Data Entry Guide for the ISARIC Data Platform

ISARIC COVID-19
RAPID Database





Table of Contents

Data Collection via the ISARIC Data Platform Electronic Data Capture REDCap Project: ISARIC COVID-19 RAPID

- 3. Access to ISARIC nCoV REDCap Project
- 4. Logging in to REDCap
- 5. Accessing Your Project
- 6. Adding a New Participant Record Step 1
- 7. The Participant Identification Number (PIN)
- 8. Adding a New Participant Record Step 2
- 9. Adding a New Participant Record Step 3
- 10. Completing the Terms of Submission (ToS) [WHO Project]
- 11. Completing the Terms of Submission (ToS) [ISARIC Project]
- 12. Completing the ISARIC ToS Electronic Signature
- 13. Completing the ISARIC ToS Paper Copy
- 14. Data Entry Schedule
- 15. Data Entry Schedule Additional Modules
- 16. Data Entry Entering Data
- 17. Data Entry Saving a Form
- 18. Data Entry Saving a Form
- 19. Data Entry Required Questions
- 20. Data Entry Results Out of Range
- 21. Data Renaming a Record
- 22. Data Deleting Data (Form Level)
- 23. Data Deleting Data (Event Level)
- 24. Data Deleting Data (Patient Level)
- 25. Data Exporting Data
- 26. Data Data Export Formats
- 27. Data Security Logging Out When Complete
- 28. Additional Resources







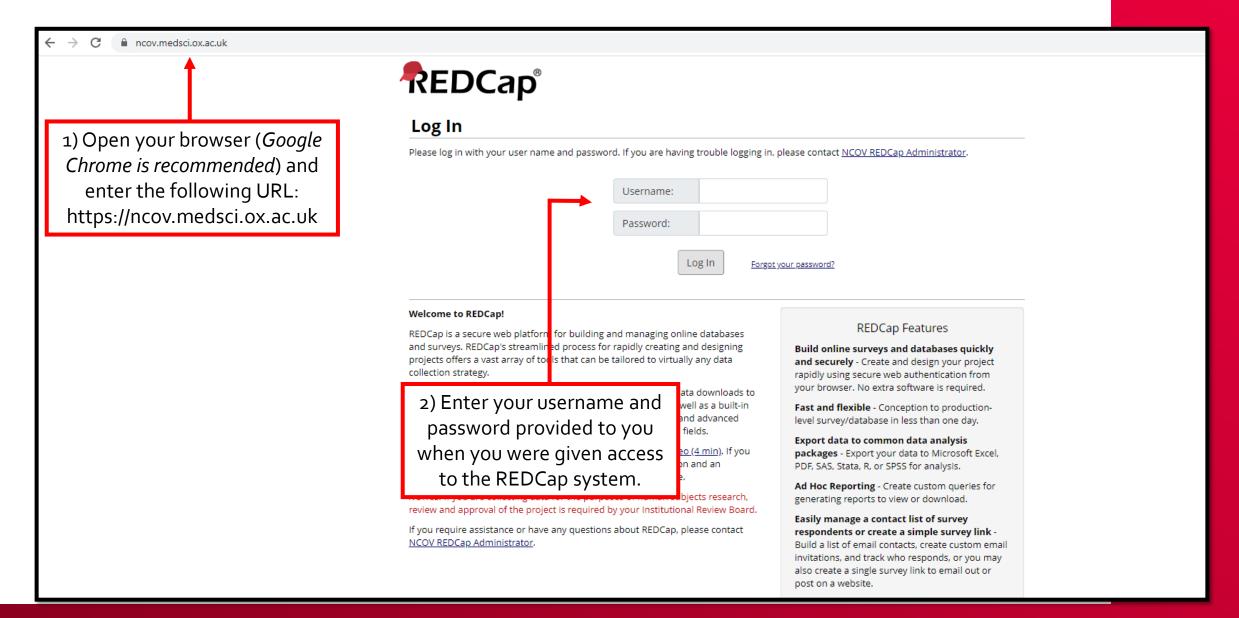
 Access to the REDCap Project is controlled via individual user accounts that are created by contacting the ISARIC Global Support Centre at ncov@isaric.org

Passwords

- When your account is created you will receive an email containing login details
 - Username
 - Temporary Password
 - You will be required to set your own password when you log in for the first time
 - You will also be asked to set a challenge question and answer that can be used to assist you should you forget your password. (If you are not able to recover your password please email ncov@isaric.org to obtain a new temporary password).

Logging in to REDCap





Accessing Your Project

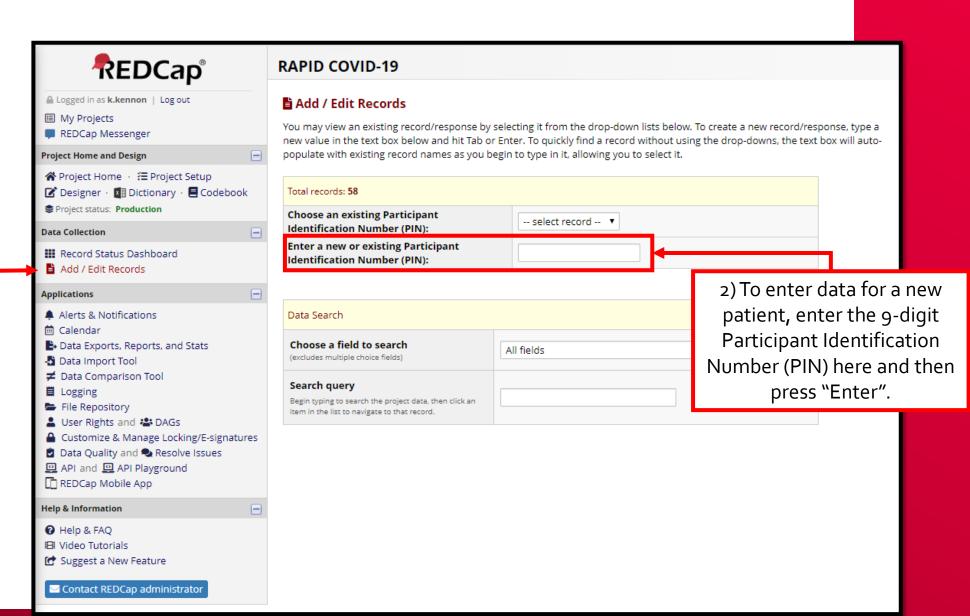




Adding a New Participant Record - Step 1



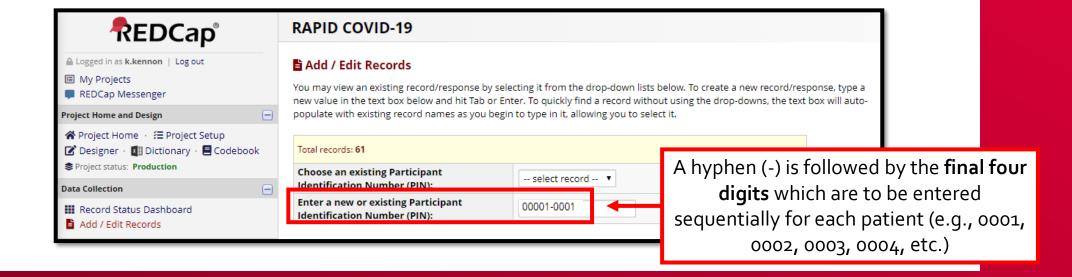
1) Clicking here (Add / Edit Records) opens the page shown here



The Participant Identification Number (PIN)



| ₹EDCap ® | RAPID COVID-19 | | | | | | |
|--|---|--|--|--|--|--|--|
| Logged in as k.kennon Log out My Projects REDCap Messenger | Add / Edit Records You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto- | | | | | | |
| Project Home and Design | populate with existing record names as you begin to type in it, allowing you to select it. Total records: 61 | | | | | | |
| A Project Home · ₩ Project Setup I Dictionary ■ Codebook | | | | | | | |
| Project status: Production | Choose an existing Participant select record ▼ | | | | | | |
| Data Collection — | Identification Number (PIN): | The first five digits are the | | | | | |
| Record Status Dashboard Add / Edit Records | Enter a new or existing Participant Identification Number (PIN): | The first five digits are the code allocated for your sit | | | | | |



Adding a New Participant Record – Step 2

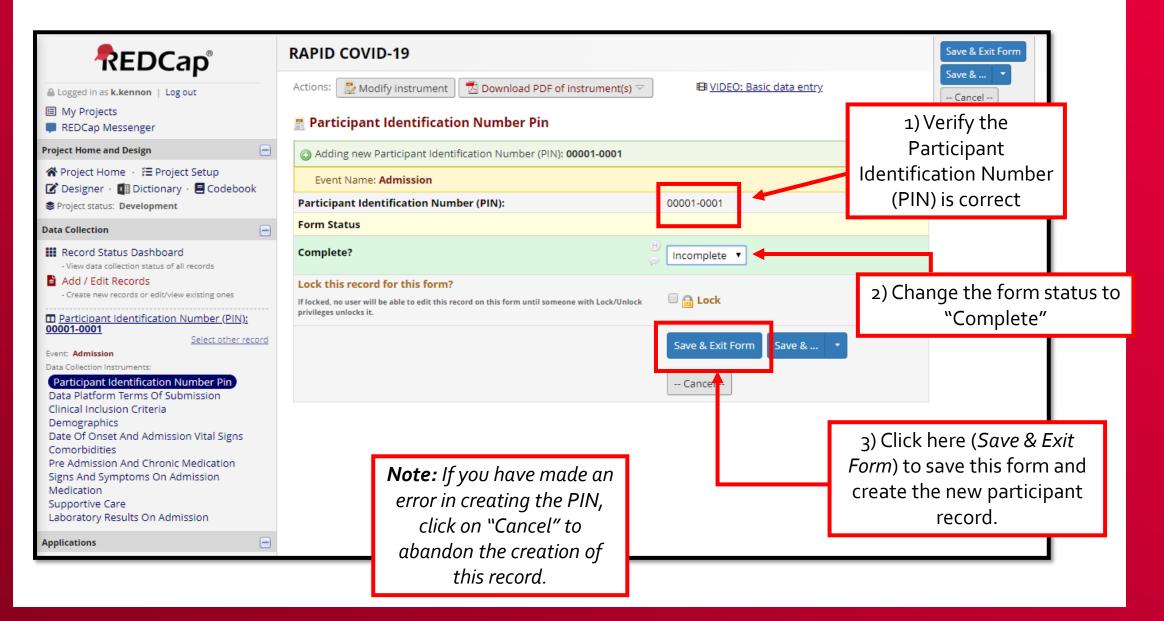


| ₹EDCap ® | RAPID COVID-19 | | | | | | | |
|--|--|-----------|-------------------|--------------------------|------------------------------------|------------|-----|---|
| △ Logged in as k.kennon Log out | ☐ Record Home Page | | | | | | | |
| ■ My Projects ■ REDCap Messenger | © Record "00001-0001" is a new Participant Identification Number (PIN):. To create the record and begin entering data for it, | | | | | | | |
| Project Home and Design | click any gray status icon below. | | | | | | | |
| ♠ Project Home · ≅ Project Setup ✔ Designer ☑ Dictionary ☑ Codebook ⑤ Project status: Development | The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the Define My Events page. Legend for status icons: Incomplete Incomplete (no data saved) Univerified My Events page. Complete My Events page. | | | ≘) | | cre gr | | |
| Data Collection | Define My Events page. Complete Many statuses (mixed) | | | | | | | |
| Record Status Dashboard - View data collection status of all records | NEW Participant Identification Number (PIN): 00001-0001 | | | | | | | |
| Add / Edit Records - Create new records or edit/view existing ones Participant Identification Number (PIN): 00001-0001 Select other record | Data Collection Instrument | Admission | Additiona Days | 1) Click here (<i>F</i> | 1) Click here (<i>Participant</i> | | | |
| | Participant Identification Number Pin | 0 4 | | Identification Nun | nher (P | 2/N/)-) +o | | |
| | Data Platform Terms Of Submission | | | | | | | |
| Applications | Clinical Inclusion Criteria | 0 | | open the page and | verity | the da | ata | |
| Alerts & Notifications Calendar | Demographics | 0 | | | | | | İ |
| Data Exports, Reports, and Stats | Date Of Onset And Admission Vital Signs | | | | | | | |
| Data Import Tool Data Comparison Tool Logging Field Comment Log File Repository User Rights and ➡ DAGs Customize & Manage Locking/E-signatures Data Quality API and ■ API Playground | Comorbidities | 0 | | | | | | |
| | Pre Admission And Chronic Medication | 0 | | | | | | |
| | Signs And Symptoms On Admission | 0 | | | | | | |
| | Medication | 0 | | | | | | |
| | Supportive Care | 0 | | | | | | |
| | Laboratory Results On Admission | 0 | | | | | | |
| | Daily Vital Signs | | 0 | | | | | |
| REDCap Mobile App | Daily Clinical Features | | | | | | | |
| Help & Information | Daily Laboratory Results | | | | | | | |
| • Help & FAO | Daily Medication | | | | | | | |
| ☐ Video Tutorials | Daily Supportive Care | | | | | | | |
| | Diagnostic Pathogen Testing | | | | | | | |
| | Complications | | | | | | | |
| | Overall Medication | | | O | | | | |
| | Overall Supportive Care | | | | | | | |
| | Outcome | | | | | | | |

Note: The new record is <u>not</u> created until you click on one of the gray status icons below and enter data in one of the forms.

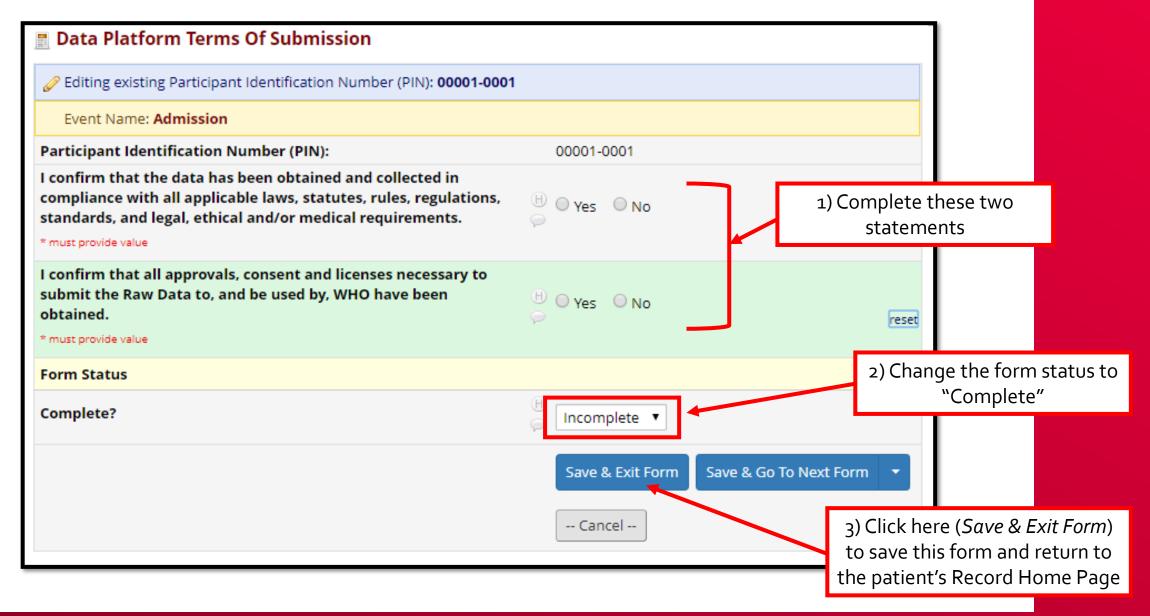
Adding a New Participant Record – Step 3





Completing the Terms of Submission (ToS) [WHO Project]





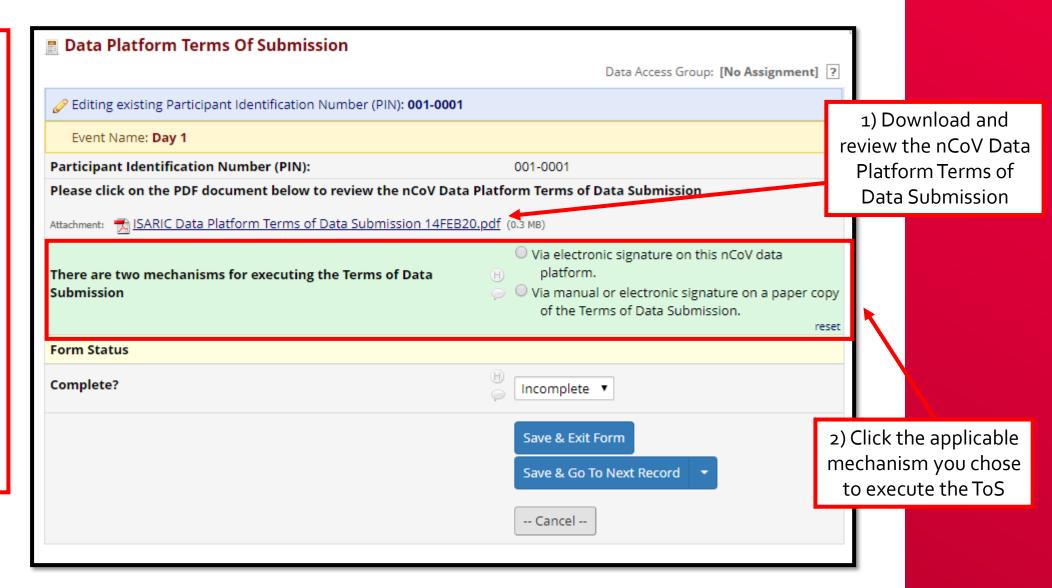
Completing the Terms of Submission (ToS) [ISARIC Project]



Note: The first time you add a patient to the database you will have to complete the Data Platform Terms of Submission.

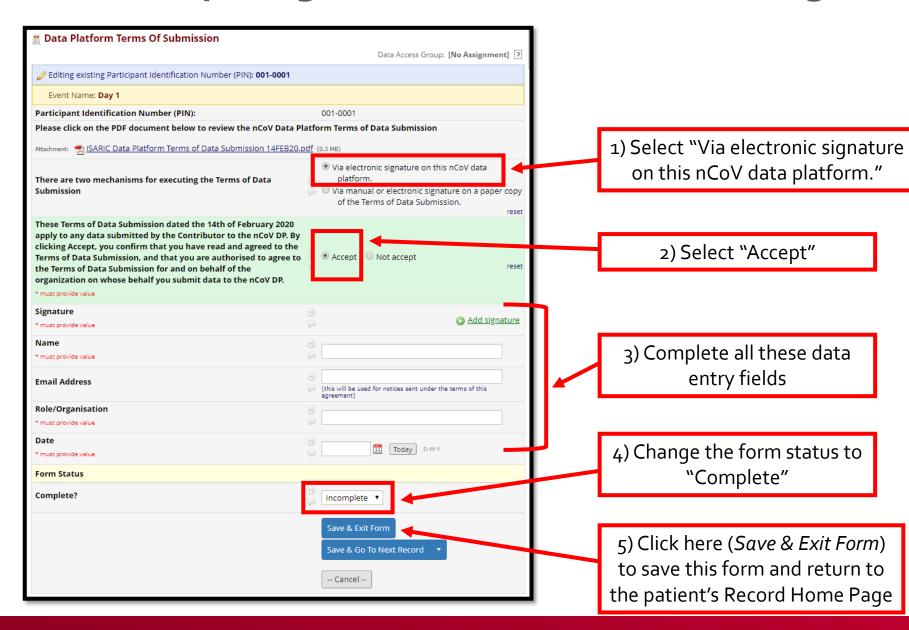
You will only have to complete this form ONCE (i.e. for the first patient and not for any following patients).

The Data Platform
Terms of Submission
Page will disappear
after you complete this
form the first time.



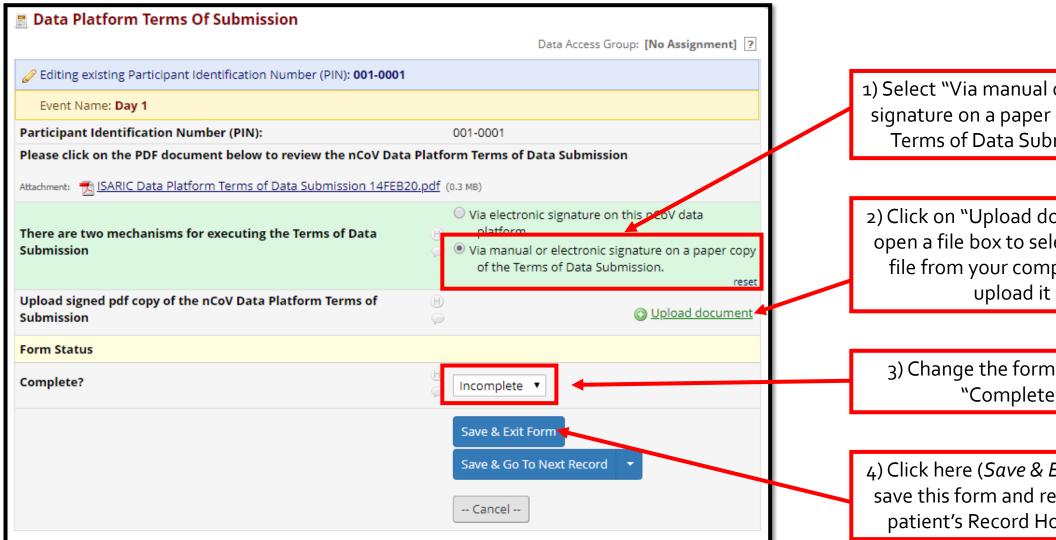
Completing the ISARICToS – Electronic Signature





Completing the ISARICToS – Paper Copy





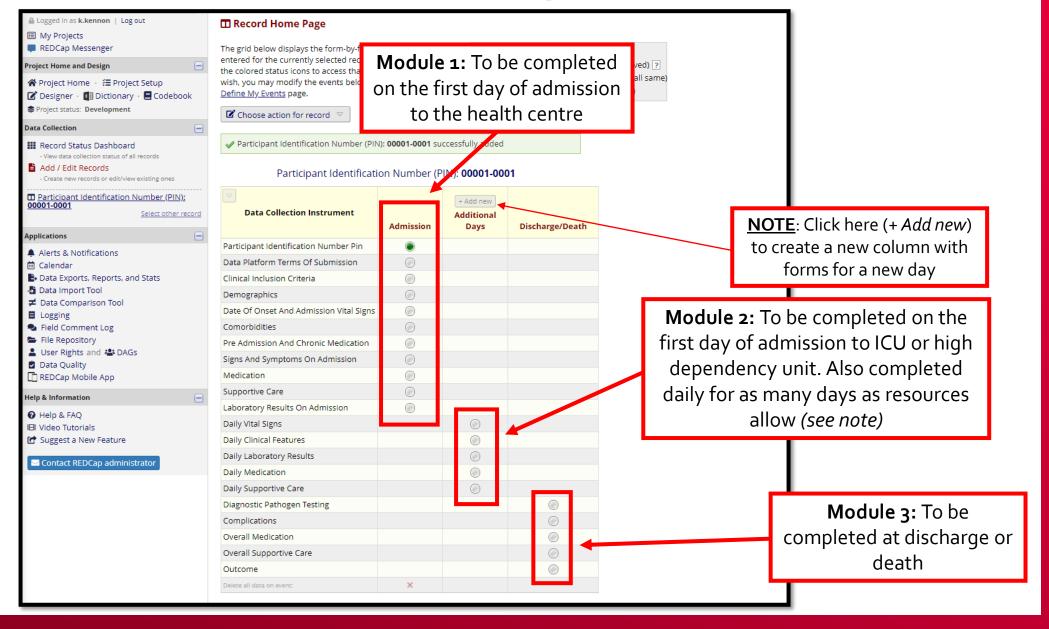
1) Select "Via manual or electronic signature on a paper copy of the Terms of Data Submission."

2) Click on "Upload document" to open a file box to select the ToS file from your computer and

3) Change the form status to "Complete"

4) Click here (Save & Exit Form) to save this form and return to the patient's Record Home Page

Data Entry Schedule





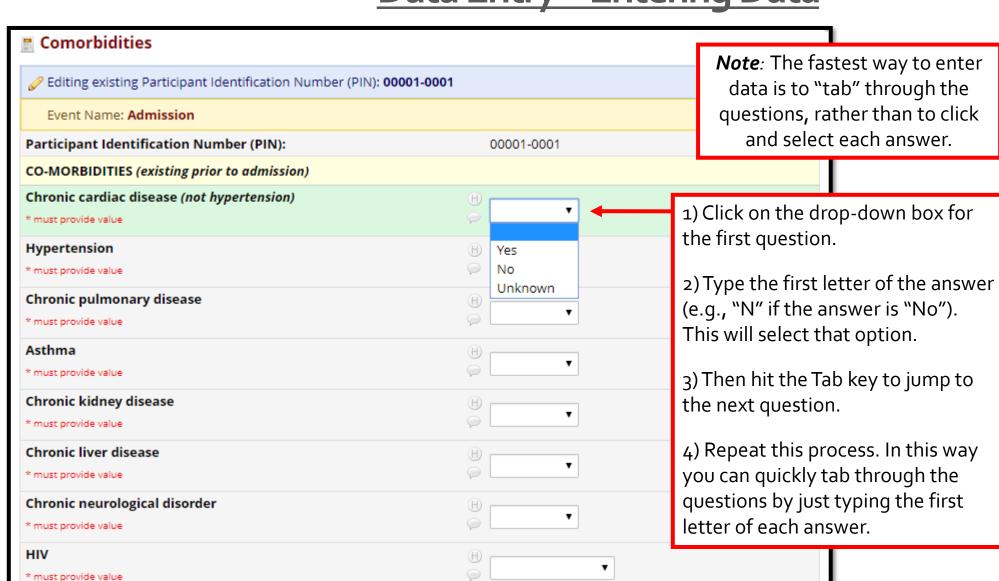
Data Entry Schedule – Additional Modules



| Logged in as k.kennon Log out My Projects | ☐ Record Home Page | | | | | |
|---|--|---|-----------------------------|-----------------|---|--|
| REDCap Messenger | | The grid below displays the form-by-form progress of data Legend for status icons: | | | | |
| Project Home and Design | entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the Define My Events page. © Incomplete Incomplete (no data saved) ? Output (Incomplete Incomplete) Many statuses (all same) (Incomplete) Many statuses (mixed) | | | | | |
| ☆ Project Home · 爰 Project Setup☑ Designer · ☑ Dictionary · ☐ Codebook | | | | - | - | |
| Project status: Development | ☑ Choose action for record ▽ | | | | | |
| Data Collection | | | | | | |
| Record Status Dashboard - View data collection status of all records | | l): 00001-0001 su | ccessfully added | | | |
| Add / Edit Records - Create new records or edit/view existing ones | Participant Identificati | Participant Identification Number (PIN): 00001-0001 | | | | |
| ☐ Participant Identification Number (PIN): 00001-0001 Select other recon | Data Collection Instrument | Admission | + Add new Additional Days | Discharge/Death | | |
| | Participant Identification Number Pin | <u></u> | | | | |
| Alerts & Notifications Calendar | Data Platform Terms Of Submission | | | | I | |
| Data Exports, Reports, and Stats | Clinical Inclusion Criteria | | | | I | |
| - Data Import Tool | Demographics | 0 | | | I | |
| ≠ Data Comparison Tool | Date Of Onset And Admission Vital Signs | 0 | | | I | |
| Logging Field Comment Log | Comorbidities | 0 | | | I | |
| File Repository | Pre Admission And Chronic Medication | 0 | | | I | |
| ■ User Rights and ♣ DAGs■ Data Quality | Signs And Symptoms On Admission | 0 | | | | |
| REDCap Mobile App | Medication | | | | I | |
| · · · · · · · · · · · · · · · · · · · | Supportive Care | | | | I | |
| | Laboratory Results On Admission | | | | | |
| Help & FAQ Help Wideo Tutorials Help Wideo Tutorials | Daily Vital Signs | | 0 | | | |
| Suggest a New Feature | Daily Clinical Features | | 0 | | | |
| | Daily Laboratory Results | | 0 | | | |
| E-contact Neb cap administrator | Daily Medication | | | | | |
| | Daily Supportive Care | | | | | |
| | Diagnostic Pathogen Testing | | | | | |
| | Complications | | | 0 | | |
| | Overall Medication | | | | | |
| | Overall Supportive Care | | | 0 | | |
| | Outcome | | | | | |
| | Delete all data on event: | × | | | | |

NOTE: Additional modules will be added to this CRF. They will appear here in the database. They are not required and should only be completed if you collect data for these modules.

Data Entry – Entering Data





Data Entry – Saving a Form



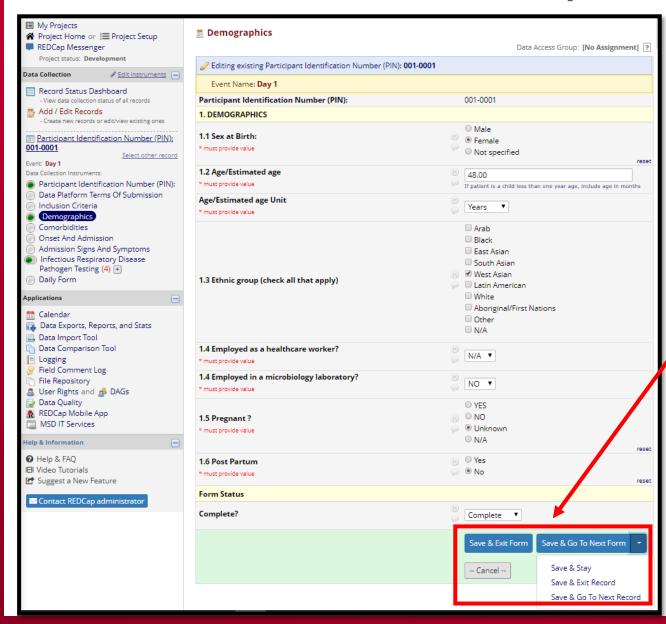
Demographics Data Access Group: [No Assignment] ? Editing existing Participant Identification Number (PIN): 001-0001 Event Name: Day 1 Participant Identification Number (PIN): 001-0001 1. DEMOGRAPHICS Male 1.1 Sex at Birth: Female * must provide value Not specified 1) Complete all data 1.2 Age/Estimated age entry fields: * must provide value If patient is a child less than one year age, include age in months Age/Estimated age Unit Years * must provide value Arab ☐ Black East Asian South Asian 🗎 🗹 West Asian 1.3 Ethnic group (check all that apply) Latin American White Aboriginal/First Nations Other ■ N/A 1.4 Employed as a healthcare worker? N/A ▼ * must provide value 1.4 Employed in a microbiology laboratory? NO ▼ YES 2) Change the form status to ⊕ NO Unknown "Complete" O N/A reset 3) Click here (Save & ⊕ © Yes No must provide value Exit Form) to save the reset Form Status form and exit back to Complete? Complete ▼ the Record Home Save & Exit Form Page for this patient. -- Cancel --

Note: There are other options to save (see next page for descriptions)

m Record Home Page grid below displays the form-by-form progress of data Legend for status icons ntered for the currently selected record. You may click on ncomplete Incom the colored status icons to access that form/event. If you Unverified (a) (a) wish, you may modify the events below by navigating to the Complete Many Define My Events page. ☑ Choose action for record ▽ Participant Identification Number (PIN): 001-0001 Data Collection Instrumen Data Platform Terms Of Submission Inclusion Criteria Demographics Onset And Admission Admission Signs And Symptoms Infectious Respiratory Disease Diagnosis Infectious Respiratory Disease Pathogen Testing Complication

Data Entry – Saving a Form





There are different options for saving:

<u>Save & Exit Form</u> – click here to save your progress and go to the Record Home Page for this patient

<u>Save & GoTo Next Form</u> – click here to save your progress and go to the next data entry form (*Comorbidities*) for this patient

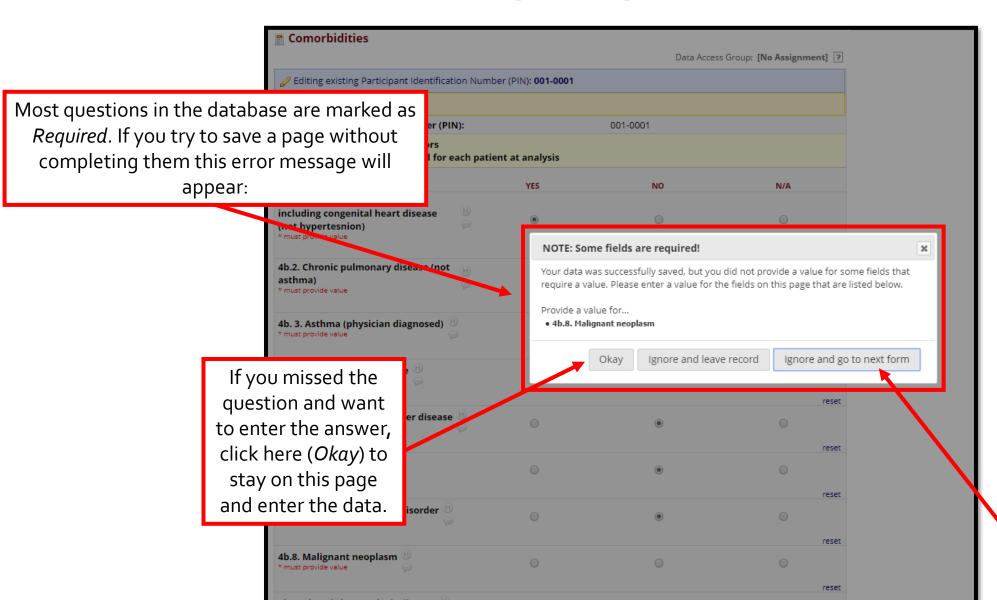
<u>Save & Stay</u> – click here to save your progress and stay on this form

<u>Save & Exit Record</u> – click here to save your progress and return to the Add/Edit Records homepage

<u>Save & GoTo Next Record</u> – click here to save your progress and go to the Record Home Page for the next patient (e.g., clicking this on the page for patient oo1-ooo1 will take you to the Record Home Page for patient oo1-ooo2) *If there is no other patient, this will return you to the current patient's Record Home Page

Data Entry – Required Questions

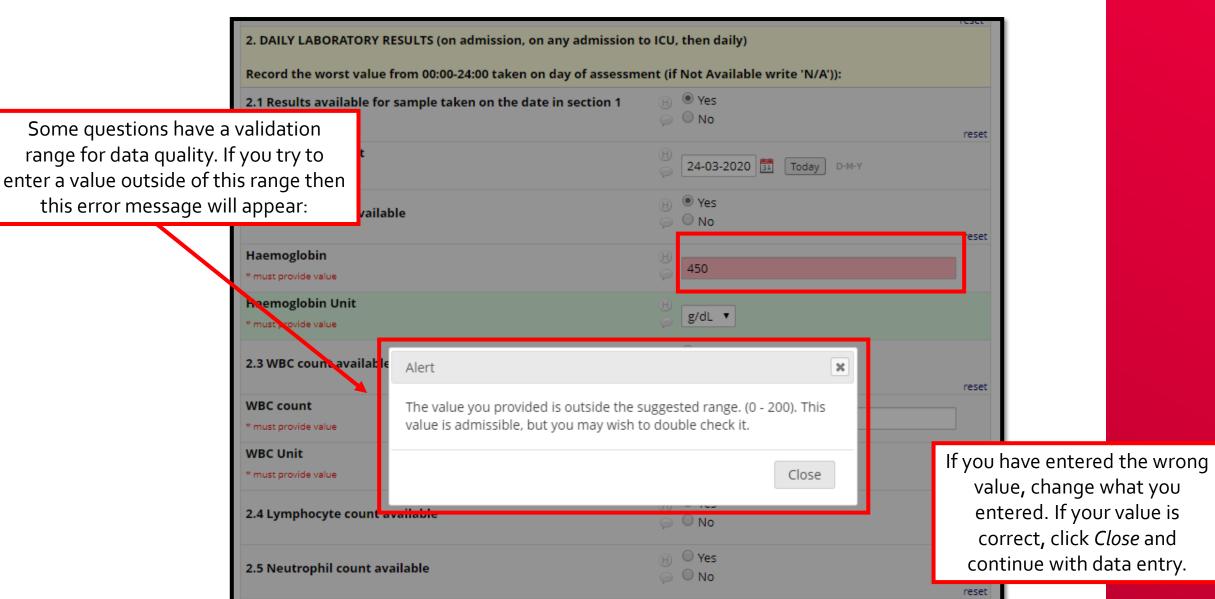




If you meant to leave the question blank, click here (Ignore and go to next form) to continue data entry.

Data Entry – Results Out of Range



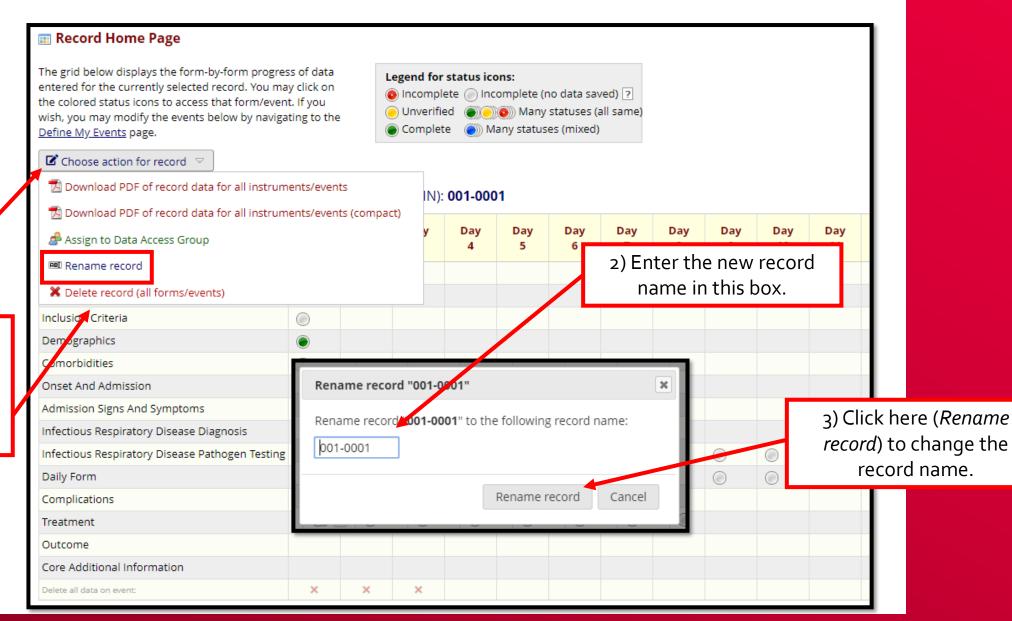


Data - Renaming a Record



You may sometimes need to rename a record

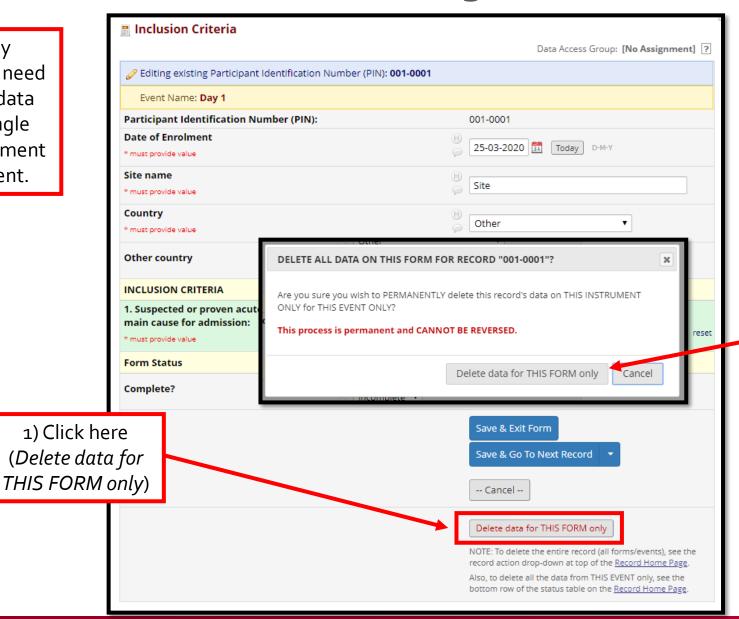
1) Click here (*Choose* action for record) to open a dropdown and then click here (*Rename record*).



<u>Data – Deleting Data (Form Level)</u>



You may sometimes need to delete data from a single form/instrument for a patient.



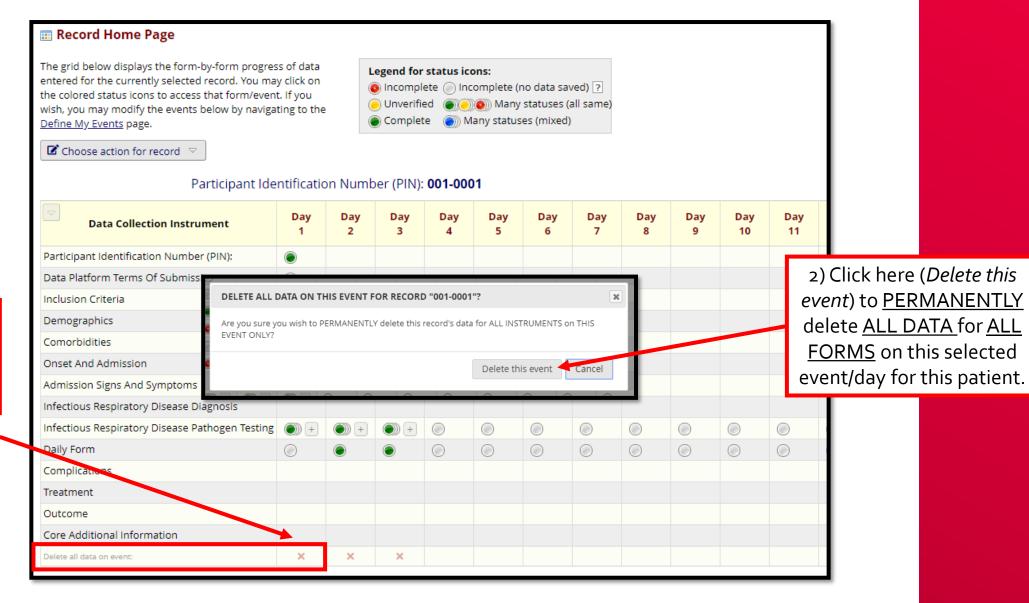
2) Click here (*Delete this* event) to <u>PERMANENTLY</u> delete <u>ALL DATA</u> on this form for this patient.

Data – Deleting Data (Event Level)



You may sometimes need to delete data from an entire event/day for a patient.

> Click here on the X for the relevant event/day:

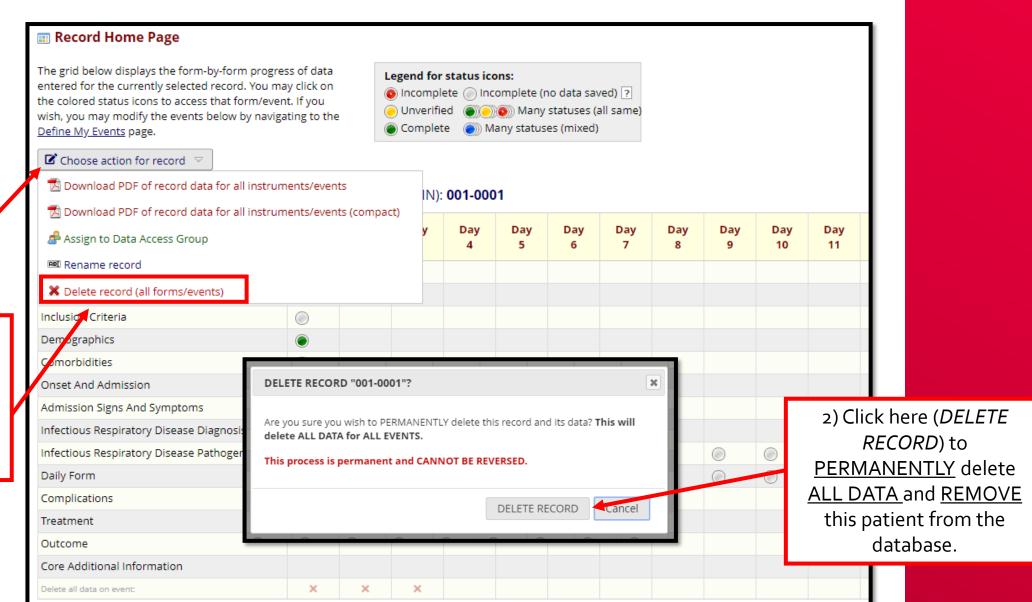


<u>Data – Deleting Data (Patient Level)</u>



You may sometimes need to delete ALL data for a patient and remove them from the database.

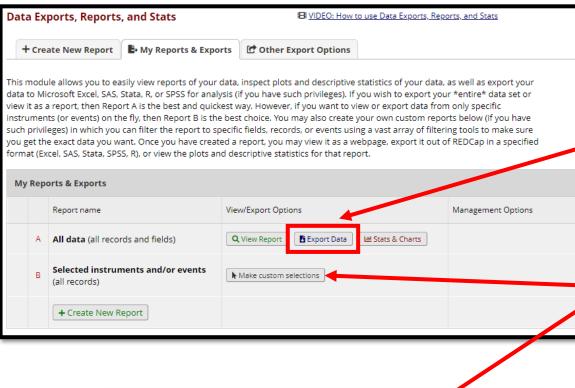
1) Click here (Choose action for record) to open a dropdown and then click here (Delete record (all forms/events)).



Data – Exporting Data







There are different options for exporting the data:

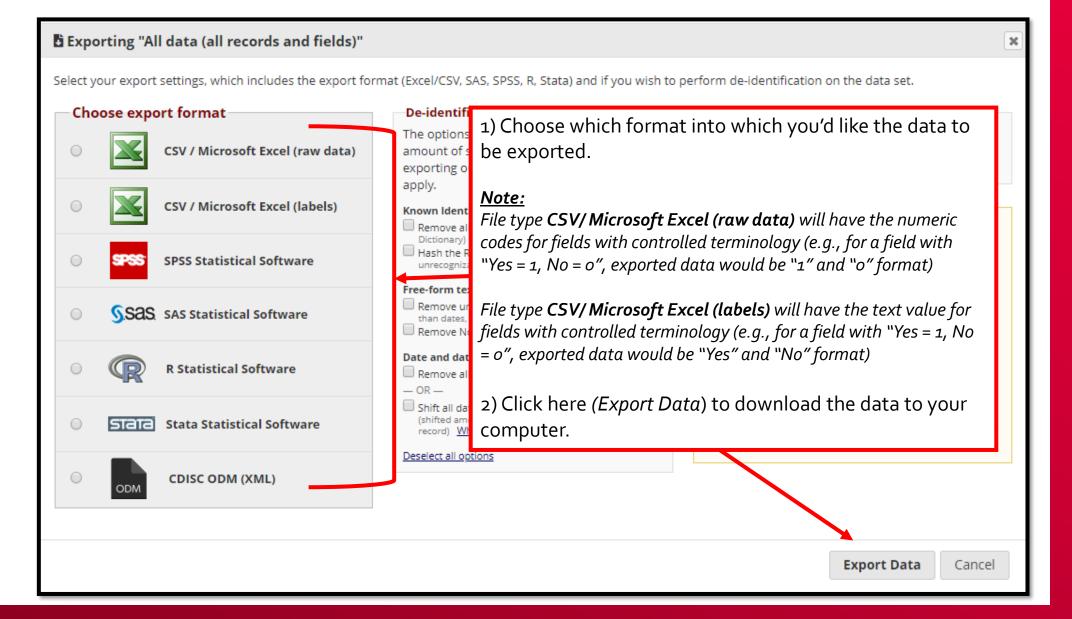
Export Data (All data) – click here export all the variables for all events (days) for all patients in a format you choose (see next page)

<u>Export Data (Selected instruments</u> <u>and/or events</u>) – click here to chose which instruments (pages) and which events (days) you want to export for **all** patients in a format you choose (see next page)

| В | Selected instruments and/or events (all records) | Select one or more instrumen records. Instruments All instruments AND Participant Identificat Data Platform Terms | Events | | |
|---|--|---|--|--|--|
| | | Inclusion Criteria Demographics Q View Report - OR - + Create report based on the | Day 3 Day 4 Tata Stats & Charts The selections above | | |

Data – Data Export Formats





Data Security – Logging Out When Complete





Always log out using by clicking here (*Log out*) after completing your tasks.

Note: Your session will time out after 60 minutes of inactivity, requiring you to log in again to continue with tasks.

Additional Resources



- Where can I get REDCap training?
 - REDCap offers detailed video training online
 - Videos are available at: https://projectredcap.org/resources/videos/



- What if I need further information or support?
 - Please direct all REDCap questions to ncov@isaric.org
 - Please direct all Protocol and Study related questions to ncov@isaric.org











BILL & MELINDA GATES foundation

Partners supporting research preparedness and response





