# EVIDENCE INFORMED INTERVENTIONS

User Manual for the REDCap System

Version 2.0 3/30/2017

# **Table of Contents**

I.	Introduction	3
II.	Contact Information	3
III.	General Overview of the Project	3
P P	uprenorphineatient Navigationeer Linkageatsitional Care Coordination	4 4
IV.	General Overview of the Websites	5
	Tracking SystemREDCap System	
V.	Background about REDCap	5
	BackgroundAdditional Information about REDCap	
VI.	Using REDCap	6
	New user requests  Logging in  My projects  Navigation in DEC projects  Intervention-specific navigation tips  Data entry tips  Saving data  Useful data entry features  Other useful features  Enter a new record in DEC assessments  rinting Forms  Printing directly from open form  Downloading and printing PDF of data	6 8 . 11 . 15 . 17 . 18 . 20 . 22 . 22
VII.	Quality Assurance	
	Using status icons to indicate status of form Using field comments for QA Review history of data edits Using Data Quality Rules	. 24 . 26

#### I. Introduction

The objective of this user manual is to provide an easy-to-follow, step-by-step, comprehensive guide to data entry for the REDCap data entry web system for the Dissemination of Evidence-Informed Interventions (DEII) studies, as created by the Dissemination and Evaluation Center (DEC). Note that there are multiple web systems used in the study. This user manual only addresses the REDCap system.

The REDCap URL for capturing assessments for the DEII studies is: https://redcap.bumc.bu.edu/

The **LIVE** project names are intervention-specific:

DEC - Buprenorphine

DEC - Patient Navigation

DEC - Peer Linkage

DEC - Transitional Care Coordination

The TEST project name is:

DEC training-FOR PRACTICE ONLY

Users will be temporarily granted access to the TEST project for training purposes, or upon special request. Otherwise, the DCC encourages users to only have access to the LIVE project to reduce potential errors in saving forms to the wrong project.

This manual provides instructions for the REDCap data entry system, only. The other systems are covered in separate manuals.

#### II. Contact Information

For questions regarding the website or study data, please contact any of the following people at the Boston University Data Coordinating Center (DCC):

Clara Chen, Project Manager [Primary Contact]

Phone: 617.638.4058 Email: cachen@bu.edu

Christine Chaisson, Project Director

Phone: 617.638.5009 Email: chaisson@bu.edu

### **III. General Overview of the Project**

The DEII project involves four interventions: buprenorphine, patient navigation, peer linkage, and transitional care coordination. Each intervention involves three sites.

#### **Buprenorphine**

For PLWH, office-based buprenorphine treatment delivered in HIV clinics is associated with decreased opioid use, increased ART use, higher quality of HIV care, and improved quality of life. Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care is intended to be implemented in HIV primary care settings that do not already provide on-site buprenorphine treatment services. The intervention is designed to increase the number of patients retained in

buprenorphine treatment and HIV primary care, as well as integrate buprenorphine treatment into the standard of care in the clinic setting.

#### **Patient Navigation**

The Enhanced Patient Navigation for HIV-Positive Women of Color intervention is designed to retain HIV-positive Women of Color (WoC) in HIV primary care after receiving support, education, and coaching from a patient navigator. Patient navigators are critical members of the health care team focused on reducing barriers to care for the patient at the individual, agency, and system levels. While engaging with patients, patient navigators lend emotional, practical, and social support; provide education on topics related to living with HIV and navigating the health care system; and support both patients and the health care team in coordinating services. In this intervention, patient navigators will work with HIV-positive WoC who are experiencing at least one of the following challenges: have fallen out of care for 6 months or more, have missed 2 or more appointments in the prior 6 months, are loosely engaged in care (have cancelled or missed appointments), are not virally suppressed, and/or have multiple co-morbidities.

#### Peer Linkage

The Peer Linkage and Re-Engagement of HIV-Positive Women of Color intervention is designed to best serve Women of Color (WoC) who are newly diagnosed with HIV or who have fallen out of HIV primary care. Trained HIV-positive WoC known as "peers" will link and re-engage patients in HIV primary care. Patients will be considered linked or re-engaged once they have attended 2 medical appointments, attended 1 case management appointment, and have completed HIV lab work (all within a 4 month period). Peers offer a unique personal perspective and can provide coaching and emotional support to patients who may need assistance in managing medical and case management appointments. In addition, peers who work closely with case managers and the clinical team can better provide individualized patient-centered services over a short time period to address immediate patient needs and build trust between the patient and the clinic team.

#### **Transitional Care Coordination**

Collaborations between public health agencies, community-based organizations, and jail health services have implications for public health and safety efforts and have been proven to facilitate linkage to care after incarceration. Medical screenings that happen for all inmates through the jail intake process offer an opportunity to implement such interventions, as do booking processes and intervention intake. Jordan et al., introduce the concept of "Warm Transitions" as an integral part of implementing the HIV Continuum of Care Model by "applying social work tenets to public health activities for those with chronic health conditions, including HIV-infection." Absent "a caring and supportive warm transition approach," pre-existing barriers to care and other stressors that come with the experience of incarceration and cycling in and out of correctional facilities will continue or be exacerbated after incarceration. Without transition assistance, people living with HIV who are released from jails are at risk of unstable housing; lack of access to health insurance and medication; overdose due to period of detoxification; exacerbation of mental health conditions due to increased stress; and lack of social supports, when exposed to the same high risk communities from which they were incarcerated. The Transitional Care Coordination intervention is designed to strengthen connections between community and jail health care systems to improve continuity of care for HIV-positive individuals recently released from jails.

#### IV. General Overview of the Websites

The project utilizes multiple web systems: a tracking system to confirm eligibility, enter encounter forms, print chart review forms, and upload audio recordings; and a REDCap system to collect research assessments by Study ID.

All 12 sites for the 4 different interventions will use the same websites for tracking and data collection purposes, but each site will only be able to see their own site's participants and associated information. Monitors at AU, BU, and HRSA will have read-only access to these websites, and will not be able to see names if they are entered onto the participant form by sites. BU DCC will have access to all data collected from the websites as the group that created and maintain the websites, but DCC will explicitly prevent other BU DEC team members from seeing names; they will be able to see visit dates and responses to assessments and encounter forms.

# Tracking System

The tracking system is used to collect and document eligibility, provides a mechanism for sites to track participants' status, enter encounter forms, print and submit chart review forms, and upload audio recordings.

# REDCap System

The research assessments will be entered into the REDCap data collection system, for baseline and follow-up visits. The REDCap system will rely on the Study ID automatically created in the tracking system as the unique participant identifier. This user manual explains how to use the REDCap System.

## V. Background about REDCap

## Background

REDCap (*Research Electronic Data Capture*) is a secure, web-based application designed exclusively to support data capture for research studies. It was developed at Vanderbilt University and includes more than 162,000 projects with 1,406 active institutional partners in 90 countries.

The main advantage to using electronic data capture is that skip patterns are built directly into the interviews, enabling the interviewer to concentrate on the participant and his/her responses, rather than trying to follow the directions on a paper questionnaire. There are also interviewer prompts to help the flow of the interviews. Alerts are programmed into the system to warn you of data entry errors. All of this will result in easier interviews and more accurate data.

## Additional Information about REDCap

REDCap is fairly intuitive and easy to use. If you are interested in learning more about the software, you may like to investigate the comprehensive documentation and instructional videos available on the REDCap website (<a href="http://project-redcap.org/">http://project-redcap.org/</a>). Though much of the information is geared toward programmers, you will also find general information that may be of interest to you.

## VI. Using REDCap

#### New user requests

Access to REDCap must be requested through the DCC (contact Clara Chen: <a href="mailto:cachen@bu.edu">cachen@bu.edu</a>). For users new to REDCap, an End-User License Agreement (EULA) will be provided. Access to REDCap may be granted when the electronically signed EULA is returned to the DCC and processed. A user may then be granted access to individual REDCap projects and assigned appropriate project user roles. When a user is added to a REDCap project, an email containing login instructions will be automatically sent via REDCap to the newly assigned user.

## Logging in

The REDCap website may be accessed via https://redcap.bumc.bu.edu/.



You will be assigned a unique username and password. After you first log in, you will be prompted to change your password. Do not share your username or password with anyone. You are responsible for any data entered under your username.

If you forget your password, select the "Forgot your password?" hyperlink to the right of the "Log In" button to reset. You will be automatically logged out after 20 minutes of inactivity.

Please log out of REDCap when you leave your computer.

#### My projects

Once you have logged in, your DEC project(s) will be available for entering, editing, viewing, or downloading participant data, depending on your user permission settings. Project appearance and functionality will be dependent on user role as well.

Your REDCap projects may include:

DEC – Buprenorphine

← enter baseline and follow-up forms

DEC – Patient Navigation

← enter baseline and follow-up forms

- DEC Peer Linkage
- DEC Transitional Care Coordination
- DEC TA tracking log
- DEC training-FOR PRACTICE ONLY
- ← enter baseline and follow-up forms
- ← enter baseline and follow-up forms
- ← enter technical assistance forms
- ← for future development and training



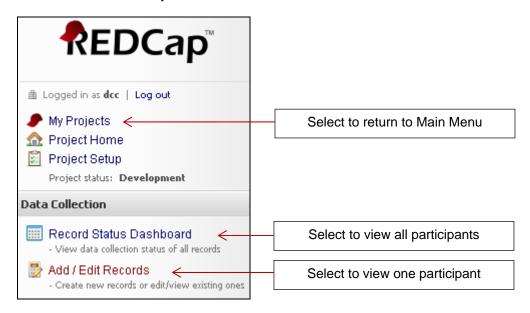
#### **IMPORTANT**

Prior to study start, you will be given access to the test project to conduct training sessions and enter test data. Only test data should be entered in the test projects (clearly labeled "-FOR PRACTICE ONLY"); only real data should be entered in the live projects.

## Navigation in DEC projects

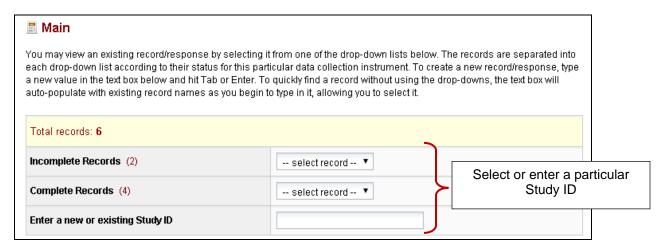
After clicking on the project name, there are two ways to access a participant's record.

- Select Add/Edit Records from the Data Collection section to access one participant's data. (You can also enter a new ID here to create a new record.)
- 2. Select **Record Status Dashboard** to view all participants. Double click on the participant ID of the record you want to view.



#### Add/Edit Records

Select **Add/Edit Records** and select or enter a participant's Study ID (as assigned by the DEC Tracking System) to access the data of a particular participant.



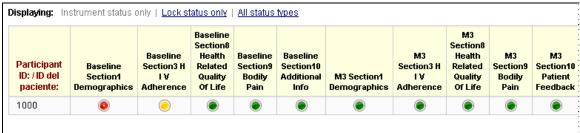


**TIP**: The "Incomplete Records" and the "Complete Records" dropdown lists refer to a particular data collection instrument, not the overall data collection status for a participant. Therefore, it may be most convenient to type the ID into the "Enter a new or existing Study ID" field.

After selecting an ID, the Record Home Page view is displayed: an ID-specific grid of data collection instruments and colored status icons indicating the data entry status for each instrument.

This grid is either a single row (for Transitional Care Coordination) or a grid by time point (for Peers, Patient Navigation, and Buprenorphine).

#### Transitional Care Coordination:



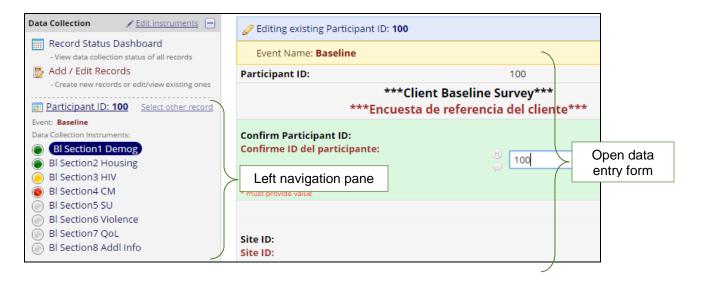
or

Peers, Patient Navigation, Buprenorphine:

Participant ID: 100					
Data Collection Instrument	Baseline	МЗ	M6		
Bl Section1 Demog					
Bl Section2 Housing					
Bl Section3 HIV	<u></u>				
Bl Section4 CM	•				
Bl Section5 SU					
Bl Section6 Violence					
Bl Section7 QoL					
Bl Section8 Addl Info					
FU Section1 Demog					
FU Section2 Housing					
FU Section3 HIV					
FU Section4 CM					
FU Section5 SU					
FU Section6 QoL					
FU Section7 Feedback					
FU Section8 Addl Info		(iii)			

Click on a status icon (colored bubble) in the Record Home Page grid to open that data collection instrument.

When a data collection form is open, a menu of instruments for the selected participant is simultaneously shown in the left margin: either a list of forms for all time points (for Transitional Care Coordination) or a list of forms for the selected time point (for Peers, Patient Navigation, and Buprenorphine). This navigation pane allows users to move directly to other forms for the same participant ID.

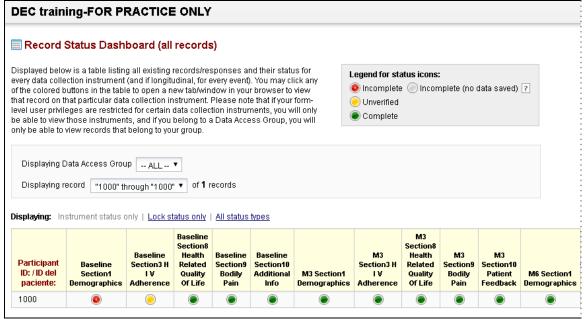


The specific differences in how forms and time points are displayed in the Transitional Care Coordination project versus the Peer, Patient Navigation, and Buprenorphine projects are described in the "Intervention-specific Navigation Tips" section below.

#### Record Status Dashboard

Alternatively, by selecting **Record Status Dashboard**, the user will be presented with a status grid that displays all IDs, all instruments for those IDs, and the data entry status for every instrument. (If an ID isn't listed, then no record has been created for that participant. Use "Add/Edit Records" to add a new record.)

For all projects, the baseline and follow-up forms are shown in a single row per participant ID, in the Record Status Dashboard view.



(Not all forms are shown in this screenshot. One would scroll to the right to see all forms.)



After selecting a status icon, the user will be presented with the specified instrument for the participant. Again, the Data Collection menu on the left-hand side of the screen will list all data collection instruments for the given participant. After completing an instrument, the user may navigate between these instruments by clicking the status icons in the data collection menu.



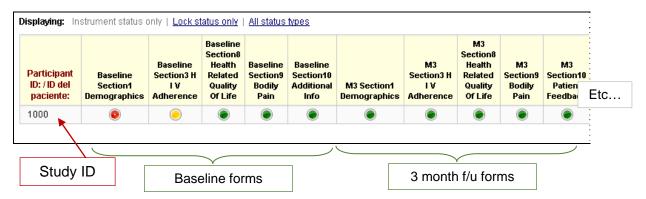
**TIP**: Set the record status to "unverified" to indicate that data entry has been completed and QA is needed. Once the QA process is complete, change the status to "Complete".

If your site does not have a QA (Quality Assurance) process for these survey assessments, simply change the form status to "Complete" once data entry is finished for each form.

# Intervention-specific navigation tips

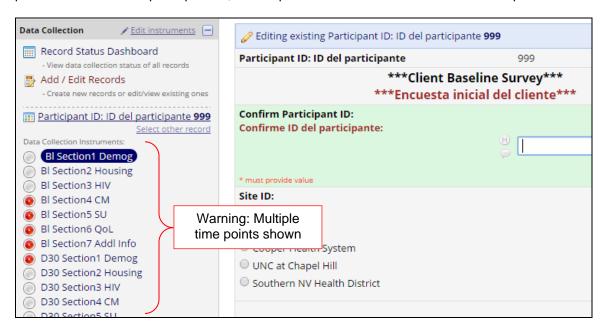
#### Transitional Care Coordination project:

For the Transitional Care Coordination project, all forms and time points will be seen in one row in the Record Home Page:



The Record Home Page data collection grid displays the selected ID and all data collection instruments for the given participant. Note the form lists are truncated in the graphic above.

For the Transitional Care Coordination project: the left navigation pane displays forms for <u>all</u> time points for the selected participant ID, once a particular data collection instrument is opened.



The first part of the form name indicates the time point (BL = baseline; D30 = 30 day post-release; M4 = 4 months post-release).

Please be cautious when nearing the end of the assessments for each time point so that surveys from the next time point are not data entered incorrectly. The initial form for each time point will have a large header at the top surrounded by 3 asterisks on either side, like this:

```
***Client Follow-Up Survey***
(4 Months post release)
***Encuesta de Seguimiento del Cliente***
(4 meses pos-liberación)
```

This should help alert the user to the fact that the form is for a new time point.



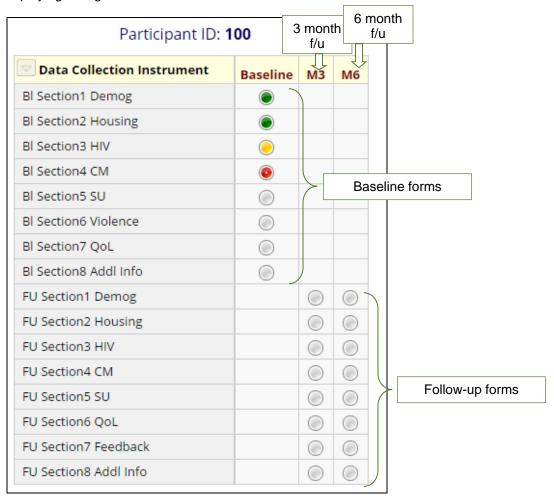
**TIP**: By clicking on the colored dots on the record home page or left navigation pane, you can navigate between instruments without having to re-enter the subject ID.



**TIP**: By clicking on "Select other record" in the left navigation pane (next to the participant ID), you can navigate between IDs without having to return to the home page.

#### Peers, Patient Navigation, and Buprenorphine projects:

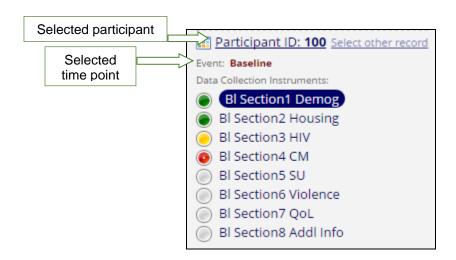
For the Peers, Patient Navigation, and Buprenorphine interventions, the forms in the Record Home Page are displayed in a longitudinal grid that separates the forms into columns by time point instead of displaying a single row:



Each time point has a separate column.

Click on a status icon (gray or colored bubble) in the Record Home Page grid to open that data collection instrument.

When a data collection form is opened for a particular participant and time point, the left navigation pane will only display forms for the selected time point, for the selected participant ID. The "Event" header just under the participant ID will specify which time point is currently open. This "Event" header is particularly useful at the follow-up time points, because the follow-up form names all start with "FU" without a specific time point designation.





**TIP**: By clicking on the colored dots on the record home page or left navigation pane, you can navigate between instruments without having to re-enter the subject ID.



**TIP**: By clicking on "Select other record" in the left navigation pane (next to the participant ID), you can navigate between IDs without having to return to the home page.

# Data entry tips



**TIP**: Use your mouse or "Tab" key to move from field to field (Note: pressing "Enter" will save your data but kick you out of the form).



**TIP**: Do NOT use the keyboard arrow keys to try to move from field to field; arrow keys will instead move within answer options in the selected question.



**TIP**: Do not use the browser arrows to move back and forth between screens/forms or you will lose data.



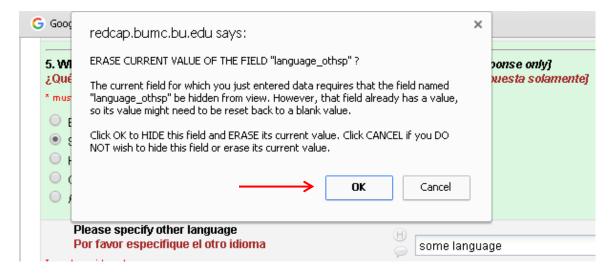
**TIP**: Confirm that you are entering data for the correct participant by checking the ID at the top of each page.



TIP: If you need to clear a radio button, use the "reset" button to the right of the question.



If resetting a field invalidates some of your later responses (the skip pattern has been compromised), then you will receive an ugly REDCap pop-up warning asking for confirmation of the change, and warning you that your previous entry will be deleted. If you intentionally changed your response, then click "OK" and continue. An example of such a warning:



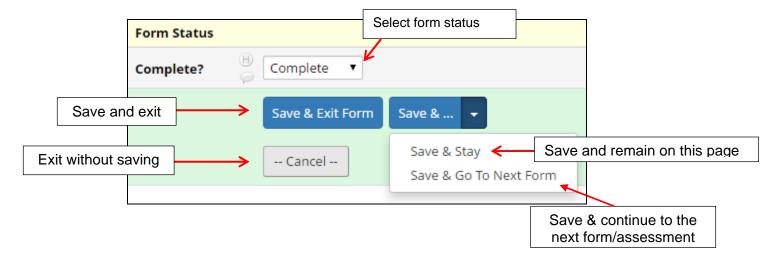
## Saving data

Note that REDCap does not save data until you either use your keyboard's "Enter" key, or you click on a "Save" button in the form status section. Using the "Enter" key on your keyboard will save your data; it will also close the data entry screen, so it is best to **TAB** between fields, instead of using the "Enter" key.

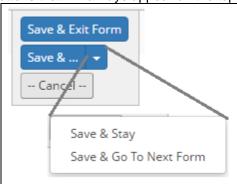
Select the status of the form—incomplete, unverified, or complete. The status icon color on the menu will change to reflect the change in status.

Select a "Save" button to save your data. Save buttons appear at the bottom of each form.





Alternatively, use the save buttons that will always appear on the top right of the screen.





**TIP**: Set the form status to "unverified" to indicate that data entry has been completed and QA is needed. Once the QA process is complete, change the status to "Complete". (If there is no QA process at your site, immediately set the form status to "Complete" once data entry is complete.)

After saving a form, a pop-up box will appear if a required response is missing. REDCap will save incomplete data, but if possible, return to the form and finish entering the data.



## Useful data entry features

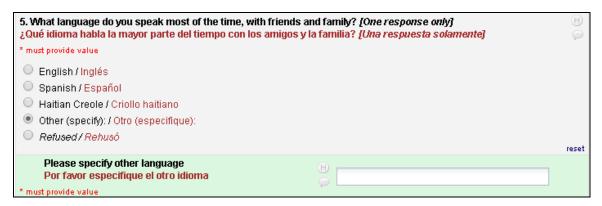
**Calendars:** A calendar function is available for entering dates. Click on the calendar icon to display a calendar. (You may also type the dates.) The "Today" button allows instant entry of today's date.



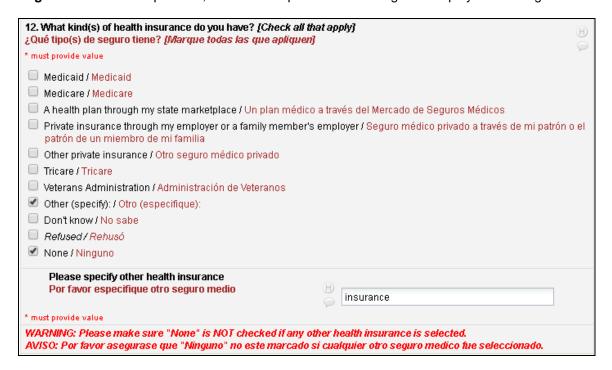
**Warnings:** Warning messages have been programmed to alert you to data inconsistencies and other information important to the user. REDCap system messages will appear if text is entered into a numeric field, for example.



**Skip patterns:** Certain responses may trigger additional questions. In this example, "Other" is selected for sexual orientation. The user is then prompted to specify in a text response.



Logic checks: Where possible, data are compared and warnings are displayed if the logic fails.

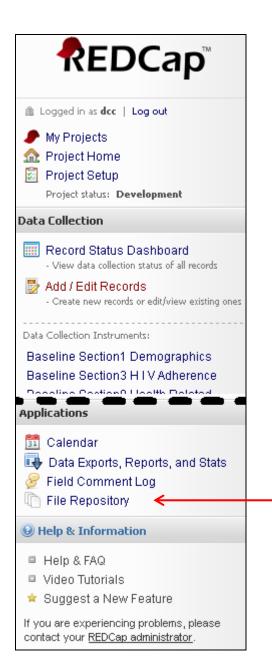


#### **IMPORTANT**

REDCap will warn you when you have not answered required fields and when your data are out of range, but it cannot prevent you from saving your data with these errors.

### Other useful features

Additional features are accessible from the main menu. If you do not see the menu, select **Project Home** to open the home page.

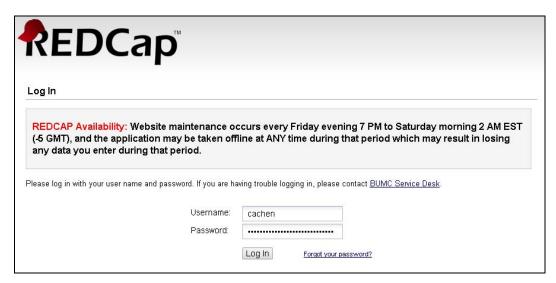


**Note:** This screen capture may show menu items that are not available to you, depending on your user permissions.

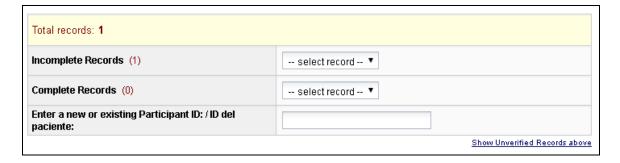
**File repository:** A file repository is accessible from the **Applications** section of the main menu. Documents such as user manuals may be placed here for your reference.

### Enter a new record in DEC assessments

1. Log in to REDCap. (See Section IV.)



- 2. Select the project for your intervention. (See Section IV.)
- On the left side of the screen under "Data Collection," click Add / Edit Records. You will be brought to the screen below. Enter the participant's ID number (as assigned by the DEC Tracking system).



If a new participant is added under an incorrect participant ID number, this is not something users can change themselves. Please contact Clara Chen at BU (cachen@bu.edu) for assistance.

4. The selected participant's Record Home Page will open. On the Record Home Page, click on the gray circle next to the first (topmost) form of the appropriate time point to begin entering data.

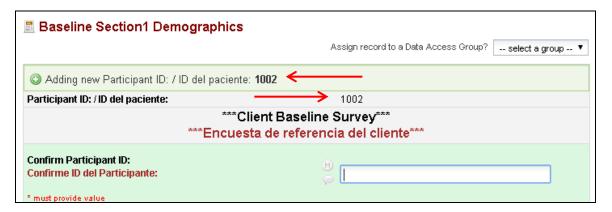
For Transitional Care Coordination users: remember that the first letters of each form name will indicate the time point. BL is baseline, D30 is the first follow-up within 30 days post-release, and M4 is the second follow-up 4 months post-release.

For Peers, Patient Navigation, and Buprenorphine users: the column headers of the Record Home Page grid will indicate which time point is which. M3 is the 3 month follow-up, M6 is the 6 month follow-up, etc.

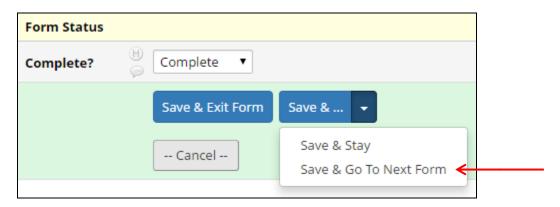
If the participant ID already exists in the REDCap project, the Record Home Page may show colored dots (based on the form status entered by the user during data entry) where forms were previously entered.

5. Click on the circle next to the form name and time point of interest to open the data collection form. If the form was already data entered, the previously entered data will be displayed. If the participant ID is new to the REDCap project, a blank form will open for that participant ID.

The selected participant's ID is shown in two places on the form, as noted in the screenshot below. However, because the participant's ID is so crucial, users must confirm the participant's ID by entering it one more time.



- 6. Answer all questions. When you have finished entering data, set the status at the bottom of the form to "Complete" (or "Unverified" if your site uses this in quality assurance). If your data entry is interrupted, leave the status as "incomplete" as a prompt for later completion.
- 7. Click on "Save & Go to Next Form." The next form will automatically open.



8. Continue through the baseline research assessments. Remember to set the status to "Complete" (or "Unverified") at the bottom of each form and click on "Save and go to Next Form" if you would like the next form to open automatically.

One could also click on "Save & Stay" which will save the data but stay on the same form, or "Save & Exit" which will save the data and then display the Record Home Page. Clicking "Cancel" will exit the form *without* saving the data and return to the Record Home page.

# **Printing Forms**

Forms may be printed from REDCap, both as blank forms and with data entered for a specific form. There are two ways one can print REDCap forms, each with different advantages and disadvantages. Note that depending on your user permissions, you may only be able to download a blank version of the form and would only be able to print using the first method.

## Printing directly from open form

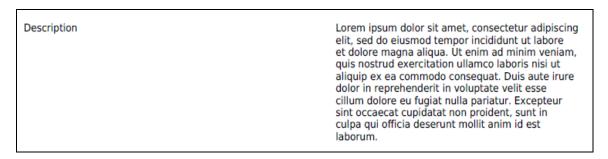
This is the faster option, but may not print out all data in the comments boxes if a lot of text has been entered there. If more data has been entered into a comments box than can be viewed in the box on the screen without scrolling, only the visible part of the comment will print using this method.



To print directly from an open form, simply press "Ctrl" and "p" together and follow the pop-up window directions to print the web page to a printer. No data is saved to the computer, in this case.

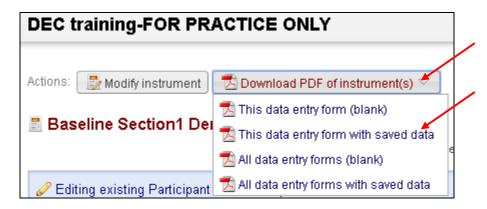
## Downloading and printing PDF of data

This method results in a prettier and more complete printout of the data, but requires a few extra steps. All text in the comments boxes should print out using this method, even if there is more text than displays on the screen.



Note this method also causes skip patterns to print including ones that are based on site. This may be confusing when viewing the downloaded form.

To download and print a PDF of the entered data, scroll to the top of the desired form and click on the "Download PDF of instrument(s)" button. Select the "This data entry form with saved data" option, unless you want to print a blank copy of the form.

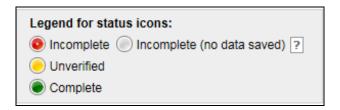


This will automatically download a PDF with the data saved on the open form to the download folder of your computer. Navigate to the download folder in order to open the PDF file and print it. After printing the PDF, **be sure to delete the downloaded PDF** from your computer and purge your computer's trash can of deleted files.

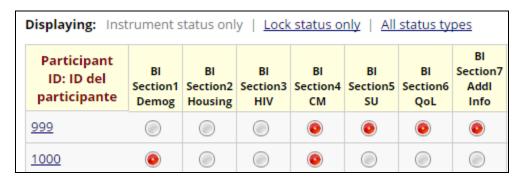
## VII. Quality Assurance

## Using status icons to indicate status of form

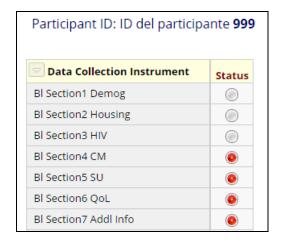
The form status icons (the colored bubbles) provide a quick visual check of the data entry completion status of each form. When a user sets the form status (incomplete, unverified, or complete) and saves the form, the form status icon changes color.



For a quick overview of data entry status, select the Record Status Dashboard from the Main Menu and you will see a list of all form IDs and the data entry status of each form. Each row displays a separate ID. Clicking on a status icon will open that instrument.



Similarly, one could select a specific participant ID and view the Record Home Page showing the data entry status of each form for the selected participant. Again, clicking on a status icon will open that form.



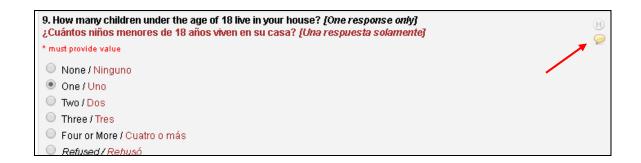
Forms should be marked "Complete" when data entry and any QA has been completed. Forms that contain data but are not marked as "Complete" will appear in the monthly data cleaning query reports generated by the DCC.

## Using field comments for QA

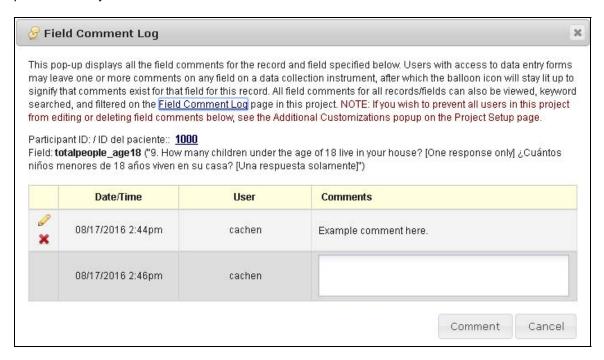
Field comments are a useful way to capture additional information about a particular response, questions you have, notes about things to follow up on, or anything else on which you wish to comment.

The field comment icon is the same gray background color if there are no field comments on that variable for that form; it is yellow if a field comment has been entered.

To create a comment, click on the comment icon next to the question.



A window will open, showing the date/time of the comment, the user entering the comment, and a place to enter your comment.

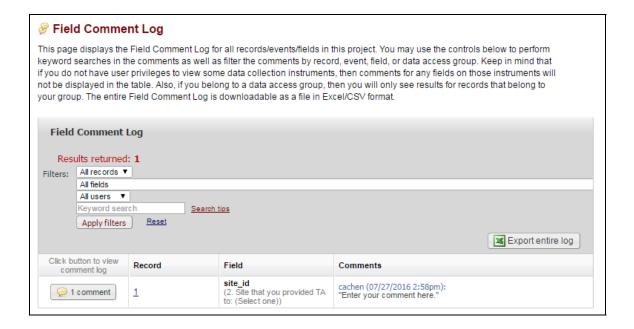


Click on the "Comment" button to save the comment. The comment icon will then turn yellow if this is the first comment added to this field on this particular form. If you do not wish to save the comment, click "Cancel" to return to the form without saving the comment.

A list of all comments is available by selecting the "Field Comment Log" in the Main Menu, if one has permissions to see it.



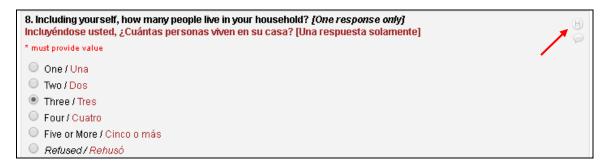
The log is searchable and can be exported as an Excel file.



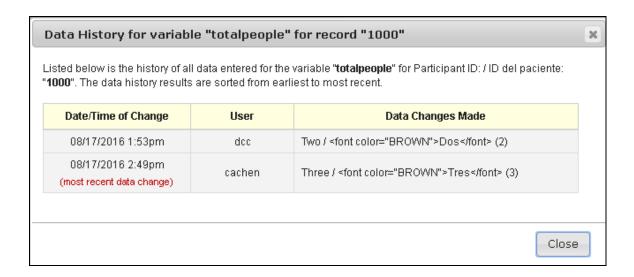
The field comment log lists all field comments for all forms in this project, although filters can be applied to show only a subset based on user or variable of interest. Users may also search the comment logs for keywords of interest.

## Review history of data edits

To view the history of all data edits for a particular field, click on the history icon.



The history log will open, displaying the date/time of each change, the user who made the change, and the data edits that were made.



## Using Data Quality Rules

With the appropriate user permissions, you can use the Data Quality function to run data cleaning queries, which REDCap calls "Data Quality Rules." There are default Data Quality Rules, such as checks for missing values, out of range values, and data outliers.



Other Data Quality Rules may be created, if one has permission to do so. For information on how to create new Data Quality Rules, select "Help & FAQ" from the bottom of the Main Menu.

From within the Data Quality Rule display, one can click on the data to open the form for editing in another window. You also have the option of selecting "exclude" to exclude the record from future reports for this particular Data Quality Rule.