REDCAP USER GUIDE

What is the CHAMP REDCap Project

How to enter research data

Version 11.25

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INTRODUCTION TO CHAMP REDCAP PROJECT

WHAT IS REDCAP, WHAT IS IN THE CHAMP REDCAP, REDCAP AND THE CHAMP STUDY WORKFLOW

WHAT IS REDCAP?

REDCap is a cloud-based platform commonly used in academic research that allows researchers to create data entry forms, surveys, and more. The platform is HIPAA compliant and widely recognized as a secure location for research data storage.

WHAT IS IN THE CHAMP REDCAP PROJECT

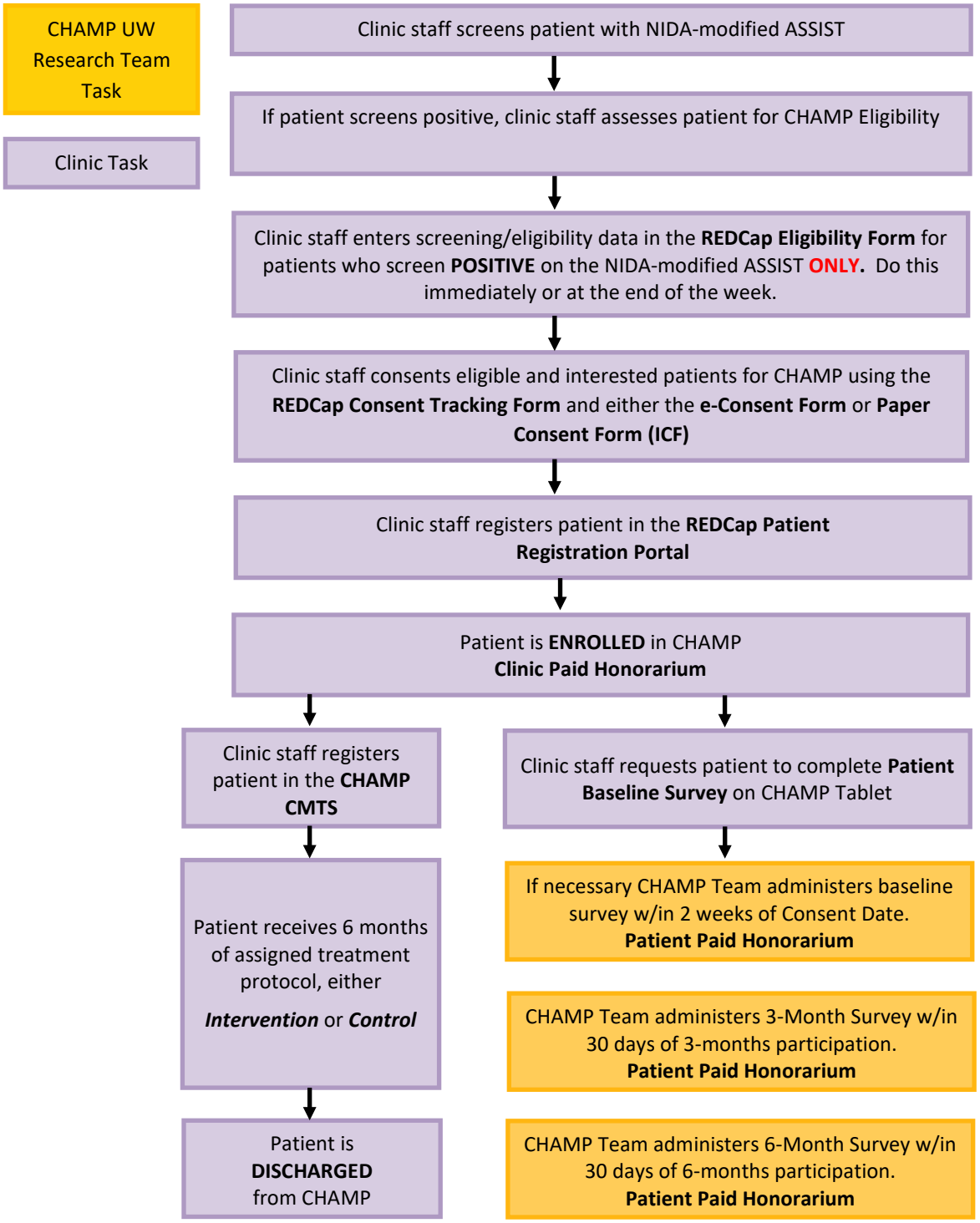
Below is a table that illustrates what is contained in the CHAMP REDCap Project (herein referred to as ***the REDCap***); further detail about each form or survey will be provided in subsequent sections of this manual.

Project Name	Form Name	Purpose and Description	Who Accesses	Entry Frequency
CHAMP Eligibility and Consent	**Patient Eligibility**	Location to enter patient screening results and eligibility status for CHAMP	Behavioral Health Care Manager	Routine; once a week.
	Consent Tracking Form	Location to enter eligible patient's name and email. E-consent form will be emailed with this information.	Consenters	As needed; for patients who will virtually consent.
	e-Consent Form	Electronic Consent Form and HIPAA Authorization Form. **UWH Clinics:** the UWH Consent Form will be available to you in REDCap.	Consenters	As needed.
	e-Consent - Spanish	Spanish version of the General e-Consent Form.	Consenters	As needed.
CHAMP Registration and Adverse Events	**Patient Registration**	Location to enter registration information for patients who consent to participate in CHAMP	Behavioral Health Care Manager	Routine; with each patient recruited.
	Adverse Event and Protocol Violation	Location to report any adverse events, serious adverse events, or protocol violations to the CHAMP Research Team	Behavioral Health Care Manager	As needed.

Any **questions** or **issues** with accessing or using the CHAMP REDCap Project should be directed towards **Danielle Bohonos**, CHAMP Research Coordinator, at dbohonos@uw.edu.

THE CHAMP STUDY WORKFLOW

The CHAMP Study Workflow illustrates the main steps in the research process and when applicable REDCap Forms are used. This workflow does not include any organization or provider level surveys and will be elaborated on in subsequent sections.



ACCESSING THE CHAMP REDCAP PROJECT

OVERVIEW OF HOW TO ACCESS REDCAP AND NAVIGATE THE PLATFORM

WHO NEEDS ACCESS TO THE REDCAP PROJECT?

In the CHAMP Study, only the Behavioral Health Care Managers (BHCM)/Consenters and support staff need individual access to the REDCap because these are the only team members who will perform direct data entry.

BHCMs, Consenters and Staff are limited to accessing, viewing, and entering data from their own clinic or clinics.

- Consenters need access to use the virtual consent forms.
- BHCMs and support staff need access to track eligibility, register patients, and report adverse events and protocol violations.

HOW TO ACCESS THE REDCAP

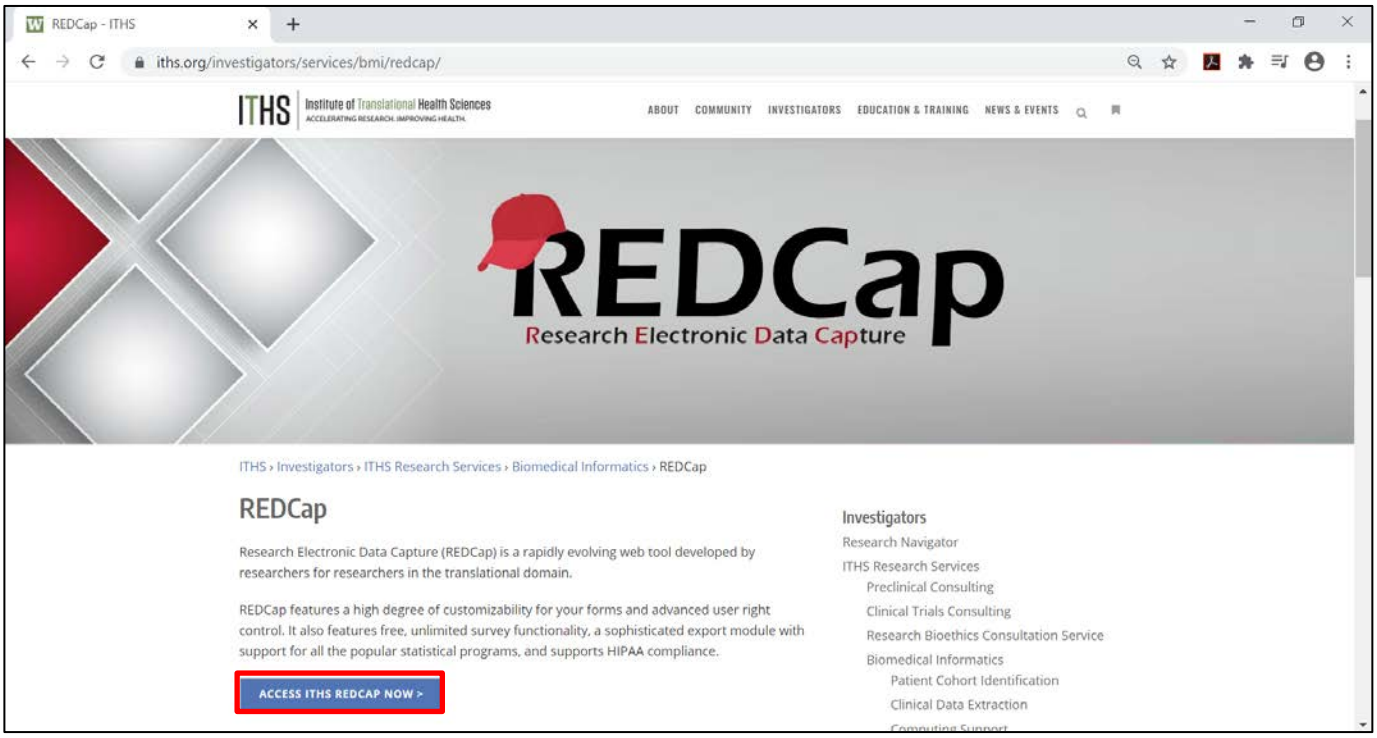
BHCMs, Consenters and Support Staff can access the REDCap in two ways:

- The CHAMP Website (https://champ.psychiatry.uw.edu/): click **"CHAMP REDCap Project"** button in the Quick Access section at the bottom of the Home Page.
- The ITHS REDCap Website (https://www.iths.org/investigators/services/bmi/redcap/).

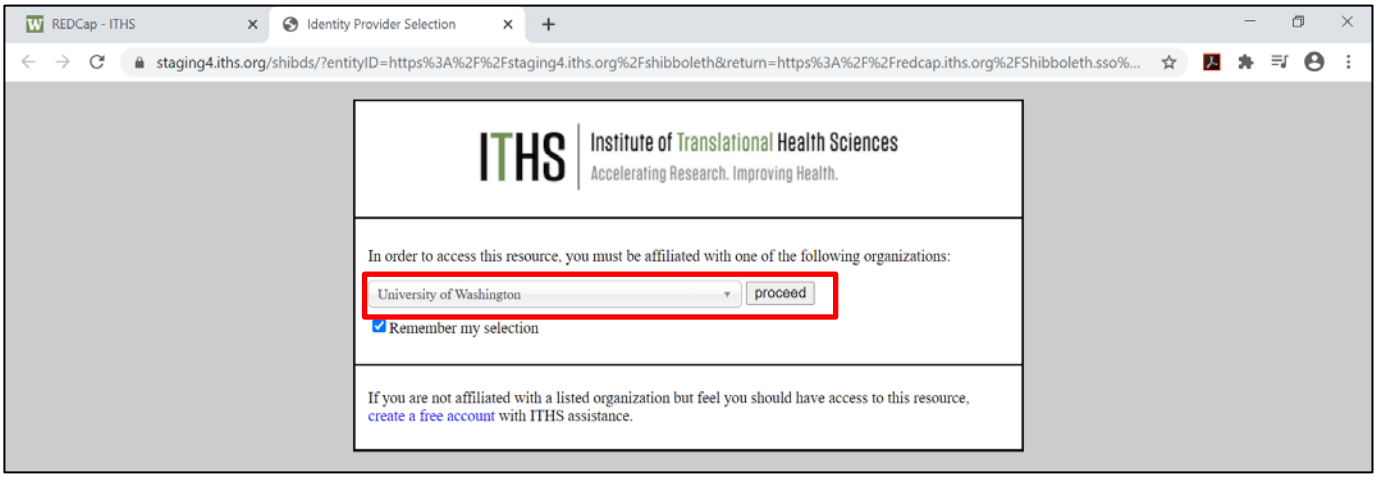
New staff should follow the steps for gaining initial access to the CHAMP REDCap in *Appendix A*.

HOW TO LOG INTO REDCAP AND GENERAL PLATFORM NAVIGATION

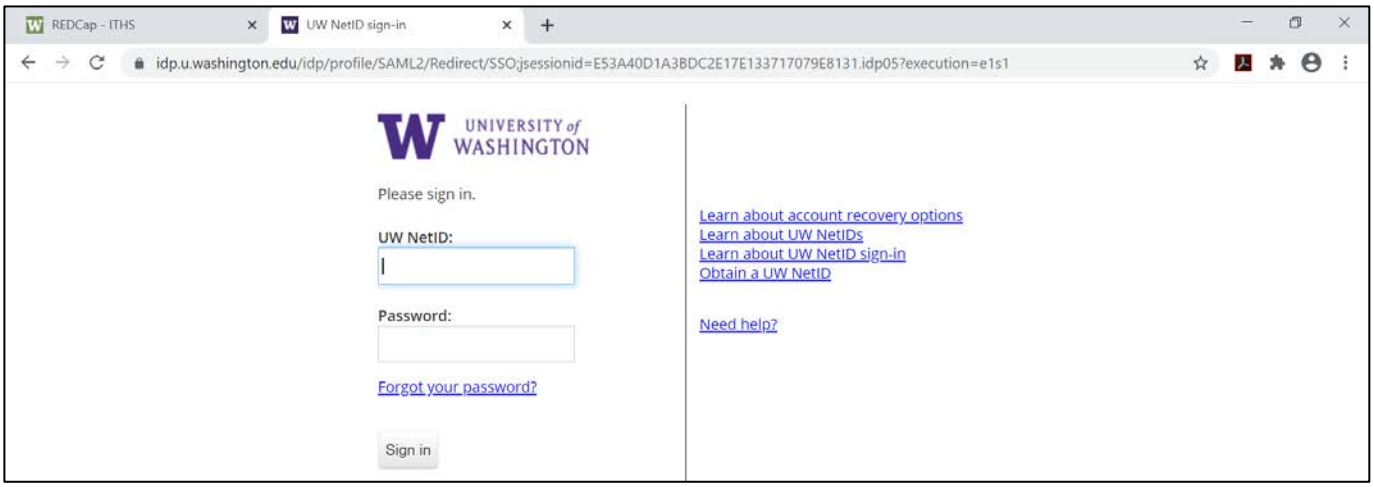
1. From the REDCap Home Page, click **"ACCESS ITHS REDCAP NOW"** button to login to REDCap.



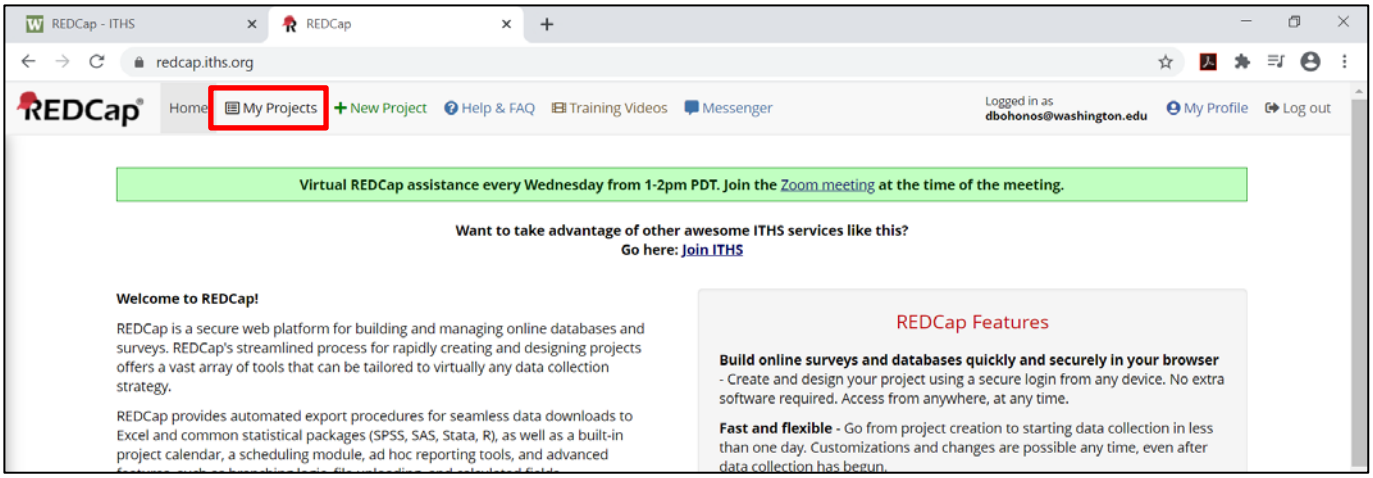
2. Select **"University of Washington"** Affiliation



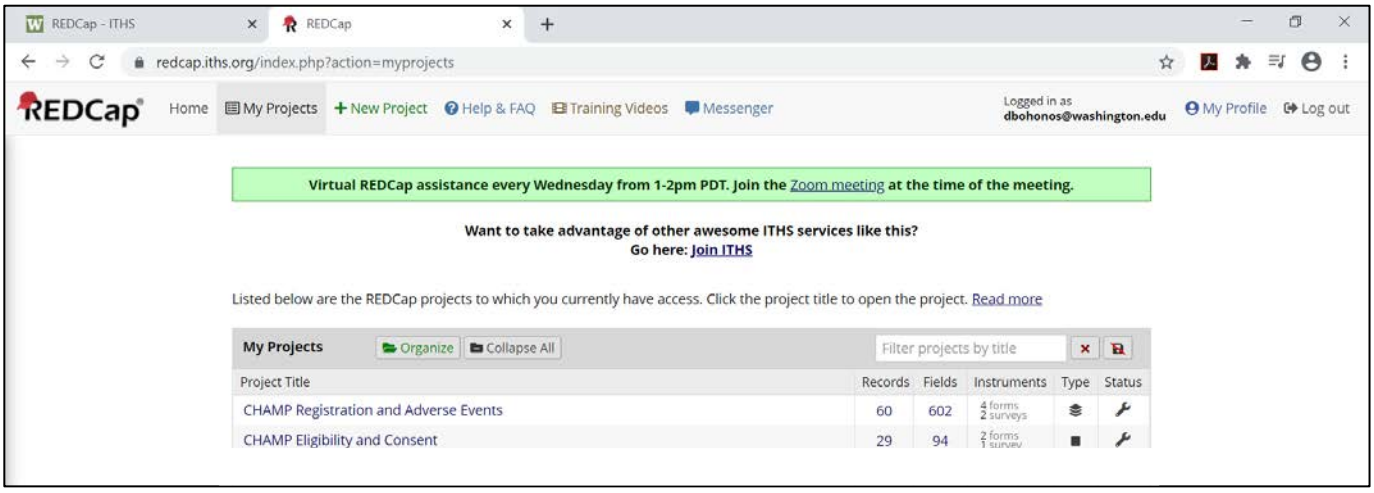
3. Enter your UW Net ID and Password.



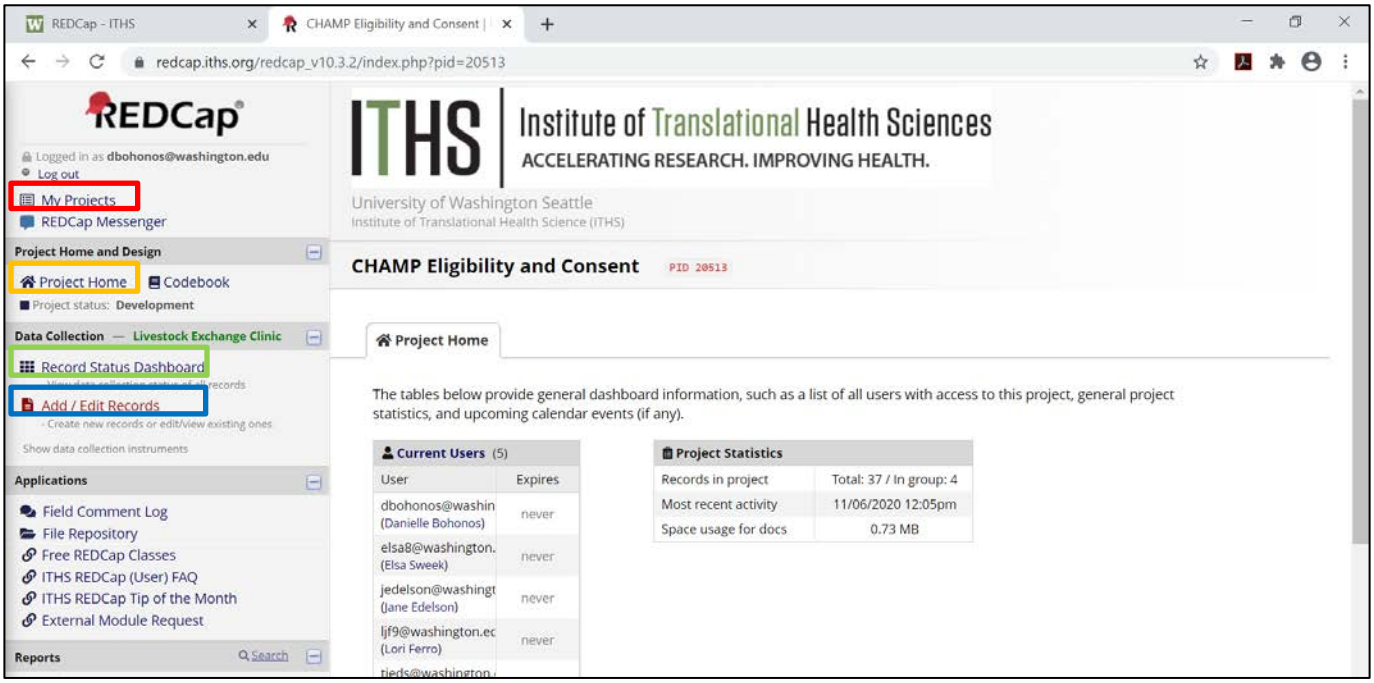
4. Click **"My Projects"** to take you to the list of REDCap projects you have access to.



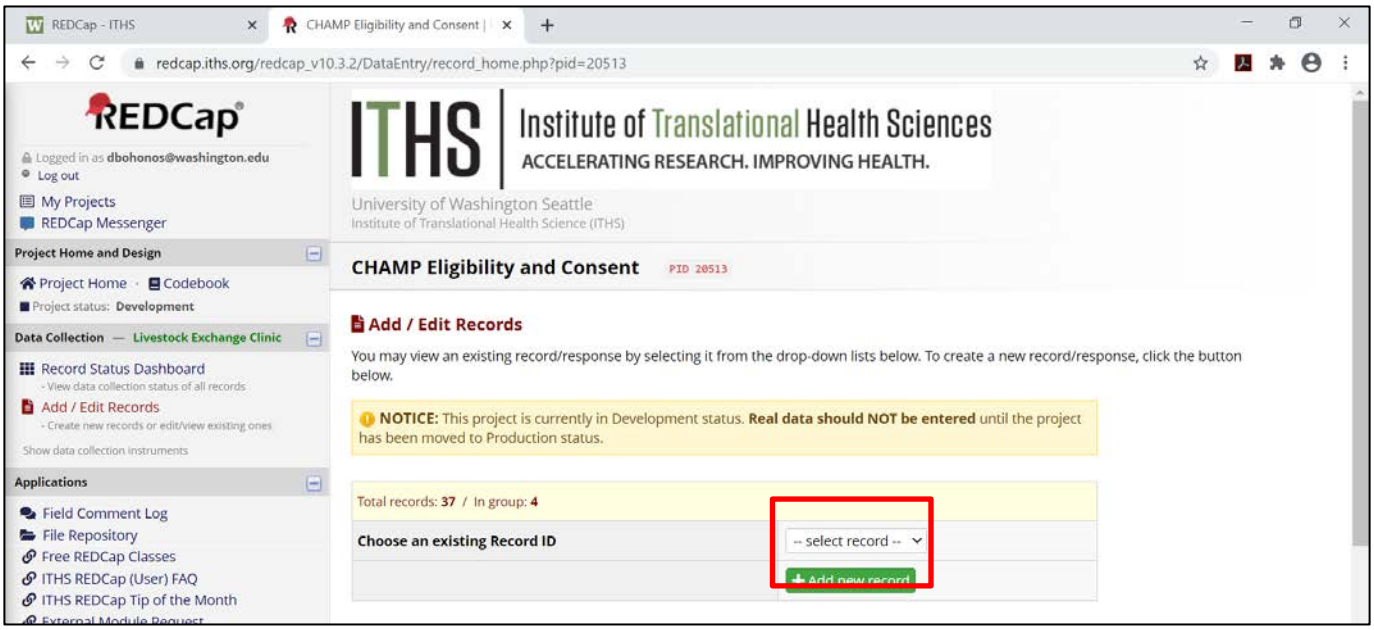
5. You will have two projects listed, the **CHAMP Registration and Adverse Events project** and **CHAMP Eligibility and Consent project**. Within each project there are forms that you will use to record eligibility, consent and enrollment.



6. Clicking on either project brings you to a menu like this. The important buttons are highlighted and described below:
    a. **"My Projects"** – sends you to My Projects page (above).
    b. **"Project Home"** – brings you to Project Home page pictured below.
    c. **"Record Status Dashboard"** – sends you to a list of all patient records you have added in the project
    d. **"Add/Edit Records"** – sends you to a page where you can add a new patient record or look up an existing patient record.

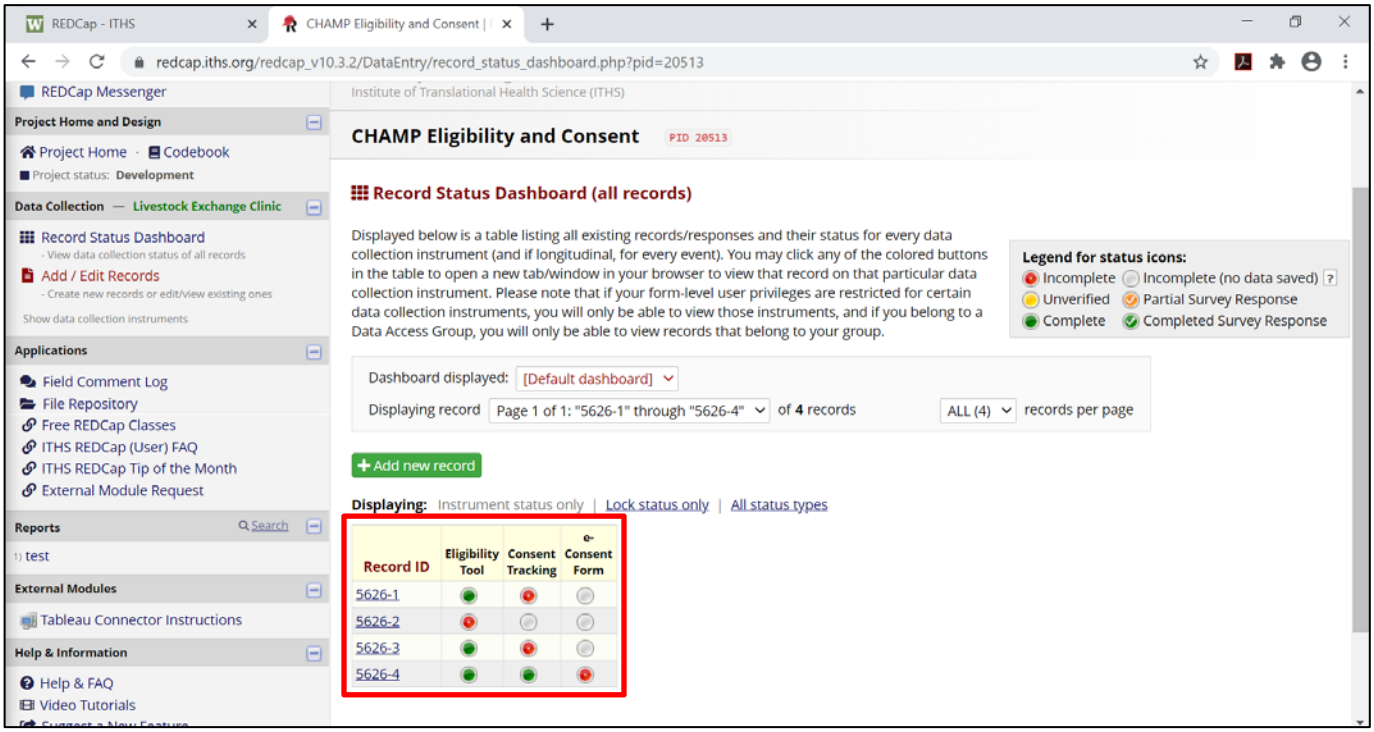


7. The Add/Edit Records page allows you to:
    a. Search and find an existing record using the **"Select Record"** dropdown
    b. Add a new patient record by clicking the **"Add New Record"** button.



8. The Record Status Dashboard page shows existing patient records, data entry forms, and their completion status.
    a. Each row in the dashboard represents one patient record and the forms in that record.
        i. The ***CHAMP Eligibility and Consent*** project dashboard is organized by patient **Record ID**
        ii. The ***CHAMP Registration and Adverse Event*** project dashboard is organized by patient **Study ID**.

From here, open **ANY** form for **ANY** patient record by clicking the circle button in the correct row and column.



SECTION 2:

REDCAP FORMS

- Descriptions of each REDCap form.
- Instructions on how to enter data for each form.

CHAMP ELIGIBILITY FORM

TRACKING ELIGBILITY DATA FOR PATIENTS WHO SCREEN POSITIVE ON THE NIDA-MODIFIED ASSIST

The CHAMP Eligibility Form is the location for entering data about patients' eligibility for CHAMP. Using this form, clinic staff will:

- Document Inclusion criteria
- Document Exclusion criteria
- Eligibility for CHAMP

AT A GLANCE

IMPORTANCE: We are required to report eligibility data to the NIH to show generalizability of the study.

PURPOSE: To ensure patients qualify for CHAMP and track their eligibility for reporting.

LOCATION: CHAMP Eligibility and Consent Project

USERS: BHCM or delegate

FREQUENCY Daily or at a minimum of once a week. Enter patients as needed or batch patients and perform data

WHEN TO ENTER A PATIENT ON THE ELIGIBILITY FORM

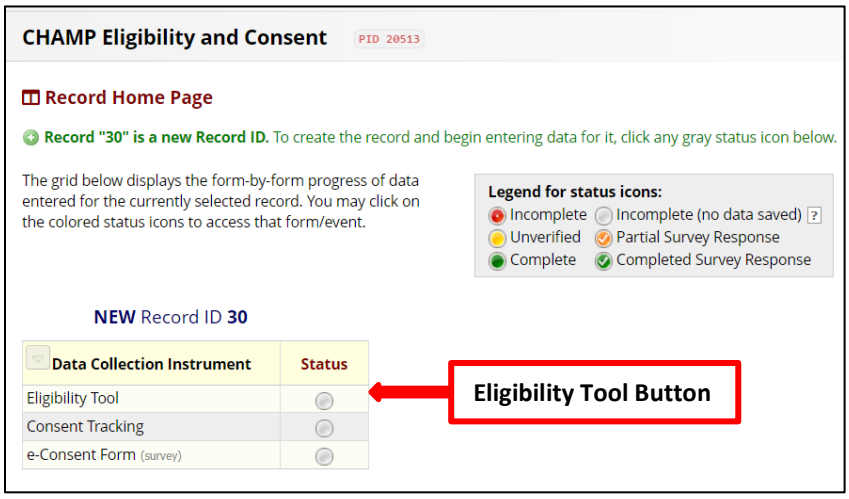
- As soon as patient screens **POSITIVE** on the NIDA-modified ASSIST
- Enter patient data once a day, or at a minimum **within one week**. One option is to batch eligibility data and enter it in one batch at the end of the week.
    - Consider using the **Eligibility Tracking Worksheet** in excel (copy in Appendix A), which BHCMs can use to track patients' screening outcomes throughout the week. Then at the end of the week transfer the data from the excel form to the REDCap Eligibility Form.
- You do **NOT** have to complete the form in one sitting. You can start the form then return to enter additional information later.

WHO NEEDS TO BE ADDED TO THE FORM?

EVERY patient who screens **POSITIVE** on the NIDA-modified ASSIST **REGARDLESS** of whether the patient is eligible or consents for the study.

HOW TO ENTER A PATIENT ON THE ELIGIBILITY FORM

1. Login to the REDCAP using your UW Net ID and Password.
2. Click on "My Projects"
3. Click on "CHAMP Eligibility and Consent" project.
4. Click on "Add/Edit Record".
5. Click the green "Add New Record" to add a new patient record. This creates an Eligibility Record ID for the patient.
6. Click on the "Eligibility Tool" button to open the form



7. Enter the following information about CHAMP Inclusion Criteria in the appropriate fields:
    a. **Medical Record Number**
    b. **NIDA-modified ASSIST (NMA) Screen Date**
        i. Screen date must be within the last 6 months. If the screen is outdated you will get an error message.
    c. **NIDA-modified ASSIST (NMA) Prescription Opioid Score**
        i. Score range is 0-39.
        ii. POSITIVE Score is 4 or greater.
    d. **NIDA-modified ASSIST (NMA) Street Opioid Score:**
        i. Score range is 0-39.
        ii. POSITIVE Score is 4 or greater.
    e. **Has the patient been assessed for DSM-5 OUD Diagnostic Criteria?** If yes,
        i. **DSM-5 OUD Diagnostic Criteria Screen Date**
        ii. **# of DSM-5 OUD Diagnostic Criteria Met:**
            1. Responses range from 0-11.
            2. POSITIVE assessment is 2 or more criteria.

MHD Screeners

NOTE: It is **NOT** required that patients are screened with all three of the below Mental Health Disorder (MHD) screeners (PHQ-9, GAD-7, and PC-PTSD-5). A patient needs to screen positive on just **ONE** of the three MHD screeners to be eligible for CHAMP.

    f. **Has the patient been screened with PHQ-9?** If yes,
        i. **PHQ-9 Screen Date:**
            1. Screen date must be within the last 6 months. If the screen is outdated you will get an error message.
        ii. **PHQ-9 Score:**
            1. Score range is 0-27.
            2. POSITIVE Score is 10 or greater.
    g. **Has the patient been screened with GAD-7?** If yes,
        i. **GAD-7 Screen Date:**
            1. Screen date must be within the last 6 months. If the screen is outdated you will get an error message.
        ii. **GAD-7 Score:**
            1. Score range is 0-21.
            2. POSITIVE Score is 10 or greater.
    h. **Has the patient been screened with PC-PTSD-5?** If yes,
        i. **PC-PTSD-5 Screen Date:**
            1. Screen date must be within the last 6 months. If the screen is outdated you will get an error message.
        ii. **PC-PTSD-5 Score:**
            1. Score range is 0-5.
            2. POSITIVE Score is 3 or greater.

8. **Review "Confirmation of Inclusion Criteria" Section:** The Eligibility Form is designed to calculate whether a patient meets the 3 Inclusion Criteria to be eligible for CHAMP.
    a. If you see a **Red Box** with the message, "Patient does not meet Inclusion Criteria DO NOT CONSENT"
        i. i.e. The patient is NOT eligible for CHAMP because they don't meet the 3 Inclusion Criteria. **END OF FORM** – click "Save & Exit Form".
    b. If you do **NOT** see a red box, then the patient has met all 3 Inclusion Criteria.
9. **Exclusion Criteria Section**. This section asks whether a patient meets any of the 9 Exclusion Criteria for CHAMP. If a patient meets **ONE** of the 9 exclusion criteria then they are INELIGIBLE regardless of whether they met all 3 Inclusion Criteria from above.
    a. Only appears if patient meets all 3 Inclusion Criteria.
    b. **Red Box** – "Patient meets Exclusion Criteria, NOT ELIGIBLE, DO NOT CONSENT"
    c. **Green Box** – "Patient does NOT meet any Exclusion Criteria, ELIGIBLE, PROCEED WITH CONSENT"
10. **Recruitment Outcome:** enter the patient's recruitment outcome if known. If not return and complete later.
11. Change "Form Status" to **Complete**
12. Click **"Save & Exit Form".**

EDITING A PATIENT'S ELIGIBILITY FORM

In certain circumstances you may need to edit a patient's eligibility form, for example if a patient's screening occurs at two different occasions. You can edit the Eligibility Form by following the below instructions.

1. Login to the REDCAP using your UW Net ID and Password.
2. Click on "My Projects" in the upper left of the screen.
3. Click on "CHAMP Eligibility and Consent Project"
4. Click on "Record Status Dashboard".
5. Find the patient's record who you are planning to consent for CHAMP.
6. Click on the "Eligibility Tool" button to open the form.
7. Make edits to the Eligibility Form.
8. Click "Save & Exit Form".

CHAMP CONSENTING PROCEDURES

OPTIONS FOR CONSENTING PATIENTS IN CHAMP AND HOW TO DOCUMENT CONSENT

OPTIONS FOR OBTAINING INFORMED CONSENT

Consenters can perform one of two approaches to obtain informed consent depending on their clinic and patient needs.

1. **In-Person Consenting:** The consenter performs consent process in-person and on-site at the clinic.
2. **Virtual Consenting**: The consenter performs consent process over telephone or tele-video.
    a. Consenters and patients do not have to be located at the clinic.

OPTIONS FOR DOCUMENTING CONSENT

Patients can document their consent in one of two ways:

1. **Paper Consent Form**
2. **E-Consent Form**: This is an electronic version of the same informed consent form, where the patient documents their consent by signing electronically on their phone, tablet or computer. Patients will use their finger or mouse to sign the form.

DETERMINING THE BEST APPROACH TO CONSENT YOUR PATIENTS

Consider the following combination of approaches for obtaining and documenting consent. In addition, consider how to facilitate patient's documentation of consent keeping in mind convenience, patient resources, and how long it will take to get the forms returned.

Obtaining Consent	In-Person Consenting		Virtually Consenting	
Documenting Consent	Paper Consent Form	E-Consent Form	Paper Consent Form	E-Consent Form
Facilitating Documentation of Consent	In-person	CHAMP Tablet	• Send/return form via mail • Patient picks up/drops off form	• Email • Text

Consequently, you can consent a patient using any of the below approaches:

1. **In-Person using a Paper Consent Form**
2. **In-Person using an E-Consent Form**
3. **Virtually using a Paper Consent Form**
4. **Virtually using an E-Consent Form**

Regardless of the approach, it is **REQUIRED** that patients have a copy of the consent form in front of them while being consented. Consider the following options for sharing the consent form:

- Share a PDF of consent form with watermark via email
- If consenting virtually via tele-video, share the consent form on your screen
- Share or direct patient to the appropriate consent form on the CHAMP Website

SUGGESTED WORKFLOWS FOR THE 4 CHAMP CONSENTING APPROACHES

Below are 4 consent process workflows to consider depending on which of the above 4 consent approaches they are using. These workflows build on Step 4 in the CHAMP Study Workflow on page 2

All workflows assume you have identified an eligible patient for CHAMP and are ready to consent them for CHAMP:

1. CONSENTING IN-PERSON WITH *PAPER CONSENT FORM*

Perform consent process in-person

- Use Paper Consent Form as a guide.
- Review CHAMP Consent Training Materials if needed

If patient consented, review the Paper Consent Form for completion

- Ensure all fields are complete.
- Give copy of signed form to patient.

Track completed consent process in REDCap Consent Tracking Form

- Complete all pertinant fields
- Scan and upload signed consent form

2. CONSENTING IN-PERSON WITH *E-CONSENT FORM* ON TABLET OR COMPUTER

Perform consent process in-person

- Use consent form as a guide.
- Review CHAMP Consent Training Materials if needed.

Fill out the Consent Tracking Form

- Open **Consent Tracking Form**, complete below fields, then save form.
  - MRN
  - Consenter Name
  - Type of Consent
  - Date Consent Obtained
  - Attestation Checkbox

Staff signs e-Consent Form

- Staff MUST sign **e-Consent Form** BEFORE patient signs form.
  - Open e-Consent Form, complete staff section
  - Click "Save & Stay"
  - When error message appears, click "Okay"

Patient completes e-Consent Form (IMPORTANT: READ BELOW)

- Before patient completes the form, the Consenter must do the following:
  - Scroll to top of **e-Consent Form**.
  - Click the "Survey Options" drop-down menu in top right.
  - Click "Log Out & Open Survey"
- Patient can now complete and submit the **e-Consent Form.**

Track completed consent process in Consent Tracking Form

- Complete below fields
  - Date Consent Signed
- Download a PDF of signed e-Consent Form and either email or print and hand it to patient.

3. CONSENTING VIRTUALLY WITH *PAPER CONSENT FORM*

Prepare the **Paper Consent Form** to mail or hand to patient

- Print copy of current consent form for your clinic.
- Hand **Paper Consent Form** to patient to take home or mail to patient's home.

Perform consent process **virtually by phone or tele-video**

- Ensure patient has the consent form in front of them during review, you may:
  - Screen share
  - Email PDF of consent form ahead of time.
- Review CHAMP Consent Training Materials if needed.

If patient consented and returns their form, **review** the consent form

- Ensure all fields are complete.
- Give copy of signed form to patient.
- **Keep in mind**: patient has 2 weeks from date consent obtained to sign the form. Mailing form back may delay its return.

Track completed consent process in **Consent Tracking Form**

- Complete all pertinant fields
- Scan and upload signed consent form.

4. CONSENTING VIRTUALLY WITH *E-CONSENT FORM*

Perform consent process **virtually by phone or tele-video**

- Ensure patient has the consent form in front of them during review
  - Screen share
  - Email PDF of consent form ahead of time.
  - Mail consent form with watermark
- Review CHAMP Consent Training Materials if needed.

Send **e-Consent Form** to patient.

- Open **Consent Tracking Form**, complete below fields, then save form.
  - MRN
  - Consenter Name
  - Type of Consent
  - Consent Preference
  - Date Consent Obtained
  - Attestation Checkbox
- This triggers the following:
  - Email or text invite/reminders to patient to complete the **e-Consent Form**.
  - Reminders to BHCM

Staff signs **e-Consent Form**

- Staff must IMMEDIATELY sign **e-Consent Form** BEFORE patient signs form.
  - Open e-Consent Form, complete staff section
  - Click "Save & Exit Form"
  - When error message appears, click "Ignore & Leave"

If patient consented, review the consent form

- Ensure all fields are complete.
- When patient submits their signed e-Consent:
  - PDF of signed consent is saved in REDCap
  - Email to BHCM
  - Email to patient with copy of form, if they have an email on file

Track completed consent process in **Consent Tracking Form**

- Complete all pertinant fields
  - Date Consent Signed
- Ensure patient receives a signed copy of their consent form, you could
  - Download the PDF and email/mail/hand the form to patient.

CONSENT TRACKING FORM

HOW TO USE THE REDCAP CONSENT TRACKING FORM AND PAPER OR E-CONSENT FORMS IN CHAMP.

The Consent Tracking Form is a required tool for tracking how patients are consenting for CHAMP. The form collects the following information:

- How consent is obtained – ex. In person or virtual
- Patient contact information – ex. Email and phone number for sending the e-Consent Form.
- Information about when the consent was obtained
- Information about when the consent form was completed

Completing certain fields in the form **triggers a series of notifications** (see table below) such as **invites** to complete the e-consent form and follow-up **reminders** for the consenter.

AT A GLANCE

IMPORTANCE: this form serves as a paper trail for our consent process, which is required by our IRB. It will allow us to audit all patient consents for the study.

PURPOSE: gather required patient info for consenting and track patient consenting.

LOCATION: CHAMP Eligibility and Consenting Project

USERS: Consenters

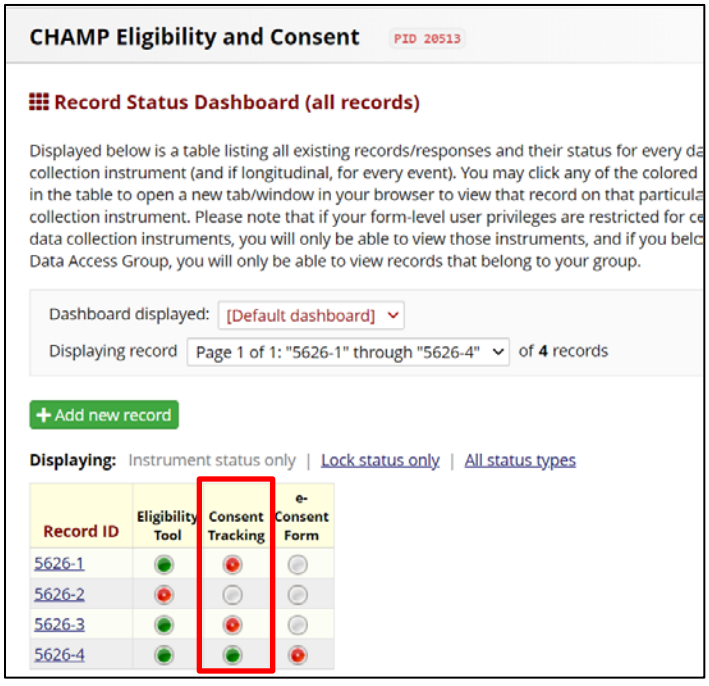
FREQUENCY: Enter patients as needed

WHEN TO ENTER A PATIENT ON THE FORM

Enter a patient on the Consent Tracking Form after you have performed the consent process with the patient. Every patient needs to be entered.

HOW TO TRACK CONSENT DOCUMENTATION IN REDCAP

1. Login to the REDCAP using your UW Net ID and Password.
2. Click on “My Projects”.
3. Click on “CHAMP Eligibility and Consent” project
4. Click on “Record Status Dashboard”.
5. Find the patient’s record who you are planning to consent for CHAMP.
6. Click the “Consent Tracking Form” button in the patient’s record.



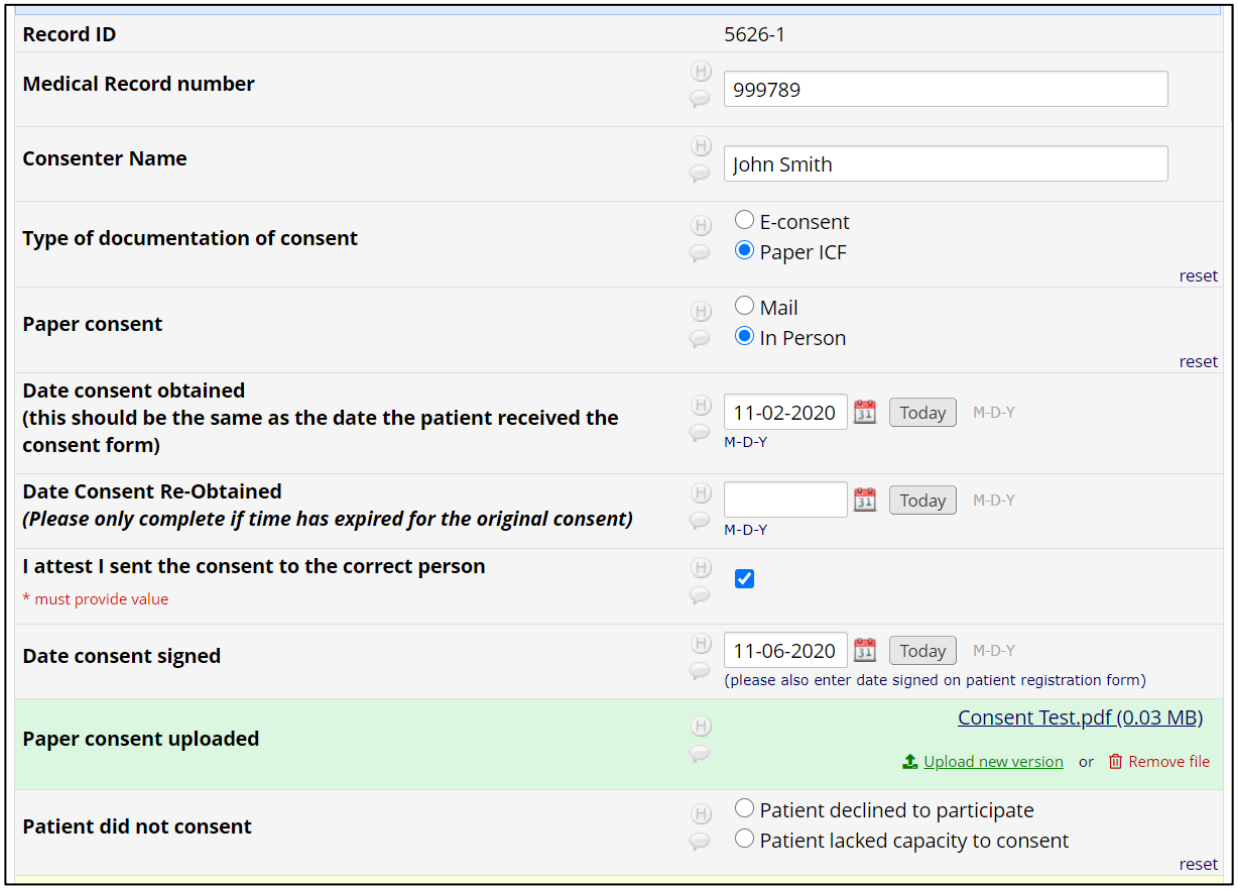
PAPER CONSENT FORM

1. Enter the following fields in the Consent Tracking Form to document the patient’s consent with a Paper Consent Form (see screenshot below).
    a. **Medical Record Number**
    b. **Consenter Name**
    c. **Type of Documentation of Consent**: choose *Paper ICF*
    d. **Paper Consent:** choose how you sent the Paper ICF to the patient.
    e. **Date Consent Obtained**: this is the date you consented the patient.
    f. **I Attest I Sent the Consent to the Correct Person**: check the box to attest.

g. **Date Consent Signed**: this is the date the patient signed on the consent form NOT the date you received the consent form.
h. **Paper Consent Uploaded**

2. Click "Save & Exit Form".

COMPLETED CONSENT TRACKING FORM IF USING A PAPER CONSENT FORM



E-CONSENT FORM

1. **Send e-Consent Form to Patient:** enter the following fields in the Consent Tracking Form to document the patient's consent with an e-Consent Form.
    a. **Medical Record Number**
    b. **Consenter Name**
    c. **Type of Documentation of Consent**: choose *e-Consent*
    d. **Does Patient Prefer the e-Consent Sent Via**:
        i. Email - enter patient's email
        ii. Text - enter patient's phone number. Patient must have a smartphone to sign the e-Consent on their phone.
        iii. Text and Email - enter patient's phone number and email
    e. **Date Consent Obtained**: this is the date you consented the patient.
    f. **I Attest I Sent the Consent to the Correct Person**: check the box to attest.
2. At this point, clicking "Save & Exit Form" triggers a series of Consent Notifications:

Notification Name	Recipient	Mode	Description
E-Consent Invite	Patient	Text or Email	Patients who choose to e-Consent are immediately sent an invite to complete the e-Consent Form. This also triggers reminders to the patient every few days to complete the form.
Consenter Reminder	Consenter	Email	Regardless of whether a patient consents on paper or on e-consent, the *consenter* receives reminders to follow-up with patients who haven't completed their consent form. • Reminders stop 14 days after the date in the **Date Consent Sent** field, because the patient needs to be reconsented after that point. • Reminders stop once the **Date Consent Signed** field is complete.

3. **Staff Signs e-Consent Form** – Should be performed IMMEDIATELY after sending out an e-Consent Form.
    a. Open patient's e-Consent Form.
    b. Scroll to" Name of Staff" section, enter the following information:
        i. Name of Staff
        ii. Date staff consented the patient
    c. Click "Save & Exit Form". You will receive an error message, click "ignore and leave form".
4. If the patient signs the e-Consent Form, it will trigger the following notifications:

Notification Name	Recipient	Mode	Description
Consent Complete Notification	Consenter	Email	if a patient signs and completes their e-Consent, the *consenter* will receive an email notification.
Auto-Email with Signed Consent Form	Patient	Email	If a patient signs and completes their e-Consent via **their email,** the patient will receive an email with a PDF of the signed e-Consent form.

5. The consenter should now, document the completion of the e-consent form on the Consent Tracking Form.
    a. **Date Consent Signed**: this is the date the patient signed on the consent form NOT the date you received the consent form.
6. Click "Save & Exit Form"

NOTE: It is required that every patient receives a copy of their signed consent form.

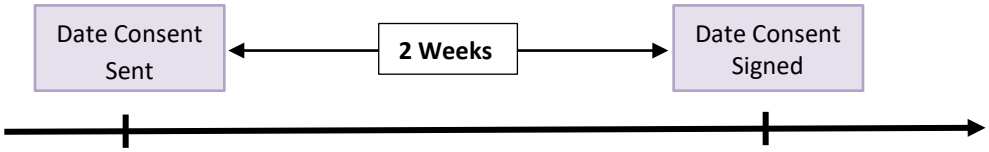
1. Patients who e-consent via email will receive and auto-email from REDCap that gives them a copy of their signed consent form
2. **Patients who e-consent via text message** will **NOT** receive an auto-email because we do not have their email on file. In this case, **the Consenter is responsible** for getting a PDF of the signed e-consent form to the patient.

COMPLETED CONSENT TRACKING FORM IF USING E-CONSENT FORM

Record ID	5626-6
Medical Record number	Adv123
Consenter Name	John Smith
Type of documentation of consent	◉ E-consent ○ Paper ICF reset
REMEMBER to add Staff Name and Date to the patient's e-consent form IMMEDIATELY after leaving this form	
Does patient prefer the e-consent sent via	◉ Email ○ Text (must have smartphone) ○ Both email and text reset
Patient email address	testemail@gmail.com
Date consent obtained **(this should be the same as the date the patient received the consent form)**	11-09-2020 Today M-D-Y M-D-Y
Date Consent Re-Obtained ***(Please only complete if time has expired for the original consent)***	Today M-D-Y M-D-Y
I attest I sent the consent to the correct person * must provide value	☑
Date consent signed	11-09-2020 Today M-D-Y (please also enter date signed on patient registration form)

RECONSENTING A PATIENT FOR CHAMP

FIGURE X. Window of Time for a Patient to Sign the Consent Form



From the date the consent form is sent, patients have **2 weeks** to sign and return their consent form. If not, the patient will need to be reconsented. Follow the below instructions to reconsent the patient:

Paper ICF Reconsent

1. Login to the REDCAP using your UW Net ID and Password.
2. Click on "My Projects" in the upper left of the screen.
3. Click on "CHAMP Eligibility Project"
4. Click on "Record Status Dashboard" in the left-hand menu. You should see a list of all the patient records you have entered into the Eligibility Project, as well as all of the data entry forms that are associated with each record.
5. Find the patient's record who you are planning to consent for CHAMP.
6. Click the bubble for the "Consent Tracking Form" in the patient's record.
7. Enter the date you resent the paper ICF to the patient in the **Date Consent Re-Obtained** field
8. Click "Save & Exit Form"

E-Consent Reconsent

1. Login to the REDCAP using your UW Net ID and Password.
2. Click on "My Projects" in the upper left of the screen.
3. Click on "CHAMP Eligibility Project"
4. Click on "Record Status Dashboard" in the left-hand menu. You should see a list of all the patient records you have entered into the Eligibility Project, as well as all of the data entry forms that are associated with each record.
5. Find the patient's record who you are planning to consent for CHAMP.
6. Click the bubble for the "Consent Tracking Form" in the patient's record.
7. Enter the date you resent the paper ICF to the patient in the **Date Consent Re-Obtained** field
8. Click "Save and Exit Form"
9. From Patient Record Dashboard, click the button for "e-Consent Form".
10. Scroll down to the Name of Staff Section. Your name should already be here from when you last sent the e-consent form.
11. Edit the **Staff Signature Date** to reflect the current date.
12. Click "Save & Exit Form".
13. An error message will pop up that is titled "NOTE: Some Fields are required!". This message is alerting you that there are required fields that have not been entered. Click "Ignore and Leave Record" to exit the form and save your staff signature.
14. Patient will need to use the link they received in their original email or text.

PATIENT REGISTRATION FORM

ENROLLING CONSENTED PATIENTS IN THE CHAMP STUDY

The Patient Registration Form is where a consented patient is formally enrolled in the CHAMP Study and receives their Study ID.

The following information is collected in this form:

- Unique patient identifiers
- Contact information
- Patient survey preferences

Completing the form also **triggers invites and reminders** to the patient asking them to complete the Patient Baseline Survey.

AT A GLANCE

IMPORTANCE: for regulatory purposes we must have a record of who is participating in the study, this form is the 'key' connecting patient identifier to their Study ID.

PURPOSE: gather patient information, choose contact methods, and trigger survey disposition.

LOCATION: CHAMP Registration and Adverse Event project

USERS: BHCM or delegate

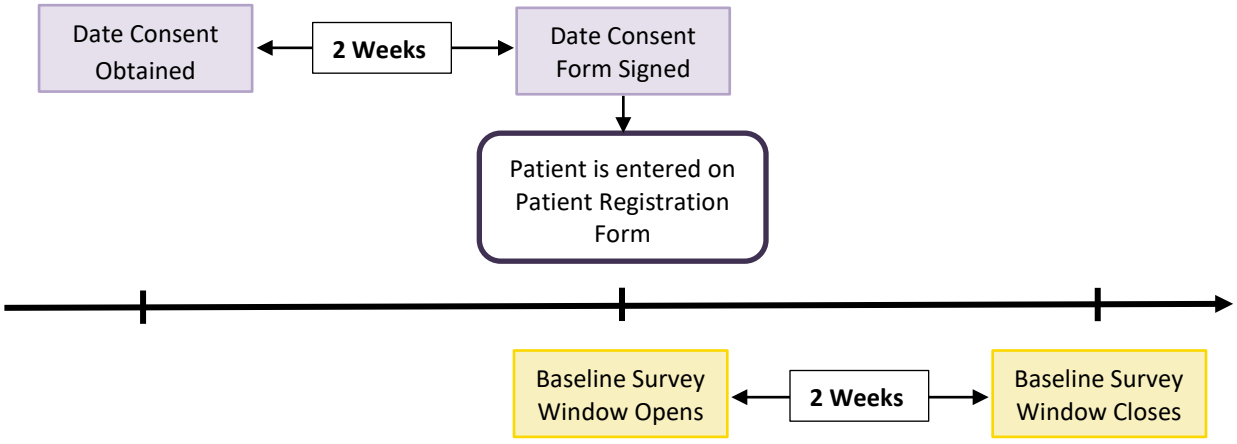
FREQUENCY: Enter patients as needed

WHEN TO ENTER A PATIENT ON THE FORM

Enter a patient **IMMEDIATELY** or **AS SOON AS POSSIBLE** after they have been consented for CHAMP. This is **CRITICAL** because once a patient consents for CHAMP they only have **2 weeks** to take the Patient Baseline Survey.

- Invites to take the Patient Baseline Survey will **ONLY** go out once the patient is entered on this form.
- We recommend that the BHCM or consenter do this at the end of the Informed Consent appointment. That way we avoid having a lag between the two processes.

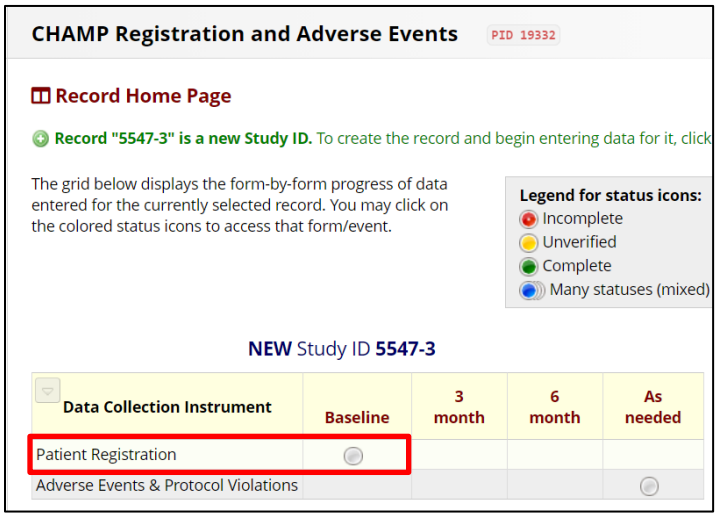
FIGURE X. When to Register a Patient Relative to the Consenting and Baseline Survey Windows



NOTE: BHCM or delegate enters patient in the Patient Registration form on the date the consent form is signed, which triggers the Baseline Survey window to open.
Window for patient to sign their consent form is 2 weeks from when the patient was consented (purple).
Window for patient to completed their Baseline Survey is 2 weeks from when the patient is entered on the Patient Registration Form.

HOW TO ENTER A PATIENT ON THE PATIENT INFORMATION FORM

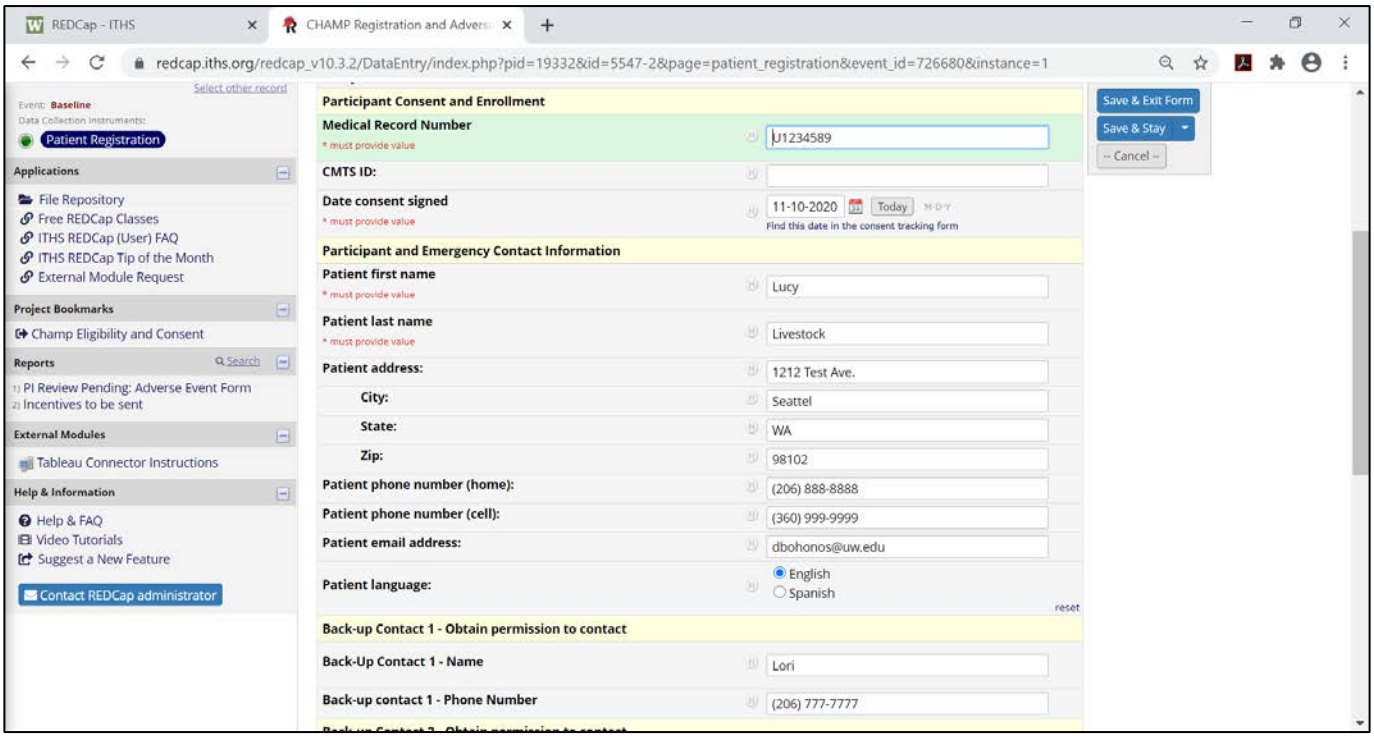
NOTE: It is critical that the patient's information is entered accurately here so that we are contacting the right person.

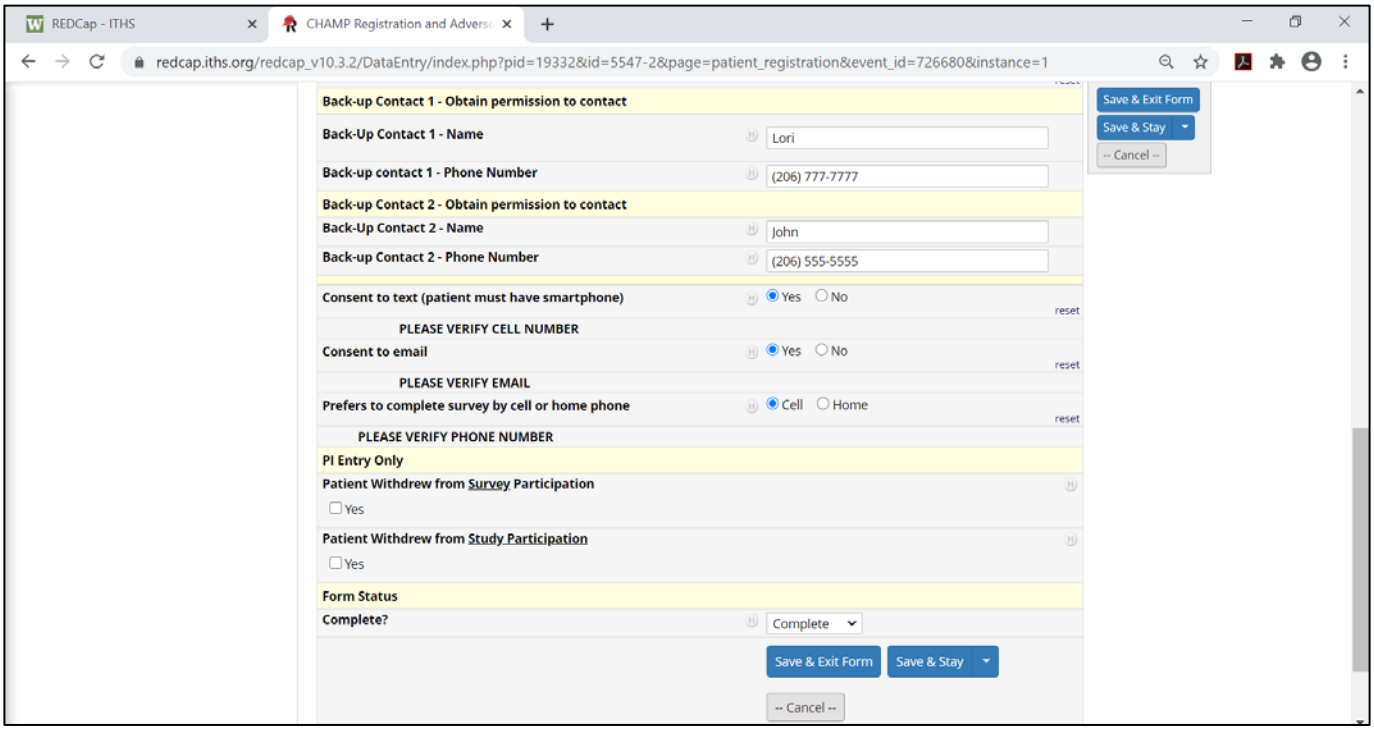


1. Login to the REDCAP using your UW Net ID and Password.
2. Click on "My Projects" in the upper left of the screen.
3. Click on the "CHAMP Registration and Adverse Events"
4. Click on "Add/Edit Record" in the left-hand menu.
5. Click the green "Add New Record" button to enter a new patient record. This will create a CHAMP 'Study ID' for the record.
6. Click on the "Patient Registration" form button to open the form.
7. Enter the following information,
    a. **Medical Record Number**
    b. **CMTS ID:** at the point you register a patient on this form you may or may not have added the patient to the Care Management Tracking System (CMTS).
        i. Once the patient is in CMTS, add their CMTS ID here and add their REDCap Study ID to CMTS.
    c. **Date Consent Signed**: you can find this in the "Consent Tracking Form"
    d. **Patient First Name**
    e. **Patient Last Name**
    f. **Patient Address**
    g. **Patient Phone Number (Home)**
    h. **Patient Phone Number (Cell)**
    i. **Patient Email Address**
    j. **Patient Language**: this field dictates if the patient receives their communications and surveys in English or Spanish.
    k. **Back-Up Contact 1 and 2:** A patient's Back-Up Contacts are people the study team can contact to get a hold of the patient if we are having a hard time reaching them.
        i. By providing the name and phone of Back-Up Contacts, the patient is giving us permission to contact them.
        ii. These fields are OPTIONAL
    l. **Consent to Text**: if yes, the patient is agreeing to receive text message invites, reminders, and communications about CHAMP
        i. Must have a smartphone to consent to text.
    m. **Consent to Email:** if yes, the patient is agreeing to receive email invites, reminders, and communications about CHAMP
        i. If a patient consents to both text and email they will receive the same communications by both text and email.
    n. **Prefers to complete survey by cell or home phone**: all patients may be contacted by phone to complete the patient surveys. This field indicates the patient's preference for where to contact them.
8. Change "Form Status" to Complete
9. Click "Save & Exit Form"

NOTE: The two fields labelled **Patient Withdrew from Survey Participation** and **Patient Withdrew from Study Participation** are for the CHAMP Team's Use ONLY. If a patient tells you they want to withdraw from the surveys or the study in general please contact the CHAMP Team or discuss it with us during one of our bi-weekly Research Check-In Meetings.

COMPLETED PATIENT REGISTRATION FORM





ADVERSE EVENT AND PROTOCOL VIOLATION FORM

RECOGNIZING AND REPORTING AN ADVERSE EVENT, SERIOUS ADVERSE EVENT OR PROTOCOL VIOLATION

The Adverse Event and Protocol Violation Form is where Project Leads, BHCMs or their delegate will report an Adverse Event, Serious Adverse Event, or Protocol Violation to the CHAMP Team. If one of these events occurs among any of your clinic's CHAMP patients you are required to report the event using this form.

Reportable event definitions and examples:

- **Adverse Event (AE):** Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or lab finding), symptom, or disease temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. CHAMP examples:
    - Non-suicidal self-injury that did NOT result in a hospitalization or ED visit
- **Serious Adverse Event (SAE):** Any adverse event temporally associated with the subject's participation in research that is potentially life threatening, results in death, requires hospitalization, results in persistent or significant disability/incapacity, or any other adverse event that, based upon appropriate medical judgment, may jeopardize the medical or surgical intervention to prevent one of the other outcomes listed here.
    - Suicide Attempt
    - Death – including a suicide attempt that resulted in death
    - Non-suicidal self-injury that DID result in a hospitalization or ED visit
    - Hospitalization or ED Visit
    - Non-lethal overdose
    - Serious medication reaction
- **Protocol Violation (PV):** An accidental or unintentional change to the IRB-approved protocol that may cause harm to subjects or others, indicates that the subjects or others are at an increased risk of harm, or has adversely impacted data integrity.
    - Sharing PHI of CHAMP study patient not in accordance with HIPAA
    - Accidental enrollment of a patient who is NOT eligible for CHAMP

AT A GLANCE

IMPORTANCE: we are responsible for the safety of all CHAMP patients, and are therefore required to report safety issues or violations to our Institutional Review Board (IRB) and/or Data Safety Monitoring Board (DSMB)

PURPOSE: to document reportable events and communicate them between clinic staff and the CHAMP Team

LOCATION: CHAMP Registration and Adverse Event project

USERS: BHCM or delegate

FREQUENCY: Enter patients as needed. Form can be used more than once per patient

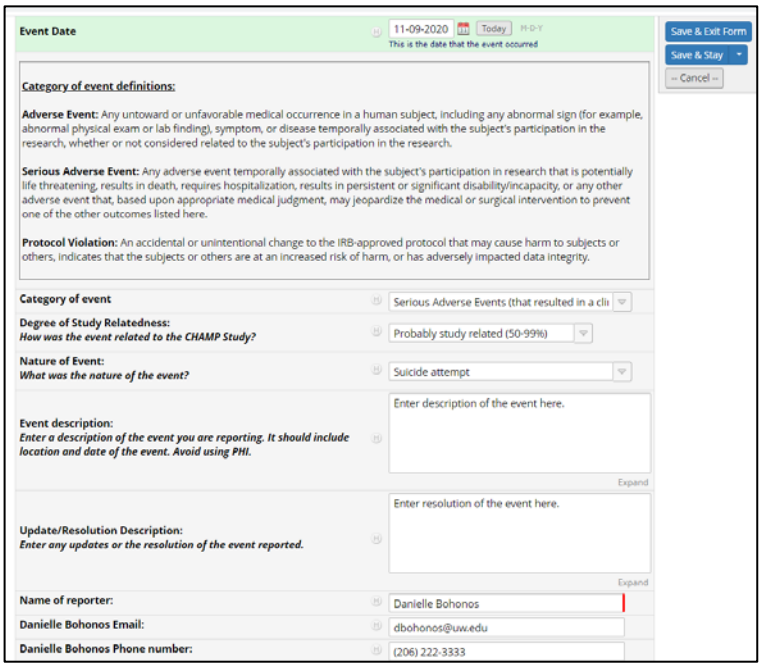
WHEN TO ENTER AN ADVERSE EVENT OR PROTOCOL VIOLATION REPORT

If you identify one of the above reportable events, report it **IMMEDIATELY**.

- This form is repeatable.
- BHCMs can enter multiple reports for the same patient if necessary.

HOW TO ENTER AN ADVERSE EVENT OR PROTOCOL VIOLATION REPORT

SITE ENTRY SECTION



1. Login to the REDCAP using your UW Net ID and Password.
2. Click on “My Projects” in the upper left of the screen.
3. Click on the “CHAMP Registration and Adverse Events”
4. Click on “Record Status Dashboard”
5. Find patient’s record, click the “Adverse Event and Protocol Violation” button to open the form.
    a. If you are adding another AE, SAE, or PV report click on the “+” button in the patient’s record.
6. Enter the following information:
    a. **Event Date**
    b. **Category of Event:** choose the type of event (AE, SAE, PV, or other).
    c. **Degree of Study Relatedness:** indicate how related the event was to the study
        i. AE and SAE only
    d. **Nature of the Event:** select a pre-determined nature of event or other
        i. AE and SAE only
    e. **Event Description:** describe the event, include location and date of event. No PHI.
    f. **Update/Resolution Description:** provide the event resolution or updates about the event as necessary.
        i. Ex. “patient released from the hospital on this date”
    g. **Name of Reporter, Email, and Phone Number**
7. Click “Save & Exit Form” – this action triggers a notification to the CHAMP Team.

PI ENTRY SECTION

Do not enter anything in the PI Entry Section. After you submit your report our team will review the report, investigate if needed, and report the event to our Institutional Review Board (IRB) and/or Data Safety Monitoring Board (DSMB).

SECTION 3: APPENDIX

GRANTING INITIAL ACCESS TO THE CHAMP REDCAP PROJECT

WHO NEEDS ACCESS TO THE REDCAP PROJECT?

In the CHAMP Study, only the Behavioral Health Care Managers (BHCM)/Consenters will need individual access to the CHAMP REDCap Project because these are the only team members who will perform direct data entry. BHCMs and Consenters are limited to accessing, viewing, and entering data from their own clinic.

- Consenters – either the BHCM or other CITI-trained clinic staff – will need access to the REDCap to use the virtual consent forms.
- BHCMs will need access to the REDCap to perform eligibility tracking, enroll patients in the study, and report any adverse events or protocol violations.

If desired, Project Leads may request access to the REDCap by contacting the Research Team.

While they **do not need direct access** to the REDCap, CHAMP Project Leads will interact with the REDCap because they are responsible for completing clinic-level surveys such as the Fidelity Assessment and Clinic Survey. Similarly, clinic providers participating in CHAMP will interact with the REDCap because they will be asked to complete a Site Provider Survey (Intervention Clinics only).

GRANTING INITIAL ACCESS TO THE REDCAP

To gain access to the REDCap each BHCM and Consenter will be given a sponsored University of Washington Net ID. These UW Net IDs will be added as individual Users in the REDCap, at which point BHCMs and Consenters will be able to freely access the REDCap.

GETTING A UW NET ID

- The CHAMP Research Team will sponsor each BHCM and Consenter using their name and email.
- BHCMs and Consenters will receive an email from the University of Washington to complete the sponsored UW Net ID process. You will be asked to create a password.

BECOMING A REDCAP USER

- Go to https://redcap.iths.org
- Select “University of Washington” as your institution.
- Login with your UW NetID and Password
- Once you login successfully for the first time, you will be asked to provide your name and a valid email address. (NOTE: provide a valid email address since this will be used to send a confirmation email).
- Use the link in the confirmation email to complete the registration process.
- **After you’re registered, log in and log out of REDCap one time**. This allows other users to find and add you to their project or you can request your own project(s).

Troubles with the registration process or forget a password? Contact UW IT Support for help at help@uw.edu, 206-221-5000