

UNIVERSITY OF TORONTO
CARDIOVASCULAR DATA MANAGEMENT CENTRE

USER MANUAL
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Background

Improving care for patients with cardiovascular disease at multiple hospitals within the University of Toronto is dependent upon the extraction of knowledge from clinical activities. We can improve the efficiency and productivity of the clinical and research missions by pooling data from multiple sites within an easily accessible management structure which facilitates quality improvement activity and clinical research for contributing members. The purpose of this document is to delineate the standard manual of operations of cardiovascular data management centre (CVDMC) which is created to server the contributing members for the cardiovascular care community within the University of Toronto.

The global vision of the CVDMC is to create a collaborative community of clinicians and researchers across the University united by a common interest in cardiovascular disease and a dedication to extracting new knowledge from our clinical and scientific activities. This collaborative community will be defined as 'the membership'. The academic centerpiece of this community will be the CVDMC. The critical ingredient is a 'Common Database' of the cardiovascular data which can be divided into two general streams: the establishment of a registry for quality improvement (QI) and the establishment of a mechanism to facilitate clinical research activity. The merged database will, therefore, serve two separate but complimentary purposes. The creation and management of the Common Database will be orchestrated by the CVDMC.

Project general description

The primary collection of personal health information (PHI) by the CVDMC is for clinical care purposes. Information is collected directly from the patient medical records. The data is subsequently de-identified at the collection site and disclosed to the CVDMC in a de-identified format for research and/or quality assurance purposes.

Objectives

1. Registry data: Provide easily accessible QI reporting for clinical groups contributing data to the CVDMC
 - a. Reports will be available to each hospital chief, each faculty participant, and the division chair using appropriate privacy guideline established by the CVDMC oversight board.
 - b. Use of registry data will allow freely available automated risk-adjusted and risk-stratified comparisons with aggregated data from the Division.
2. Clinical research: Facilitate University-wide clinical research
 - a. Respond to database queries from any member contributing to the CVDMC database
 - b. Manage expansion of the database as required with new layers of data fields to facilitate clinical research projects
 - c. Provide statistical support, assistance with study design, and publication support

Parts of the UTorCVDb User Manual

This user manual is divided into the following sections:

- 1) Section 1: Applications and access control
- 2) Section 2: Database structure
- 3) Section 3: Data entry

Section 1: Applications and access control

The instructions to fill out the CVDMC applications to access databases are described in sections:

- Section 1.1: User account request (for new users only)
- Section 1.2: Requesting database/module access
- Section 1.3: Requesting database changes
- Section 1.4: Requesting password recovery
- Section 1.5: Requesting password reset
- Section 1.6: User account deletion

User accounts to both the ONCOA software and the REDCap web interface are provided only on a need-to-know basis and level of access (as described in the security matrix below) is tailored to the role and function of each applicant. As part of the user account application process, a justification of the level of access requested will be required.

CVDMC security matrix (next page):

	RC Backend*	ONCOA Backend*	RC Data entry	RC record deletion	ONCOA Data entry	RC record locking	RC record unlocking	RC report generation	RC data export	ONCOA data export	Rationale for access
CVDMC											
Directors (executive and managing)	3	3	3	3	3	3	3	3	3	3	Full administrative rights to oversee all the processes the CVDMC staffs are involved in. Once a record is locked, only CVDMC directors can unlock it for further data entry/edits. When required, decryption of IDs will be done.
Database managers/programmers	3	3	3	3	3	3	0	3	3	0	Database modifications and user account setup would be done through the backend panels. Access to data entry and export is required to generate reports for QI & for analysis purposes.
Data clerks/ administrative assistants	0	0	3	3	3	3	0	0	0	0	Data entry and record deletion rights to validate existing data. Can lock records following data validation. This level of access will allow CVDMC admin assistants to keep track of all database changes and also to ensure data quality.
Contributing sites											
Chief of Division	0	0	2	2	2	0	0	2	2	0	Site-level administrative rights to oversee the CVDMC databases. Data export and report generation functionality for QI & site-level data analysis.
Physicians	0	0	2	0	2	0	0	1	C	0	View, create or edit records and report generation to facilitate the physician-level data entry. Prior approval required for data export.
Local CVDMC administrator	0	0	2	2	2	0	0	2	C	0	Report generation for the site-level QI work. Can delete site-specific patient data. Prior approval required for data export.
Data clerks/ administrative assistants	0	0	2	0	2	0	0	0	0	0	Access limited to data entry (view, create & edit records) only.

*Database setup and modifications, user rights; 3=global; 2= site-level; 1=physician-level; C=CVDMC approval required

Section 1.1: Requesting a UTorCVDb REDCap user account

Form required:	UTorCVDb user account request (Format: <i>fillable pdf</i>)
Needed for	Currently not holding a REDCap account but needs potential access to University of Toronto cardiovascular database (UTorCVDb)
Form fields (11)	<ol style="list-style-type: none"> 1) First name 2) Last name 3) Institution (select one) <ul style="list-style-type: none"> • Sunnybrook Hospital • St. Michael's Hospital • The Hospital for Sick Children • Toronto General Hospital 4) Clinical division <ul style="list-style-type: none"> • Cardiology • Cardiovascular surgery • Critical care medicine – cardiac • Diagnostic image • Other (enter text) 5) Position (select one or type in) 6) Employee number 7) Module request and level of access within the CVDMC (Select all that apply) <ul style="list-style-type: none"> • Navigation • STS cardiac surgery • Cardiology (ECHO) • Hearts & Minds Clinic • Biobank 8) Do you have an existing REDCap account? 9) Requestor's name (printed) 10) Requestor's signature 11) Requestor's email This email will be used for all your future CVDMC correspondence 12) Date of signature (requestor) 13) Division chief's signature 14) Date of signature (chief of division)
Next steps	<ul style="list-style-type: none"> • Please scan and email the completed form to CVDMC.requests@sickkids.ca • A validation email with a temporary password will be sent to the email address you provided. • Click on the link in the validation email and log in using the user name and the temporary password provided in the email. • Once you log in using your temporary password, set up your new password and security question. • Please log out and log back in using your new password.

	<ul style="list-style-type: none"> Your account request will not be complete until you click on the link provided in the validation email. For module access, CVDMC will verify the request and the requestor will get another email (one email for each module) as below: <i>"You have been given access to the REDCap project named "UTorCVDb - xxxx ". Using your user name "aaaa.aaaa", you may log in to the project using the link below"</i>
Load	Approximate time to complete the application for the user: 5 minutes
Note	Please allow CVDMC to create the account with the information you provided in the form. The new user will get the validation email within 2 business days.

Please find the screenshot of the form below:

CARDIOVASCULAR DATA MANAGEMENT CENTRE
User Account Request Form
 Form version date: April 17, 2013

Requestor's Information

First name: Last name:
 Institution: Clinical Division:
 Position: Employee Number:

Module request and level of access within the CVDMC (select all that apply)

CVDMC Modules:	Access level(s):		
Navigation	Read <input checked="" type="checkbox"/>	Write <input checked="" type="checkbox"/>	Export <input checked="" type="checkbox"/>
STS Cardiac Surgery	Read <input type="checkbox"/>	Write <input type="checkbox"/>	Export <input type="checkbox"/>
Cardiology (ECHO)	Read <input type="checkbox"/>	Write <input type="checkbox"/>	Export <input type="checkbox"/>
Hearts & Minds Clinic (Toronto General Hospital only)	Read <input type="checkbox"/>	Write <input type="checkbox"/>	Export <input type="checkbox"/>
Blobank	Read <input type="checkbox"/>	Write <input type="checkbox"/>	Export <input type="checkbox"/>

Do you have an existing REDCap account? Yes/No
 If yes, please indicate your username

Requestor's Signature

By signing below I agree that, in accordance with the Personal Health Information Protection Act of Ontario, I am responsible for adhering to all conditions and restrictions imposed by the CVDMC and local policies governing the use, security, disclosure, return and disposal of any personal health information. I am also responsible for reporting immediately any privacy breaches to the CVDMC and appropriate local REB Chair. I will ensure that the personal health information is used, only as necessary, to fulfill the specific objectives imposed by the CVDMC.

Name (print) Signature
 Email Date

Signature of Chief of Clinical Division is required

Signature Date

Please fill out all necessary fields and provide the required signatures. You can scan, upload and e-mail the completed User Account Request form to CVDMC.requests@sickkids.ca or you can fax the completed form to (1) 416-813-8261 ATTENTION: CVDMC. If you are submitting by fax, contact the CVDMC within 48 hours of submission at 1 (416) 813-7654 x.228304. You may download this form at www.cvdmc.utoronto.ca

Approval status for user account request (to be completed by CVDMC administrator only)

Signature of CVDMC Managing or Executive Director Date

CVDMC User Account Request Form version 2.3 April 2013

Section 1- Figure 1.1.1: CVDMC user account request form



Section 1.2: Requesting database/module access

Form required:	UTorCVDb database access request (Form format: <i>fillable pdf</i>)
Requirements	You must have a REDCap user account to request for access to databases. If you don't have any, please see section A to apply for a REDCap user account.
Form fields (3)	<ol style="list-style-type: none"> 1) REDCap user email Please type in the email associated with your REDCap account. This is required for CVDMC to provide you access to the database. 2) Name of the databases (check all that apply) Please select the databases you need access to: <ul style="list-style-type: none"> • UTorCVDb main • Biobank • 22q11DS 3) Name/signature of the chief/PI Please type in the name of the chief/PI. This is required for the CVDMC to verify the user has proper authorization from the chief to access the database.
Next steps	<ul style="list-style-type: none"> • Please email the completed form to CVDMC.requests@sickkids.ca • Once CVDMC has verified the request, the user will get an email as below: <i>"You have been given access to the REDCap project named "UTorCVDb - xxxx ". Using your user name "aaaa.aaaa", you may log in to the project using the link below."</i>
Load	Approximate time to complete the application for the user: 2 minutes
Note	Please allow CVDMC to verify the request. Verification can take up to 1 business day.

Section 1.3: Requesting database changes (REDCap online)

Form required:	UTorCVDb database field change request (Form format: <i>REDCap online</i>)
Requirements	You must have a REDCap user account to request for any database changes. If you don't have any, please see section A to apply for a REDCap user account.
Fields	Please follow the link below to submit an online request:
Next steps	<ul style="list-style-type: none"> • Please submit the completed form to CVDMC.requests@sickkids.ca • Acknowledgement of receipt will be emailed from CVDMC • Upon verification, CVDMC will email you with the update
Load	Approximate time to complete the application for the user: 4 minutes
Note	Please allow CVDMC to verify the change. Verification can take up to 5 business days.

Section 1.4: Requesting password recovery

In case of a forgotten password, please follow the steps below to reset the password for your REDCap account. Beside the “log in” tab on the REDCap home page, click on “forgot your password?” to display the password recovery windows as below. Please check your email after a minute or two to get the password. A paper application is not required since the password reset is processed online.

REDCap Password Recovery

You may use this page to reset your REDCap password. You must first provide your REDCap username, and once it is verified as an authentic REDCap account, you will then need to answer a security question that you have previously set for yourself. If you answer the security question correctly, your password will be reset and an email will be sent to you containing a temporary password to access your account.

Username:

REDCap Password Recovery

You may use this page to reset your REDCap password. You must first provide your REDCap username, and once it is verified as an authentic REDCap account, you will then need to answer a security question that you have previously set for yourself. If you answer the security question correctly, your password will be reset and an email will be sent to you containing a temporary password to access your account.

Please answer the security question below.

In what city or town was your first job?

REDCap Password Recovery

You may use this page to reset your REDCap password. You must first provide your REDCap username, and once it is verified as an authentic REDCap account, you will then need to answer a security question that you have previously set for yourself. If you answer the security question correctly, your password will be reset and an email will be sent to you containing a temporary password to access your account.

✓ **SUCCESS!** You correctly answered the security question. An email containing your new temporary password has just been sent to the email address associated with the REDCap username "tanveer.collins".

(Please do not refresh this page, as it will re-send the email with a new password.)

Section 1- Figure 1.4.1: REDCap password recovery (using security question)

[This message was automatically generated by REDCap]

Your password has been reset for the following application:

REDCap - <https://redcapexternal.research.sickkids.ca/>

Use the following information to log in:

Username: tanveer.collins
Password: f0ea79

You will be prompted to change your password the next time you log in. If you have any questions, please contact ResearchHelpDesk at ResearchHelpDesk@sickkids.ca.

Section 1- Figure 1.4.2: REDCap password recovery – temporary password in email

Set Your Password

Your password has not been set yet or has been reset. You will need to set your password here to whatever value you wish. Please enter your desired password below and click the 'Submit' button. Once your password has been set, you may use it with your user name whenever you log in to any REDCap project. Please make sure that you write down or remember your new password for future use. The password must contain only letters, numbers, and underscores, and it must consist of at least one lower-case letter, one upper-case letter, and one number.

Username:	<input type="text" value="tanveer.collins"/>
Password:	<input type="password"/>
Re-type password:	<input type="password"/>

Password Changed!

Your password has now been changed. You may now click the button below to navigate back to REDCap.

Section 1- Figure 1.4.3: REDCap password recovery – logging back following a password recovery

Section 1.5: Requesting password reset

Password reset for REDCap account is left to user's discretion. REDCap password won't expire except in circumstances where the account may be deleted by CVDMC administrators (see section 1.6 for details). CVDMC recommends password reset at regular intervals to ensure user account security. In order to edit your profile, navigate to the "my profile" window from user home page and click "reset password" to find the following pop-up screen (see below). Password must be between 10-15 characters long and contain at least one lower-case letter, one upper-case letter and one number.

Edit Your User Profile

If you wish, you may edit your User Profile information below. This information will not be given out to anyone but will be used to help us better keep track of who is using REDCap and also in case you need to be contacted regarding your access to REDCap.

Basic Information

First name:

Last name:

Primary email:

Additional Options

While your primary email address is used for receiving emails and notifications from REDCap, your secondary and tertiary email addresses can only be used when sending out emails from REDCap (e.g. sending survey invitations), in which they appear as the 'From' address in the email.

Secondary email:

Tertiary email: [Remove](#)

RESET YOUR PASSWORD? ✕

Do you wish to reset your password for logging in to REDCap? If so, you will be asked to set your new password now.

Password Changed!

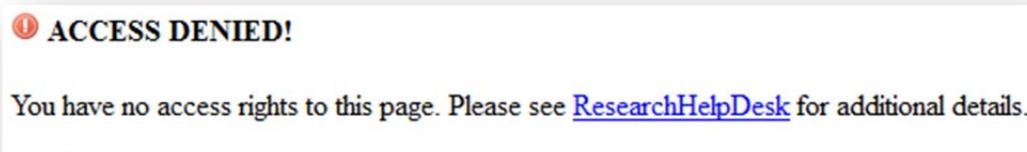
Your password has now been changed. You may now click the button below to navigate back to REDCap.

Section 1- Figure 1.5.1: REDCap password reset

Section 1.6: User account deletion and access control

UTorCVDb user access will be reviewed by the CVDMC every year. Furthermore, user account can be changes or deleted anytime when there is a request from Chief of division or local CVDMC administrators. Upon receiving the email for a request to change the level of access or delete a user account, CVDMC managing director will complete the process in the two steps mentioned below:

- 1) **UTorCV databases access:** CVDMC managing director will prohibit access to the databases within 1 business day of receiving the notification to delete the user account. Access level change requests will be processed within the same time frame. The user without the access to the UTorCV databases will come across the following message:



Section 1- Figure 1.6.1: Online message when user has no access to REDCap databases

- 2) **SickKids REDCap account access:** User's SickKids REDCap account will be deleted, provided the user does not require access to any other databases hosted at the SickKids server. In this case, the email with the request will be forwarded to the SickKids REDCap administrators. Following message will appear when the user with no SickKids REDCap account will try to access the database link:



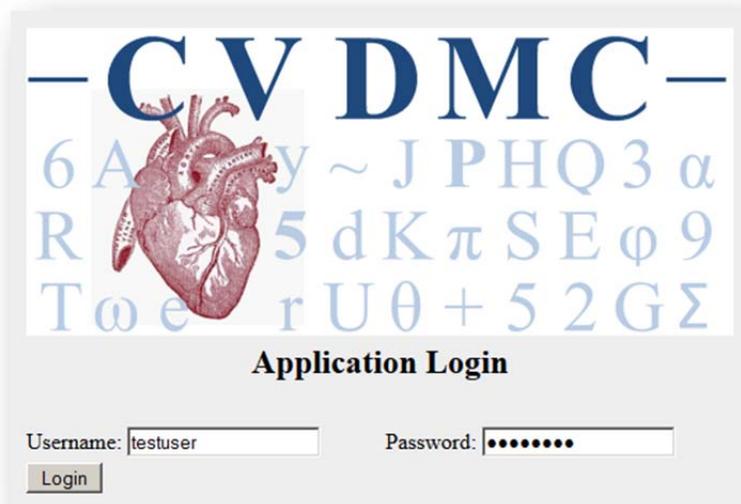
Section 1- Figure 1.6.2: Online message when user has no or invalid REDCap account

Section 2: Database structure and walkthrough

Section 2.1: Patient identifier encryption using ONCOA

Patient identifier encryption software (ONCOA) will allow users to be able to work on specific patient data cross sites without the issues of privacy or PHI arising, as once the unique ID for patients are created, no PHI data is ever transmitted across networks, removing a possible impediment with working on specific patient records.

When you enter whatever URL you've decided on, on first load, you'll be presented with a screen asking you for a username and password. If you don't have an ONCOA user name, please ask your manager. Verify that you have it before continuing, as it is not the same as your REDCap login. See figure below:



Section 2- Figure 2.1.2: ONCOA login page

Here you would enter the ONCOA login that was provided to you, verifying that you have the username and password typed in correctly, and the caps lock not turned on. Once finished, click Login to submit your username and password into the ONCOA software for validation.

Upon successful log-in, you'll see the following screen as shown in Figure 2.1.2.



Section 2- Figure 2.1.2: ONCOA main screen

On the main screen (see the figure 2.2.2 above), you will be able to search for data by the patients OHIP number, their MRN number, or their last name. You will need to enter data in the "Search by" field, along with what type of data you are searching for in the dropdown below. Not entering anything in the Search field, or not selecting an option in the Search By field will cause your form to fail on submission, highlighting what items were missing for easy identification. Verify that all fields have the correct values, and then try again.

If no error occurs submitting the aforementioned form, one of three actions will occur, depending on the result of the search.

- **No match could be found** – When searching for the particular patient OHIP number, MRN number, or last name, there was not a match. The application will route you to a form to enter the patient's data that you're searching for. See [Figure 2.1.3](#) for an example.
- **Multiple results were found** - When searching for the particular patient OHIP number, MRN number, or last name, multiple matches of what you were searching for were discovered. The application will route you to a screen where you can compare the discovered data, and click on the patient that matches the ones that you're searching for. See [Figure 2.1.4](#) for an example.

Note: If multiple results are found when searching for either an OHIP number or an MRN number, please contact either your manager or Cvdmc.requests@sickkids.ca immediately.

- **A matching record was found** - When searching for the particular patient OHIP number, MRN number, or last name, there was a match. The application will then route you to the main page of the navPanel module within REDCap. See [Figure 2.2.1](#) for an example.



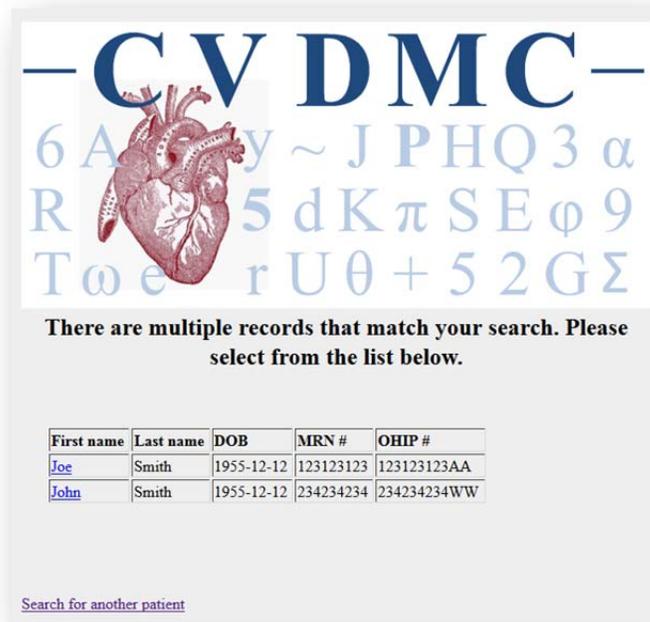
Enter a new patient

All fields are required unless otherwise indicated
 For out of province patients, if there is any indication that this patient has had a previous cardiac intervention at any other Toronto hospital, please contact CVDMC before creating a new ID.

OHIP: Leave blank if out of province
 MRN:
 Date of Birth: Dates in YYYY-MM-DD format
 First name:
 Last name:

Section 2- Figure 2.1.3: Entering a new patient record

Here you see the form to add a new patient data record into ONCOA. Please endeavor to enter as much information as possible, as it will aid positive identification if there are multiple records with similar matching fields (especially last name). Once complete, click on “Create ID” to have ONCOA validate the form, and if everything matches, the program will route you to the main page of the navPanel module within REDCap. See [Figure 2.1.4](#) for an example. If the OHIP or MRN number isn’t matching the specified format, or the date of birth isn’t in the specified format, the program will return with an error and ask you to try again.



Section 2- Figure 2.1.4: Selecting from multiple patient records

Here you see the form that if multiple matches were found, they will be displayed with all of their particular data in a chart form. This will allow you to make an easier identification of which record, if any, matches your current patient. If you see the record that matches your patient’s data, click on the link in their first name, and the application will route you to the main page of the navPanel module within REDCap. See [Figure 2.2.1](#) for an example. If you don’t see the record for your patient, click on “Search for another patient” and try searching using another item of that patients data.

Note: If multiple results are found when searching for either an OHIP number or an MRN number, please contact either your manager or Cvdmc.requests@sickkids.ca immediately.

This would bring us to the end of usage instructions for ONCOA.

Section 2.2: NavPanel

Before we begin:

- Do you have a REDCAP login? This would have been to you by SickKids (Cvdmc.requests@sickkids.ca) or by your manager. Verify that you have it before continuing, the module will be inaccessible without it.
- Do you have a valid ONCOA id? Normally this will be part of the URL that will take you to the patient’s navigational panel, but you will need to cut and paste it into the REDCap database more than once, so it’s good to make sure you have it.
- Records that you’ll need to enter into REDCap. Kind of a given, but it never hurts to verify.



- Verify that there is not a pop-up blocker in place for the browser that you are. If unsure, contact your IT department to verify.

With these items verified, check to see that you have the following screen displayed, as shown in Figure 2.2.1:



Section 2- Figure 2.2.1: REDCap login screen

Here you can see we have a sample user named creed ready to log in. Verify your username and password make sure that your caps lock isn't on, and once entered, hit log in. If unsuccessful it will ask you to try logging in again. Otherwise, here's screen you should now be seeing, as shown by Figure 2.2.2.



Section 2- Figure 2.2.2: Empty Patient Navigational Panel

There are a few things to view and verify here. First, make sure that you had a pop-up window appear, showing you the patient name and MRN#. If no popup appeared, you may have a popup blocker, and



may need to have IT resolve that issue. Once this is completed, we see the ID for the patient, along with four sections. These relate to the following types of data.

Surgical dB – This will display all surgical related information

Followup – This display the last contact with the patient, and their last clinical followup date

Biobank – This will show what specimen, if any, is available for this patient

Hearts & Minds – This applies for Heart & Minds clinic related activities and assessments

Let’s start with entering a surgical record for our patient. Click on the “Add new surgery for this patient” link. This will open a new tab which will load the corresponding REDCap database screen for adding a new surgical record, as showing in Figure 2.2.3.

The screenshot shows the REDCap 'SURGICAL DATABASE' form. At the top, there are fields for 'Record ID' (containing 'TEST') and 'Patient ID' (containing 'TEST'). Below this is a yellow header for 'SURGICAL DATABASE'. The form includes several sections with radio buttons for 'Yes' and 'No' and a 'reset' link:

- Date of operation:** A date picker set to 'Today' in Y-M-D format.
- Coronary artery bypass:** Radio buttons for 'Yes' and 'No'. A note says 'Yes > Complete form "OR: CABG"'. A 'reset' link is present.
- Valve surgery:** Radio buttons for 'Yes' and 'No'. A note says 'Yes > Provide answers to the 4 pop-fields below and Complete form "OR: Valve Surgery"'. A 'reset' link is present.
- VAD implanted or removed:** A dropdown menu set to 'No'. A note says 'Yes > Complete form "OR: Mech Cardiac Assist Devices"'. A 'reset' link is present.
- Other cardiac procedure (other than CABG and/or Valve procedures):** Radio buttons for 'Yes' and 'No'. A note says 'Yes: Procedures performed on the aorta, pulmonary arteries or veins and/or the intrathoracic inferior/superior vena cava. This may also include but is not limited to left ventricular aneurysm (LVA), acquired ventricular septal defect (VSD), surgical ventricular restoration (SVR), transmyocardial revascularization (TMR), cardiac trauma, pericardial window, cardiac tumor, or heart transplant. Yes > Complete form "OR: Other Cardiac Procedures"'. A 'reset' link is present.
- Other non-cardiac procedure:** Radio buttons for 'Yes' and 'No'. A note says 'Yes: if patient underwent surgical removal of plaque or carotid stenting or any procedures involving other vessels/thorax/pleura in conjunction with the primary surgical procedure. Yes > Complete form "OR: Other non-cardiac Procedures"'. A 'reset' link is present.

Section 2- Figure 2.2.3: Adding a new surgical record in REDCap

First, make sure that you enter the patient ID in the patient ID field from the navigation panel page. You'll find the ID at the top of the page (it's the super long string of numbers and letters). If you know how to copy and paste data in a browser, this will make it much easier to enter into the patient ID field.

Other than Patient ID, there are three fields that should be entered to have the surgical record in the navigation panel show correctly.

Hospital – The hospital that the surgery took place in

Date of surgery

Surgery type – This will be found below Date of operation in the Surgical Database section

Fill out as much as you can, and then hit save record to save your changes. You can then close this tab in your browser.

When you are back at the navigational panel, refresh the page (hitting f5 here will perform this function) and it will update all records for this patient. So for our example, you should see the following, as per figure 2.2.4.

NAVIGATION TO UtorCVDb MODULES

Patient ID: 54c867e6e4226bb840782bcf2868b05cd1e3cb5a3a7777080238d52e1634091c

Note to user: the information included in this navigation panel gives a summary of the data holding for this given patients across the CVDMC environment. Access to detailed data is restricted by institution. For queries regarding cross-institutional data access, please contact the CVDMC at cvdmc.requests@sickkids.ca or CVDMC help desk at 416-813-7654 x.228304

Logout

Link to UofTCVDb - SURGICAL dB ?

ID: 1 - 2013-09-27 - CABG, AV Replacement, MV Repair, Other TV, Other PV, Other Procedure - TGH

[Show all surgeries for this patient](#)

[Add new surgery for this patient](#)

Link to Followup ?

Date of last contact: 2013-09-02 [Update](#)

Note to users: date of last contact should be verified and updated if necessary every time the record is accessed.

Date of last clinical follow-up: 2013-09-09

[Add new clinical followup](#)

Link to Biobank ?

Sample available in biobank: Yes

[Sample Inventory Record](#)

Institution holding sample: TGH

Heart & Minds clinic record: Yes ?

[Hearts and Minds navigation panel](#)

CVDMC

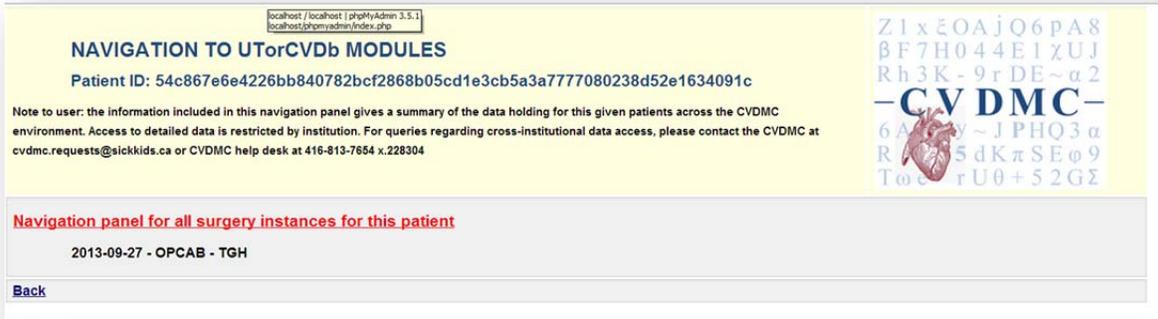
Section 2- Figure 2.2.4: NavPanel with surgical record

As you can see, the surgery that we entered is now showing, and quickly tells us that this patient has had a wide variety of surgeries performed at Toronto General Hospital on the 27th of September, 2013. If this user was a staff member of Toronto General, this data would show as a link where upon being clicked, would show the REDCap record for this surgery.

As the amount of entries rise, the main navigational panel will limit the surgeries displayed to only the most recent three. So how do we view all of the surgeries for this patient if they have more than three?



If you look at Figure 2.2.4, you'll see a new link has appeared named "Show all surgeries for this patient". Click on this link and the following screen will appear which will look like the one shown in Figure 2.2.5.



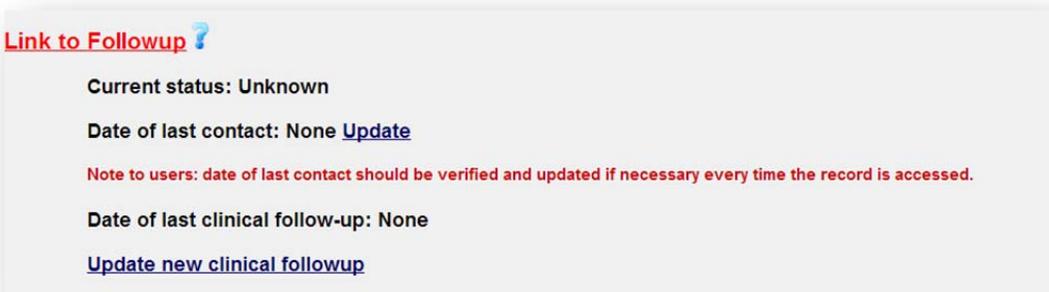
Section 2- Figure 2.2.5: Show all surgeries for this patient

While only one shows in this example, if this patient had multiple surgeries, they would all be listed chronologically by date from newest to oldest.

Next we need to update the follow-up information for this patient, as an interaction has occurred between the patient and his doctor and/or surgeon.

Navigation to the Follow-up database

If you have access to this module, it will be visible after the surgery module on the navigational panel, and will look like this.



Section 2- Figure 2.2.6 Followup module with no data entered

Before performing any operations with this module verify that you have the following data, as all three fields will be required.

- The patients current status (aka are they still alive? Are they dead?)



- What was the date that the patient was last contacted?
- What was the date of their last clinical follow-up?

Once all three of these data points have been verified, click on update to proceed to the REDCap screen where you will enter the patients follow-up details. Make sure to copy and paste the Patient ID from the top of the page as it will be needed.

Section 2- Figure 2.2.7 Short followup form

Once you have completed entering data with this form, hit save and proceed back to the navigation panel, and press F5 to refresh the page. You should now see the following

Section 2- Figure 2.2.8 Followup module with data

From here, you can click *Update new clinical follow-up* to enter a new clinical visit with the patient. The page you should see when you click on that link is the following

UTorCVDb - Surgical Follow-up

Patient Status [Modify this instrument](#) [VIDEO: Basic data entry \(16 min\)](#)

Download PDF of - select PDF download option -

Adding new Record ID 1

Record ID 1

PATIENT STATUS

Patient ID * must provide value Please enter the ONCOA generated ID

Status of patient at the time of last follow-up Alive Died (late death) Lost to follow-up reset

If death: put date and primary cause of death below

Date of the most recent clinical follow-up Y-M-D

Re-operations Yes No reset

Form Status

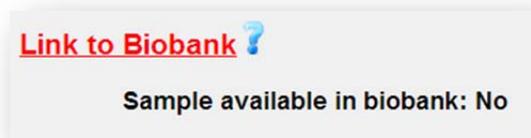
Complete?

Section 2- Figure 2.2.9 Clinical followup REDCap form

As you can see there's a lot more information to enter. Don't forget to copy and paste the patient ID into the proper field.

Navigation to the Biobank database

If you have permissions to view this module, it will show as the third section of the navigation panel, and upon patient creation, look like this:



Section 2- Figure 2.2.10: Biobank module with no sample

If the patient has a biobank entry, the complete record will look as such:

[Link to Biobank ?](#)

Sample available in biobank: Yes

[Sample Inventory Record](#)

Institution holding sample: TGH

Section 2- Figure 2.2.11 – Biobank record with sample data

Where, depending on your permissions, you can see where this entry is located and its REDCap entry details by clicking on the *Sample Inventory Record* link.

Navigation to the Hearts & Minds clinic records

If you have permissions to view this module, the default view will show that there is no record for the patient being viewed, and to allow you to access the Hearts and Minds navigation panel

[Heart & Minds clinic record: No ?](#)

[Hearts and Minds navigation panel](#)

Section 2- Figure 2.2.12 – Hearts and minds entry with no record for patient

To add a record into the Hearts and Minds database, you will need to add both a patient record, and an assessment record (or just an assessment record if the patient record has already been entered) in the following screen.

NAVIGATION TO UTorCVDb MODULES

Patient ID: 54c867e6e4226bb840782bcf2868b05cd1e3cb5a3a7777080238d52e1634091c

Note to user: the information included in this navigation panel gives a summary of the data holding for this given patients across the CVDMC environment. Access to detailed data is restricted by institution. For queries regarding cross-institutional data access, please contact the CVDMC at cvdmc.requests@sickkids.ca or CVDMC help desk at 416-813-7654 x.228304

Navigation panel for Heart & Mind clinic

Date of last H&M clinic assessment: None

Date of last update of patient-level data: None [Add Patient Data](#)

[Back](#)

Section 2- Figure 2.2.13 – Hearts and Minds main Panel

If **Date of last update of patient-level data** is set to None, click on Add Patient Data. This will take you to a screen that will allow you to enter patient related data for the patient in question. Make sure to copy and paste the Patient Id from the navigation panel screen as it'll be needed.

Patient Features Modify this instrument VIDEO: Basic data entry (16 min)

Download PDF of - select PDF download option -

Editing existing Record ID 1 (Patient ID 54c867e6e4226bb840782bcf2868b05cd1e3cb5a3a7777080238d52e1634091c)

Record ID 1
(To rename this record, modify the value immediately below.)

Record ID

Patient ID
* must provide value

Record last updated on: Today Y-M-D
* must provide value

DEMOGRAPHICS

Age (years)

Gender Female Male reset

BMI?

FAMILY HISTORY

Family history of CHD Yes No reset
if YES: please specify in the pop-up field below

SCREENING AND DIAGNOSIS OF PROBAND

Molecular screening method FISH SNP markers MLPA reset

Section 2- Figure 2.2.14 – Hearts and Minds REDcap Patient database

Make sure to have the patientID and Record Last updated on fields filled out. Both are required, both will cause issues if they are not entered correctly.

Once the new record is saved, refresh the navigation panel screen (hit F5 on your keyboard), and you should see the following.

NAVIGATION TO UToR CVDb MODULES

Patient ID: 54c867e6e4226bb840782bcf2868b05cd1e3cb5a3a7777080238d52e1634091c

Note to user: the information included in this navigation panel gives a summary of the data holding for this given patients across the CVDMC environment. Access to detailed data is restricted by institution. For queries regarding cross-institutional data access, please contact the CVDMC at cvdmc.requests@sickkids.ca or CVDMC help desk at 416-813-7654 x.228304

Navigation panel for Heart & Mind clinic

Date of last H&M clinic assessment: None

[Add a new clinic assessment for this patient](#)

Date of last update of patient-level data: 2013-10-02 [Update Patient Data](#)

[Back](#)

Section 2- Figure 2.2.15 – Hearts and Minds with patient data

Here you see that we now have a date for when the record was updated, as we just inserted a new record. You can update the patient record by clicking on **Update Patient Data** to make any changes.

To add a new assessment record, click on the [ADD A NEW CLINIC ASSESSMENT FOR THIS PATIENT LINK](#). This will take you to REDCap where you will be able to enter the needed data for the assessment as shown below.

22q11 - Assessment

Followup Functional Assessment [Modify this instrument](#) [VIDEO: Basic data entry \(16 min\)](#)

Download PDF of - select PDF download option -

Editing existing Record ID 1

Record ID 1
(To rename this record, modify the value immediately below.)

Record ID

Patient ID
* must provide value

Date of assessment Today Y-M-D

SOCIAL FUNCTIONING

Marital status

- Married or common law
- Separated, divorced, or annulled
- Never married

reset

Romantic relationship

- Never
- Previous only
- Current only
- Both current and previous

reset

Home environment

- House or apartment
- Boarding house/group home
- Hospital/treatment facility

reset

Section 2- Figure 2.2.16 – Hearts and Minds REDCap assessment screen

As with the patient form, make sure that both patient ID has been copied and pasted from the navigation panel screen, and that date of assessment has been entered. Once you have saved the new record, refresh the navigation panel screen. You should now see the following.

NAVIGATION TO UToRCVDb MODULES

Patient ID: 54c867e6e4226bb840782bcf2868b05cd1e3cb5a3a7777080238d52e1634091c

Note to user: the information included in this navigation panel gives a summary of the data holding for this given patients across the CVDMC environment. Access to detailed data is restricted by institution. For queries regarding cross-institutional data access, please contact the CVDMC at cvdmc.requests@sickkids.ca or CVDMC help desk at 416-813-7654 x.228304

Navigation panel for Heart & Mind clinic

Date of last H&M clinic assessment: 2013-10-15

[Show all H&M clinical assessment for this patient](#)

[Add a new clinic assessment for this patient](#)

Date of last update of patient-level data: 2013-10-02 [Update Patient Data](#)

[Back](#)

Section 2- Figure 2.2.17 – Hearts and Minds record for complete patient data and at least one clinical record

From here you can now click on Show all H&M clinical assessment for this patient to show every date that a clinical assessment has been performed.

Section 2.3: What is REDCap v5.6.4?

REDCap is a secure, web-based application for managing clinical data and UToTCV/CVDMC databases are built on the REDCap platform. The following sections will review the structure and basic principles of data entry using REDCap interface. Alternatively, you can get an overview on data entry from the REDCap HELP panel.

Term	Description
Project/ database	Each REDCap project is a single database into which data will be stored.
Case report form (CRF) or Data collection instrument (DCI)	A form created for the purposes of capturing data. Each database may contain multiple DCI/CRFs.
Section	Each DCI or CRF is divided into multiple sections to organize similar fields together. Each section is composed of several fields.
Field/ variable	Area that captures one single information or data.
Field note	Some fields have a field note, shown in small font below the data field. These notes provide field-specific information to assist the person entering data and preserve data quality. See figure below.
Record	A complete set of information for a person or object. Each record is composed of one or more fields.
Study ID	A unique key that can identify each record in the database.
Event/ Visit	A scheduled or unscheduled occurrence for which data is captured using a predefined CRF (DCI).
Form status	Status of the form completeness and denoted with a color; red – incomplete; yellow – unverified; green – complete.
Chief/ Principal investigator (PI)	The ultimate person who is in charge of the database/project.
User	The person who has access to a database/project. Access is provided on a project-by-project basis as determined by the chief of the project. Each project may have many users; each user may have many projects. Users will only see projects listed in their My Projects page for which they have access and within a project they will only see the CRFs to which they have access.

Chronic lung disease

Yes No

(H) **Mild:** FEV1 60% to 75% of predicted, and/or on chronic inhaled or oral bronchodilator therapy.
Moderate: FEV1 50% to 59% of predicted, and/or on chronic steroid therapy aimed at lung disease.
Severe: FEV1 < 50% predicted, and/or Room Air pO2 < 60 or Room Air pCO2 >50

Hyperlipidemia

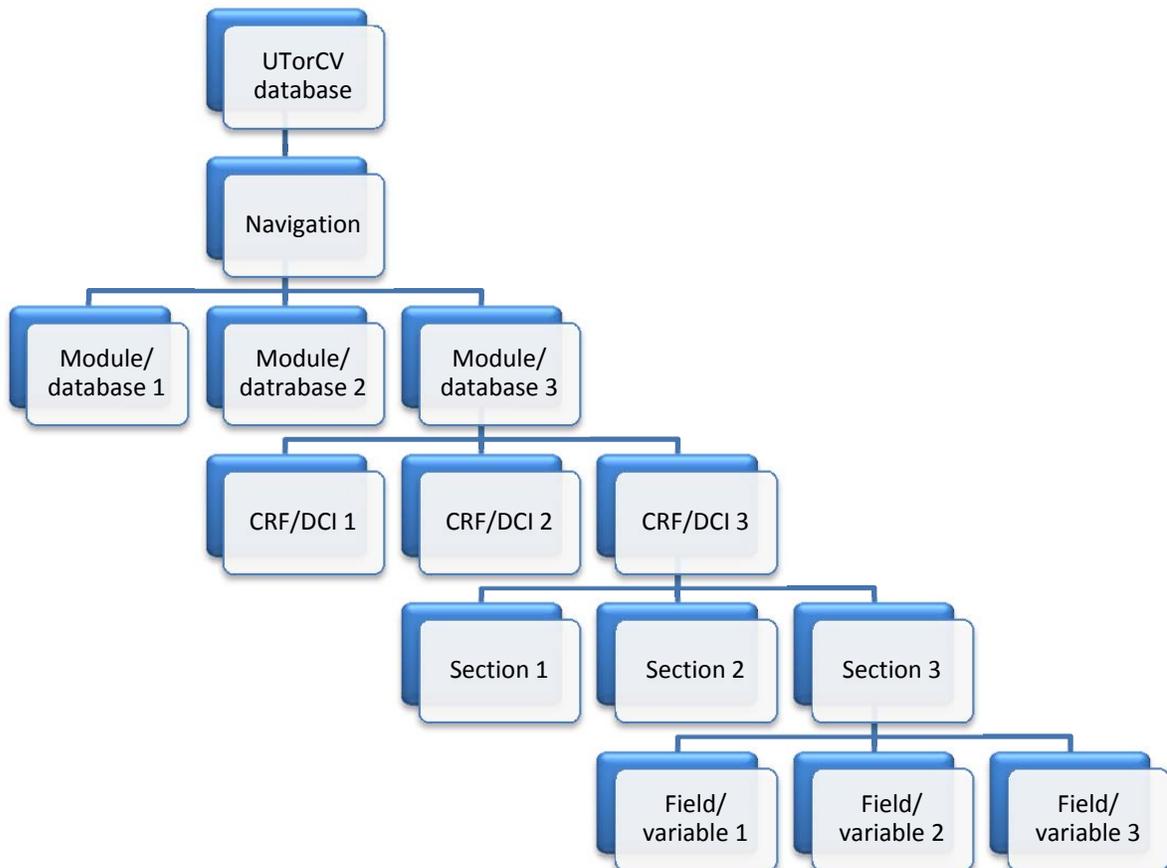
Yes No

(H) **Yes:** current or previous diagnosis of dyslipidemia (any one of the following):
 1) Total chol >5.18mmol/L;
 2) LDL >=3.37 mmol/L;
 3) HDL < 1.04mmol/L in men & < 1.30mmol/L in women

reset

Section 2- Figure 2.3.1: Field note

Section 2.4: UTorCVdb/CVDMC database structure (on REDCap v5.6.4)



Section 3: Data entry

Section 3.1: REDCap web interface – main window

The frontend interface panel (see figure below) is divided in the following manner:

Brief overview of the sections is given below:

Sections	Description
My projects	Takes you to the home screen of your REDCap account. Here it lists all the databases/modules accessible to you.
Project home	Takes you to the home screen of a particular database/module. This home screen will have the following subsections: <ul style="list-style-type: none">• Quick tasks: shortcut to database/module applications• User list: the current users of the database/module• Project statistics: summary of the database/module• Calendar events: only applicable to selected users
Project setup	Modifies the database appearance; applicable to CVDMC administrators only
Record status dashboard	Using legend, this dashboard will list the current status of every form in the database of all patients.
Add/edit records	Create new patient records or edit/view existing ones
Data collection instruments	Lists all the CRFs/forms available in the database. Depending on the user level access, some CRFs may not be visible to all end users.
Applications	Will list all built-in applications. Only the applications authorized to be used for the end user will be displayed. Applications might include data export, graphical data view, report builder etc. Please refer to the “user rights panel” for details of the built-in applications.
Help & Information	FAQs and vide tutorials on REDCap can be found here.

REDCap™

Logged in as **tanveer.collins**
 Log out

My Projects
 Project Home
 Project Setup
 Project status: **Development**

Data Collection [Edit instruments](#)

Record Status Dashboard
 - View data collection status of all records

Add / Edit Records
 - Create new records or edit/view existing ones

Data Collection Instruments:

Navigation Panel

- Biobank
- Preop History
- Preop Cardiac Status
- OR Common
- OR CAB
- OR Valve Surgery
- OR Mech Cardiac Assist Devices
- OR Other Cardiac Procedures
- Postop

Applications

- Calendar
- Data Export Tool
- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository
- User Rights
- Record Locking Customization
- E-signature and Locking Mgmt
- Graphical Data View & Stats
- Data Quality
- Report Builder

[Help & Information](#)

UofTCVDb - Main

[Project Home](#) [Project Setup](#) [Other Functionality](#) [Project Revision History](#)

Quick Tasks

- Export data**: Export your data from REDCap to open or view in Excel or various stats packages.
- Create a report**: Build custom reports for quick views of your data, and export reports to Excel/CSV.
- Check data quality**: Build or execute data quality rules to find discrepancies and errors in your project data.
- User Rights**: Grant new users access to this project or modify user privileges for current users.
- Online Designer and Data Dictionary Upload**: Create new fields/questions on your data collection instruments or modify existing ones using the Online Designer or by uploading a Data Dictionary. Quick link: [Download the current Data Dictionary](#)
- Data Access Groups**: Create groups of users to limit user access to certain records/responses, in which only users within a given Data Access Group can access records created by users within that group.

Project Dashboard

The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any).

Current Users

User	Expires
cedric.manhiot (Cedric Manhiot)	never
chris.reed (Chris Reed)	never
cvdmc.smh (cvdmc.smh cvdmc.sr)	never
cvdmc.sun (cvdmc.sun cvdmc.su)	never
cvdmc.tgh (cvdmc.tgh cvdmc.tgh)	never
tanveer.collins (Tanveer Collins)	never

Project Statistics

Records in project	2
Most recent activity	04/23/2013 7:04pm
Space usage for docs	1.29 MB
Project status	Development

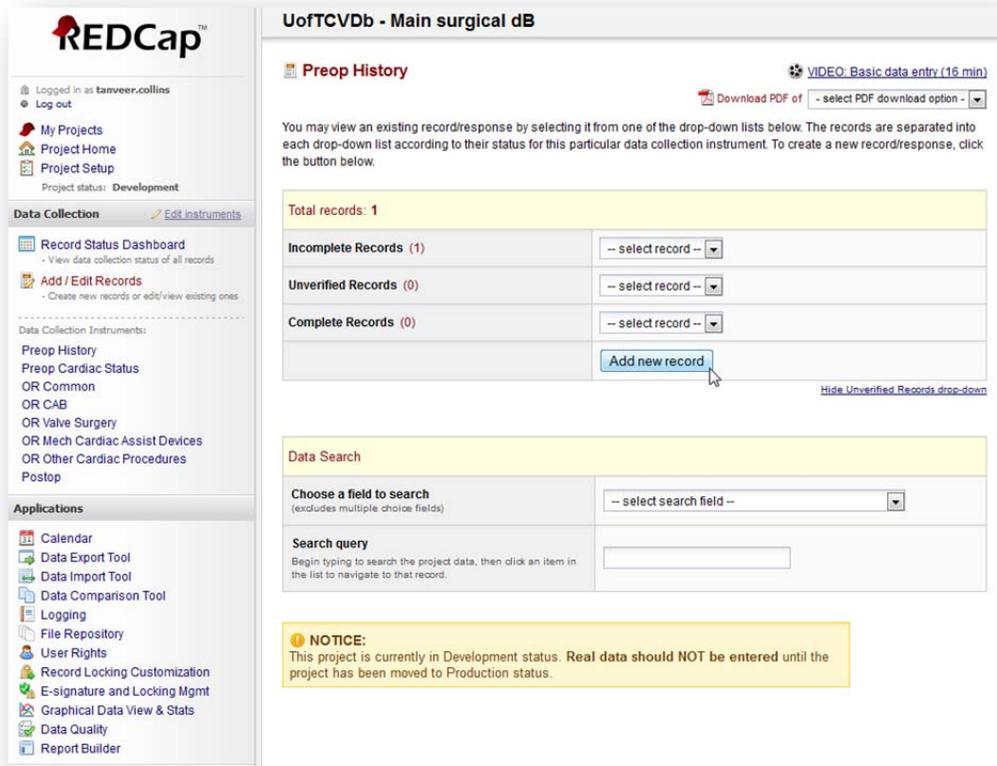
Upcoming Calendar Events (next 7 days)

Time	Date	Description
		No upcoming events

Section 3- Figure 3.1.3: REDCap interface: main window

Section 3.2: Adding/selecting a record

Click on “add/edit records” from the left panel.



Section 3- Figure 3.2.1: REDCap interface - "Add/select record" window

You may wish to update an existing record or create a new record. As in the figure above, you have four options to enter data:

- 1) Updating an incomplete or unverified record by selecting the record from the drop down box as seen in #1 below
- 2) Updating a complete record by selecting the record from the dropdown box as seen in #2 below
- 3) Entering a specific record number in #3 below to update the record
- 4) Entering a new record number (Study ID) in #3 below.

If an already existing study ID is entered in the new/existing record field, new data form will **not** appear (the form with existing data for that ID will appear instead). This is because REDCap checks that the study ID you entered is unique before creating a new dB record. If the study ID does not exist, only then a new record is created and the data form (with no data) appears.

Section 3.3: Navigating across CRFs of a record

When the first CRF appears on the right panel (see figure below), the left panel will list all the CRFs in the “Data Collection” section. You can now navigate across the same study ID by selecting the CRF from the list in the left panel.

The screenshot displays the REDCap interface for 'Example Database'. The left sidebar shows the user is logged in as 'site_admin' and lists various project and data collection options. Under 'Data Collection', 'Month 1 Data' is selected, indicated by a red dot. Other CRFs like 'Month 2 Data' and 'Month 3 Data' have yellow dots, while 'Demographics' and 'Baseline Data' have green dots. The main panel shows the 'Month 1 Data' form for 'Study ID 12'. The form includes fields for 'Date of Month 1 visit', 'Serum Albumin (g/dL)', 'Serum Prealbumin (mg/dL)', 'Creatinine (mg/dL)', 'Normalized Protein Catabolic Rate (g/kg/d)', 'Cholesterol (mg/dL)', 'Transferrin (mg/dL)', 'Kt/V', 'Dry weight (kilograms)', 'Number of treatments missed', and 'How compliant was the patient in drinking the supplement?'. Below these are sections for 'Hospitalization Data', 'Mortality Data', and 'Form Status'. The 'Form Status' section shows 'Complete?' set to 'Incomplete'. At the bottom right, there are buttons for 'Save Record', 'Save and Continue', and 'Save and go to Next Form'.

Section 3- Figure 3.3.1: Navigation across CRFs

The colored dots beside each CRF represent the status of the form completeness (legend: red – incomplete; yellow – unverified; green – complete).

To navigate a different study ID, click on “select other record” from the left panel and this will take you to the initial window to enter another ID.



Section 3.4: Data entry & validation

Enter a value in the data field by keyboard strokes or clicking the mouse. Move to the next field by clicking in it, or pressing the [Tab] key.

To remove previously entered value, please delete the value from textboxes, checkboxes or click on the “reset”, located beside the value, to remove values from radio buttons or slider scales. Please refer to section 3.5 for different types of data entry fields.

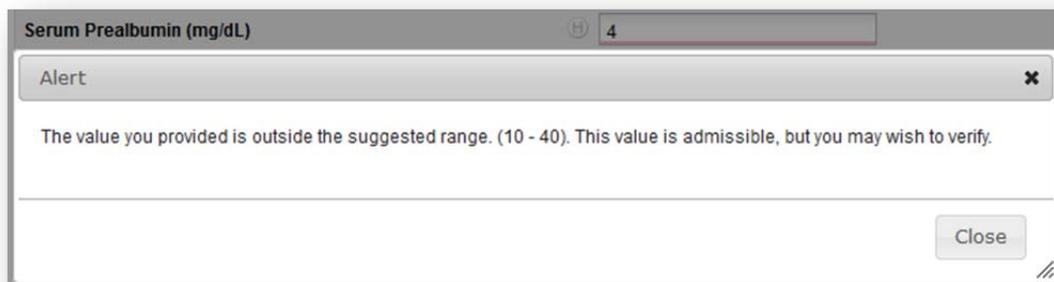
Navigate between fields using [Tab] or mouse clicks. If you press [Enter], you will save the form, and exit the current screen.

If you navigate off the form without pressing [Enter] or clicking on one of the “Save” buttons on screen, your **work will be lost**.

If a field has validation associated it with you may see a warning or error message indicating that the value you entered does not match requirements set up for the field.

For example, text fields may require the value entered fall between minimum and maximum values. REDCap will not prevent you from continuing, but it will alert you to a value that is outside the pre-defined acceptable range. See figure below.

Some fields are required to be filled out before you proceed to the next form. When saving the CRF and proceeding to the next, validation window will also prompt you to enter data if you miss to enter data into the required fields.



Section 3- Figure 3.4.1: Data validation pop-up note

Section 3.5: Data entry field types

The following figure below illustrates an example of a data entry form. The data type for each field determines the appearance of the field. There are several field types in REDCap:

Field types	Description
Text box	To enter short text
Notes box	To enter long texts
Radio buttons	Select only one answer
Drop-down lists	Select only one answer
Checkbox lists	Select all answers that apply
Slider analog scale	Set response by dragging a bar on the scale
File upload	To upload file e.g., scanned image or .pdf file
Calculated fields	Calculated fields are automatically populated based on data of one or more field values. For example, subject's age could be calculated by subtracting the date of birth from a date provided at the baseline visit.

The screenshot displays a REDCap data entry form titled "Adding new Participant ID 1". The form includes several fields:

- Participant ID:** 1
- NEW SECTION 1:**
 - Date:** A date picker set to "Today" in Y-M-D format.
 - Time:** A time picker set to "Now" in H:M format.
 - Radio buttons:** Three radio buttons labeled "First answer", "Second answer", and "Third answer".
 - Drop-down list:** A dropdown menu with three options: "First answer", "Second answer", and "Third answer".
- NEW SECTION 2:**
 - Checkbox (check all that apply):** Three checkboxes labeled "First answer", "Second answer", and "Third answer".
 - Slide/visual analog scale:** A horizontal slider with "low", "medium", and "high" markers. A blue bar is positioned above the slider, and a text prompt says "Click bar above and then drag to set response".
 - Calculated field:** An empty text box with "View equation" and "Disclaimer" links.
 - File upload link:** A green "Upload document" button.
 - Notes box:** A large text area for notes.
- Form Status:** A yellow bar at the bottom with a "Complete?" dropdown menu set to "Incomplete".

Section 3- Figure 3.5.1: Data entry field types

Alternatively, you can get a brief overview of the data field types from the REDCap HELP panel.

Section 3.6: Saving forms

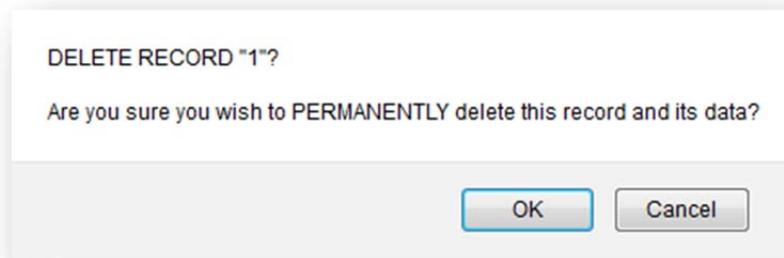
Please note that **there is no auto save in REDCap**. Once you have completed entering the information on a form, you **MUST** click one of the save option buttons at the bottom of the screen (or in the floating box). The “Form Status” section will allow you to identify if the record is incomplete, unverified or complete.

The screenshot displays the REDCap interface for editing an existing record in Study ID sk10009. The interface is divided into several sections:

- Left Sidebar:** Contains navigation options for Data Collection Instruments (Demographics, Baseline Data, Month 1 Data, Month 2 Data, Month 3 Data, Completion Data), Applications (Calendar, Data Export Tool, Data Import Tool, Data Comparison Tool, Logging, File Repository, User Rights, Graphical Data View & Stats, Report Builder), Reports (Records Status, Demo Report), and Help & Information (Help & FAQ, Video Tutorials, Suggest a New Feature).
- Main Form Area:** Displays the record being edited. The top bar indicates "Editing existing Study ID sk10009". The form includes fields for "Baseline Measurements" such as "Date of baseline visit", "Date blood was drawn", "Serum Albumin (g/dL)", "Serum Prealbumin (mg/dL)", "Creatinine (mg/dL)", "Normalized Protein Catabolic Rate (g/kg/d)", "Cholesterol (mg/dL)", "Transferrin (mg/dL)", "Kt/V", "Dry weight (kilograms)", "Collected Plasma 1?", "Collected Plasma 2?", "Collected Plasma 3?", "Collected Serum 1?", "Collected Serum 2?", "Collected Serum 3?", "Subject Global Assessment (score = 1-7)", and "Date patient begins supplement".
- Form Status Section:** Located at the bottom of the form, it includes a "Form Status" header and a "Complete?" dropdown menu currently set to "Incomplete".
- Buttons:** At the bottom right of the form area, there are three buttons: "Save Record", "Save and Continue", and "Save and go to Next Form". A red box highlights these buttons. A "Cancel" button is also present at the very bottom.
- Save Record Dialog:** A floating dialog box in the top right corner contains the text "Save Record" and two buttons: "Save and Continue" and "Save and go to Next Form".

Section-3 Figure 3.6.1: Saving CRFs in REDCap

Save Record	Saves the data and returns to the record (study ID) selection screen for the current form
Save and Continue	Saves the record and remains on the form for the same Study ID
Save and go to Next Form	Saves and navigates to the next form on the list for the study ID
Cancel	Leaves the current screen and DOES NOT SAVE the changes you made. If you want to save the changes made, you must press enter or click one of the three “save” options mentioned above before navigating off the form screen.
Locking and e-signatures	If you have locking and/or e-signature rights, you may choose to lock the form and/or e-sign the form.
Delete record	Deletes the complete set of data that exist across all CRFs for one particular study ID. This will be followed by a warning message (see figure below) asking if it is okay to permanently delete this record and its data.



Section-3 Figure 3.6.2: Warning message when deleting a record in REDCap

Section 3.7: Correction of data after locking

Correction of data after a record has been locked is possible only by CVDMC staff with records locking/unlocking privileges. Record correction can be necessary in the case of a data entry mistake not previously identified through the CVDMC mechanisms or because of a request for correction of personal health information at the participating institution level. Accuracy of personal health information is the responsibility of the submitting site. Sites are required to respond to personal health information requests and make appropriate corrections if necessary as per standard hospital policies. CVDMC must be informed of any such corrections inasmuch as it affects data previously submitted to the REDCap web interface and locked by a CVDMC administrator.

Section 3.8: Data security and privacy violation

Every end user will need to complete training on ethics and protection of personal health information as applicable at each institution.

If a security violation is discovered or occurs (whether associated with the REDCap web interface or the ONCOA software) whether it happens at the end-user level or central CVDMC administration, it should be reported immediately to the CVDMC (cvmdc.requests@sickkids.ca or 416-813-7654x228304) and CVDMC Managing Director (cedric.manlhiot@sickkids.ca). CVDMC will notify the SickKids Privacy Office (privacy.office@sickkids.ca or 416-813-7474) and the privacy offices of the other concerned institutions (if any) as soon as possible. Furthermore, CVDMC will review and assess the situation. The CVDMC will work with the Privacy Office to make appropriate changes as necessary. The completed assessment report will be forwarded to the institution.

The Hospital for Sick Children has several policies dealing with security violations and prevention. Please see the attached policies:

- Information Security Policy
- Theft/Loss Prevention and Reporting policy

CVDMC is bound by all policies and procedures governed at SickKids for privacy and security of data.

CVDMC will use the REDCap built-in user rights panel, data and user tracking systems to ensure data entry is following the appropriate protocol. Please refer to the CVDMC – Manual of Operations for description of the data security systems.