

Overview

- 1. The Community Engagement Reporting System is in REDCap. REDCap is a secure web platform for building and managing online databases and surveys.
- 2. With this system, you will only need to complete one (1) report, regardless of how many Networks your site is affiliated with.
- 3. Please note that the system is broken up into different pages. Each page will require some input or action on your part. This guide provides specific instructions about the action required for each section. Please complete all the appropriate sections for your site.
- 4. As you go through the sections, click the "Save and Exit Form" button located at the upper right of each section or at the bottom of each section whenever you need to leave the page. This makes certain that the information you input is saved.
 - a. You have the ability to start entering data and return later to finish. To do so, <u>mark any page as</u> **incomplete** in the Form Status section at the bottom of the <u>page</u>, then click **Save and Exit Form**.
 - b. When all information has been entered and a section is complete, please go to the "Form Status" section at the bottom and change the status to **Complete**.
 - c. When the Work Plan Signature Page has been marked as Complete (which should be your last step), the system will notify the project managers at the networks that your plan is complete and ready to be reviewed.
- 5. You can check the status of each of the pages in the system by viewing the circles adjacent to each of the pages. The colors show whether the page is complete (green), incomplete (red), or has not been started (blank circle). When the project manager has reviewed the plan and determined that it is approved, the sections will be locked and a yellow padlock icon will be displayed. We do not use the "Unverified" (yellow circle) option.





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New Account Setup/Resetting User Access

- If you require access to the Cross-Network Community Engagement Reporting System, please contact your site's Community Program/Project Manager who will initiate the request. <u>Do NOT contact the REDCap Administration team directly, as they will not be</u> <u>able to assist you with this task.</u>
- If you are unable to log-in and/or reset your password, please contact your site's Community Program/Project Manager who will initiate the request. <u>Do NOT contact the</u> <u>REDCap Administration team directly, as they will not be able to assist you with this</u> <u>task.</u>
- Accounts will be suspended if they are not used in the prior 8 months. You will need to contact your Community Program/Project Manager to have your account reset.
- If staff members are added to the site team or leave their position at the site, please notify your Community Program/Project Manager so that a new account can be created, or to delete a User ID that will no longer be needed.

Logging In/Accessing Reporting System

Logging In:

Step 1: Open your browser and go to the URL http://redcap.fredhutch.org/

Step 2: Enter User ID and Password

Accessing Reporting System:

Step 1: Click on the **Cross Network Community Engagement Reporting System** link. This will take you to the project home page.

On the **Project Home** page you should see the following:

Project Statistics (center of screen)

Data Collection (left hand menu)

- Record Status Dashboard
- View/Edit Records



Applications (left hand menu)

- Calendar
- Data Exports, Reports, and Stats
- Fred Hutch Redcap Training

Entering Data into Reporting System

Step 1: To enter/view data, click on View/Edit Records

- Go to "Choose Your Site" and select your site from the drop-down menu.
- Once your site is selected, you will be taken to the "Record Home Page" automatically.
- Make sure the site indicated is your site (you shouldn't be able to access another site's information)
- Scroll down to the "Data Collection Instrument" Section and you will see the list of sections and columns for each of the reporting periods. **Be sure that you are entering information in the correct year!**
- You can go to a section by clicking on the circle to the right of it, no matter what color circle is displayed. Make sure you are clicking the circle under the appropriate reporting year you want to see/edit!

Work Plan Evaluation

The *Evaluation* page describes the key areas of how your annual work plan will be evaluated by the Network Community Staff. Additionally, this page also describes the metrics that are used by the HVTN Network Evaluation Committee (NEC) to evaluate community engagement at clinical research sites. Only HVTN sites are required to comply with the HVTN NEC requirements.

<u>Action Step</u>: Read this page to ensure you understand how plans will be reviewed. Under Form Status select <u>complete</u>, then click <u>Save and Exit Form</u>.



Community Assessment

The Community Assessment page is where you will describe important information regarding the community where your site is located. This information helps "paint a picture" of some of the key elements of the community, and potential influencers of education, recruitment, and retention activities.

Race and Ethnicity Data: Please enter the racial and ethnic demographic data for your site's city, as well as the HIV incidence data for your local community. This is data that should be readily available online; a Google search of "[city's] population by race" should yield the population demographics. HIV incidence data can usually be found through your local health department. Please check for the most recent data available to enter into your Community Assessment. The race/ethnicity categories provided are those required to be collected by the US government because we receive public funding. Sites can also enter an additional category that is unique to their location (e.g., sites in Peru may want to list Mestizo/a). Answers in each field should be shown as percentages with one decimal place (e.g., 10.5). As part of reviewing the plan, Network staff will be looking at whether the recruitment objectives the site has included are expected to be successful in helping the site to enroll participants whose diversity reflects their city's demographics at a minimum, and whether the objectives will move the site toward the aspirational goal of enrolling participants whose diversity reflects the city's HIV incidence rates.

Action Step: Please review the questions thoroughly. New sites should complete the full assessment. Experienced sites should update their assessment from the previous year. All sites will complete the demographic and HIV incidence data. When you are finished, change the **Form Status** to **complete**, then click **Save and Exit Form**.

Site Community Engagement (CE) Team

The *Site Community Engagement* Team page is for you to describe your community education, recruitment, and retention team members, and what assets are in place to assist these team members in carrying out their work.



Action Step: All sites should input their community staff member information in the required boxes, including the first and last name, role, and marking whether the staff person works a part-time or full-time schedule. All sites should respond to the questions as completely as possible. When you are finished, change the **Form Status** to <u>complete</u>, then click <u>Save and Exit Form</u>.

CAB

The *CAB* page is for you to describe the composition of your sites' CAB (and/or Community Working Group, or any other name for this group that you use locally), including chair and cochair information, the information for your Global CAB/Network CWG representative(s), CAB objectives, CAB training, and CAB demographics. If the demographic information is unknown to you (such as people's sexual orientation or their age), you are not required to collect this data from your CAB members. Rather, we would like you to share the information that your staff members already know.

Action Step: All sites should complete the section. Input the number of CAB meetings that are scheduled for the reporting period, and the number of meetings an Investigator of Record (IoR), Principal Investigator (PI), or co-investigators (Co-PIs) are scheduled to attend. Input the training activities that the CAB will be involved in during the reporting period and respond to the questions as completely as possible. When you are finished, change the **Form Status** to **complete**, then click **Save and Exit Form**.

Annual Work Plan

The Annual Work Plan page is where sites will describe the specific community education, recruitment, and retention goals and objectives your site and CAB have agreed to work on. Both the community education and recruitment portions of this section have a space to input an additional goal if your site and CAB have agreed to a site-specific goal that is not already listed. It is advised that you try to keep your objectives brief yet specific, describing the specific work to be done and who will do it [Example Objective: Recruiters will post recruitment flyers in 10 community locations monthly; frequency will be 12 (once per month)]. Having clear objectives will help sites to evaluate their own work throughout the year, and know when your activities are successful. All of the objectives submitted in this section will automatically carry



over and populate the Mid-Year and End-of-Year report sections so that you do not need to retype the information into the reports later.

Objectives as Directed: Depending on the network affiliation and the kinds of trials your site may implement, sites may be asked to complete "Objectives as Directed" to address certain kinds of studies and/or populations for each Network. For example, all HVTN sites will be asked to write an objective about VISP education, but only sites in particular regions will be asked to write objectives about recruitment for TB or pediatric studies. The HPTN has specific requirements as well.

Retention objectives are intended to capture those things that your site may do in addition to routine retention activities like making visit reminder calls. Trying to capture the frequency for things that are done routinely for every participant would be very challenging, and these activities can be described in the narrative section (described below). Instead, consider objectives for retention activities such as these examples:

- an annual party to thank volunteers (frequency = 1),
- sending out holiday cards to all participants in December (frequency = 1), or
- sending out a quarterly volunteer newsletter (frequency = 4).

Action Step: All sites should write objectives for community education, recruitment, and retention that are measurable, as well as how many times the activity will occur in the reporting period, and which goal(s) the activity addresses (from the list of goals at the beginning of each section). Complete the Objectives as Directed as relevant for your site, and submit the ones that have been assigned to your site. When you are finished, change the **Form Status** to **complete**, then click **Save and Exit Form**.

Annual Work Plan Narrative

The Annual Work Plan Narrative is for you to describe the specific components of your recruitment and retention process, and how you intend to work with specific populations that may be needed for different studies. It also describes how different members of the site staff are responsible for various steps in the enrollment and retention process. This allows the network project managers to understand how your process may be supporting or hindering



your sites' Community Engagement efforts, so that we can provide support or share ideas that have been successful at other sites. Please note that some new questions have been added for the 2023-2024 plan. These include questions about your process for obtaining consent from adults/parents/guardians as well as assent from children/adolescents, and information about reasons why people who may be eligible for a study decide not to enroll.

Action Step: Please respond to the questions/prompts on this page thoroughly. When you are finished, change the **Form Status** to **complete**, then click **Save and Exit Form**.

Work Plan Signature Page

***Please do not change the name of your site that is shown in the Site Name field. ***

We recognize that sites may go by different names as they work in their local communities, but the Site Name field corresponds to how the site is referenced in other DAIDS and Network listings. **Do not make any changes.**

Sites should include the names of all staff members that contributed to writing the plan, regardless of the role they work in. Sites should also include the names of all CAB members who participate in reviewing the plan and providing feedback about it. Sites are required to have CAB review of their Annual Plan.

The signature of the CRS/CTU Principal Investigator (PI) or Investigator of Record (IoR) is an indication of their support for the work described in the plan. Their signature represents a willingness to provide the resources (financial, human, or other) needed to successfully implement the plan. Signing the page is done using a mouse (on a computer) or your finger/a stylus (on a tablet).

<u>Action Step</u>: Please complete all of the fields in this section. When you are finished, change the **Form Status** to <u>complete</u>, then click <u>Save and Exit Form</u>. When the Signature Page has been marked as "complete," <u>an email notification will automatically be sent to your Network Community Program/Project Manager(s) to let them know that your completed plan is ready for review.</u>

PAUSE: You have completed the primary components of the Annual Plan for Community Engagement. Your Network Community Program/Project Manager(s) will be in touch with any feedback about the plan, instructions regarding any revisions that are needed and a



resubmission date, or a notice of their approval of the plan. When the plan is considered final and approved, the Program/Project Manager will lock the sections. If sites feel that they need to revise the plan during the course of the year, they can contact their Program/Project Manager to unlock the plan, and to have the revisions reviewed.

Mid-Year and End-of-Year Reports

Mid-Year and *End-of-Year* reports are designed to assist the Networks in assessing sites' progress toward completing their stated objectives, and to get a glimpse into any successes and challenges the site may be having. The objectives in the Annual Work Plan will automatically be carried over into the reports along with the target number sites hope to achieve so that sites do not need to enter the information again (and the form will not allow you to do that). Please pay attention to the reporting period covered by each report.

Action Step: All sites will complete the *Mid-Year* and *End-of-Year* reports. Complete the target audience and number of times that each objective occurred. If the activity did not occur in the reporting period, please leave the target audience and number of times fields blank. Briefly summarize the major highlights, including successes and challenges, of your efforts in community education, recruitment, retention, and CAB in the narrative fields just below each portion of the section. Complete the fields regarding the number of CAB meetings held and investigator attendance. When you are finished, change the **Form Status** to **complete**, then click **Save and Exit Form.** An email notification will automatically be sent to your network project manager to make them aware that the report is complete and ready for review.

User Support

If you are having any challenges or issues navigating the system, gaining access, or for questions regarding any of the sections of the plan, please email your site's Network Community Program/Project Manager directly, or you may email the Community team for the appropriate network. HPTN: community@hptn.org HVTN: vtn.ceu.pm@hvtn.org