# User Guide for ROCSS-EX Database



## User Guide Contents


| Section | Page |
|---|---|
| Error! Not a valid result for table. | **1** |
| **Access to REDCap** | **1** |
| **Logging into REDCap** | **1** |
| **Data Entry** | **3** |
| Selecting a patient record | 3 |
| Selecting a form to enter data | 4 |
| Adding data to the database | 5 |
| Missing Data | 6 |
| Comments | 6 |
| Form statuses | 7 |
| **Data Queries** | **8** |
| Responding to data queries | 8 |
| **PI sign-off** of data | **11** |
| **Consent for ROCSS-EX** | **11** |


## Background

The purpose of this user guide is to provide guidance for staff on the use of the ROCSS-EX REDCap data entry portal used for all data needed for the trial.

Ideally, data will be entered directly in to electronic Case Report Forms (eCRFs) within the REDCap database. Alternatively data may initially be collated on paper versions of the eCRFs, and then uploaded into REDCap later on. Completed worksheets should be retained and filed in the ISF but do not need be sent to the ROCSS-EX Trial Office.

REDCap can be accessed via all typical web browsers.

## Access to REDCap

To be provided with access to the ROCSS-EX REDCap database staff must be delegated the task of "Completion of electronic CRFs/data entry including data query resolution" on the ROCSS-EX Site Signature and Delegation Log. The Site Signature and Delegation Log document is available for download and will need to be completed, signed and returned to BCTU before access can be provided to the REDCap database.

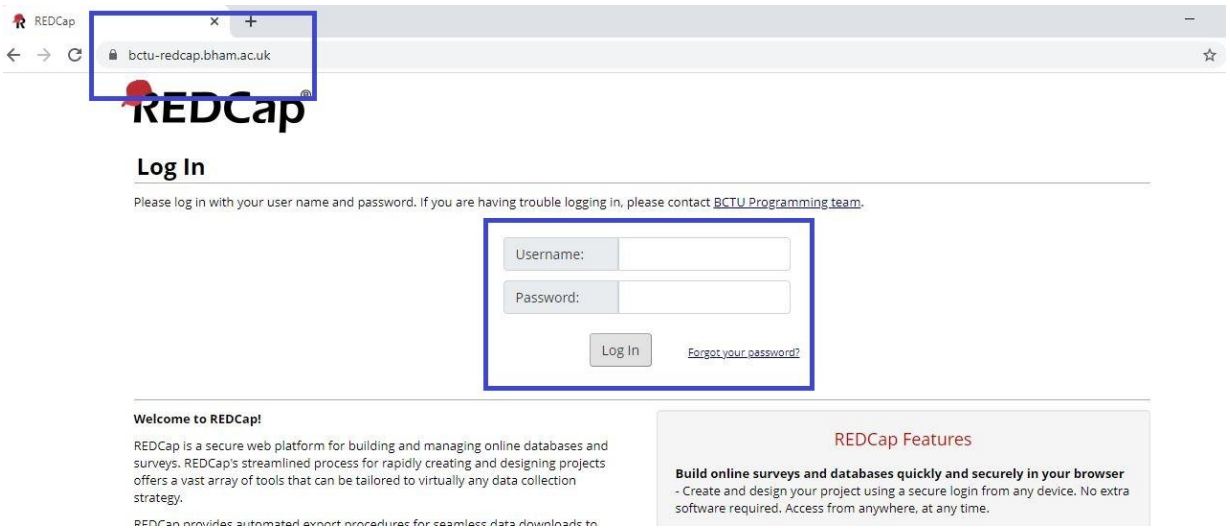
To request a username and password for REDCap, send a request to the trial mailbox (rocss@trials.bham.ac.uk).

Your username will be assigned by BCTU and returned via email along with instructions on how to set up a password. Please do not reveal this username and password to anyone.

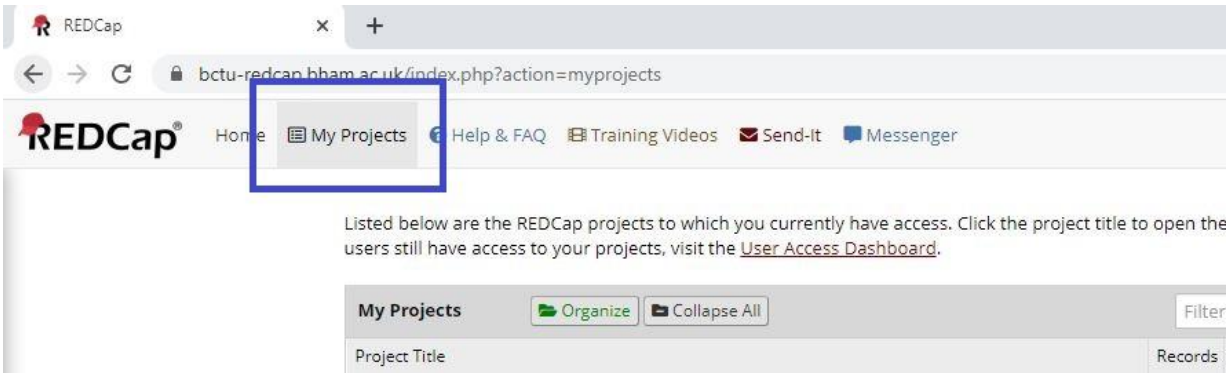
## Logging into REDCap

The ROCSS-EX REDCap database is located online at https://bctu-redcap.bham.ac.uk.

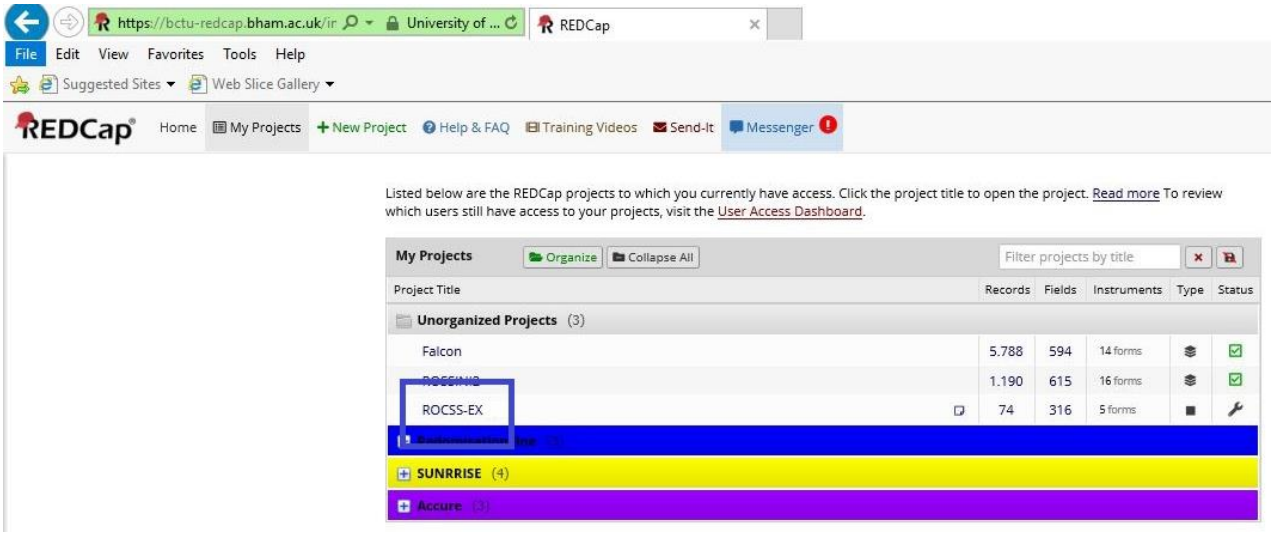
- Enter **UserName** and **Password** on the REDCap homepage.



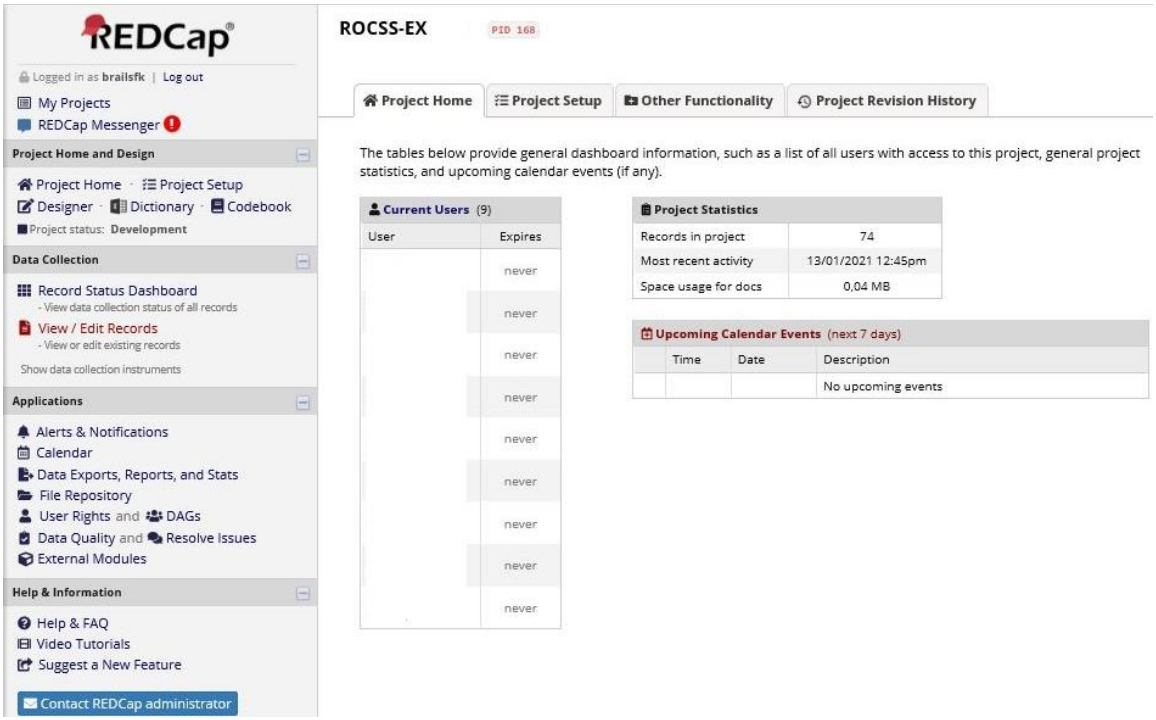
- If access to REDCap has been granted, the database is located within **'My Projects'**.




- Select ROCSS-EX to enter the database.




- The **Project Home** dashboard is the starting point for all data entry/activity.



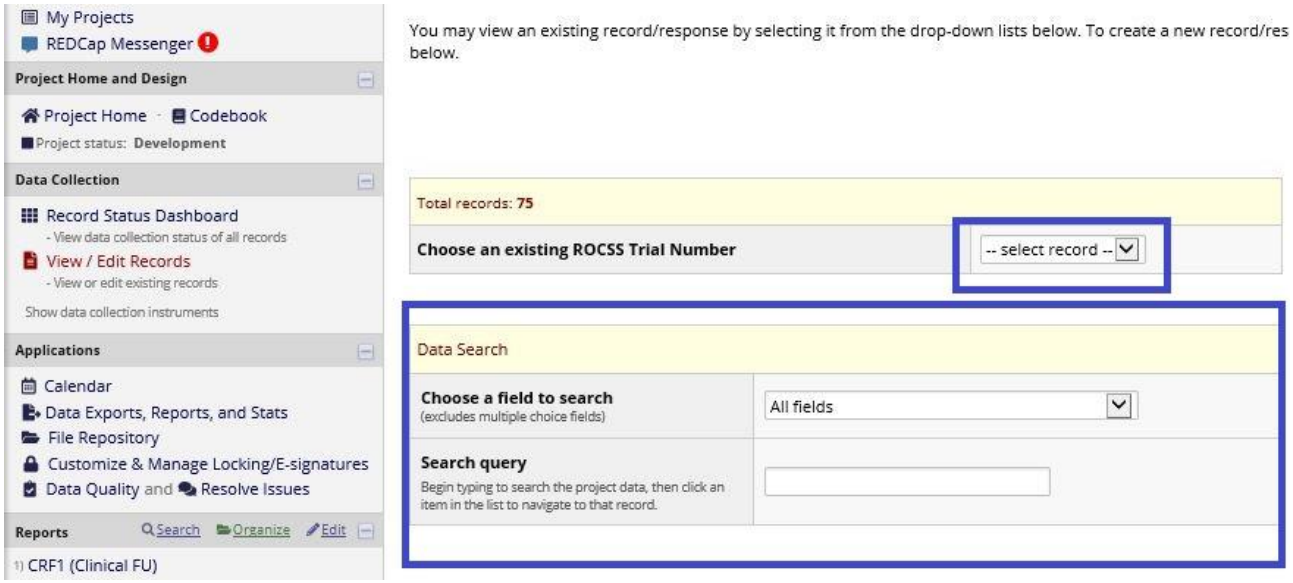
- You can return to the **Project Home** dashboard by clicking on the Project Home Tab from any page in the database.

## Data Entry

### Selecting a patient record

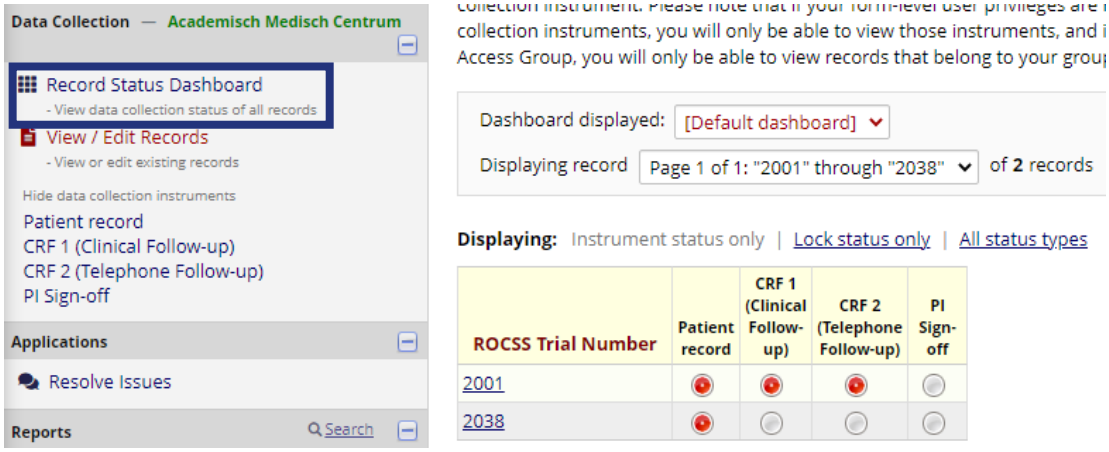
- To view and edit a patient's record click on **'View/Edit Records'** under Data Collection in the navigation pane to the left of the screen.

- A participant's trial number can then be selected from the dropdown menu. This will navigate to the **'Record Home Page'** for the selected patient.



- The "Data Search" section can also be used. Here simply type in the search term (trial number, patient name, hospital number etc.) and you will be shown a list of records that meet the search criteria.

- Alternatively, select "Record Status Dashboard" under Data Collection in the navigation pane to the left of the screen. This will show you all the records for your site, and the status of each of the forms for that record. Red indicates the form has not been completed.




## Selecting a form to enter data

- In ROCSS-EX the are 4 forms;

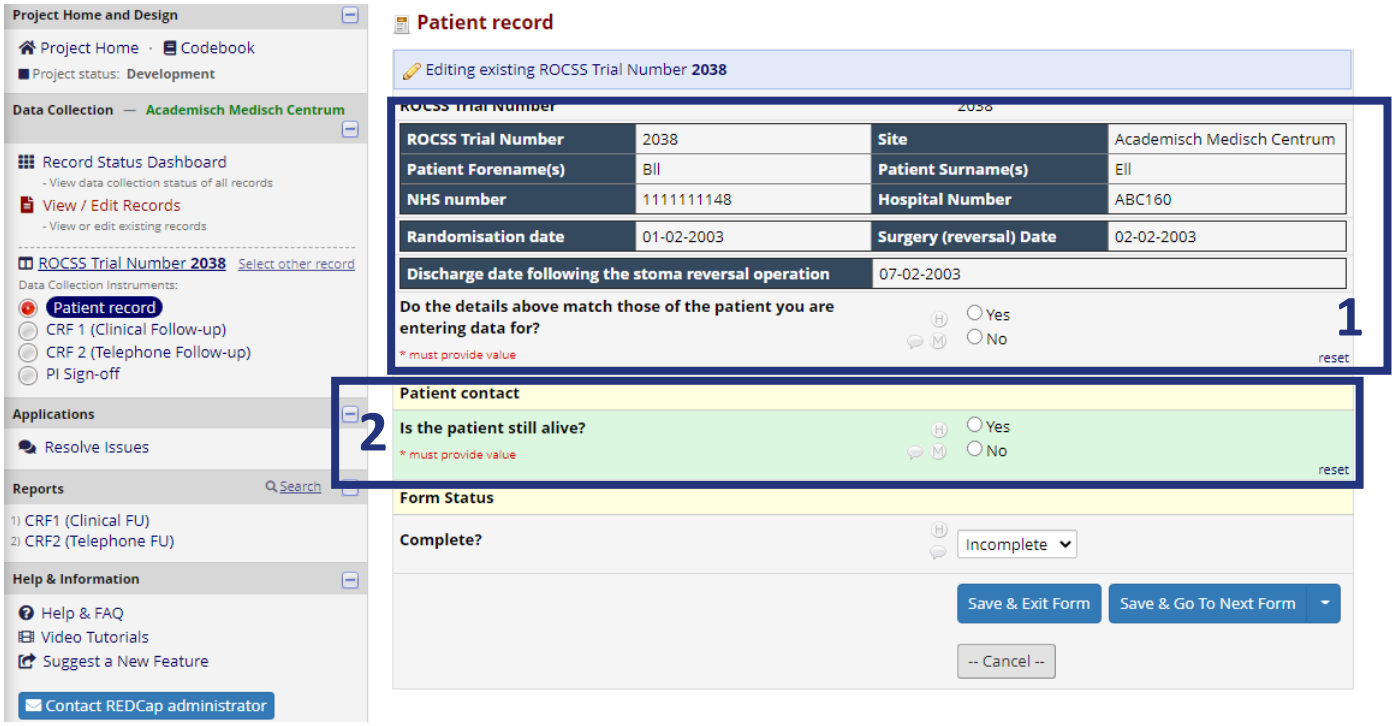
| Form | Role | Access |
|---|---|---|
| Patient Record | Site Staff | View & Edit |
| | Site PI | View & Edit |
| CRF 1 (Clinical Follow-up) | Site Staff | View & Edit |
| | Site PI | View & Edit |

| Form | Role | Access |
|---|---|---|
| CRF 2 (Telephone Follow-up) | Site Staff | View & Edit |
| | Site PI | View & Edit |
| PI Sign-off | Site Staff | Read only |
| | Site PI | View & Edit |

- Each form has a corresponding circular icon which must be clicked to access the form. If you click on the Trial number, this will be your view.
    - *Also see 'Form Status' section*

- Patient Record should be accessed first – it contains:
    1. Summary of the participant details – this should match the ROCSS Patient Identification Log within the Investigator Site File (ISF), and there is a check question for this.

2. Patient contact – there are a series of questions to establish the participant's status; are they alive, have they been contacted and have they agreed to participate. **Answers are required to 'unlock' data entry for the CRFs 1 and CRF 2 - *also see Figure 1*.**




## Adding data to the database

- Please complete every field on the form.
  - Fields where data is mandatory are indicated by '* must provide value'
  - If an exact date is not known for any relevant field, enter the approximate date of month and year with 15th for the day component AND a comment added to tell us this has been done – see *'Comments' section*
  - If exact duration is not known for any medication field, enter the best estimate AND a comment added to tell us this has been done – see *'Comments' section*

- Whilst entering data, alerts may appear as some data fields have in built validations. For example, the number of ITU days exceeds the number of total inpatients day. Any data prompting an alert should be checked to ensure it is correct.

- Once data entry for the form has been completed, select **'Unverified'** from the dropdown list at the bottom of the form and then **'Save and Exit Form'**. The form will now have a yellow status icon which alerts the BCTU that the form is ready for review.
  - *Also see 'Form Status' section*

- When saving data prompts may appear to inform you:
  - mandatory data fields have been left blank
  - data quality checks have identified a possible error

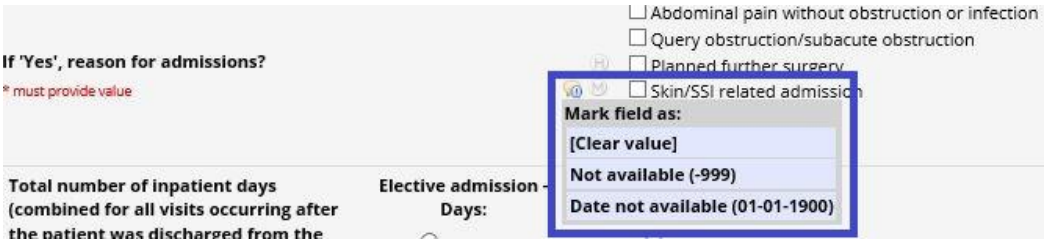
  Any data prompting an alert should be checked to ensure it is correct.

- Data entry on CRF1 and CRF2 will not be immediately available – if you access the forms, instructions on what is required to enable/'unlock' data entry are given, usually requiring an update to 'Patient Record', or you will be informed if data entry cannot be unlocked. *For instance, CRF2 data entry fields will only be available if it has been confirmed that the patient has agreed to participate in ROCSS-EX.*
  - Where instructions inform that data entry cannot be unlocked, 'Unverified' is still to be selected from the dropdown list at the bottom to demonstrate acknowledgment of the circumstances.

## Missing Data

- If data is unavailable and can never be provided/collected "Missing Data Codes" are to be used, and are added using the 'M' icon next to data field AND should be accompanies by a comment to explain – see '*Comments' section*

- Selecting the missing icon displays the available codes that identified as not available:
  - Not available (-999) – to be used for any field except dates fields
  - Data not available (01-01-1900) – to be used for date fields only

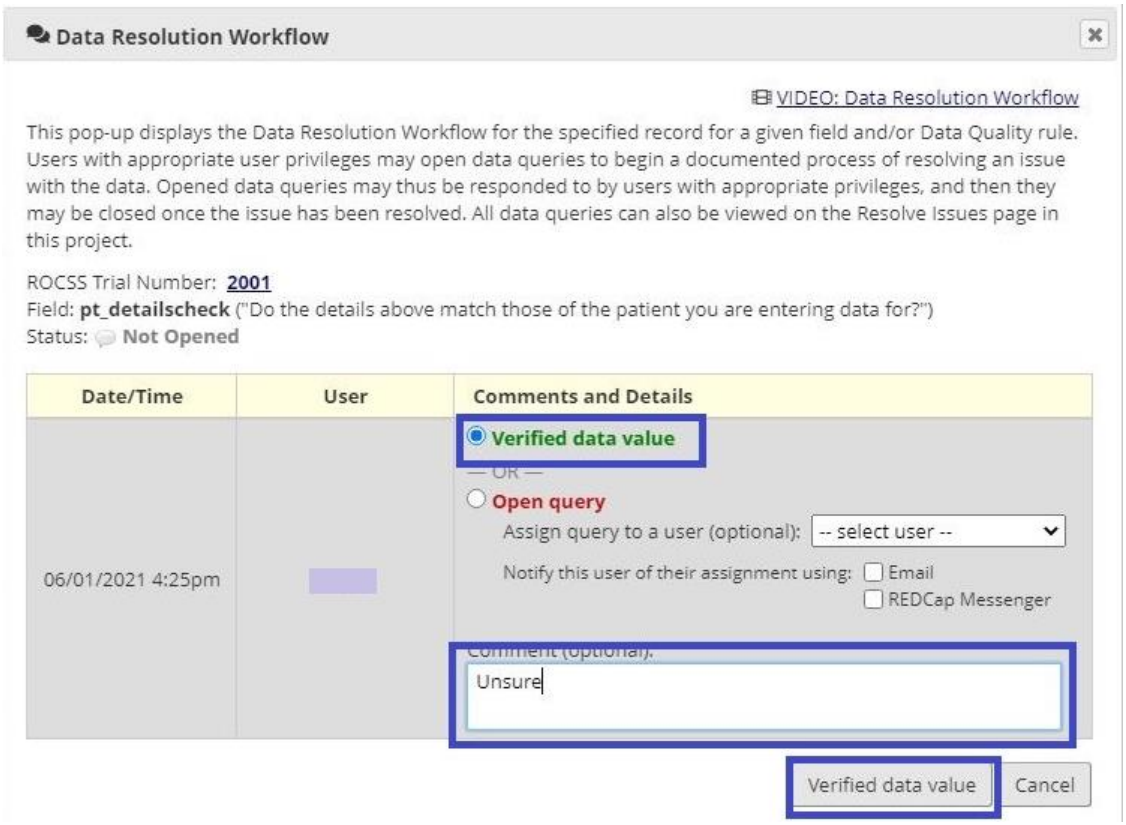



## Comments

There may be times when comments or notes need to be added to a data field to make us aware of any issues or to provide an explanation of the data provided.

- Comments can be added by clicking the speech bubble icon to the left of the data field.

- Add text to the comment box leaving "Verified Data value" selected and click 'Verified data value' button to save.




- The speech bubble icon will change once a comment has been saved.

## Form statuses

The form status can fall into one of four categories and the status of all patient forms can be viewed on the **'Record Status Dashboard'**:

| Icon & Status | Meaning |
|---|---|
| Incomplete (no data saved) | No data has been saved. |
| Incomplete | Some data has been entered and saved by site. |
| Unverified | Data has been entered and saved by site, and the form has been marked as 'Unverified' by the site to indicate data entry is finished and is ready to be reviewed by BCTU - **it is essential that sites mark data that is due to be checked as 'unverified'**. |
| Complete | Data reviewed by BCTU and is now verified as complete. **Forms should only be marked as complete by the site when instructed by BCTU.** |

- The Trial Office is automatically notified when a form is saved with an '**Unverified**' status. The data will be reviewed, and if any queries are identified these will be raised using the Date Resolution Workflow. If there are no queries, or once they are resolved, the Trial Office will notify sites by email that they can set the form status to '**Complete**'.
    - *Unfortunately, REDCap lacks the functionally that would allow the Trial Office to modify a single data field within a form – access is managed at the form level.*

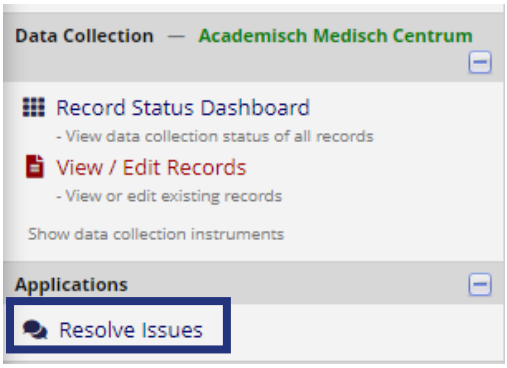
- The Trial Office is automatically notified when a form is saved with a '**Complete**' status. The form will then be locked to prevent any changes to the data.
    - If further changes are required, contact the Trial Office to request the form be unlocked.

## Data Queries

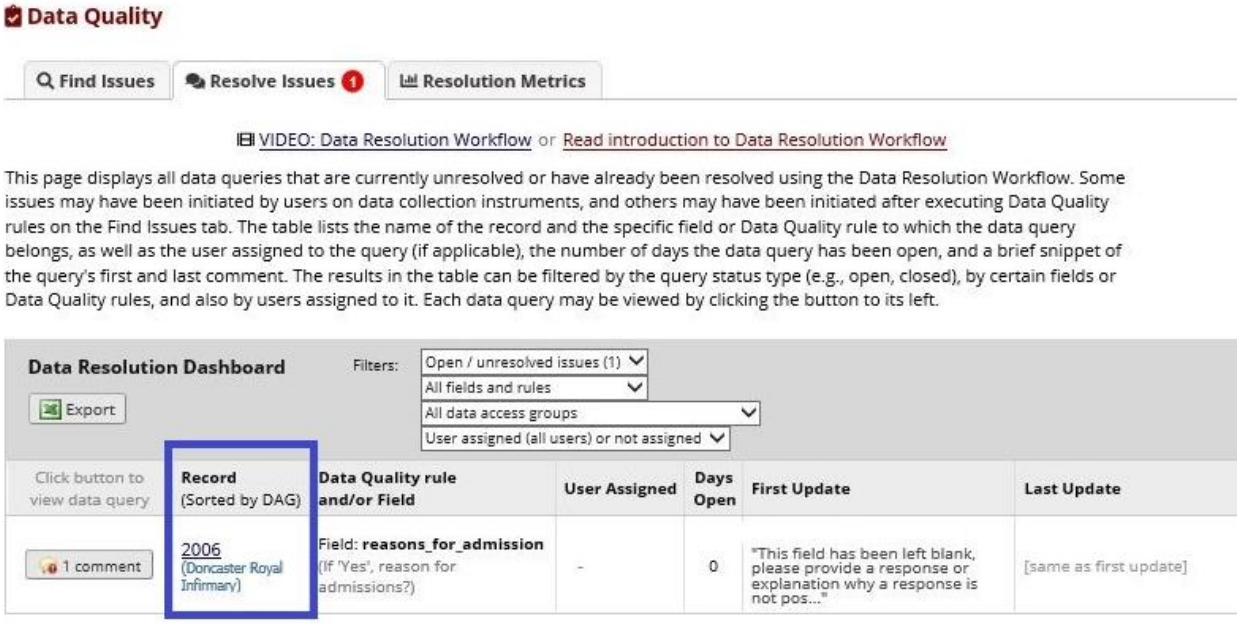
Any questions from the BCTU team querying any data entered at your site will be conducted through the ROCSS-EX REDCap database using the Data Resolution Workflow.

### Responding to data queries

- Data queries raised by the ROCSS-EX Trial Office can be viewed by clicking **'Resolve Issues'** under '**Applications**' in the navigation pane on left of the screen.




- All queries raised for the specific site are displayed on the **'Data Quality'** page.

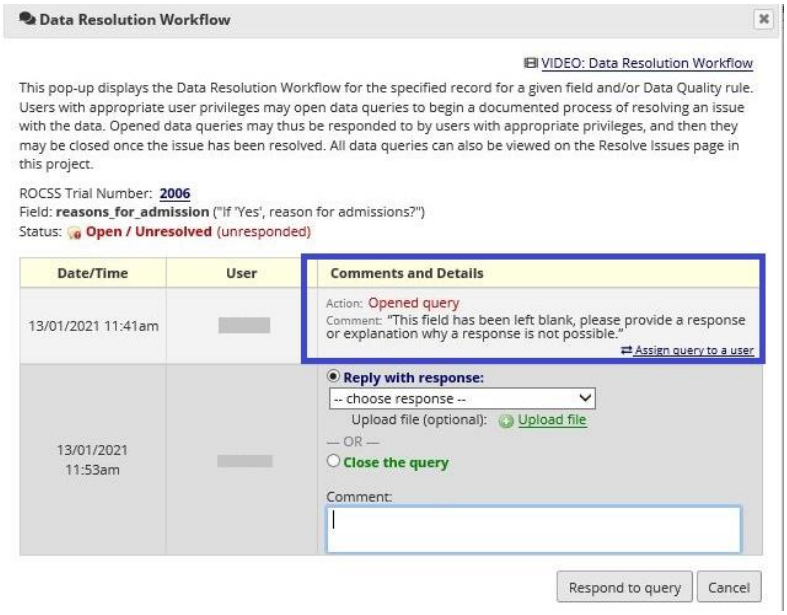



- The '**Record**' column lists the patient trial numbers and forms which have been queried. The '**Data Quality rule and/or Field**' column identifies the data field that has been queried.

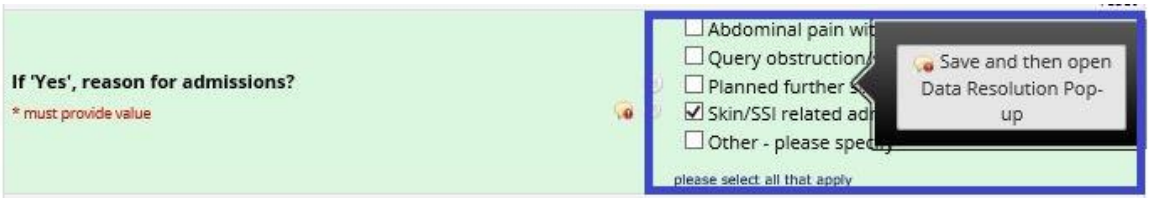
- You can click the button in the first column to view the query but you can also access it from within the form the query is on (see below)

- To address a query, click on the patient trial number in the **'Record'** column - this will navigate to the field being queried, which will have a red data query icon on the left hand side.

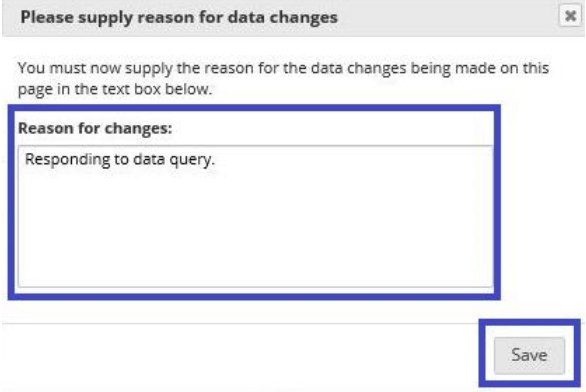
- Click the red data query icon to access the query.



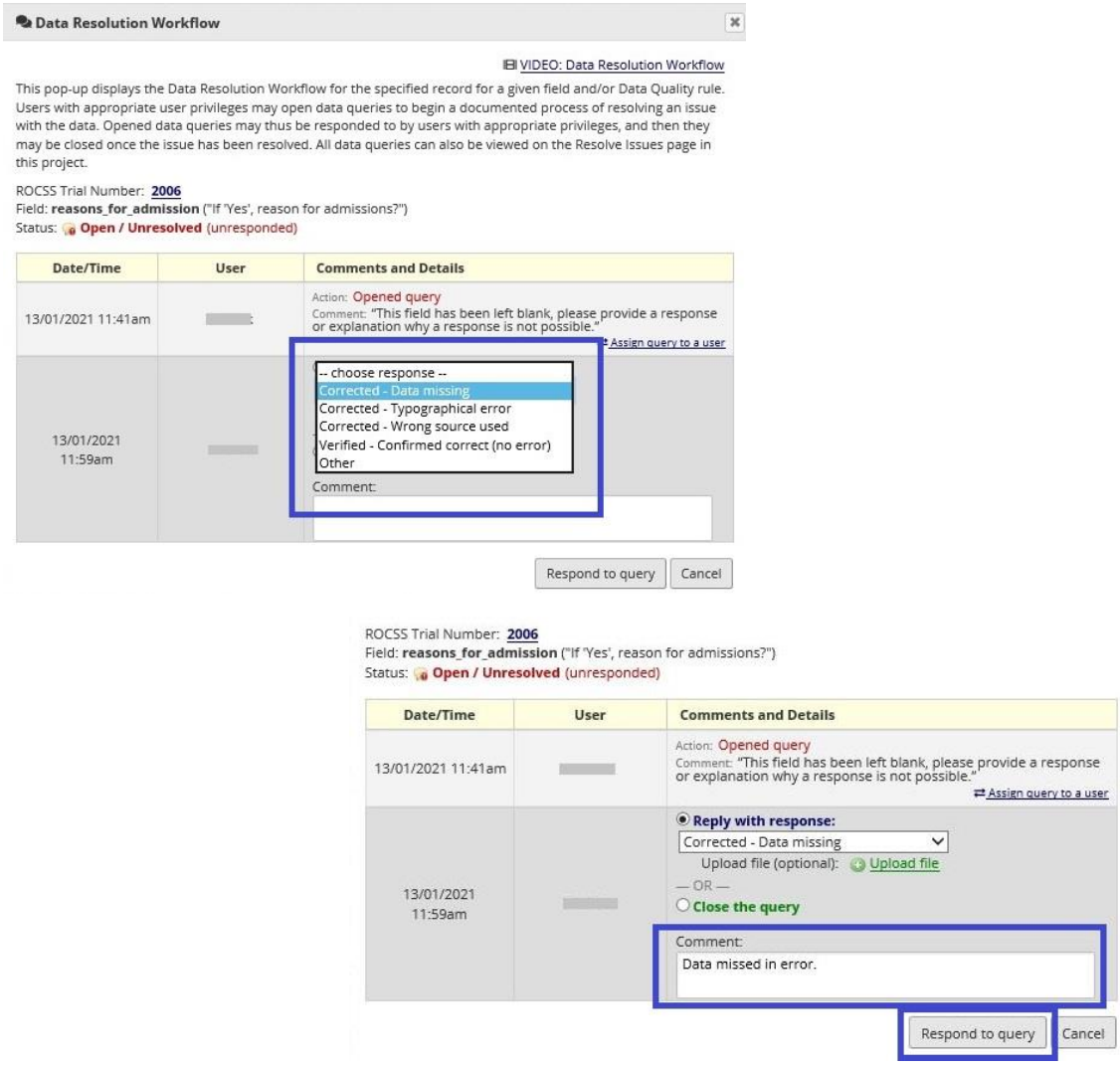

- Click 'Cancel' to return to the form to then edit the data address to address the query and save the form.




- Because the data has been amended, a prompt will appear asking to provide 'Reason for changes'. Please provide a reason why the data was amended e.g. responding to a data query, and save.



- Once the edit has been saved the Data Resolution Workflow may re-open. If not, click the red data query icon to access the query. From the drop-down list select a response which is in line with the edit made to the data in response to the query raised, e.g. where missing data was queried and has now been added, select 'Corrected - Data missing'.
    - A comment is to be added to the query to provide further details regarding the response. To save the response click 'Respond to query'.




- The query icon next to the data field will appear blue once a response has been provided to the query.

## PI sign-off of data

PI sign-off of the data is required – it is their responsibility to ensure that the information that has been provided is up-to-date and accurate.

- Only the Site PI has can complete the **PI Sign-off** form – other members of the local research team have read only access.
- The **PI Sign-off** form should be completed once all data has been entered and queries resolved – this is indicated by Status Icon button for Patient Record, CRF1 and CRF2 being **green**.
    - The ROCSS Trial Office will prompt PIs when data sign-off is appropriate.
- The froms will have been locked by BCTU, so please if PIs wish to make changes the data in Patient Record, CRF1 and CRF2, the Trial Office should be contacted by email to request a form be unlocked.
    - The status of the form where data is changed should be set back to '**Unverified**' and the process described above (in *Adding data to the database* and *Form statuses*) in will begin again.
- As with the other forms, the PI Sing-off should be saved with the status 'unverified' once completed.

## Consent for ROCSS-EX

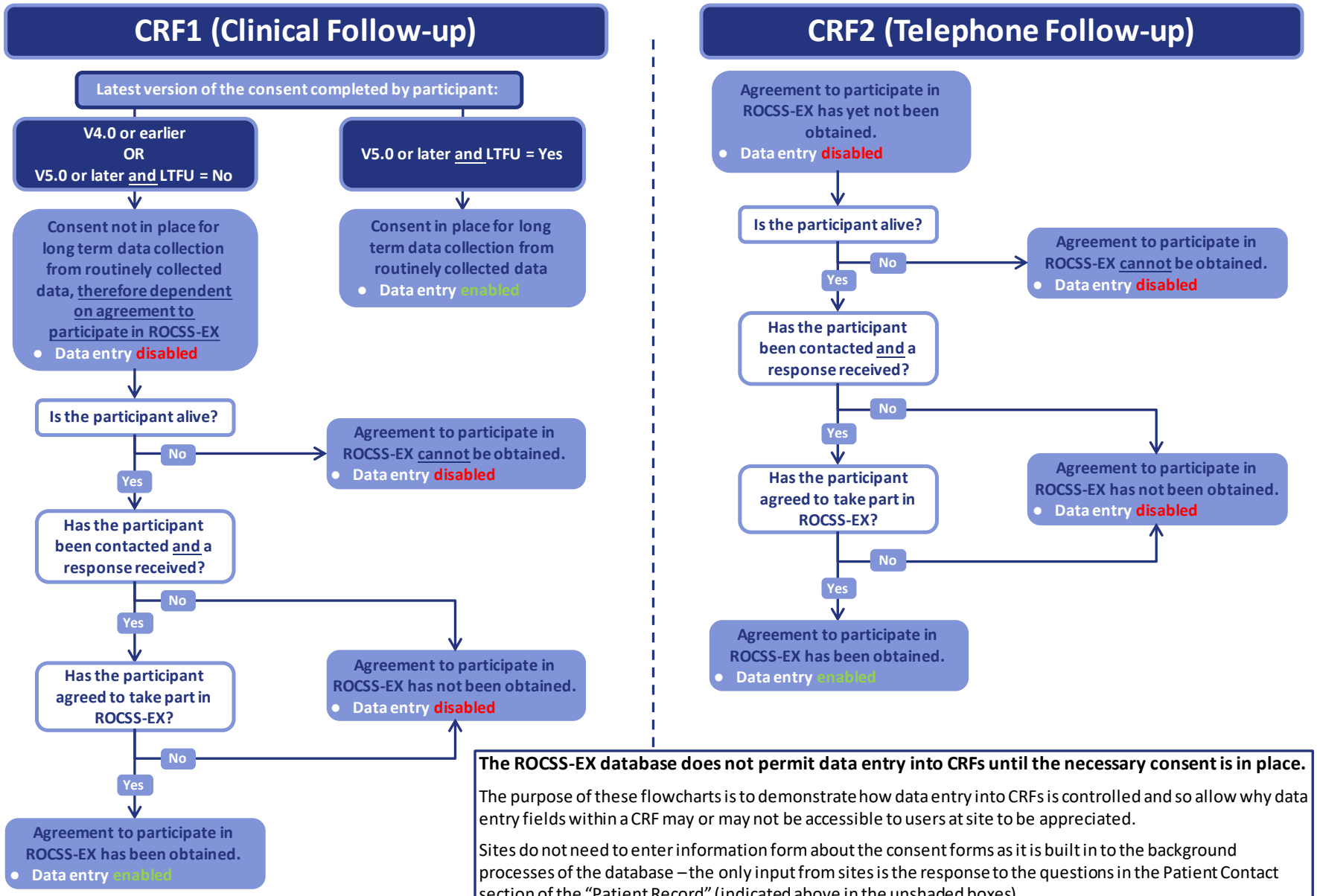
The availability of data entry fields within the ROCSS-EX eCRFs is dependent upon what consent is in place. This is determined by the consent form completed during the original ROCSS trial and responses to questions in "Patient Record" within the Patient Contact section. Figure 1 presents the requirements for data entry to be enabled.

- **CRF 1 (Clinical Follow-up)** – data entry is enabled when:
    - There is pre-existing consented to long-term follow-up using routinely collected data, which is already present in the background of the database (i.e. site input is not required).
    - the participant agrees to take part ROCSS-EX where there was is not pre-existing consented to long-term follow-up using routinely collected data, which is recorded in the Patient Contact section of "Patient Record".
- **CRF 2 (Telephone Follow-up)** – data entry is enabled when the participant agrees to take part in ROCSS-EX, which is recorded in the Patient Contact section of "Patient Record".

## General Information

- All trial data entered onto the REDCap database via the online web application/data entry portal is TSL encrypted and the system is hosted on servers at the University of Birmingham campus.
- The Trial Team at BCTU have read only access to the data entry fields present in Patient Record, CRF1, CRF2 and PI data sign-off.
- Once data entry is completed and checked, forms will be locked. This will prevent any changes to the data. If further changes are required, contact the Trial Office to request the form be unlocked.

*Figure 1 - Flowcharts for each CRF demonstrating the condition required to enable data entry*




**The ROCSS-EX database does not permit data entry into CRFs until the necessary consent is in place.**

The purpose of these flowcharts is to demonstrate how data entry into CRFs is controlled and so allow why data entry fields within a CRF may or may not be accessible to users at site to be appreciated.

Sites do not need to enter information form about the consent forms as it is built in to the background processes of the database – the only input from sites is the response to the questions in the Patient Contact section of the "Patient Record" (indicated above in the unshaded boxes).