



Case Report Forms RedCap Instructions

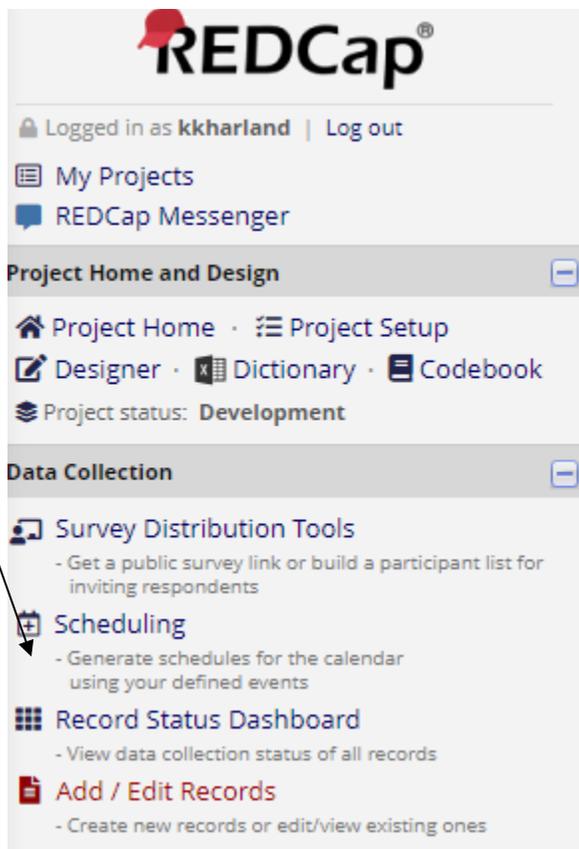
Provided by the Project COVERED Data Coordinating Center at the University of Iowa

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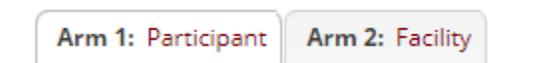
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Record Status Dashboard

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- i. Use this form to document if a participant has withdrawn from the study and the reason they have withdrawn.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



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.
 - a. 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

Search Table not displaying pre

Record ID record_id	Event Name redcap_event_name	Repeat Instrument repeat_instrument	Repeat Instance repeat_repeat_instance	Data Access Group redcap_data_access_group	What is your last name? lastname	What is your primary job? primary_job	Does your institution have a dedicated intubation team for COVID-19 ... form_endotracheal_intubation? int_team	Are you a member of the COVID-19 intubation team? member_int_team	How many emergency endotracheal intubations have you personally performed? int_performed	In your hospital/setting, do you anticipate performing endotracheal ... patients in the next 3 months? covid_int	Do you intend to be working in your current place of employment through August 2020? cont_employment	On average, over the last three months, how many hours per week, on average, do you expect to be working in the ED? avg_wkly_hrs	Over the next 12 weeks, how many hours per week, on average, do you expect to be working in the ED? wkly_hrs	Over the next 12 weeks, how many weeks do you anticipate working cl ... ime, or off-service rotations. clin_weeks	Ti in is to pe in pe
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)	11-12 weeks (every week) (1)	

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:

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

 Data Collection Instrument	Screening	Eligibility	Baseline
Participant Interest Screening Form <small>(survey)</small>	<input checked="" type="checkbox"/>		
Eligibility <small>(survey)</small>		<input type="checkbox"/>	
Informed Consent Document <small>(survey)</small>			<input type="checkbox"/>
Participant Enrollment Form <small>(survey)</small>			<input type="checkbox"/>
Medical History <small>(survey)</small>			<input type="checkbox"/>
Weekly Participant Survey <small>(survey)</small>			
Intubation/Cardiac Arrest Form <small>(survey)</small>			
Patient Information Form (Intubation/CPR) <small>(survey)</small>			
Serology Laboratory Form <small>(survey)</small>			<input type="checkbox"/>
Serology Laboratory Acknowledgement <small>(survey)</small>			<input type="checkbox"/>
Post Serologic Testing <small>(survey)</small>			
6 Month Participant F/U <small>(survey)</small>			
Compensation <small>(survey)</small>			
Withdrawal			
Delete all data on event:	<input checked="" type="checkbox"/>		

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:

 Editing existing Record ID **109** Hobbs

Event Name: **Eligibility (Arm 1: Participant)**

Record ID 109

This individual is eligible to participate in this project. Yes No
* must provide value reset

Form Status

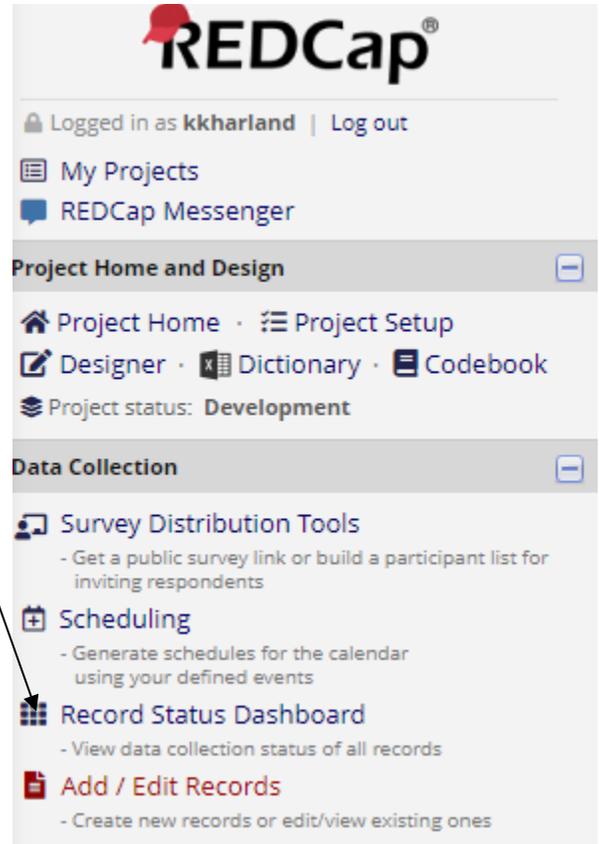
Complete? Incomplete dropdown arrow

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.

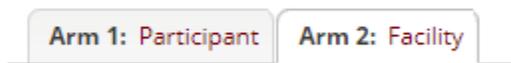
NOTE: If you are not able to get 20 recruits per study role using the “Pre-Screen Eligible Data” reports, contact the DCC to set up a meeting to go through other potentially eligible recruit that did not meet all study inclusion criteria.

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

[+ Add new record for this arm](#)

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.

NEW Record ID 54

Arm 2: Facility

Data Collection Instrument	Baseline Facility	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7
Facility Characteristics (survey)	<input type="radio"/>							
Weekly Facility Survey (survey)	<input type="radio"/>							
6 Month Facility F/U (survey)								

- Click on the button under “Baseline Facility” to begin the baseline facility form.
- After you fill in the facility information you have three options at the bottom of the form for form’s completion status

Form Status	
Complete?	<input type="radio"/> Incomplete ▾

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”.

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

Legend for status icons:	
<input type="radio"/>	Incomplete
<input type="radio"/>	Unverified
<input type="radio"/>	Complete

- 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.

Record ID in Arm 2: Facility	Site

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 patients COVID-19 status. The intubating physician will access these forms using a survey queue link which is provided to them weekly via email.

Week 1		
Weekly Participant Survey	Intubation/Cardiac Arrest Form	Patient Information Form (Intubation/CPR)

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.

Legend for status icons:	
	Incomplete
	Unverified
	Complete
	Many statuses (mixed)

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

Kari Harland, PhD, MPH
Kelli Wallace, MS, CCRC

Project COVERED, Data Coordinating Center
University of Iowa Carver College of Medicine

<http://www.covered-study.org>

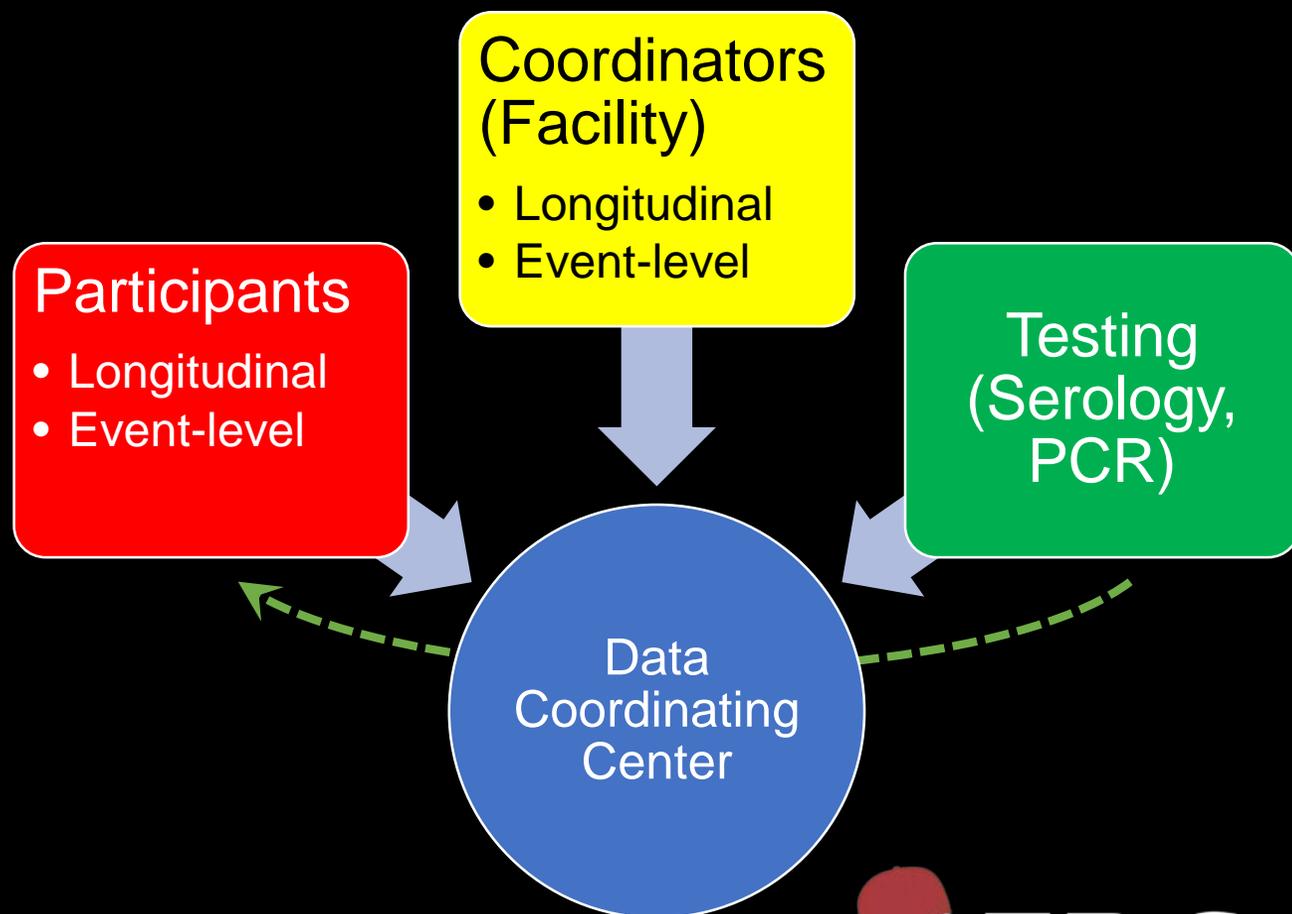
EmergencyIDNet-COVERED@uiowa.edu

(731)ID-COVER

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



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

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

Participant Activities

Coordinator Activities

Record Status Dashboard

Arm 1: Participant		Arm 2: Facility						
Record ID	Screening	Eligibility	Baseline					
	Participant Interest Screening Form	Eligibility	Informed Consent Document	Participant Enrollment Form	Medical History	Serology Laboratory Form	Serology Laboratory Acknowledgement	Project Completion
103 Jones								
104 Jackson								
105 Kid								
106 James								

Legend for status icons:

- Incomplete
- Unverified
- Complete
- Many statuses (mixed)
- Incomplete (no data saved) ?
- Partial Survey Response
- Completed Survey Response
- Many statuses (all same)

Record Status Dashboard



Default

- Determine recruitment eligibility
- Complete facility-level data



Recruited participants

- Use after recruitment to monitor participant progress

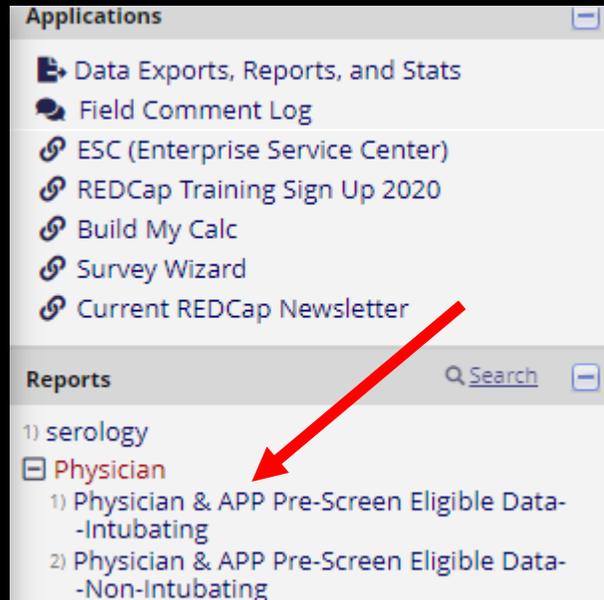
Data Overview

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Participation Interest	Red																	
Inclusion Form		Yellow																
Baseline Enrollment		Red																
Facility Baseline		Yellow																
Serology/Nasal Swab		Red		Red		Red		Red		Red		Red		Red				
Weekly Survey			Red															
Facility Weekly			Yellow															
6-Month Participant																		Red
6-Month Facility																		Yellow
Intubation/CPR		Event-Level Form																
Patient Information		Event-Level Form																

Participant Activities

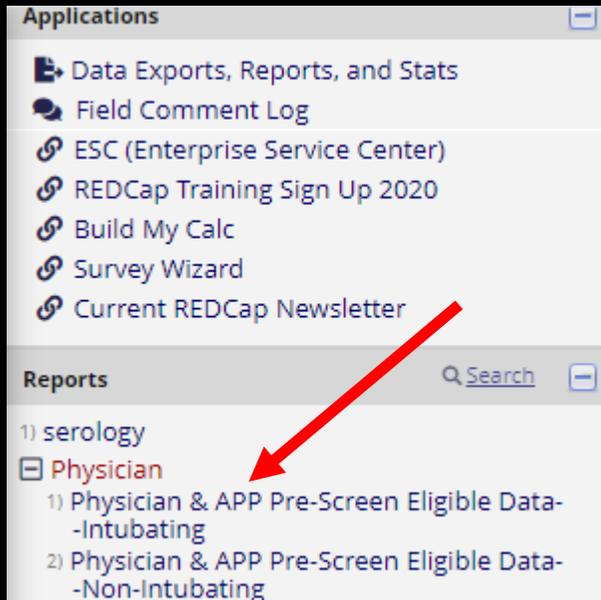
Coordinator Activities

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

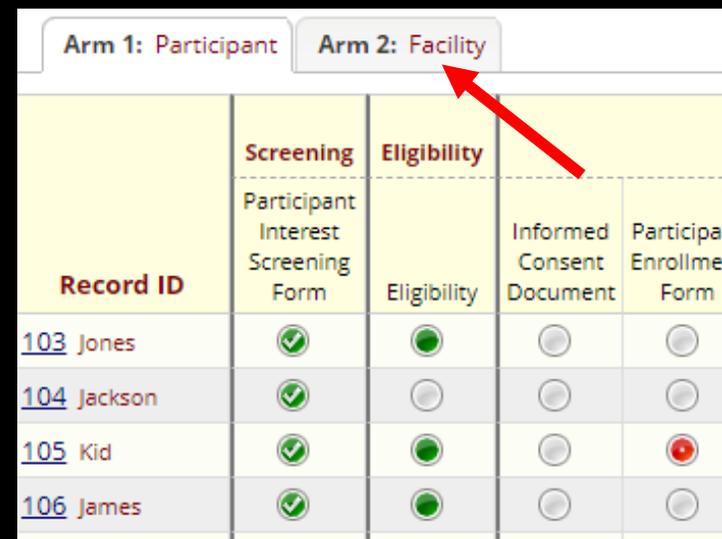
Week	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	...	24
Participation Interest	Red																	
Inclusion Form		Yellow																
Baseline Enrollment		Red																
Facility Baseline		Yellow																
Serology/Nasal Swab		Red		Red		Red		Red		Red		Red		Red				
Weekly Survey			Red						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

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.



Arm 1: Participant		Arm 2: Facility		
Record ID	Screening	Eligibility	Informed Consent Document	Participant Enrollment Form
	Participant Interest Screening Form	Eligibility		
103 Jones	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
104 Jackson	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
105 Kid	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
106 James	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

+ Add new record for this arm

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

Editing existing Record ID 7357-1

Event Name: Week 1 (Arm 2: Facility)

Record ID

Site: UCLA

Hospital Facility: UCLA Olive View

Hospital Facility →

Data Overview

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

Participant Activities

Coordinator Activities

Recording Intubation and CPR data

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]

Data
Coordinating
Center

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

EACH INTUBATION/CPR PATIENT MUST HAVE BOTH FORMS COMPLETED

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?

Have you been quarantined because of an exposure or potential exposure to COVID-19?

* must provide value

Yes, by a public health authority

Yes, by my employer

Yes, by my own decision

No

pe_2898

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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