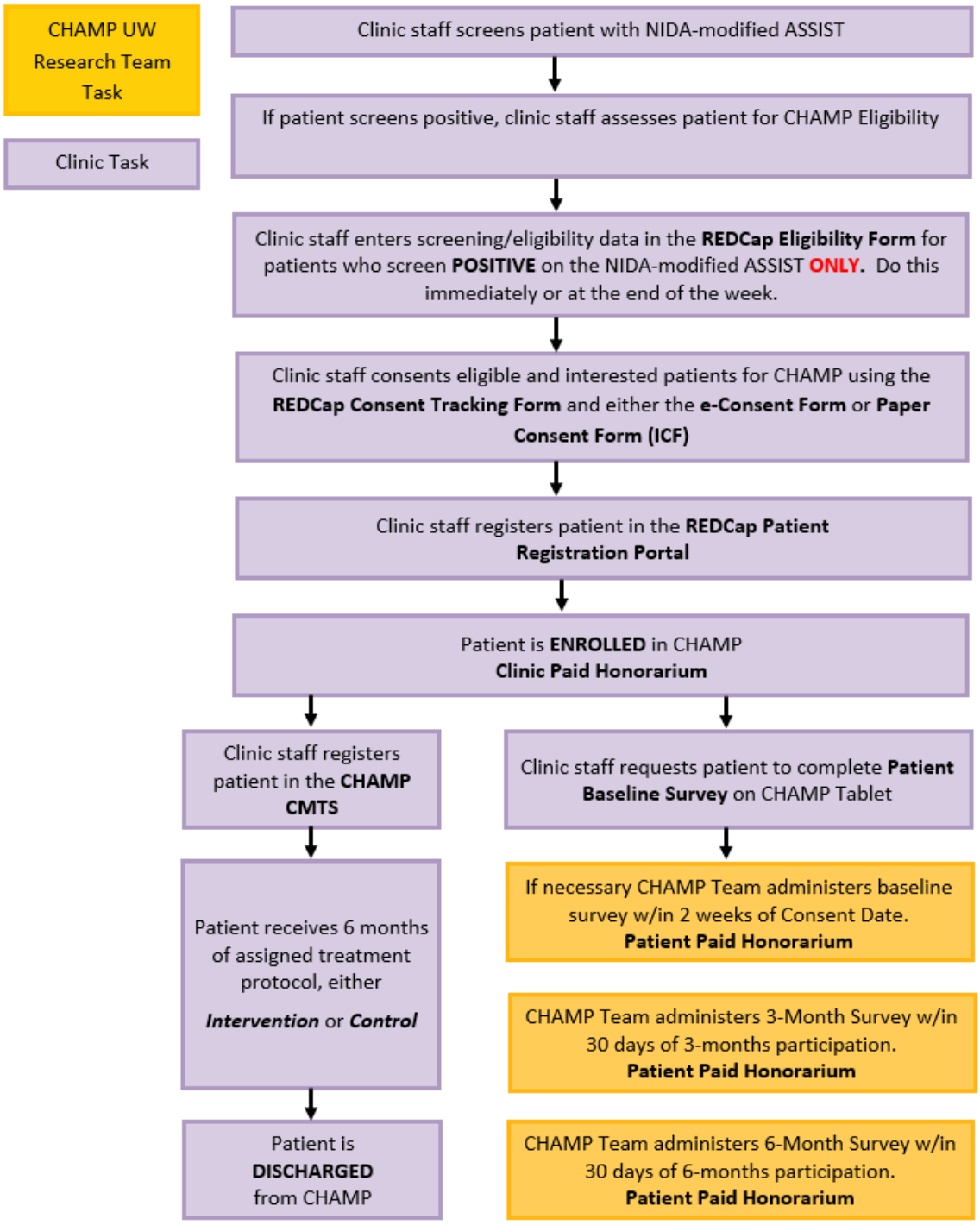
CHAMP Study Research Workflow

The basic research workflow for the CHAMP Study, which indicates what REDCap forms to use and when to use them.



Suggested Consent Workflows by Consent Approach

Below are 4 consent process workflows to consider using depending on which approach is right for your patient. Workflows 3 &4 have additional detail to walk you through how to use the e-Consent Form in the context of each scenario.

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.

CHAMP REDCap Quick Reference

Log in: REDCap | * =triggers email or text to Patient or Staff or Study Team.

CHAMP Eligibility & Consent Project

Eligibility Form

- **Record ID (auto)**
- MRN
- NMA screen date
  Within past 6months
- NMA prescription score
- NMA street score
- DSM-5 screened/date
- # of DSM-5 dx met
- PHQ9 screened/score
- GAD7 screened/score
- PCPTSD screened/score
- Exclusion Criteria check
- Recruitment outcome

Consent Tracking Form

*Patient has **14 days** to sign the consent form.*

- **Record ID (auto)**
- MRN
- Consenter Name
- Type of Consent (e* or paper)
- Choice/Email, Text, Both
  E-Consent invites/reminders to patient by email/text/or both.
  Reminder emails to BHCM/Consenter.
- Date consent obtained
- Reconsent sent date (>14dys)
- Consenter Attestation
- Date consent signed
- Paper consent uploaded
- Patient did not consent

E- Consent Form

- Name of staff/date
- Name of subj/date
- Patient (e)signature

HIPAA Form

- Name of health org
- Permission initials
- Patient name/date
- Patient DOB
- Patient (e)signature
- Patient submits*
  Email goes to BHCM/Consenter
  If Patient's email on file, email goes to Patient with copy of signed consent

CHAMP Registration & Adverse Event Project

Registration Form

*Completing this form triggers the baseline survey window to open. Patient has **14 days** to complete.*

- **Study ID (auto)**
- MRN
- CMTS ID *(clinic staff enters)*
- Date consent signed
- Patient first Name
- Patient last name
- Patient address
- Phone# (home)
- Phone #(cell)
- Email address
- language
- Back up Contact 1/phone
- Backup Contact 2/phone
- Consent to text and/or email*
  Web survey invite to patient by text/email
- Survey pref: home/cell

For use by the CHAMP UW PI

- Patient withdrew from survey
- Date of withdrawal
- Reason for withdrawal

Reportable Events Form

- **Study ID (auto)**
- Event Date
- Category of event
  *Adverse Event**
  *Serious Adverse Event**
  Protocol Violation
- Degree of study relatedness
- Nature of event
- Event description
- Update/Resolution description
- Name of reporter (staff)
- Email of Staff
- Phone of Staff
- Save Form*
  Email to CHAMP research team