Case Report Forms
RedCap Instructions

Provided by the Project COVERED Data Coordinating Center at the University of Iowa
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Record Status Dashboard

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’
4. Near the middle of the page you will see two tabs: “Arm 1: Participant” and “Arm2: Facility”. Click on Arm1: Participant
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. Serology Laboratory Form
      iv. Serology Laboratory Acknowledgement
   d. The next 12 columns are labeled Week 1 through Week 12
      i. Odd weeks (e.g., week 1, 3, etc) have three sub-columns
         1. Weekly participant survey
         2. Intubation/Cardiac Arrest Form
         3. Patient Information Form (Intubation/CPR)
      ii. Even weeks (e.g., week 2, 4, 6 etc) have five sub-columns
1. Weekly participant survey
2. Intubation/Cardiac Arrest Form
3. Patient Information Form (Intubation/CPR)
4. Serology Laboratory Form
5. Serology Laboratory Acknowledgement

   e. 6-month follow-up
      i. A survey that is completed by a participant in November 2020, approximately 6 months after Project COVERED launch

   f. Withdrawal
      i. Use this form to document if a participant has withdrawn from the study and the reason they have withdrawn.

6. Custom Dashboard
   Two dashboards are available for viewing, the [default dashboard] and one called “Recruited HCP”. The default dashboard has all potential recruits who filled out the participant interest screening form at your site. The “Recruited HCP” Dashboard has only those participants at your site who have been deemed eligible to participate in Project COVERED (we go over how enroll someone in the next step). You can select the dashboard you wish to view by clicking on the drop down next to “Dashboard Displayed”.

**Project COVERED**

### Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: [Default dashboard]

**IMPORTANT:** After you have finished enrolling HCP, use the “Recruited HCP” Dashboard to monitor participant study progress. Use the default dashboard to enter facility level data.
Enrolling recruits

1. In left hand column of the Project COVERED RedCap you will see a grey header called “Reports”

2. The following reports will be visible to you:
   - **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. In the reports that end with “Pre-Screen Eligible Data” are potential recruits at your site, by their project role reported on the screening form, that have met all project eligibility criteria but have yet to be recruited into the project.
   - For Physician and APP Pre-Screen Eligible Data there are two reports: one for your intubation cohort (ends in “Intubating”) and one for your non-intubating cohort (Ends in “Non-Intubating”)

4. Double click on this report for the project role you wish to enroll. You will only see data for your site. Below is an example of test data for Detroit for the Physician & APP Screen Eligible Data—Non-intubating.

   **Physician & APP Pre-Screen Eligible Data—Non-Intubating**

   | Event Name | Reports | What is your primary job? | Data Access Group | What is your name? | Intubation cohort? | Able to perform intubation? | Intubation performed | Intubation procedure? | In your hospital/setting during the last three months? | Worked at least 16 hours a week? | Working in the ED? | Over the next 12 weeks, how many hours per week do you anticipate working? | Over the next 12 weeks, how many weeks do you anticipate working in off-service rotations? |
|-------------|---------|---------------------------|------------------|-------------------|-------------------|------------------------|------------------------|------------------------|------------------------|-----------------------------|---------------|----------------|-----------------------------------------------------------------|----------------------------------------------------------------|
| 109 Hobbs   | Screening (Arm 1: Participant) | Detroit Hobbs Emergency Medicine Resident (2) | No (0) | 1-3 (1) | No (0) | No (0) | Yes (1) | 31-40 hours (4) | 31-40 hours (4) | 31-40 hours (4) | 31-40 hours (4) | 31-40 hours (4) | 31-40 hours (4) |

5. Using the example above, if you would like to enroll Dr. Hobbs into the project at your site, you will click on ‘109’ in the record_id column. The following screen will appear:
At the top of this screen you can see the record ID and last name of the participant you wish to enroll. To enroll this participant, click in the [ ] in the ‘Eligibility’ column. The following will appear:
6. Review that the correct Record ID # and Last Name at the top of the form. If you wish to enroll this recruit 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 enrollment form documents immediately.
   a. **DO NOT ASSIGN A RECRUIT AS ELIGIBLE** unless your site is able to complete the baseline blood draw and nasal swab within 2 days. For example, do not make a recruit eligible on a Friday unless your site is able to complete the blood draw and nasal swab on that Friday, Saturday or Sunday.

7. Once the recruit has been enrolled, they will appear in the “Recruited Data” reports and the “Recruited HCP” Dashboard. You should use the “Recruited Data” reports to keep track of the number of recruited HCP in each study role that have been recruited.

8. Return to the “Pre-Screen Eligible Data” report to enroll additional recruits by repeating steps 4-7.

**NOTE:** If you are not able to get 20 recruits per study role using the “Pre-Screen Eligible Data” reports, contact the DCC to set up a meeting to go through other potentially eligible recruit that did not meet all study inclusion criteria.
Entering data into the facility forms

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’
4. Near the middle of the page you will see two tabs: “Arm 1: Participant” and “Arm2: Facility”. Click on Arm2: Facility
5. The first time you enter this dashboard you will need to create a new record to record your facility’s baseline characteristics. Click here 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 8-14 and 6-month facility follow-up form.
6. Click on the button under “Baseline Facility” to begin the baseline facility form.

7. After you fill in the facility information you have three options at the bottom of the form for form’s completion status

By default, this status is “incomplete”. If you have collected some of the data elements but not all of them and will need to return to the form to enter data, set the form status to “unverified” as this allow you to easily see which forms you have started but not completed. When the entire form is completed, you can change the form status to “complete”.

8. When you return to the Record Status Dashboard, the facility button will be a certain color based on the form completion status.

9. Unless you are at a project site with more than one hospital approved for recruitment in Project COVERED, you will only have one line of data in Arm 2: Facility.

Special instructions for sites with two hospitals
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.
Record here the record id and for which hospital it pertains so that all information for that hospital is entered into the same record.

<table>
<thead>
<tr>
<th>Record ID in Arm 2: Facility</th>
<th>Site</th>
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In addition, at the top of each weekly facility form the name of the hospital you are recording data for will appear.
Entering patient data for intubations and CPR

Starting in Week 1 you will see a column named “Intubation/Cardiac Arrest Form” in the Record Status Dashboard. This form is filled out by the intubating physician (faculty or resident). This form can be repeated multiple times in a week for each intubation completed or CPR event regardless of the patient’s COVID-19 status. The intubating physician will access these forms using a survey queue link which is provided to them weekly via email.

The form “Patient Information Form (Intubation/CPR)” will need to be completed by the site coordinator for each intubation or CPR event. 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 a + button appears next to the recorded instances to add a new event for a new patient with an intubation or CPR event.

Each patient who has had an intubation or CPR event should have an Intubation/Cardiac Arrest Form AND a patient information form. Use your site EMR report to review intubations and CPR events daily to ensure both of these forms are completed for each patient.

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. Set the form status to “unverified” as this allow you to easily see in the dashboard which forms you have not collected these long-term outcome data. When the entire form is completed, 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(s) 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.
Reports

Missing Weekly Activities
In the left-hand column in the reports section of Redcap, you will see a group of reports called “Missing Weekly Activities”. These reports will alert you to missing weekly surveys or missing bi-weekly blood draws or nasal swabs.

- **Missing Weekly Surveys-Any**
  - This report will list the record ID for any participant who has missed any weekly survey and which weekly survey was missed. The report has columns for week 1 survey missed up to week 12 survey missed. In this report a ‘1’ indicates that weekly survey was missed.

- **Missing Weekly Surveys-2 consecutive weeks**
  - This report will list the record ID for any participant who has missed two consecutive weekly survey and which weekly survey was missed. The report has columns for week 1 survey missed up to week 12 survey missed. In this report a ‘1’ indicates that weekly survey was missed.

- **Missing Weekly Surveys-3 consecutive weeks**
  - This report will list the record ID for any participant who has missed three consecutive weekly survey and which weekly survey was missed. The report has columns for week 1 survey missed up to week 12 survey missed. In this report a ‘1’ indicates that weekly survey was missed.

- **Missing Blood Draws-Any**
  - This report will list the record ID for any participant who has missed any blood draws and which week(s) was missed. The report has columns for week 2, week 4, week 6, week 8, week 10 and week 12 blood draw/nasal swab missed. In this report a ‘1’ indicates that weekly collection was missed.

- **Missing Blood Draws-2 consecutive**
  - This report will list the record ID for any participant who has missed two blood draws and which collections were missed. The report has columns for week 2, week 4, week 6, week 8, week 10 and week 12 blood draw/nasal swab missed. In this report a ‘1’ indicates that weekly collection was missed.
Missing Blood Draws-3 consecutive
- This report will list the record ID for any participant who has missed three blood draws and which collections were missed. The report has columns for week 2, week 4, week 6, week 8, week 10 and week 12 blood draw/nasal swab missed. In this report a ‘1’ indicates that weekly collection was missed.

Missing Nasal Swabs-Any
- This report will list the record ID for any participant who has missed any nasal swabs and which week(s) was missed. The report has columns for week 2, week 4, week 6, week 8, week 10 and week 12 blood draw/nasal swab missed. In this report a ‘1’ indicates that weekly collection was missed.

Missing Nasal Swabs -2 consecutive
- This report will list the record ID for any participant who has missed two nasal swabs and which collections were missed. The report has columns for week 2, week 4, week 6, week 8, week 10 and week 12 blood draw/nasal swab missed. In this report a ‘1’ indicates that weekly collection was missed.

Missing Nasal Swabs -3 consecutive
- This report will list the record ID for any participant who has missed three nasal swabs and which collections were missed. The report has columns for week 2, week 4, week 6, week 8, week 10 and week 12 blood draw/nasal swab missed. In this report a ‘1’ indicates that weekly collection was missed.
Case Report Form Training

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COVID-19 Evaluation of Risk in Emergency Departments
Objectives

• Data overview of Project COVERED

• View project completion
  • Record Status Dashboard

• Enter data
  • Enroll recruits
  • Enter Facility-Level Data
  • Entering patient data for intubations and CPR

• Review data
  • Reports
Data Overview

Participants
• Longitudinal
• Event-level

Coordinators (Facility)
• Longitudinal
• Event-level

Testing (Serology, PCR)

Data Coordinating Center

Role of Local Project Coordinator
• Enter facility-level longitudinal data
• Track intubations/CPR to ensure participant forms are completed
• Enter patient-level data for intubation/CPR patients
• Coordinate blood/nasal specimen collection
• Ship specimens to reference laboratory (ARUP)
• Track participant form completion
# Data Overview

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</tbody>
</table>

**Participant Activities**
- Intubation/CPR
- Patient Information

**Coordinator Activities**
- Event-Level Form
## Record Status Dashboard

<table>
<thead>
<tr>
<th>Record ID</th>
<th>Arm 1: Participant</th>
<th>Arm 2: Facility</th>
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<td>106 James</td>
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</tbody>
</table>

### Legend for status icons:
- **Red**: Incomplete
- **Orange**: Incomplete (no data saved)
- **Yellow**: Unverified
- **Green**: Partial Survey Response
- **Black**: Completed Survey Response
- **Blue**: Many statuses (mixed)
- **Red**: Many statuses (all same)
Record Status Dashboard

**Default**
- Determine recruitment eligibility
- Complete facility-level data

**Recruited participants**
- Use after recruitment to monitor participant progress
## Data Overview

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**Participant Activities** | **Coordinator Activities**

- Event-Level Form
- Event-Level Form
How to enroll participants

• Participants complete the “Participation Interest Form”

• Based on responses, participants may be:
  • High-quality candidates (REPORT “Pre-Screen Eligible Data”)
  • Acceptable candidates
  • Ineligible

• This process will ENROLL a participant in the project
  • Sends consent document and baseline enrollment form by e-mail
How to enroll participants

• **DO NOT ASSIGN A PARTICIPANT AS ELIGIBLE** until you are ready to collect blood/nasal specimens (within 2 days of consent)

• Unable to find 20 participants per group?
  • Contact the DCC to set up a meeting to go through other acceptable candidates for inclusion
# Data Overview

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**Participant Activities** | **Coordinator Activities**
Recording Facility Data

• Use the [default dashboard]
• 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.
SPECIAL CASE: Two Hospitals

- If you have been approved to use two hospitals for the project you will have two lines of data on the Arm 2: Facility dashboard.
- Every facility form will be completed TWICE (one for each hospital).
- In this record the site AND hospital name will appear at the top of each facility survey.

![Weekly Facility Survey](image)
# Data Overview

| Week       | -1 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | ... | 24 |
|------------|----|---|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|
| Participation Interest |   |   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |
| Inclusion Form |   |   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |
| Baseline Enrollment |   |   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |
| Facility Baseline |   |   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |
| Serology/Nasal Swab |   |   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |
| Weekly Survey |   |   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |
| Facility Weekly |   |   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |
| 6-Month Participant |   |   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |
| 6-Month Facility |   |   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |
| Intubation/CPR |   |   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |
| Patient Information |   |   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |

**Participant Activities** | **Coordinator Activities**

- Event-Level Form
Each intubation/CPR patient must have both forms completed.

**Intubation/CPR Form**
- Information known at time of intubation
- Techniques/equipment used
  - [Complete within 24 hours]

**Patient Information Form**
- Detailed patient information
- Clinical outcomes
  - [Start within 24 hours, then SAVE – complete after discharge]

Coordinator should screen EMR daily for intubations/cardiac arrests treated by project physicians without an Intubation/CPR form.

**Data Coordinating Center**
Review data

• REPORTS monitor missing weekly surveys, bi-weekly blood draws and nasal swabs
• MONITOR frequently

- Missing Weekly Activities
  1) Missing Weekly Surveys-Any
  2) Missing Weekly Survey-2 consecutive weeks
  3) Missing Weekly Survey-3 consecutive weeks
  4) Missing Blood Draws-Any
  5) Missing Blood Draws-2 consecutive
  6) Missing Blood Draws-3 consecutive
  7) Missing Nasal Swabs-Any
  8) Missing Nasal Swabs-2 consecutive
  9) Missing Nasal Swabs-3 consecutive
How do I report an issue with a survey item?

QUESTIONS are identified by an alphanumeric identifier.

Report this item number to the DCC for troubleshooting. In the example above, the item # is pe_2898
Data queries

Data queries will be sent to your site weekly
Case Report Form problems

Contact the DCC immediately (e-mail or telephone)
  • DCC technical support hours 7a-5p CDT M-F
  • 24-hour hotline available for clinical questions

We will set up a Zoom video conference to see the problem you are having and walk you through the solution in real time
Case Report Form Training

Kari Harland, PhD, MPH
Kelli Wallace, MS, CCRC
Project COVERED, Data Coordinating Center
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