# EVIDENCE INFORMED INTERVENTIONS

User Manual for the DEC Tracking System

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#### 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 DEC Tracking web system. Note that there are multiple web systems used in this study.

The *LIVE* tracking system URL is: <a href="https://wwwru.bumc.bu.edu/DCC\_DEC/">https://wwwru.bumc.bu.edu/DCC\_DEC/</a>
The TEST tracking system URL is: <a href="https://devdcc.bumc.bu.edu/DCC\_DEC\_Test/">https://devdcc.bumc.bu.edu/DCC\_DEC\_Test/</a>

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 websites/project for training purposes, or upon special request. Otherwise, the DCC encourages users to only have access to the LIVE websites/project to reduce potential errors in saving forms to the wrong system.

#### **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: <a href="mailto:chaisson@bu.edu">chaisson@bu.edu</a>

#### 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 the ITAC, DEC, 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. The ITAC, DEC, and HRSA users 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 and provide a mechanism for sites to track participants' status, enter encounter forms, print and submit chart review forms, and upload audio recordings. This manual provides details about how to use the Tracking System.

# REDCap System

The DEC 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. Please refer to the REDCap user manual for details about how to use the REDCap System.

# V. Basics of the DEC Tracking System

# **Browser Suggestions**

The tracking website is optimized for Internet Explorer browser, although all data entry functionality is checked using other browsers including Chrome, Firefox, and Safari. Known browser-related differences include slower screen refreshing

and having to download weekly reports before viewing them, instead of opening them within another browser tab.

# Logging In

Use a web browser to navigate to the DEC Tracking System URL. The website is: https://wwwru.bumc.bu.edu/DCC\_DEC/

Log in by entering your unique username and password.

Each user will be given a separate user account. Do not share your account or user credentials with anyone else. Individuals who need access to the system should contact the DEC project manager (Alexis Marbach: <a href="mailto:amarbach@bu.edu">amarbach@bu.edu</a>) and the DCC project manager (Clara Chen: <a href="mailto:cachen@bu.edu">cachen@bu.edu</a>) to request their own account.

There is a link on the login page to click if you have forgotten your password. A new temporary password will be sent to your email address; you will be required to change this when you next log in to the system.

#### **User Permissions**

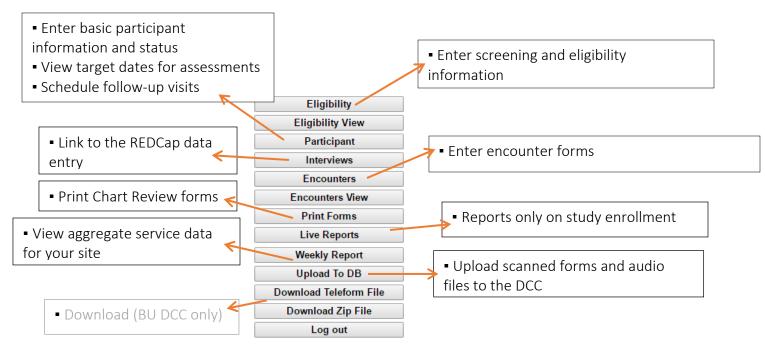
Certain functions, forms, or reports may be restricted based on user roles. If, while reviewing the sections of this user manual, you are unable to see the buttons, links, or forms that are described, this means you do not have permission for that functionality. If you feel this is in error, please contact Clara Chen (cachen@bu.edu).

# Home Page

The home page is the webpage that displays after logging in to the system. The home page of the screening system displays links to screening and tracking forms, chart review forms, reports, and links to upload files. You may not see all buttons in the screenshots, depending on your individual user permissions.

# Dissemination of Evidence Informed Interventions

Test Site - Do not enter real data.



Once you enter your username and password, you will be taken to the Main Menu screen shown above. Make sure that you are in the live website if you are working with real data. The practice website will include a warning: "Test Site – Do not enter real data."

# **Navigation Links**

There are buttons on the each page to return you to "Home" (the home page shown above); some pages will also have buttons to bring you "Back" to the previous page, or allow you to "Log out" and exit the system without closing the web browser. Closing the browser will also log the user out of the tracking system.

# Saving Data

Answers will NOT be saved when the "Home" or any button is clicked other than a "Submit" button. Users must click one of the gray "Submit" buttons in order for answers to be saved to the database. This is the case for all forms.

#### General flow

In general, the forms listed on the home page mimic the order in which the forms should be completed.

Data for each potential participant is first entered into the Tracking System with the screening eligibility form. After an individual screens eligible and consents, the Participant form should be entered. Then, click on the Interview button for a quick link to the REDCap assessment forms (login required). Encounter forms should be entered daily for each day in which there are interactions with or on behalf of the participant.

If a participant becomes inactive, leaves the study, or passes away, site staff should update the status field on the Participant form.

#### **Protected Information**

On the Participant form, there are optional fields for sites to enter participant names if they wish. If names are data entered, the BU Data Coordinating Center (DCC) will have access to these information as the group that created and maintain the tracking website. The DCC would use that information only to display participant names on the site-specific tracking and summary reports, for the site staff's convenience. However, the rest of the BU DEC team and the ITAC would remain blinded to these specific fields; they would only see "Participant: [Study ID #]" in place of the name, on all forms and reports. If sites opt not to enter names, they would also only see "Participant: [Study ID #]" on their forms and reports.

# VI. Data entry

The electronic data entry forms may all be accessed through the tracking system website, either through direct data entry as described below, or via a link to the REDCap assessment forms. The TELEform chart review forms, which use optical character recognition to convert the information to an electronic format, can also be printed and uploaded to the DEC team through the tracking system.

# Screening eligibility form

The screening eligibility form includes intervention-specific eligibility questions. Only the questions relevant to the user's site will be displayed, and users will only be able to see data collected from their own site.

To enter a screening eligibility form, click on the "Eligibility" button from the home page. Additional questions may appear as responses are data entered, including fields to document consent date or reasons for refusing to consent.

Once a potential participant screens eligible and consent is documented, this form will also automatically assign the participant's Study ID. Note that audio recording consent is not needed for the participant to be enrolled and for a Study ID to be assigned; only the overall study consent is required for a Study ID to be assigned.

The screening eligibility form must be entered before any other information can be entered into the Tracking System for this participant, and before any REDCap forms may be entered. The Study ID assigned on the Eligibility form will be used throughout the DEC websites to refer to each participant. Please make a note of it when it is assigned on the screening eligibility form!

There is also a "View Eligibility" button on the home page, which will allow users to view existing screening eligibility forms from the user's site.

#### Participant Form

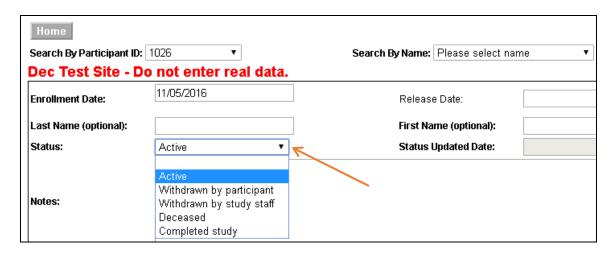
This form is used to track participant status and completion of scheduled visits. For participants in the Transitional Care Coordination (jails) intervention, this is also the form where the participant's release date is recorded.

Note that the participant's name is optional on this form. If sites would like to use name for ease of tracking, only that site's staff will be able to see this information, whether on site-specific reports or on this participant form. ITAC and DEC staff will only be able to see "Participant: [Study ID #]", which is what will appear for the site staff also if names are not entered. (The exception to this rule is that BU DCC staff who work for the DEC will be able to see all data entered into the web systems, as they created and maintain them. However, they also strictly control access to these protected information and not even other BU staff members will have access to those PHI.)

Based on the enrollment date (and/or release date for Transitional Care Coordination participants) entered on this form, windows for each follow-up visit and chart review are calculated and displayed at the bottom of the web page. As each visit is scheduled and completed, each visit's status should be updated. Similarly, chart review completion should also be documented here.

Visit dates that are out of window will result in a warning, but can still be saved. Similarly, warning messages for unexpected date changes (changes to enrollment date after the Participant Form is initially saved, or for Transitional Care Coordination (jails) intervention sites, release dates that are earlier than enrollment dates) will appear to remind staff to double check the dates in question - but these dates can still be saved.

If a participant's status changes during the course of the study – if they complete the study, withdraw from the study, or pass away – this should be noted on the Participant Form by changing the "Status" dropdown field.



The Status field automatically defaults to "Active" when the Participant Form is created.

Enrollment and tracking reports will be based on the documentation on the Participant form.

# Interview (REDCap Assessments)

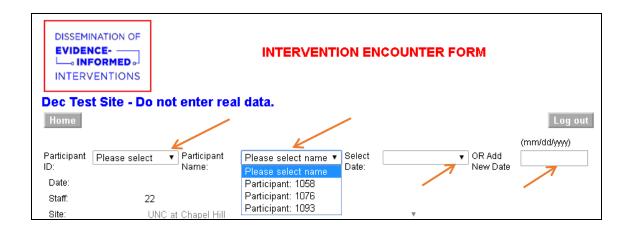
This button on the home page provides a link to the REDCap website. A separate login is required for the REDCap website. Please see the REDCap user manual for details regarding the REDCap system.

#### **Encounter Form**

Encounter forms should be entered daily for each day in which there are interactions with or on behalf of the participant. Different staff at the same site may interact with or on behalf of the same participant on the same day, so encounter forms are unique to each participant, day, and staff person. Users may only enter and edit their own encounter forms, but may view other encounter forms for participants at their site using the "View Encounter" button.

The questions on the encounter forms are generally the same across interventions, but some interventions have a few additional intervention-specific encounter types listed at the bottom of the form. The question numbering may include some skipped numbers at the bottom of this page because of this changing visibility based on the user's site.

To enter an encounter form, click on the "Encounters" button on the home page. On the encounter form, first select the participant of interest either by selecting the participant's Study ID or the participant's name. If names are not entered, the participant name dropdown list will display as "Participant: [Study ID #]" and will be functionally equivalent to the Study ID dropdown list.



Then to the right of those fields, either select an existing encounter form date by using the dropdown "Select Date" menu or enter a new date in the field just to the right of the "OR Add New Date" text. Then use the "Tab" or "Enter" key to move off the field, or use the mouse to place the cursor elsewhere on the web page.

If an encounter form already exists for that combination of participant ID, date, and the staff ID of the user entering those parameters, the data from that form will populate the web page. If no encounter form already exists with that combination of participant ID, date, and staff ID, then a new encounter form is begun with those fields pre-populated. Staff ID and Site are always pre-populated on the encounter form based on the user logged in. Please remember to always enter forms using your own unique login; do not share your login information.

Data enter the rest of the form, including whether an encounter occurred or not, the encounter location, and the encounter activities, types, and durations in minutes. If an encounter did NOT occur, the table of encounter activities will automatically hide so that users do not need to scroll down as far to reach the "Submit" button. If an encounter DID occur, please note that an encounter "type" should be chosen from the dropdown menu for each checked encounter activity row, and a "duration" in minutes should also be entered for each activity row selected. After all encounter form data have been entered for the specified date, click "Submit" at the bottom of the web page. The web page will automatically calculate the total amount of time spent by summing the entered durations for each encounter activity endorsed.

Remember that the data are only saved if you click "Submit" at the bottom of the page! If you click on the "Home" or "Log out" button without clicking "Submit" first, the form data will not be saved. Always click on the "Submit" button to save your data.

If further encounter activity should occur for a participant after an encounter form has been entered for that same date by the same user, simply pull up the previously entered encounter form, add the additional encounter information, and

click "Submit". The total duration for the day will automatically recalculate based on the updated information.

If a field that opens a skip pattern is entered in error, please delete the data in the sub-question fields before correcting the error that closes the skip. For example, if "Location of encounter: other" is selected, this opens the "other specify" text box so the other location can be specified. If these fields were entered in error and the user wants to remove the "location of encounter: other" checked box, the "other specify" text box should have its contents deleted before unchecking the box. Similarly, if an encounter activity was entered in error, the duration should be changed to "O" minutes and the type should be changed to "Please select" before unchecking that specific encounter activity's check box.

#### **Print Forms**

This web page will allow users to print chart review forms pre-populated with participant ID and time windows of interest for certain chart review components. A separate training will occur on these TELEform (optical character recognition) forms at a later time.

# Live and Weekly Reports

These include real-time ("Live Reports") and periodic ("Weekly Reports") reports that summarize study enrollment and track participants' visits and chart review completion. "Weekly Reports" will include data cleaning reports that will be updated monthly; automated emails will notify users when these data cleaning reports are updated. Reports will be site-specific although overall numbers will be available to ITAC and DEC staff. Note that only the site-specific reports will include the optional participant names; the ITAC and DEC staff will only be able to see these listed as "Participant: [Study ID #]". Reports and forms will also display only "Participant: [Study ID #]" if names are not entered onto the Participant form.

The "Live Reports" displays a list of buttons, one for each real-time report. To open "Live Reports", simply click on the button displaying the report title of interest.

The "Weekly Reports" page displays a list of all available reports, including an informative title and the date and time that each report was last updated. To open "Weekly Reports", click on the "Select" link next to the report of interest. In some browsers, such as Chrome, this may prompt the user to download the file rather than automatically open it; this is a known difference in web browsers. If you use a web browser that prompts a download first, please be mindful of PHI and remember to delete reports from downloaded locations.

# VII. Uploading files

This section of the tracking website allows users to securely upload both completed chart review forms and zipped audio files to the DEC.

Chart review data collection forms will be printed using the "Print Form" as described in an earlier section of this manual. After the forms are manually completed using blue or black ink, they should be scanned and then uploaded to the DEC using this secure upload page. The upload page includes detailed instructions about how to scan and upload chart review forms for best quality results. Additional training on the chart review forms will be provided at a later time.

Audio files should be zipped prior to upload as the secure upload function will not accept unzipped audio file formats. To turn the raw audio file into a zip file, use any compression software (WinZip is readily available on Windows machines; 7-zip is a free package available at <a href="www.7-zip.org">www.7-zip.org</a>) and then follow the upload instructions to send the zipped file to the DEC. If you have questions about this process, please contact Clara Chen (cachen@bu.edu).