completed the necessary follow-up surveys and cannot find the link to their forms, the project team should contact the DCC and request they send the project participant a personalized link to their own forms.

4.5.1 Incomplete surveys

If a participant is completing a survey they must complete all the required responses and click the "submit" button. If they close their browser window without completing all required responses and click "submit," it will show up in the dashboard as a partial survey response. REDCap will automatically continue to send them email reminders at 2 days and 4 days with the survey link so they can return to complete their survey. If needed, the DCC can manually send an email invitation as well.

If there are incomplete surveys in REDCap and the survey is still in window, the project team should contact the participant directly to encourage them to complete incomplete survey sections quickly. Project team coordinators are urged to contact participants via email, phone, and/or text messaging to ensure completion of these surveys.

Site coordinators cannot edit surveys for participants. The DCC will send each project site a data quality report summarizing incomplete and illogical survey responses on a regular basis. The project team will attempt to capture the missing or inaccurate information and send to DCC for entry.

The participant will only receive compensation if they provide all required responses and complete the survey. They will not receive compensation for partial completion of a survey.

4.6 Weekly facility survey

Each week, the site coordinator will complete a facility survey to reflect the past calendar week (midnight Sunday through 23:59 Saturday). The weekly survey will be added by clicking on the Record Status Dashboard and the Arm 2: Facility tab to record that week's facility level data. Note that there are 28 weeks of weekly facility surveys (while only 20 weeks of participant surveys)—this is to ensure that facility level data is collected for participants who were not enrolled in the project in the first project week. If there is more than one hospital at the site, project coordinators should refer to section 8.2.3.1 to ensure data are entered appropriately and correctly for each hospital.

The Facility Characteristics Baseline survey needs to be completed the week that the first participant is enrolled. So, if a site enrolls their first participant, e.g., Monday May 18, the facility survey will collect data from the last calendar week (May 10-17). Each of the surveys asks the coordinator to report on the previous calendar week from midnight Sunday to 23:59 Saturday. Ideally, these weekly surveys should be completed each week by Friday, in the example above, by May 22, to allow time for review and correction before the next weekly survey.

For the question, "Prior to COVID-19, how many total hours of coverage were provided by all providers in each category during one week?," sites may use coverage in their ED in January 2020 to respond.

4.7 Nine-month participant survey

Each participant will be receive an email and text with a link to complete the Project COVERED 9-month follow-up survey. This survey will be sent out 270 days after the site has launched the project.

4.8 Nine-month facility survey

Site coordinators will need to complete a 9-month facility survey 270 days after the site has launched.

5.0 Blood and swab specimen handling

In order to facilitate immediate and appropriate labeling of specimens as they are being collected, the project team should use the Excel spreadsheet distributed to the sites by the DCC. This spreadsheet will include the participant's first name, last name, Record ID, which will be used as the "Subject Identifier" on the specimen labels, and the site number which will be entered as "site#' (see section 5.2 below). The "Subject Identifier" number should be listed as a 4-digit number. Therefore leading zero's will need to be added in most cases. The project team member who will label the specimens as they are collected should have this spreadsheet readily available when blood draws and swab specimens are obtained from participants.

5.1 Blood draw collection

The tube for blood collection will not be provided. Therefore, the individual drawing the blood (i.e., nurse, phlebotomist, etc.) should obtain a 5 mL gold top serum separator tube (SST) from their facility (see Figure 1). This tube contains a clot activator and serum gel separator. Using an appropriately gauge needle, blood will be drawn allowing the tube to fill until the vacuum is exhausted. A label (see Figure 5) should be placed on the gold top tube and filled out completely. The blood collection tube should be gently inverted 5 times (see Figure 2) to ensure mixing of clot activator with blood. Be careful with this step to avoid vigorous mixing. Next, the vacutainer drawn blood should be allowed to sit at room temperature in a vertical position for at least 30 minutes. This will give the blood enough time to clot.

Figure 1

= 1 Inversion

Figure 2
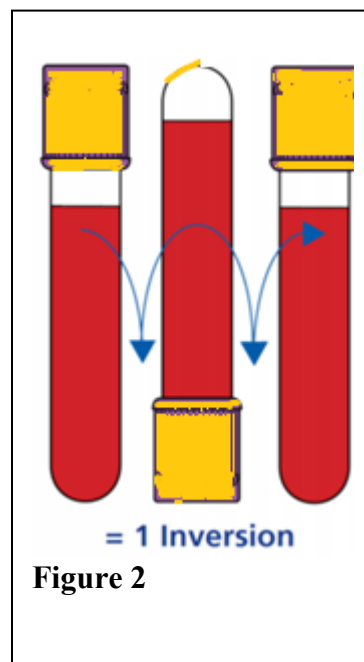
5.2 Blood processing

The specimen should be gently transported to the local lab or wherever the centrifuge is located, but shaking the specimen should be avoided. The specimen should be centrifuged within 90 minutes of blood collection at 1300-2000 g for 10 minutes, or until a complete barrier has formed. This will allow the serum to separate from the red blood cells (see Figure 3). The site's local lab should be consulted for their centrifuging standard practice for an SST tube. The gold stopper should be removed and all serum should be carefully transferred using a disposable pipette into the 4 mL standard transfer specimen transport tube (see Figure 4) provided by ARUP Laboratories at the start of the project. Serum should be clear and free from all red cells. A minimum of 1.0 mL of serum must be transferred, but sites are encouraged to transfer the maximum available volume to maximize the ability to perform appropriate and accurate testing.
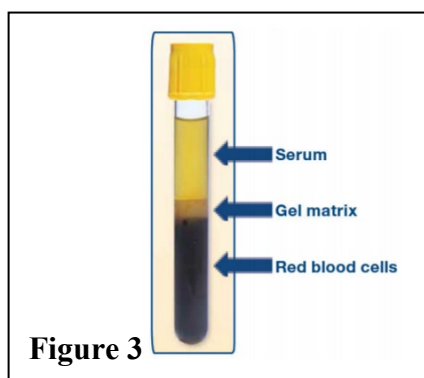

Figure 3

Figure 4

Using one of the labels provided (see Figure 5), a "Subject Identifier," which is the unique identification number assigned to the participant (see section 5.0 above), should be completed. **The "Subject Identifier" should be entered as a four digit number** so if there are only three digits in the REDCap Record ID, the project team member should add a leading zero to the "Subject Identifier." For example, if the Record ID is "25," the Subject Identifier should be written as "0025."

Also on the label, the "Site#," which is a unique number assigned to each site (see Table 1 below), should be completed. For those sites that have participants working at 2 hospitals, both sites will have the same Site Number. The label should be filled completely, including the date and time of collection of the blood draw.

Figure 5

Table 1. Site Number for blood draws and nasal swabs	
Site	**Site #**
Allegheny General Hospital	7346
Baystate Medical Center	7347
Denver Health	7348
Detroit Medical Center (Detroit Receiving/Sinai-Grace)	7349
Hennepin County Medical Center	7350
Jackson Memorial Hospital	7351
Johns Hopkins Medical Institute	7352
Louisiana State University	7353
Mount Sinai Health System (Mount Sinai Manhattan/Elmhurst)	7354
Orlando Regional Medical Center	7355
UAB Hospital	7356
UCLA (Ronald Reagan/Olive View)	7357
UCSF Zuckerberg San Francisco General	7358
University of Iowa	7371
UMass Memorial Medical Center	7360
University of Mississippi Medical Center	7361
UT Southwestern Medical Center- Parkland Memorial Hospital	7362
Thomas Jefferson University	7363
Truman Medical Center	7364
Washington University/Barnes-Jewish Hospital	7365

5.3 Blood storage

The serum (minimum 1.0 mL) that has been collected in the standard transfer specimen transport tube should be placed in a -20℃ or -70℃ freezer for storage until shipment. Another option is to refrigerate the specimen in a 2-6℃ refrigerator temporarily, but the specimen must be in the freezer for 5 hours prior to shipping to ensure frozen specimen for transport. The sample can only remain viable in the refrigerator for a maximum of 14 days, but in the freezer, the specimen can remain viable for a maximum of 30 days (note that because samples are being shipped within a week of collection, none of the samples will approach the viable storage life). The specimens should remain upright during storage to ensure that the frozen sample is in the bottom of the tube for automated processing at the reference laboratory. A cardboard rack provided by ARUP laboratories (see Figure 6) should be used to store specimens upright. If the specimen cannot be placed in a refrigerator or freezer immediately after transferring the serum, the serum specimen may be left ambient for a maximum of 24 hours from time of transfer. If collection is occurring in a location where no refrigerator or freezer is available, a portable ice chest may be used during transport. All specimens should be labeled immediately at the time of collection.

At least 5 hours prior to shipment, the specimens must be placed upright in a -20℃ or -70℃ freezer to allow the specimens to freeze before shipping on dry ice.
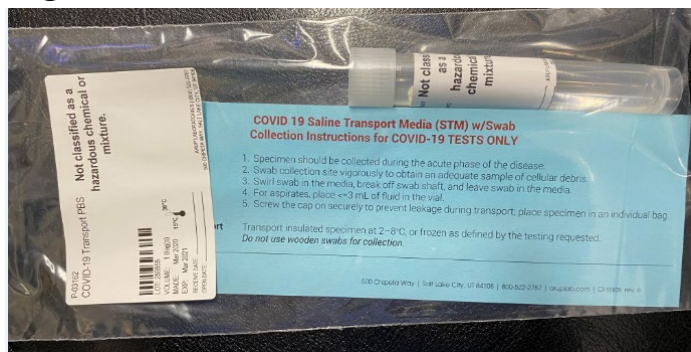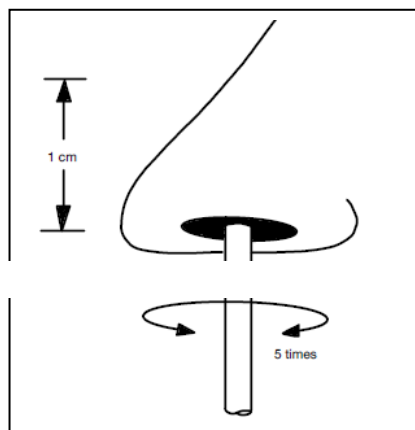
Figure 6

5.4 Nasal swab collection

Each participant will collect their own mid-turbinate nasal swab using the nasal swab provided by ARUP laboratories (see Figure 7)

Figure 7

The participant should be provided the following instructions:
1) Insert the swab about ½-1 inch into either the right or left nares. This is where resistance will be met at the turbinates.
2) Rotate the swab several times against the nasal wall for about 10-15 seconds.
3) Repeat steps 1-2 on the other nare (both nares must be sampled with the same swab).
4) Remove swab from nare and place in sterile viral transport media tube and gently break off the applicator stick at the designated marking.

The label provided (see Figure 5) should be completed following the instructions in section 5.2. On the label, the date and time of nasal swab collection should be included. The completed label should be placed on nasal transport media tube.

5.5 Nasal swab storage

The nasal swab should be placed upright in a -20°C or -70°C freezer immediately after collection (e.g., within 15 minutes) if possible. If immediate freezer storage is not possible, the nasal swab can also be placed upright immediately in a 2-6°C refrigerator. The cardboard rack provided by ARUP laboratories (see Figure 6) should be used to store specimens upright. However, if it is not possible to place the nasal swab in a freezer or fridge immediately after collection, the specimen should be placed in ice or wrapped in a cold pack until it can be moved to the appropriate storage conditions. The specimens should not be left at ambient temperature. All specimens should be labeled immediately at the time of collection using same methods as described in Section 5.2.

The nasal swab can be left in the freezer for a maximum of 30 days. However, it remains viable in a refrigerator for a maximum of 2 days. At least 5 hours prior to shipment, the specimens must be placed upright in a -20°C or -70°C freezer to allow the specimens to freeze before shipping on dry ice.

Any questions about specimen collection, processing, or storage should be directed to the project e-mail.

5.6 Central Laboratory testing

All samples will be shipped priority overnight from sites for testing to ARUP laboratories in Salt Lake City, Utah.

5.6.1 Blood sample testing

The blood samples will be tested for antibodies to SARS-CoV-2 using the Abbott anti-SARS-CoV-2 IgG test. The antibody testing performed on blood samples is the Abbott anti-SARS-CoV-2 IgG test. The results of this test are reported as "negative," "indeterminate," and "positive." This test received an Emergency Use Authorization (EUA) from the FDA, but no current anti-SARS-CoV-2 antibody tests have received FDA approval.

Samples that yield a positive result on the Abbott test will be confirmed using another antibody assay, the EUROIMMUN test. This test provides both a qualitative interpretation and a quantitative interpretation. The ratio-based quantitative result is classified as follows:

- Ratio < 0.8 = Negative
- $0.8 \leq$ Ratio <1.1 = Borderline/Indeterminate
- Ratio $\geq$ 1.1 = Positive

5.6.2 Nasal swab sample testing

The nasal swab will undergo PCR testing for SARS-CoV-2 virus particles. Self-inserted nasal swabs are less invasive than clinician-inserted nasopharyngeal swabs, and they are currently thought to have similar sensitivity. This test has received an Emergency Use Authorization (EUA) from the FDA, but no current SARS-CoV-2 viral tests have received FDA approval.

5.7 Laboratory test results

<u>At baseline</u>, participants with positive results on either the Abbott test or the nasal swab PCR test will be considered as positive for SARS-CoV-2 and withdrawn from the study. Participants with positive results at baseline on the Abbott test and negative or indeterminate on the EUROIMMUN test will be withdrawn from the study, since the tests might have different performance characteristics in these individuals.

<u>After baseline</u>, results of the laboratory tests performed by ARUP laboratories will be interpreted as follows:

-   Participants with positive results on both the Abbott test and the EUROIMMUN test will be considered as positive for SARS-CoV-2.

-   Participants with positive results on the Abbott test and negative or indeterminate on the EUROIMMUN test will be considered negative for SARS-CoV-2.

-   Participants with positive nasal swab PCR results will be considered as positive for SARS-CoV-2.

Laboratory test results for specimens shipped will be available approximately 2-6 days after ARUP laboratories receives the shipment <u>and</u> corrects any errors. Note site teams should notify their participants that depending on when their samples were collected, the participant should expect their results approximately 6-12 days after collection. All results will be sent to the DCC for upload into REDCap. The results of all collected serology and nasal swab PCR data will be shared with the participant through a personalized REDCap portal. The participant will receive an email and a text message when their results are ready to be reviewed on the portal.

When the participant clicks on the link, they will be prompted to enter the password that they created during the enrollment process. Once entered, they will see their lab results and be asked to acknowledge that they have been viewed. After acknowledging the results, participants may download their results as a pdf document. The site coordinator will be able to track which lab results are available to view and which ones have been viewed on their REDCap dashboard.

5.7.1 SARS-CoV-2 positive test results from central laboratory
At the start of the project, the ARUP laboratory contacted the CCC or DCC to notify them immediately of a PCR positive result, but due to increased testing performed at ARUP, this was discontinued in mid-August, 2020. Thus, upon receipt and review of serologic and PCR testing results from ARUP laboratories, the DCC will be aware of any positive serologic or PCR results.

As soon as the CCC or DCC are made aware of positive test results, they will contact an appointed person at the site, who will then call the participant to let them know their result. Finally, after notifying the participant, the appointed person should let the CCC or DCC know this was done to close the loop. This plan for notifying participants of a positive result will be adjusted as necessary.

If a participant has a positive nasal PCR test and negative serology and after being notified of their result, the DCC will send the participant an additional consent asking whether they would be willing to provide a blood sample after they have been cleared to return to work and approximately 21 days after their positive PCR test result for repeat serologic testing (see section 4.2.1). Site teams should confirm the participant consented to this additional testing before scheduling and performing their blood draw. If the day 21 serology test result is negative, the site team will schedule another blood draw for approximately 6 weeks after their positive PCR test result.

5.6.2 SARS-CoV-2 positive test outside the project

If site team becomes aware that a participant tested positive for SARS-CoV-2 outside the project (after their baseline serology and swab PCR tests were both negative), then they will notify the DCC immediately. The participant will continue with their weekly surveys and follow their institutional policies about when to return to work.

If the participant had a positive nasal PCR test outside the project, after they have been cleared and have returned to work and approximately 21 days since their positive PCR test result, the DCC will send the participant an additional consent asking whether they would be willing to provide additional blood sample. If the participant consents, the site team should contact the participant to schedule a blood draw for repeat serologic testing. If the day 21 serology test result is negative, the site team will schedule another blood draw at approximately 6 weeks after their positive PCR test result to confirm seroconversion.

If the participant has a positive serologic test outside the project, and is asymptomatic at the time of their next blood draw/swab, the project team will not consider this participant as positive for SARS-CoV-2 and should continue with scheduled blood draws/swabs.

MOP Version 4.0

6.0 Shipping Specimens

6.1 Requisition form

The excel spreadsheet titled "Auto Order Requisition" should be opened. The first tab titled, "Client," has already been pre-populated by ARUP laboratories with the project information--**nothing should be changed on this tab**. The second tab titled, "Patients," is where participant specific sample details will be entered as shown below.

Once the "Patients" tab with a list of all the samples being sent, is filled out, "Run" should be clicked. The project coordinator should then go to the third tab titled "Hardcopy Creator." This will generate a list of all the specimens listed for shipment. Print this page. This is the Requisition Form to be included when shipping. No new information should be changed or entered on this tab. The site numbers are in Section 5.2 in Table 1.

6.2 Shipping

Designated personnel at each site with IATA certification will qualify for packing and shipping the frozen serum and nasal swabs. Sites will remove the cardboard racks from freezer and make sure the specimens are in the same order as listed on the Requisition Form. Nasal swabs and serum tubes should not be on the same rack. Next, place 1 rack in the provided Frozen Temperature Specimen bag (see Figure 8). An absorbent sheet will also be added to the bag.

Figure 8

The date, client number, and specimen count should be filled in on the bag. The date will be "date of shipment." The client number can be found on the "client" tab of the Auto Order Requisition excel spreadsheet. Specimen count is the total number of specimens placed in that bag. The printed Requisition Form should be folded and placed in the outside pouch of the bag.

Each bag with specimens should now be placed in the Styrofoam insert of the provided Therapak shipping box (see Figure 8). Up to a total of 80 specimens should be placed in the bottom of the box, or can be stacked one bag on top of another if necessary.

A minimum of 15 lbs. and maximum of 20 lbs. of dry ice should be obtained to be included in the Styrofoam box with the specimens. If dry ice is purchased as a block, it should be broken up first so that there is enough dry ice to completely cover all the specimens. The box should be closed and seal securely with packing tape.
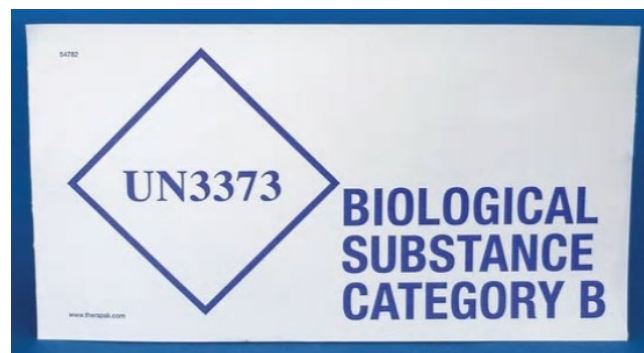

Figure 9

Figure 10

On the outside of the box, any side, place the "UN3373 Biological Substance Category B" sticker (see Figure 9) provided. This should not be placed on the top of the box. The "Dry Ice UN1845" sticker should be placed on the same side of the box as the UN3373 sticker. The sticker should be filled out with the required information (see Figure 10). The Consignee name and address is:

ARUP Laboratories
ATTN: Specimen Processing
500 Chipeta Way
Salt Lake City, UT 84000

One of the pdf FedEx shipping labels provided should be printed and taped on the top of the box. These labels indicate shipment will be sent Priority Overnight. A copy of the tracking number should be kept for your records.

The project coordinator should send an email to marcie.traballoni@aruplab.com, CTShippingNotifications@aruplab.com,and emergencyidnet-covered@uiowa.edu with completed "Auto Order Requisition" excel spreadsheet and tracking number.

FedEx should be called for shipment pickup. Specimens should only be sent from the site Sunday-Wednesday. The site team should track each shipment and ensure shipments arrive at ARUP laboratories on time. If the site team is aware of any delays, they should notify the CCC immediately by email.

7.0 Participant Compensation

Debit card compensation for all project participants will be managed by the DCC at the University of Iowa. All compensation will be placed on a VISA debit card. After the participant completes and submits the baseline survey, the card will be mailed to them from the bank and should arrive within 7-10 business days. There will be instructions included on how to create a login and password to access the card balance information. If a card does not arrive during that time, the participant or coordinator should contact the DCC using the project e-mail.

Every week, the card will be uploaded adding value based on completed surveys, blood draws and nasal swabs. An email will be sent to each participant detailing the amount that was loaded for each project task (i.e.: baseline/weekly/intubation surveys, blood draw, nasal swab) and the dates the compensation covers. Note that payment for sample collection will be tracked and uploaded based on the date the samples are shipped to the central laboratory and not by the date/time the samples are collected. A sample of the email is below. For more information regarding each project task compensatory amount, please refer to Appendix B.

Subject: Project COVERED Compensation

Thank you for your continued participation in Project COVERED. The following project compensation was requested for you on <Date Requested filled in by mail merge>

Project COVERED Activity

Activities for the dates between <beginning date filled in by mail merge> and <ending date filled in by mail merge >.

Participant Enrollment:	<filled in by mail merge>
Weekly Participant Survey:	<filled in by mail merge>
Intubation or CPR Survey:	<filled in by mail merge>
• <Num of int forms> forms completed x $10/form	
Biological Samples:	<filled in by mail merge>
Six Month Follow-up Survey:	<filled in by mail merge>
TOTAL:	<filled in by mail merge>

You should expect to see this value added to your card within the next 5 business days. If you have any questions about this compensation, please contact the Project COVERED team at EmergencyIDNet-Covered@uiowa.edu or (713)ID-COVER (432-6837).

If a participant has questions regarding card compensations, the project team should refer them to contact the DCC at EmergencyIDNet-Covered@uiowa.edu.

8.0 REDCap Instructions

8.1 REDCap Access

All project team members who need access to REDCap must email their name, title, institution, email address, and cell phone number to emergencyidnet-covered@uiowa.edu to obtain access to REDCap. The DCC will send a request to University of Iowa IT to obtain a HawkID. This will generate an email from University of Iowa IT to the relevant project team members. After they set up their Hawk ID, they must login to this website: https://redcap.icts.uiowa.edu/redcap/ to access REDCap.

If a project team member has questions about or an issue with a particular question in REDCap, the coordinator or the participant should record the item number that is below the answer response for that question and send an email to emergencyidnet-covered@uiowa.edu

8.2 Form specific instructions

Appendix C lists all the forms, a description of the form, when it should be completed, and by whom.

When entering dates, if birth date is unknown, enter "1/1/1900", e.g., on patient information form. For any other unknown date, use "4/15/2020."

8.2.1 Eligibility Form Instructions

1. In the left hand column of the Project COVERED REDCap page there is a grey header called "Reports"

2. The following reports will be visible:

   Physician
     1) Physician & APP Pre-Screen Eligible Data
     2) Physician & APP Recruited Data
   Nurse
     1) Nurse Pre-Screen Eligible Data
     2) Nurses Recruited Data
   Non-Clinical
     1) Non-Clinical Pre-Screen Eligible Data
     2) Non-Clinical Recruited Data

3. The reports that end with "Pre-Screen Eligible Data" are the potential recruits at the site, by their project role as reported on the screening form, who have met all project criteria. Note that there is only one report for all physicians and APPs and it is not separated out by intubating vs. non-intubating since we expect there to be crossover. The site team should ensure that, of the physicians and APPs they are enrolling, approximately 50% will be intubating and 50% will not be intubating during the project period and keep track

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of this on their end. We expect there to be crossover between these two groups, i.e., individuals expected not to intubate will intubate during the project period and vice versa.

4. This report tab should be double clicked for the anticipated project role upon enrollment. The project coordinator will only see data for their site.

5. Using the example above, if one would like to enroll Dr. Hobbs into the project at the site, one would click on '109' in the record_id column. The following screen will appear:

Record ID **109** Hobbs
Arm 1: Participant — Detroit

Data Collection Instrument	Screening	Eligibility	Baseline
Participant Interest Screening Form (survey)	✓		
Eligibility (survey)		○	
Informed Consent Document (survey)			○
Participant Enrollment Form (survey)			○
Medical History (survey)			○
Weekly Participant Survey (survey)			
Intubation/Cardiac Arrest Form (survey)			
Patient Information Form (Intubation/CPR) (survey)			
Serology Laboratory Form (survey)			○
Serology Laboratory Acknowledgement (survey)			○
Post Serologic Testing (survey)			
6 Month Participant F/U (survey)			
Compensation (survey)			
Withdrawal			
Delete all data on event:	✗		

At the top of this screen, the record ID and last name of the participant to be enrolled is shown. To enroll this participant, the ○ project coordinator should click in the 'Eligibility' column.
The following will appear:

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6. The Record ID # and Last Name at the top of the form should be reviewed for correctness. If a project coordinator wishes to enroll a recruit, he/she should click "yes", change the form status to "complete," and click on "Save & Exit Form". Upon clicking "Save & Exit Form" the recruit will be sent an email with the consent and Baseline Survey forms immediately. If the project coordinator does not wish to enroll a potential recruit, the he/she should click "no", change the form status to "complete," and click on "Save & Exit Form".

7. Once the participant has been enrolled, they will appear in the "Recruited Data" reports. These reports should be used to keep track of the number of participants in each project role that have been recruited.

8. The project coordinator should return to the "Pre-Screen Eligible Data" report to enroll additional recruits by repeating steps 4-7.

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8.2.2 Record Status and Participant Dashboard

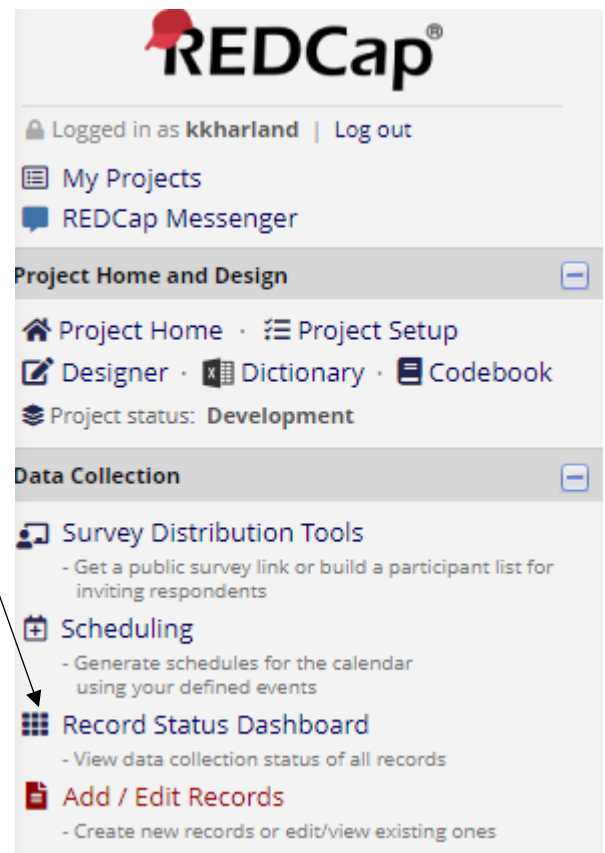Study coordinators should use the following procedures to access the participant record status.

1. Log into https://redcap.icts.uiowa.edu/ using your Hawk ID and password
2. Under My Projects click on 'Project COVERED'
3. In the left-hand column, click on 'Record Status Dashboard'

REDCap®

🔒 Logged in as **kkharland** | Log out

▣ My Projects
💬 REDCap Messenger

Project Home and Design ⊟

🏠 Project Home · 🗁 Project Setup
📝 Designer · 🞨 Dictionary · 📘 Codebook
📚 Project status: **Development**

Data Collection ⊟

🗐 Survey Distribution Tools
  - Get a public survey link or build a participant list for inviting respondents
⊞ Scheduling
  - Generate schedules for the calendar using your defined events
▦ Record Status Dashboard
  - View data collection status of all records
📄 Add / Edit Records
  - Create new records or edit/view existing ones

4. Near the middle of the page you will see two tabs: "Arm 1: Participant" and "Arm2: Facility". Click on Arm1: Participant

| Arm 1: Participant | Arm 2: Facility |
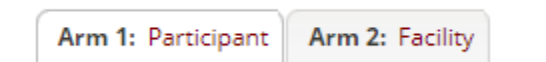
5. When you click on this tab you will see as many rows of data as you have participants at your site (approximately 80). At the top of the large table with the rows of data are the following column titles:

   a. Record ID
      i. A unique record ID for each participant. For ease of finding a participant, the participant's last name is also shown in the record ID column.
   b. Screening: Participant Interest Screening form [completed by participant]
   c. A "Baseline" event with several sub-columns
      i. Informed Consent Document
      ii. Participant Enrollment Form
      iii. Medical History
      iv. Serology Laboratory Draw Form
      v. Serology Laboratory Result Form
   d. The next 12 columns are labeled Week 1 through Week 20
      i. Weeks with no blood draw/swab (e.g., week 1, 3, etc.) have three sub-columns
   1. Weekly participant survey

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       2. Intubation/Cardiac Arrest Form
       3. Patient Information Form (Intubation/CPR)
    ii. Weeks 2, 4, 8, 12, 16, 20 have five sub-columns
       1. Weekly participant survey
       2. Intubation/Cardiac Arrest Form
       3. Patient Information Form (Intubation/CPR)
       4. Serology Laboratory Draw Form
   5. Serology Laboratory Result Form

8.2.3 Baseline Facility Form

Study coordinators should use the following procedures to complete the Baseline Facility Form

1. Log into https://redcap.icts.uiowa.edu/ using their Hawk ID and password. Under "My Projects," click on 'Project COVERED."
2. Under My Projects click on 'Project COVERED'
3. In the left-hand column, click on 'Record Status Dashboard'
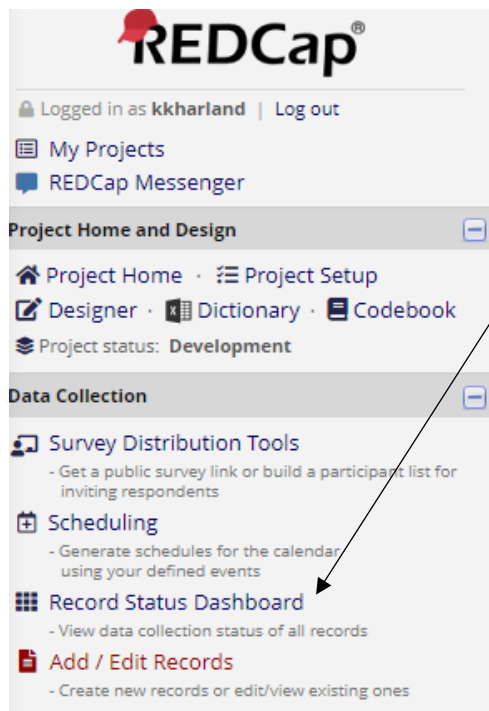
4. Near the middle of the page you will see two tabs: "Arm 1: Participant" and "Arm 2: Facility". Click on Arm 2: Facility.
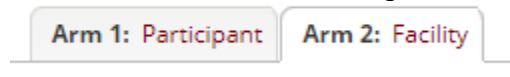
The first time you enter this dashboard you will need to create a new record to record your facility's baseline characteristics. Click on the button "Add new record for this arm", as displayed below to create a new record.

When you click the new record button the screen below will appear. As you scroll to the right, you will see weeks 8-20 and 9 month facility follow-up forms.

5. Click on the button under "Baseline Facility" to begin the baseline facility form.

8.2.3.1 Special instructions for sites with two hospitals

1. As a project site with two hospitals approved for recruitment in Project COVERED, you will have two lines of data on Arm 2: Facility. The first question within the baseline facility form will be "Please indicate which site you are providing information about" with a radio button for the names of your two hospitals.

2. Record here the record id and for which hospital it pertains so that all information for that hospital is entered into the same record.

Record ID in Arm 2: Facility	Site

3. In addition, at the top of each weekly facility form the name of the hospital you are recording data for will appear.

8.2.4 Intubation/CPR form

Study coordinators should use the following procedures to complete the Patient information forms associated with the Intubation/CPR forms that are completed by participants.

To add the first instance of a patient information form, you will click on the grey button. You will notice in the figure to the left that once an intubation and/or CPR event has been recorded by a participant a + button appears next to the recorded instances to add a new event for a new patient with an intubation or CPR event.

By default this status is "incomplete" and will appear grey. If the patient was tested for COVID-19 the patient information form requires some data that may not be able to be collected on the day of the intubation or CPR event such as hospital discharge disposition. We recommend you set the form status to "unverified" as this allow you to easily see which forms you have not collected these long term outcome data. When the entire form is completed, you can change the form status to "complete".

When you view the Record Status Dashboard, the Intubation/Cardiac Arrest Form AND a patient information form buttons will be a certain color based on the form completion status.

Given these forms can be completed multiple times, you may see a blue circle which means there are several different statuses of records with some being complete while others may be unverified and need additional data added.

8.2.5 Weekly facility forms

Weekly facility forms are completed by the site team. The facility forms should be completed for all weeks that their participants are still being followed. So, the final weekly facility form will be the same week that their last enrolled participant provides their week 20 blood draw/swab.

When reporting the form variable asking about the weekly number of positive staff members, if a participant has a positive PCR test within the project, they should be included in the count. However, if the participant had a positive serology only (within or outside the project), the site team should not include this in the count of positive staff members for that week.

9.0 Quality Assurance

The CCC and DCC and site teams will be responsible for tracking quality indicators during the project period.

The following project quality indicators will be tracked:
1) Informed consent;
2) Eligibility;
3) Baseline surveys and medical history form;
4) Baseline facility forms;
5) Baseline sample collection;
6) Weekly participant surveys;
7) Weekly facility forms;
8) Sample collection completed and within window;
9) Intubation/Cardiac Arrest forms;
10) Patient Information Intubation/Cardiac Arrest form completion;
11) Post Serologic Testing Survey;
12) Nine month participant follow-up Survey;
13) Nine month facility follow-up Survey;
14) Timely shipment of samples; and
15) Appropriate processing and handling of samples.

Note: Additional indicators may be added by site or DCC if necessary.

Several of the above quality indicators will be tracked for completion, timeliness (i.e., completed within window), logic, and accuracy using reports generated through REDCap. Reports will be reviewed by the DCC and CCC regularly and any issues will be communicated to the site PIs and their teams.

The site PI and team are responsible for tracking the above quality indicators at their site. If they identify any issues, then they will notify the DCC and CCC immediately by sending an email to the project email address. Additionally, the site PI and team must acknowledge receipt of communications from DCC regarding quality assurance issues that arise at their site immediately.

The site PI and team are responsible for addressing the issues/errors and developing corrective actions to either correct the issue or if not possible, prevent the issues/errors from continuing to occur. If they are unable to figure out corrective actions and a plan for implementation, they should contact the DCC and CCC to schedule a meeting to discuss.

9.1 Protocol and procedure deviations

The CCC will determine which protocol deviations require documentation from sites and will notify sites to submit a Note to File in those cases.

If prompted to submit a Note to File by the CCC, the following information should be included at a minimum:
1) date of the deviation(s);
2) the record ID(s) affected if applicable;
3) a description of the deviation(s);
4) the date it was reported to the DCC or CCC if applicable; and
5) any corrective actions implemented to correct the deviation(s) and/or prevent further similar deviations.

A Note to File should be sent to emergencyidnet-covered@uiowa.edu.

10.0 Post 20 week follow-up procedures

10.1 Participant communication

Follow-up of participants will either end on the date of their final 20 week blood draw/swab or date they complete their week 20 survey, whichever comes later. All replacements will be withdrawn on the date of their final blood draw/swab corresponding with the target date of the 20 week blood draw/swab of the participant they replaced. Participants will no longer receive weekly surveys after follow-up. Site teams will no longer need to schedule regular blood and nasal swab collection. However, they will continue to follow any participants who had a positive PCR test during follow-up and consent to provide a follow-up blood draw to confirm seroconversion.

When all participants have completed 20 weeks of follow-up, the site teams should notify their participants they will no longer receive weekly surveys. They should also notify participants that in approximately 4 months they will be receiving a text message and email link to complete a nine-month follow-up survey (Section 4.7) and they should **KEEP THEIR DEBIT CARDS** until they complete that survey to ensure they can receive their compensation when they complete it.

10.2 Final data collection and cleaning

Site teams will continue to complete weekly facility survey forms until the final follow-up week of their active participants, i.e., the week their last enrolled participant provides their week 20 blood draw/swab. All site teams should ensure that all required data (including weekly facility forms and patient information forms associated with intubation/cpr events) are entered into REDCap, checked for errors, and marked as complete.

In preparation for analysis, the DCC will be checking the data for missingness, inconsistencies and logic errors. The DCC will contact the site teams for their help to resolve any inconsistencies or errors found in REDCap. Sites should address errors as quickly as possible to ensure timely correction and release of results.

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10.3 Final sample shipments and remaining materials

All samples collected through week 20 should be shipped to ARUP laboratories. The DCC will notify site teams of any positive PCR tests and let sites know which participants will require repeat serology (see Section 4.2.1) past the follow-up phase.

The CCC will contact site teams and provide instructions on what to do with any remaining project materials.

10.4 Nine-month follow-up surveys

In January 2021, the COVERED executive committee will send out an update to sites and participants summarizing findings from the project. Included in this update will also be an announcement that participants will be receiving an email/text message with a final follow-up survey soon.

All participants (who were <u>not</u> withdrawn for non-compliance or because they did not want to participate further in the project) will receive a link by email and text approximately 270 days after they were enrolled to consent to and complete a nine-month follow-up survey. If a participant does not access the link to the nine-month survey, the DCC will contact site teams for their help to make sure participants received the link. Participants who complete this survey will be compensated with $20 credited to their debit card.

Site teams will be asked to complete a final nine-month follow-up facility form approximately 270 days after project enrollment was initiated at their site (Section 4.8). **Site teams should save their REDCap login and password information so they can complete this final survey when prompted to by the DCC.**

Appendix A. Project COVERED invitation email template

Thank you for your interest in Project COVERED (COVID Evaluation of Risk for Emergency Departments)! As you know, Project COVERED is an exciting effort to try to understand what the attributable risk is of providing emergency care to patients with COVID, and to identify ways to reduce that risk. To answer these questions, we are enrolling emergency department physicians, advanced practice providers, nurses, and nonclinical staff in a 12-week* surveillance project.

I am reaching out to you because I think you would be a great addition to the project. If you qualify for the project and choose to participate, you will be asked to complete a baseline survey and weekly surveys about your risk, your PPE, your procedures, and other details about care you have provided. We will also draw a blood sample and collect a self-administered nasal swab every 2 weeks to detect evidence of COVID-19 exposure or infection.

At the beginning of the project, you will receive a personalized debit card by mail, and you will be paid (onto the account connected to the card) every week for each survey, blood draw, and nasal swab you complete. We have attached the fee schedule detailing your compensation for completing each survey, blood draw, and nasal swab.

Participants qualify if they (1) have not had COVID-19 previously and do not have a positive COVID-19 serology on the first blood test or positive nasal swab on the first nasal swab, (2) work in one of the predefined risk groups at least 24 hours per week, and (3) will be able to complete the 12-week project (special procedures exist for graduating residents).

If you are still interested in participating, please complete a participation interest survey. This survey will gather information about your job to make sure you qualify for the project. At the end of the survey, you will provide your name and e-mail address. If you qualify, you will receive a follow-up e-mail from the project system within 2 days that will prompt you to enroll in the project. Please click on the following link to get started: [*LINK TO site-specific REDCap Screening Form*].

If you have any questions when reviewing the electronic consent and about the project, please feel free to contact me directly.

Note 6/27/20: This was the initial invitation email sent to participants at the start of the project. About 4 weeks into the project, the follow-up was extended to 20 weeks.

Appendix B. Participant Compensation Schedule

Physicians

Survey/Procedure	Quantity	Amount	Total
Baseline Survey	1	$15.00	$15.00
Weekly Survey	20	$10.00	$200.00
Blood Draws/Nasal Swabs	7	$15.00	$105.00
Intubation/CPR Reports	Participant-specific	$10.00	Participant-specific
Final Survey	1	$20.00	$20.00

Minimum Total $340.00

Nurses

Survey/Procedure	Quantity	Amount	Total
Baseline Survey	1	$15.00	$15.00
Weekly Survey	20	$10.00	$200.00
Blood Draws/Nasal Swabs	7	$15.00	$105.00
Final Survey	1	$20.00	$20.00

Total $340.00

Nonclinical Staff*

Survey/Procedure	Quantity	Amount	Total
Baseline Survey	1	$10.00	$10.00
Weekly Survey	20	$5.00	$100.00
Blood Draws/Nasal Swabs	7	$15.00	$105.00
Final Survey	1	$15.00	$15.00

Total $230.00

*Please note that nonclinical staff will receive less compensation for surveys because the baseline, weekly, and final surveys have significantly fewer questions than the clinical surveys.

Note: Participants who have positive baseline serology or PCR test results, will be withdrawn from the project but asked to complete a final survey. If they complete the survey, they will be compensated $25.

Appendix C. List of Instruments/Surveys

Instrument Name	Instrument Description	Frequency	Who completes
Participant Interest Screening Form	Completed by potential participants to express interest in participating in the project. This form will be reviewed by the Site PI's and coordinators and the Project COVERED team to select participants at your site.	Once	Potential participants
Eligibility	Enrolls participant in the project	Once	Site PIs and Coordinators will review the Participant Interest Screening form using the redcap reports and enroll participant in Project COVERED
Informed Consent Document	Once a participant has been selected for enrollment, the informed consent document will be displayed and acknowledged prior to starting the Participant Enrollment Form.	Once	Participant
Participant Enrollment Form	This form is the Baseline Survey and will be completed as the first form after project enrollment. Includes reporting information only on themselves.	Once	Participant
Medical History	Starts directly after the baseline survey but is viewable only at UI DCC for participant protection of medical history.	Once	Participant
Facility Characteristics	This form is the Baseline Survey for facility-level variables that is completed by the site research coordinator/site-PI.	Once	Site Coordinator or Site PI

Instrument Name	Instrument Description	Frequency	Who completes
Weekly Participant Survey	This form will measure COVID exposures and infections. It collects information on PPE use, treatment of patients with COVID, and if the participant shows any COVID symptoms. -A unique link is provided for each participant in a weekly email and text	Weekly	Participant
Weekly Facility Survey	This form measures ED-level COVID infections and workforce	Weekly	Site Coordinator or Site PI
Intubation/Cardiac Arrest Form	This form will be completed by a project participant who is a physician on an ad hoc basis whenever an endotracheal intubation is performed or whenever a patient in cardiac arrest is managed with CPR. -A unique link is provided for each participant in a weekly email and through the survey queue	Per intubation/CPR	Physician participants
Patient Information Form (Intubation/CPR)	This form will accompany an intubation/CPR form with patient-level covariates.	Per intubation/CPR	Site Coordinator
Serology Laboratory Form	Updated by the DCC each time a laboratory sample is collected and submitted to the central laboratory for processing via the order excel provided by ARUP	Per blood draw	UIowa Data Coordinating Center
Serology Laboratory Acknowledgement	This form will display serology results for a participant and the participant will need to acknowledge they have received their results by clicking 'yes'. A participant will receive an email and a text each time the serology results are updated	Per blood draw	UIowa Data Coordinating Center

Instrument Name	Instrument Description	Frequency	Who completes
Post Serologic Testing Survey	Stress/anxiety measure survey	4 week post enrollment (goes out with 4 week weekly survey)	Participant
9 Month follow-up	Measure long term participant outcomes. Questions are self-report about themselves.	Once at 9 most post-enrollment	Participant
9 Month facility follow-up	Measures long term facility outcomes	Once at 9 months post project start	Site Coordinator or Site PI
Withdrawal Survey	Measures risk and outcomes of initial positive baseline testing	Once 2 weeks after positive test result (on baseline testing ONLY)	Participant