

**PROJECT COVERED REPLACEMENT PROCEDURE**  
**Data Coordinating Center**  
**Version 1.1 (May 25, 2020)**

**Purpose:** The purpose of this document is to outline procedures for replacing Project COVERED participants during the conduct of the project.

**Indications for Replacement:** Participants may be replaced for any of the following reasons:

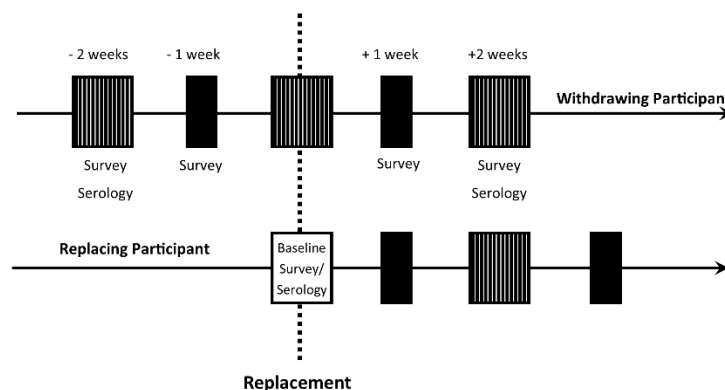
1. Positive baseline SARS-CoV-2 serology or nasal PCR
2. Residency graduation (leaving institution) or schedule change
3. Voluntary participant withdrawal
4. Nonadherence with project procedures (repeated noncompletion of surveys or missing >2 blood draws/PCR)

**Option 1: 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 project 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



**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).

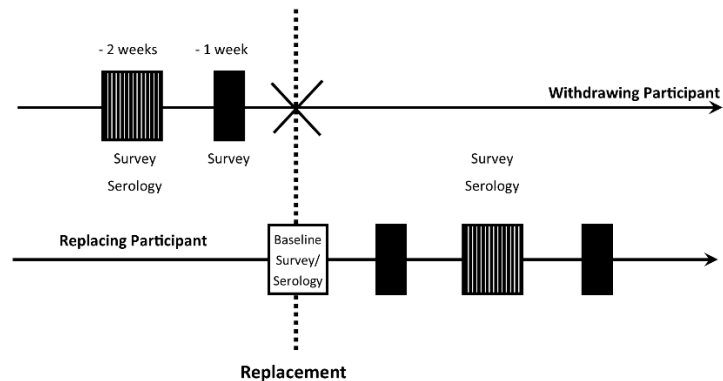
performed on June 11 and June 25, with accompanying weekly surveys and intubation forms (if applicable).

Any participant being replaced will use an identical procedure. Sites will use the following timeline to initiate the replacement procedure.

*Timeline*

- 4 weeks prior to Participant Withdrawal (2 weeks prior to the replacing participant starting) – E-mail [EmergencyIDNet-COVERED@uiowa.edu](mailto:EmergencyIDNet-COVERED@uiowa.edu) with the replacement plan:
  - Subject: <SiteName> Replacement Procedure
  - Body: We intend to replace the following participants:  
Withdraw: <Record ID> <Name>, Replacement: <Name>, Replacement Date: <Planned date>, Reason: Reason
- 18 days prior to Participant Withdrawal (4 days prior to the replacing participant starting) – Send Participant Interest Form link (along with project documentation) to the replacing participant
- 15 days prior to Participant Withdrawal (1 day prior to the replacing participant starting) – Enter participant into cohort
  - Participant will complete baseline enrollment form, have serology and nasal testing completed, and will start all project procedures.
  - Withdrawing participant will complete all procedures for next 2 weeks also.
- Participant Withdrawal – After the last weekly form and blood draw are completed, site coordinator should complete the Withdrawal Form for the participant withdrawing from the project.

**Option 2: 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:*



**Figure 2. Emergency replacement procedures will occur with no overlap.** As soon as replacement becomes necessary, the replacing participant can be invited and the withdrawing participant will be withdrawn.

*Noncompletion of project procedures because of COVID-19 infection should **NOT** trigger withdrawal or replacement procedures after an initial negative baseline.*

#### *Timeline*

- At time of Participant Withdrawal – E-mail [EmergencyIDNet-COVERED@uiowa.edu](mailto:EmergencyIDNet-COVERED@uiowa.edu) with the replacement plan:
  - Subject: <SiteName> Replacement Procedure
  - Body: We intend to replace the following participants:  
Withdraw: <Record ID> <Name>, Replacement: <Name>, Replacement Date: <Planned date>, Reason: Reason
- At time of Participant Withdrawal – Send Participant Interest Form link (along with project documentation) to the replacing participant
- Immediately upon receipt, confirmation of eligibility, and approval – Enter participant into cohort
  - Participant will complete baseline enrollment form, have serology and nasal testing completed, and will start all project procedures.
- Participant Withdrawal – At the time of participant withdrawal, please complete Participant Withdrawal Form.

*Special Note:* Emergency participant withdrawal should be rare (except for baseline positive COVID-19 testing). We would like to encourage participation as much as possible. If sites have an issue that may lead to participant withdrawal, please contact the coordinating center at [EmergencyIDNet-COVERED@uiowa.edu](mailto:EmergencyIDNet-COVERED@uiowa.edu) as soon as possible to discuss accommodations and procedures.

**Reclassification:** Some sites may have graduating residents who will remain at the project center 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, please request reclassification from the Data Coordinating Center:

- 1 week prior to Reclassification – E-mail [EmergencyIDNet-COVERED@uiowa.edu](mailto:EmergencyIDNet-COVERED@uiowa.edu) with the reclassification request:
  - Subject: <SiteName> Reclassification Request
  - Body: We would like to request reclassification of the following participants:  
Participant: <Record ID> <Name>, New Role: <Role>, Effective Date: <Planned date>
- Please select the new role from the following (in most cases, this will be reclassification of a resident as an Emergency Medicine Attending or Fellow):
  - Emergency Medicine Attending or Fellow
  - Emergency Medicine Resident
  - Advanced Practice Provider (PA, NP, CRNA)

- Non-Emergency Medicine Faculty or Fellow
- Non-Emergency Medicine Resident
- Emergency Department Nurse
- Emergency Department Non-Clinical Staff Member (any ED worker with little direct patient contact)

**Questions:** If sites have any questions about replacement procedures, please contact the project e-mail at [EmergencyIDNet-COVERED@uiowa.edu](mailto:EmergencyIDNet-COVERED@uiowa.edu) as soon as possible. Project COVERED staff can provide individual guidance by telephone or e-mail as necessary.