COLLABORATING TO HEAL ADDICTION AND MENTAL HEALTH IN PRIMARY CARE

Welcome

UW CHAMP TEAM CONTACTS

CHAMP OPERATIONS TEAM

The CHAMP Operations Team will be your **point of contact** for questions regarding CHAMP.

PRIMARY CONTACT
LORI FERRO, MHA, PMP
CHAMP Research Project Director
(206) 221-8523
Ljf9@uw.edu

SECONDARY CONTACT
LINDA NZABAMWITA, MPH
CHAMP Research Coordinator
(206) 685-7583
umuton@uw.edu

REDCAP CONTACT
KAT JAMES, BA
CHAMP Research Coordinator
kjames11@uw.edu

CHAMP STUDY TEAM

Below is a list of core team members involved in the Training and Implementation of the CHAMP Study.

CHAMP PRINCIPAL INVESTIGATORS

ANNA RATZLIFF, MD, PHD	CHAMP Implementation Director
ANDY SAXON, MD	CHAMP Intervention Director, Addictions Spec.
JOHN FORTNEY, PHD	CHAMP Evaluation Director

CHAMP CLINICAL TRAINING AND SUPPORT TEAM - INTERVENTION

MARK DUNCAN, MD	Psychiatrist, CoCM/Addiction Specialist
JOE MERRILL, MD, MPH	Primary Care Provider, CoCM/Addiction Spec.
TRACY SIMPSON, PHD	Psychologist, Behavioral Activation Coach
Paul Barry, MSW, LICSW	CHAMP Practice Coach and BHCM Coach

CHAMP CLINICAL TRAINING AND SUPPORT TEAM - CONTROL

JOHN KERN, MD	Psychiatrist, CoCM
ANNIE MCGUIRE, MS, LMHC, MHA	Behavioral Healthcare Manager Trainer,
PATRICK RAUE, PHD	Psychologist, Behavioral Activation Coach
Ashley Heald, MA, CPHQ	CoCM Practice Coach

TABLE OF CONTENTS

ORDER OF DOCUMENTS		
Name of Document	**Brief Description**	**Link to Website**
CITI Training	UW faculty, staff and research collaborators who are involved in research with human subjects are encouraged to complete the CITI trainings. These include **CITI Research with Human Subjects Course** and the **CITI Good Clinical Practice – Social and Behavioral Research.**	Research, Ethics, and Compliance Training | CITI Program
CHAMP REDCap Workflow	This is a basic research workflow for the CHAMP Study indicates what REDCap forms to use and when to use them.	REDCap Workflow
Patient Eligibility Criteria	Describes the inclusion and exclusion criteria for patients to enter the CHAMP Study. Also includes workflow to determine eligibility.	CHAMP-Clinical-Eligibility-Workflow-for-Update
REDCap Description / Registration	About REDCap and how and where to access it.	Instructions and timeline Included in packet
REDCap Checklists	REDCap forms that were designed to help teams collect information to add into the electronic REDCap forms online.	Included in packet.
Consent Workflow (in-person)	This workflow describes the process for consenting with a paper consent form.	CHAMP Consent Workflows
Consenter Workflow (e-consent)	This workflow describes the process for consenting with an e-consent form.	CHAMP Consent Workflows
Consenter Script (Control and Intervention)	This is a script that can be used for approaching the patient for consent to CHAMP.	Consent Script – Intervention Consent Script – Control
E-consent Form for Review	A PDF version of the consent to review with patients that are e-consenting.	CHAMP – e-Consent Form for Review
REDCap User Guide	In depth guide on how to use REDCap.	CHAMP – REDCap User Guide
CHAMP Website	Main website that holds resources for study procedures and clinical care.	CHAMP – UW Department of Psychiatry & Behavioral Sciences

CLINIC RESEARCH GUIDE

Citi Training – Consenters Only
CHAMP Study Workflow
Patient Eligibility Criteria
REDCap Description & Checklist Form
Consenter Workflow & Script
E-Consent Form

CITI TRAINING – CONSENTERS ONLY

RESEARCH WITH HUMAN SUBJECTS TRAINING REQUIREMENTS

Eligible patients recruited for the CHAMP study are required to provide informed consent to participate in the trial. All clinic personnel who are providing informed consent to patients are required to complete a series of **CITI training courses** on performing research with human subjects and good clinical practices.

First, clinic personnel will need to go to the CITI Website and register as an affiliate of the University of Washington. As a University of Washington affiliate, clinic personnel will have access to a variety of courses related to conducting research. Please see the UW HSD Website for detailed instructions on how to register as a University of Washington affiliate.

ACTION: Please register for and complete the below CITI Training Courses by **March 1, 2023;** email a copy of each completion certificate to Kat James. If clinic personnel have *already completed* a comparable CITI training, send a copy of the completion certificate to Kat James for review.

1. **CITI Research with Human Subjects Course (4-6 hrs)**
   Course Description: UW faculty, staff and research collaborators who are involved in research with human subjects are encouraged to complete this training. Key personnel for NIH funded human subjects research can fulfill the NIH training requirement by completing this training. Take the Human Subjects Learners course to fulfill any requirement for training in the protection of human subjects. This course can be used as either a basic or a refresher course.
2. **CITI Good Clinical Practice – Social and Behavioral Research (2-3 hrs)**
   Course Description: Principal investigators and clinical trial staff for NIH funded clinical trials can fulfill the NIH training requirement by completing this training. The GCP training program emphasizes the practical roles and responsibilities of the research team. The course is intended to provide the necessary training for investigational site personnel - such as investigators and study coordinators - to understand the principles of Good Clinical Practice and to better understand their own responsibilities in planning and conducting clinical research. The Social and Behavioral Research course is tailored to behavioral trials.

CITI TRAINING RENEWAL REQUIREMENTS

1. **CITI Research with Human Subjects Course (4-6 hrs)**
   a. To be renewed, at the Expiration Date or **3 years** after the Completion Date if your CITI certificate does not indicate an Expiration Date.
   b. UW affiliated renewal course: ***CITI Research with Human Subjects Refresher Course***
2. **CITI Good Clinical Practice – Social and Behavioral Research (2-3 hrs)**
   a. To be renewed, at the Expiration Date or **3 years** after the Completion Date.
   b.

UW affiliated renewal course: ***CITI Good Clinical Practice – Social and Behavioral Research***

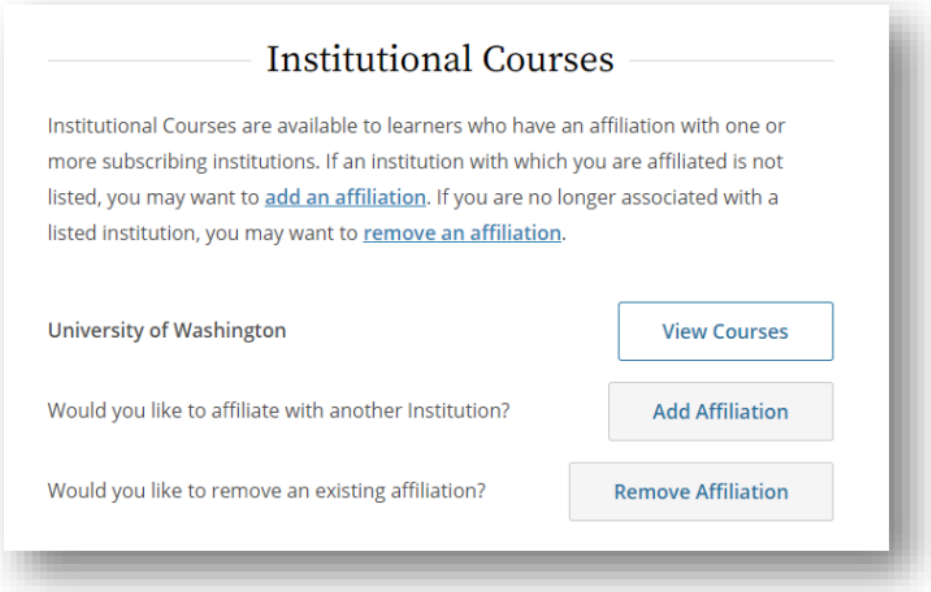
CITI TRAINING – CONSENTERS ONLY

SEE INSTRUCTIONS FOR HUMAN SUBJECTS TRAINING

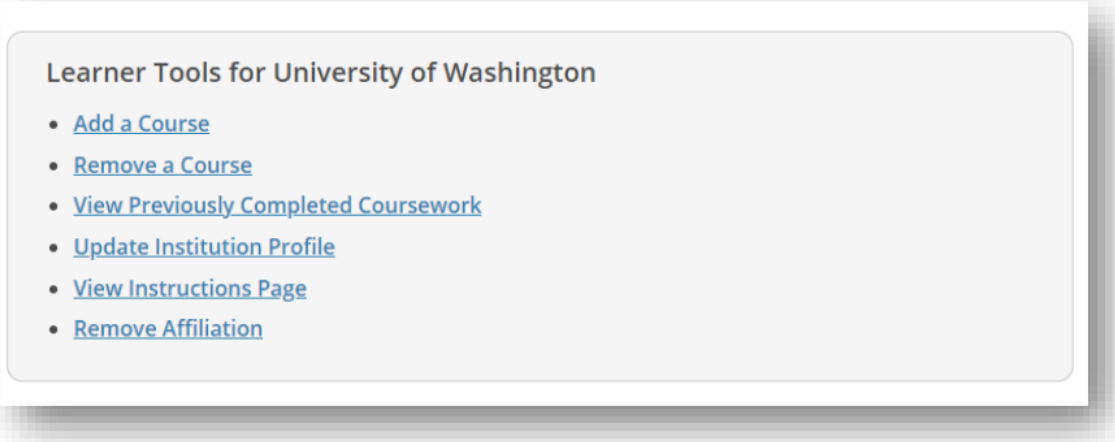
INSTRUCTIONS FOR ADDING A COURSE

First you need to log in using the account you created before.

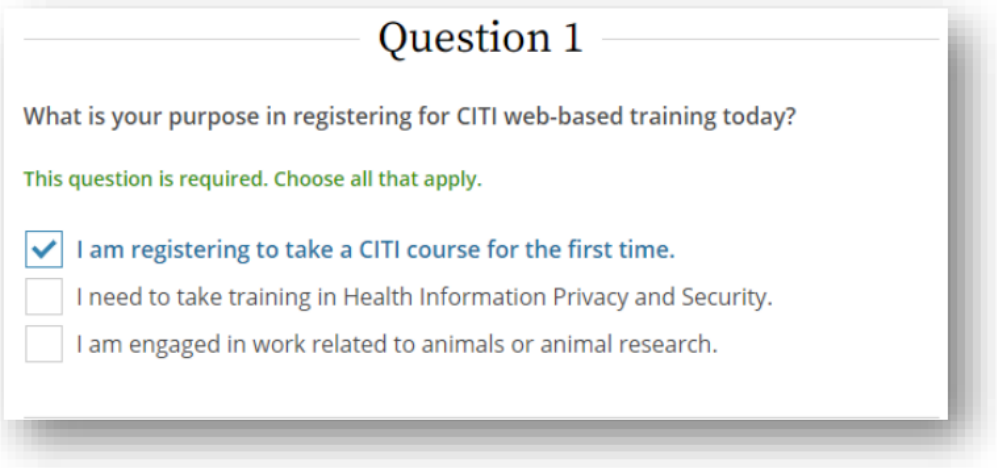
Once you log in, on the home page you'll go to **View Courses** under '**Institutional Courses**.'



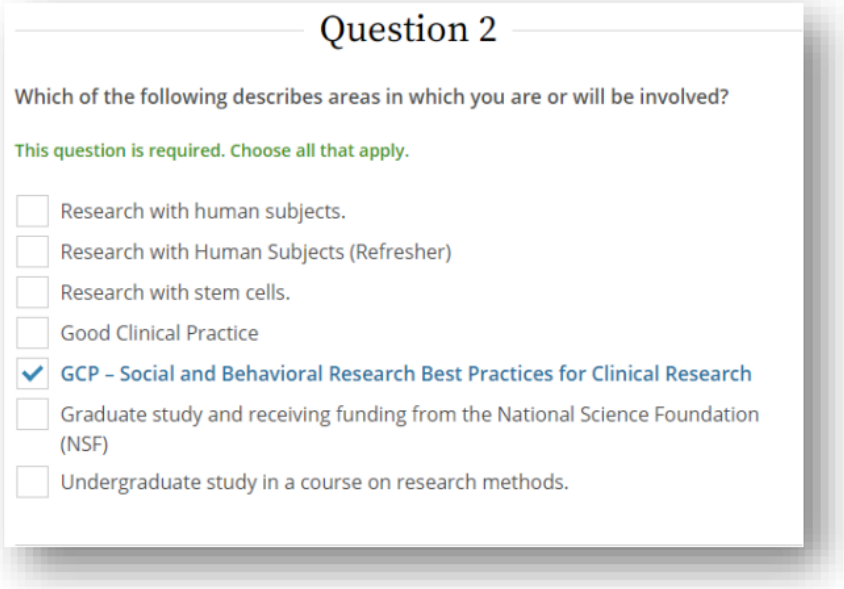
It will bring you to page with your courses listed. At the very bottom of the page, under **Learner Tools for University of Washington**, click **Add a Course**.



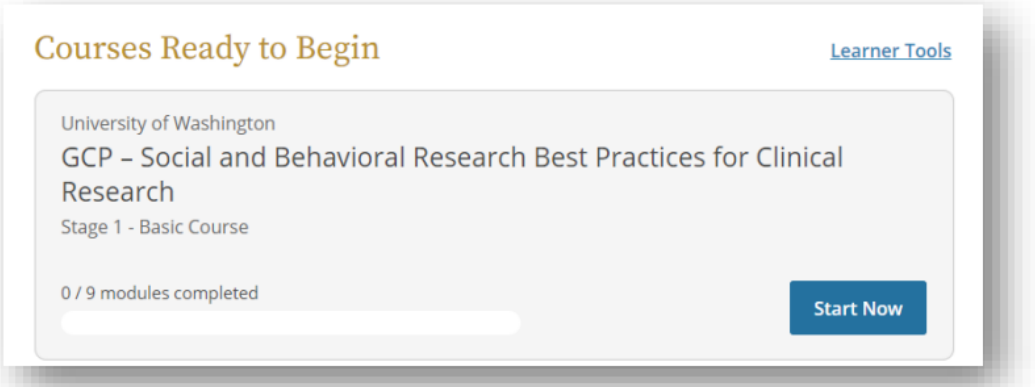
The next page says, "Select Curriculum" and gives you descriptions of 4 courses. At the very bottom there's a **Question 1** to answer. Click the '**I am registering to take a CITI course for the first time'** option.



The next page it will look similar, but at the bottom there's a **Question 2**. Click **"Research with human subjects"** i you have not completed that module, or **"GCP – Social and Behavioral Research Best Practices for Clinical Research."**

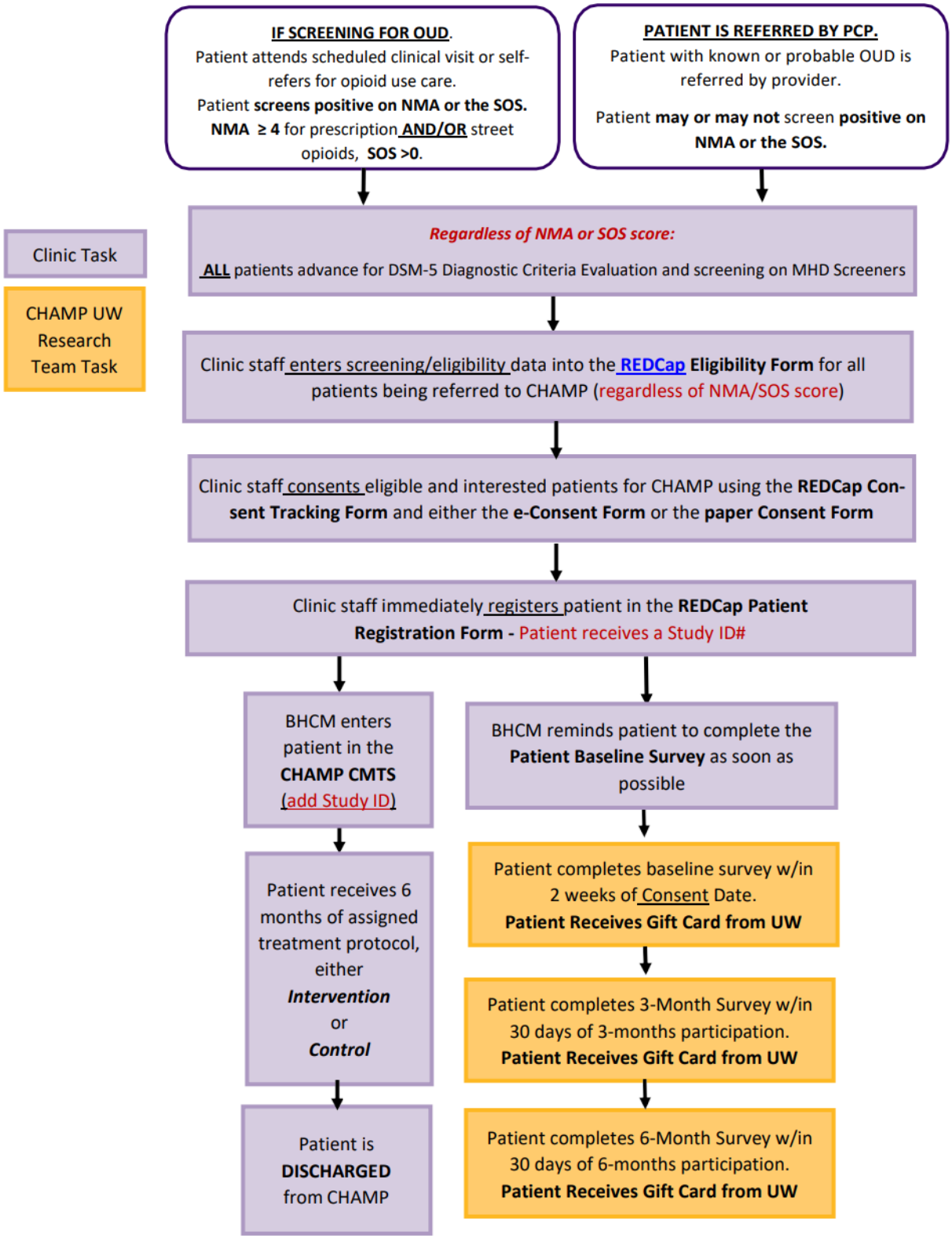


Once you click that, it will take you to a page that says you're enrolled for the course, and it will be listed below. Click the blue **Start Now** button to start the course.



CHAMP REDCAP WORKFLOW

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



CHAMP ELIGIBILITY CRITERIA

Inclusion Criteria:

Patients are potentially **ELIGIBLE** for CHAMP if they meet the inclusion criteria below.

1. **≥ 4 NIDA Modified-ASSIST (NMA) for CHAMP OR >0 on the Short Opioid Screen (SOS) OR** Provider

Referral

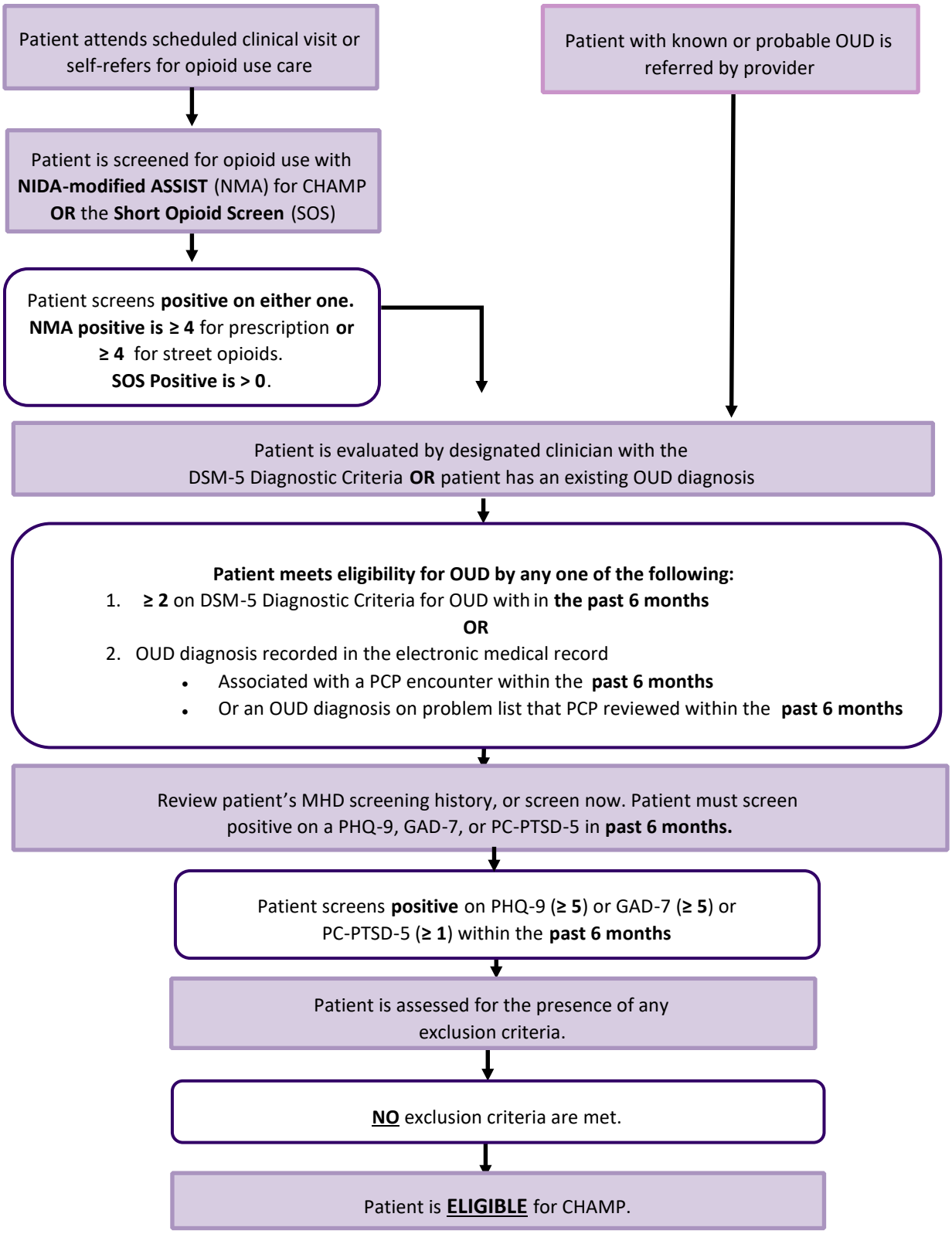
1. **≥ 2 DSM-5 Diagnostic Criteria** for Opioid Use Disorder (OUD) **OR** an OUD diagnosis recorded in the electronic medical record that is associated with a PCP encounter in the *past 6 months* **OR** OUD diagnosis on problem list that the PCP reviewed in the *past 6 months*.
2. **A positive screen on ONE of the below Mental Health Screeners (MHD)** *in the past 6 months:* **≥ 5 on the PHQ-9** AND/OR **≥ 5 on the GAD-7** AND/OR **≥ 1 on the PC-PTSD-5**

Exclusion Criteria:

Patients are **INELIGIBLE** for CHAMP if they meet **ANY** of the following categories (even if they meet all of the inclusion criteria)

1. Patient prefers, or is *currently* being prescribed psychotropic medication (including mOUD) by a Mental Health Care Specialist or board certified Addiction Medicine Specialist.(***NOTE**: it is acceptable if the addiction specialist is a primary care provider in your clinic or health system).*
2. Patient is currently in, or is planning on entering a federally licensed opioid treatment program (i.e. methadone treatment program) (***NOTE**: If patient actually does not enter an opioid treatment program or is later discharged from an opioid treatment program, patient could then become eligible).*
3. Patient is currently in, or is planning on entering a specialty substance use disorders residential treatment program *(**NOTE**: If patient actually does not enter a residential treatment program or is later discharged from a residential treatment program, patient could then become eligible).*
4. Patient enrolled in CoCM for MHD and OUD for more than 14 days (***NOTE**: relevant for Intervention Clinics only)*
5. Patient does not speak English or Spanish
6. Patient is younger than 18 years of age
7. Patient has a diagnosis of dementia
8. Patient lacks the capacity to provide informed consent
9. Patient doesn't plan on getting care at the clinic for the next 6 months

CHAMP PATIENT ELIGIBILITY WORKFLOW



REDCAP

REDCap Description, Access
REDCap Checklist Forms
Consenter Workflows & Scripts
E-Consent Form

ABOUT REDCAP

Research Electronic Data Capture (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.

REDCap can be accessed through this website: https://www.iths.org/investigators/services/bmi/redcap

WHO NEEDS REDCAP?

In the CHAMP Study, only the Behavioral Health Care Managers (BHCM)/Consenters and support staff need individual access to 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 send the virtual consent forms.
- BHCMs and support staff need access to track eligibility, register patients, and report adverse events and protocol violations.

GETTING ACCESS TO REDCAP

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

NOTE: REDCap access is given after the 1-hour training session. Leads or supervisors may request access to REDCap without the need for training if the purpose is for viewing only. Contact **Kat James** at kjames11@uw.edu for access or to request training.

GETTING A UW NET ID

- Kat James will sponsor each BHCM/Research Staff and Consenter using their name and email.
- BHCMs/ Research Staff and Consenters will receive an email from the University of Washington IT Service Center to complete the sponsored UW Net ID process. You will be asked to create a password.
- Once your UW NetID is created, Kat James will follow-up with specific instructions on registering for REDCap.

REDCAP CHECKLISTS FOR CHAMP

There are 5 REDCap checklists to facilitate the required documentation for CHAMP. The below checklists show the forms and fields that need to be entered into each electronic REDCap form for CHAMP.

As a tool - these forms can be used to record eligibility information and/or patient information and passed on to another staff person that may enter the data into REDCap.

Eligibility & Consent Project Checklist:

- Patient Eligibility Checklist for Staff: Patients that are approached for CHAMP need to be documented as eligible for the study.
- Patient Eligibility Checklist for PCPs: In the case that the PCPs want to complete the eligibility checklist when they meet with the patient – this form may be useful.
- Consent Tracking Checklist: this is required for consent or e-consent of patients. This form sends the e-consent to the patient – or the signed paper consent must be uploaded to this form.

Registration and Adverse Events Project Checklists:

- Registration Checklist: After consent, patient needs to be registered into the study to receive the Surveys
- Adverse Events Checklist: In case a patient goes to the hospital, ER or has violation of their confidentiality, etc. we will need to

PATIENT ELIGIBILITY CHECKLIST FOR STAFF

Record ID: _____ *(auto-populates in form)*
Date: _____ *(auto-populates in form)*
MRN: _____

INCLUSION CRITERIA

Has the patient been screened with NIDA-modified ASSIST (NMA)? If yes, record scores and date: YES NO

NMA Screen Date: _____
NMA Prescribed Opioid Score (scores from 0-39): _____
NMA Prescribed Opioid positive is ≥ 4. If the patient has not been screened, please leave blank.
NMA Street Opioid Score (scores from 0-39): _____
NMA Street Opioid positive is ≥ 4. If the patient has not been screened, please leave blank.

Has the patient been screened with Short Opioid Screener (SOS)? If yes, record scores and date: YES NO

SOS Screen Date: _____
SOS Question 1 (use of prescribed opioid medications): YES or NO (circle one)
SOS Question 2 (use of opioids not prescribed): YES or NO (circle one)
Any yes answer is a positive screen.

Has the patient been assessed with DSM-5 OUD Diagnostic Criteria? If yes, record number of criteria and date: YES NO

The DSM-5 OUD Criteria is not required if patient has an OUD diagnosis.

# of DSM OUD Diagnostic Criteria Met: _____

NOTE: If you do not have a score for DSM5 Criteria – please go back to the EMR or PCP and confirm an OUD dx has been recorded and use the OUD dx for CHAMP Eligibility instead of the DSM5 Criteria. If you cannot locate a score or an OUD dx – please make a note in the comments section.

Does the patient have an OUD diagnosis recorded in the electronic medical record associated with a PCP encounter within the past 6 months, or an OUD diagnosis on problem list reviewed by PCP within the past 6 months? YES NO

The OUD diagnosis is not required if a patient scores >=2 on the DSM-5 Criteria for OUD.

Date of PCP encounter/problem list review by PCP: _____

Has the patient been screened with PHQ-9? If yes, record score and date: YES NO
PHQ-9 Screen Date: _____ Score: _____

Has the patient been screened with GAD7? If yes, record score and date: YES NO
GAD-7 Screen Date: _____ Score: _____

Has the patient been screened with PC-PTSD? If yes, record score and date: YES NO

PC-PTSD Screen Date: _____ Score: _____

REFER A FRIEND

YES NO

Patient was referred to the study by a CHAMP patient. If yes, answer below.

Referring CHAMP patient Study ID: _____

Patient was referred to the study by a NON-CHAMP patient. If yes, circle and a gift card will be sent to the clinic. YES NO

EXCLUSION CRITERIA

Patient prefers or is currently being prescribed psychotropic medication (including MOUD) by a Mental Health Care Specialist/board-certified Addiction Medicine Specialist. YES NO

Patient is currently in, or is planning on entering a federally licensed opioid treatment program (i.e. methadone treatment program). YES NO

Patient is currently in, or is planning on entering a specialty substance use disorders residential treatment program. YES NO

Patient enrolled in CoCM for MHD and OUD for more than 14 days (relevant for intervention clinics only). YES NO

Patient does not speak English or Spanish. YES NO

Patient is younger than 18 years of age. YES NO

Patient has a diagnosis of dementia. YES NO

Patient has a diagnosis of dementia. YES NO

Patient lacks the capacity to provide informed consent. YES NO

Patient doesn't plan on getting care at the clinic for the next 6 months. YES NO

Recruitment Outcome:

☐ Eligibility Assessment NOT Complete

☐ Eligible - Approached for consent

☐ Eligible - Not Approached (please explain in note below)

☐ Eligible - Refused (to participate in CHAMP)

☐ Ineligible

Notes (No PHI):

PATIENT ELIGIBILITY CHECKLIST FOR PCPS

If the PCPs would like to use this checklist for eligibility – it can be very helpful for REDCap data entry.

INCLUSION CRITERIA

Medical Record # _____ **Date: _____**

Has the patient been assessed with DSM-5 OUD Diagnostic Criteria and has a score *>=2*? YES NO

# of DSM OUD Diagnostic Criteria Met: _____

OR

Does the patient have an OUD diagnosis recorded in the electronic medical record associated with a PCP encounter within the past 6 months, or an OUD diagnosis on problem list reviewed by PCP within the past 6 months? YES NO

Date of PCP encounter/problem list review by PCP _____

Has the patient been screened with PHQ-9? If yes, record score and date: YES NO

- PHQ-9 Screen Date _____ Score_____

Has the patient been screened with GAD7? If yes, record score YES NO

- GAD-7 Screen Date _____ Score_____

Has the patient been screened with PC-PTSD5? If yes, record score YES NO

- PC-PTSD-5 Screen Date _____ Score_____

EXCLUSION CRITERIA

Patient prefers or is currently being prescribed psychotropic medication (including MOUD) by a Mental Health Care Specialist/board-certified Addiction Medicine Specialist. YES NO

Patient is currently in, or is planning on entering a federally licensed opioid treatment program (i.e. methadone treatment program). YES NO

Patient is currently in, or is planning on entering a specialty substance use disorders residential treatment program. YES NO

Patient enrolled in CoCM for MHD and OUD for more than 14 days (relevant for intervention clinics only). YES NO

Patient does not speak English or Spanish. YES NO

Patient is younger than 18 years of age. YES NO

Patient has a diagnosis of dementia. YES NO

Patient lacks the capacity to provide informed consent. YES NO

Patient does not plan on getting care at the clinic for the next 6 months. YES NO

CONSENT TRACKING FORM CHECKLIST

Record ID: _____ (*auto-populates in form)*

Medical Record #: _____ (*auto-populates in form)*

Consenter First and Last Name (NOT the patient's name): _____

Type of Documentation of Consent:

Paper Consent (given by): ☐ Mail ☐ In-Person
E-consent (English or Spanish):
☐ Email: _____
☐ Text *(smartphone ONLY):* _____
☐ Both Email and Text *(fill fields above)*

Date Consent Sent (M-D-Y): _____
(This should be the same as the date the patient received the consent form)

Date Consent Re-Sent (M-D-Y): _____
(Please only complete if time has expired [*14 days*] for the original consent)

I attest I sent the consent to the correct person ☐

Date Consent Signed (M-D-Y): _____
(Please also enter date signed on patient registration form)

Paper Consent Upload:
ONLY for paper consenting. Please scan and upload ALL pages of the consent form with every field completed and signed in FULL.

Patient did not consent:
(Fill out only if patient did not consent):
☐ Patient declined to participate
☐ Patient lacked capacity to consent

PLEASE REMEMBER TO REGISTER/ENROLL THE PATIENT WITHIN 24 HOURS OF CONSENT IN THE CHAMP REGISTRATION AND ADVERSE EVENTS PROJECT

PATIENT REGISTRATION FORM CHECKLIST

Study ID: _____ *(auto-populates in form)*
Today's Date: _____*(auto-populates in form)*

PLEASE REMEMBER TO REGISTER/ENROLL THE PATIENT WITHIN 24 HOURS OF CONSENT IN THE CHAMP REGISTRATION AND ADVERSE EVENTS PROJECT

PATIENT CONSENT & ENROLLMENT

ONLY consented patients can be entered into the patient registration form.

Date Consent Signed: _____ (M-D-Y)

Medical Record Number: _____

CMTS ID: _____

Was the patient referred from a non-CHAMP clinic within your health system? Yes ☐

PATIENT AND EMERGENCY CONTACT INFORMATION

Patient First Name: _____
Patient Last Name: _____
Patient Address: _____
City: _____
State: _____
Zip: _____
Patient Phone Number (home): _____
Patient Phone Number (cell): _____
Patient Email Address: _____
Patient Language:

☐ English
☐ Spanish

BACK-UP CONTACT 1 - OBTAIN PERMISSION TO CONTACT

Back-Up Contact 1 Name: _____
Back-Up Contact 1 Number: _____

BACK-UP CONTACT 2 - OBTAIN PERMISSION TO CONTACT

Back-Up Contact 2 Name: _____

Back-Up Contact 2 Number: _____

SURVEY PREFERENCES

Consent to text (patient must have a smart phone):

☐ Yes

☐ No

If yes, please verify phone number is correct

Consent to email:

☐ Yes

☐ No

If yes, please verify email is correct

Prefers to complete survey by cell or home phone:

☐ Cell

☐ Home

☐ Neither

Patient wants to participate in the Refer a Friend opportunity:

☐ Yes

☐ No

ADVERSE EVENTS & PROTOCOL VIOLATIONS FORM

Study ID: _____ (auto-populates in form)
Today's Date: _____ (auto-populates in form)
Event Date: _____

Category of event definitions:

Adverse Event: 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.

Serious Adverse Event: 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.

Protocol Violation: 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.

Category of events:
☐ Serious Adverse Events (that resulted in clinical encounter)
☐ Adverse Events
☐ Protocol Violation
☐ Other

Degree of Relatedness: How was the event related to the CHAMP Study?
☐ Definitely Study Related (100%)
☐ Probably Study Related (50-99%)
☐ Possibly Study Related (1-49%)
☐ Definitely Not Study Related (0%)

Event Description:
(Enter a description of the event you are reporting. It should include location and date of the event. **Avoid using PHI**)

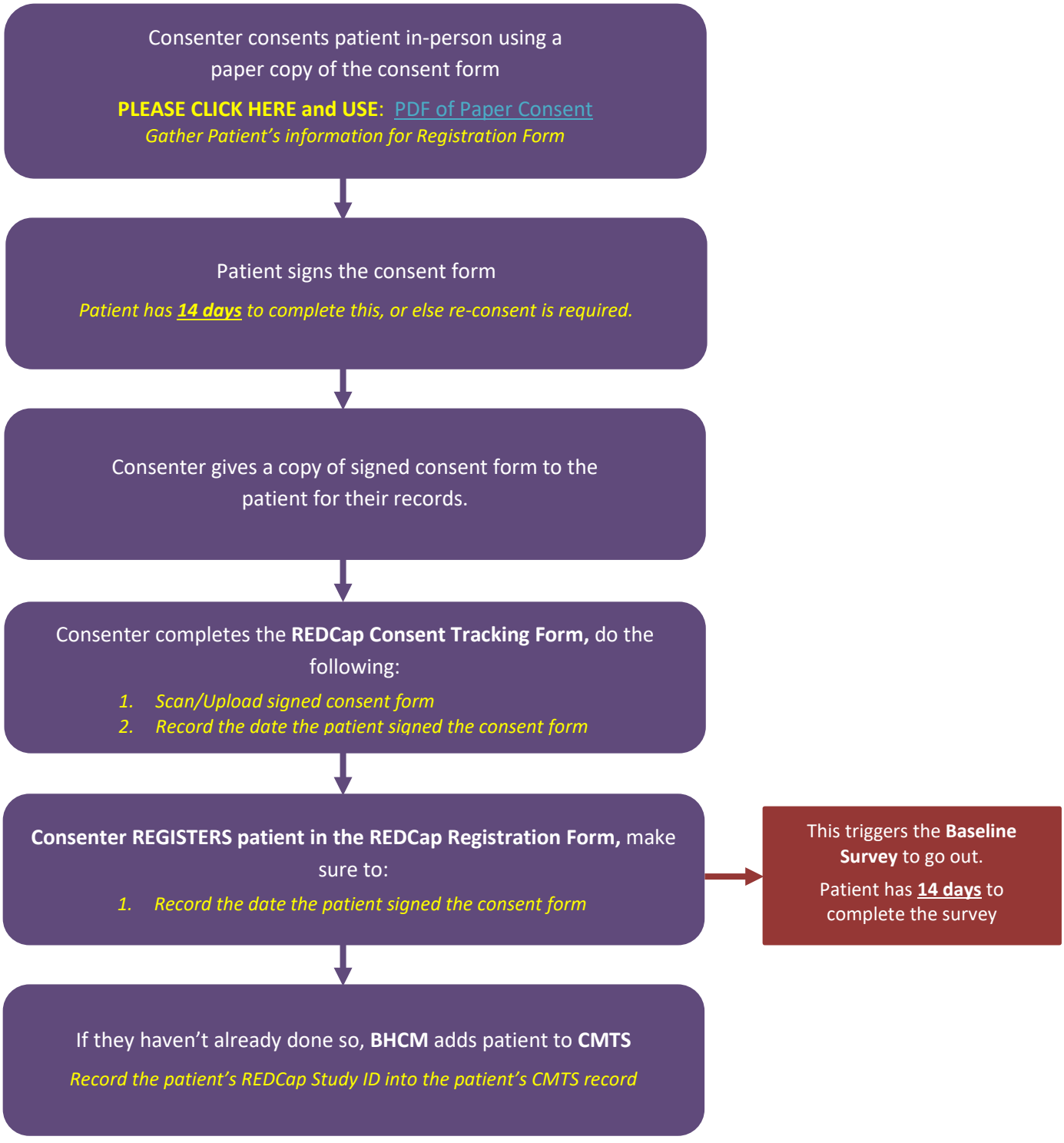
Update/Resolution Description:
(Enter any updates or the resolution of the event reported)

Name of Reporter: _____
Email Address: _____
Phone Number: _____

CONSENTING WORKFLOWS

Below are 2 workflows that show how to consent patients into CHAMP, choose whichever process works best for you, your clinic, and your patient.

Consenting In-Person: Use a Paper Consent Form



Consenting Over the Phone or Tele-Video: Use an e-Consent Form

Consenter mails or emails a PDF copy of the consent form to patient for review.
PLEASE CLICK HERE and USE: PDF of E-Consent

↓

Consenter consents patient by phone or tele-video
Gather Patient's information for Registration Form

↓

Consenter walks the patient through the process of e-signing the e-
PLEASE CLICK HERE and USE: How to E-Consent

↓

Consenter completes the **REDCAP Consent Tracking Form**
*This will automatically SEND the **e-Consent Form** to patient's email and/or phone*

→ **Patient** gets consent Invite and reminders

→ **Consenter** gets email alerts for outstanding e-consent

↓

Patient submits their e-Consent Form: **SEE BELOW FOR DETAILS**
*Patient has **14 days** to complete this, or else re-consent is required*

→ **Consenter** gets Email Alert when e-consent is e-signed

↓

Consenter finalizes the **REDCAP Consent Tracking Form**,
do the following:
1. *Record the date the patient signed the consent form*

↓

If they haven't already done so, **BHCM** adds patient to **CMTS**
Record the patient's REDCap Study ID into the patient's CMTS record

CONSENTER SCRIPTS

CHAMP Recruitment Script – Control

Recruitment Scripts for Research Personnel

Mr. /Mrs. /Ms., the answers you gave to the questions about your opioid use and mental health suggest that you may not be feeling as good as you could be emotionally. Because many of the patients at our clinic experience similar symptoms, we are working with the University of Washington to help our patients get access to more effective substance (opioid) use and mental healthcare services. I want to tell you about a research study we are doing at our clinic.

Do you have any questions so far?
Yes – Answer the questions.
No – Great.

Primary Care Clinics in eight states are working with the University of Washington to find better ways to help people who are experiencing similar symptoms as you. You may or may not be offered treatment for opioid use together with mental healthcare treatments where you and your primary care doctor would work together to decide which one is best for you. These standard mental health treatments would be offered in different ways so we can find out the best way to provide mental healthcare treatments to people. You can even choose no treatment, and still be in our study. You will also be asked to complete three surveys over the web on your own or over the phone with someone from the University of Washington during the course of your treatment. You will receive up to $150 for taking the time to complete the surveys. All survey responses will remain confidential.

May I tell you some more about the study I am working on?

No – No problem.
I don't have time – No problem
If patient does not have time, ask to call the next day, provide a copy of the consent form for review. Collect contact information.

Yes – Great.
We are experienced in delivering health care using Collaborative Care. This model provides mental health care as a team. Dr. [NAME] will still be your primary provider and will write your prescriptions if needed. Our care manager [NAME] will work mostly with your day-to-day functions and symptoms. Our consulting psychiatrist [NAME] will meet with our care manager weekly to work "behind the scenes" to make sure we offer you the best treatment options possible. We will communicate as a team about your care. When you are working with one team member you are working with the whole team.

If relevant: We can do this using interactive video. By interactive video, I mean a video camera and microphone connected to a computer. It allows the care manager located at [CLINIC] to communicate with you. You can see and hear the care manager and they can see and hear you. Have you heard of interactive video?

No – I would be happy to show you the equipment if you want, before you consent to enroll into the study.
Yes – Great.

The purpose of this study is to determine whether Collaborative Care that addresses mental health conditions with opioid use treated within or referred outside of the primary care clinic, can improve patient lives. If you participate in our study, you will be enrolled in Collaborative Care. You will receive all your treatment at our clinic and all visits with the mental health specialists will be in person, or via interactive video, whichever is better for you.

All treatments that will be offered to you are used routinely to treat patients. These include medication and behavioral treatments. This study is NOT testing experimental drugs, devices or therapies.

Does that sound acceptable to you?

No – Can you tell me what your concerns are?
Address the concerns if possible.
If refuse, record concern.

Yes – If you decide to participate, you will be asked to complete a survey over the phone or on the Internet. The survey will take about an hour and will ask questions about your health and use of health services. You will then be asked to complete two follow-up surveys 3 and 6 months later. To show our appreciation for your time, you will receive $50 after completing the first survey, $50 after completing the 3-month survey and $50 after completing the 6-month survey for a total of $150. If you decide later that you don't want to be in the study, you can quit at any time.

If you are still interested, I'll need to obtain your informed consent. Basically, I need to make sure you understand the study, and exactly what is involved. First, I'll need you to read a description of the study and then I will answer any questions you have. I would also be happy to read the description to you if you would like.

CHAMP Recruitment Script – Intervention

Recruitment Scripts for Research Personnel

Mr. /Mrs. /Ms., the answers you gave to the questions about your opioid use and mental health suggest that you may not be feeling as good as you could be emotionally. Because many of the patients at our clinic experience similar symptoms, we are working with the University of Washington to help our patients get access to more effective substance (opioid) use and mental healthcare services. I want to tell you about a research study we are doing at our clinic.

Do you have any questions so far?
Yes – Answer the questions.
No – Great.

Primary Care Clinics in eight states are working with the University of Washington to find better ways to help people who are experiencing similar symptoms as you. You may be offered treatment for opioid use and mental healthcare treatments where you and your primary care doctor would work together to decide which one is best for you. These standard mental health treatments would be offered in different ways so we can find out the best way to provide mental healthcare treatments to people. You can even choose no treatment, and still be in our study. You will also be asked to complete three surveys over the web on your own or over the phone with someone from the University of Washington during the course of your treatment. You will receive up to $150 for taking the time to complete the surveys. All survey responses will remain confidential.

May I tell you some more about the study I am working on?

No – No problem.
I don't have time – No problem
If patient does not have time, ask to call the next day, provide a copy of the consent form for review. Collect contact information.

Yes – Great.
We are experienced in delivering health care using Collaborative Care. This model provides medication assisted treatment for opioid use and mental health care as a team. Dr. [NAME] will still be your primary provider and will write your prescriptions if needed. Our care manager [NAME] will work mostly with your day to day functions and symptoms. Our consulting psychiatrist [NAME] will meet with our care manager weekly to work "behind the scenes" to make sure we offer you the best treatment options possible. We will communicate as a team about your care. When you are working with one team member you are working with the whole team.

If relevant: We can do this using interactive video. By interactive video, I mean a video camera and microphone connected to a computer. It allows the care manager located at [CLINIC] to communicate with you. You can see and hear the care manager and they can see and hear you. Have you heard of interactive video?

No – I would be happy to show you the equipment if you want, before you consent to enroll into the study.
Yes – Great.

The purpose of this study is to determine whether Collaborative Care that addresses both mental health conditions and co-occurring opioid use can improve patient lives. If you participate in our study, you will be enrolled in Collaborative

Care. You will receive all your treatment at our clinic and all visits with the mental health specialists will be in person, or via interactive video, whichever is better for you.

All treatments that will be offered to you are used routinely to treat patients. These include medication and behavioral treatments. This study is NOT testing experimental drugs, devices or therapies.

Does that sound acceptable to you?

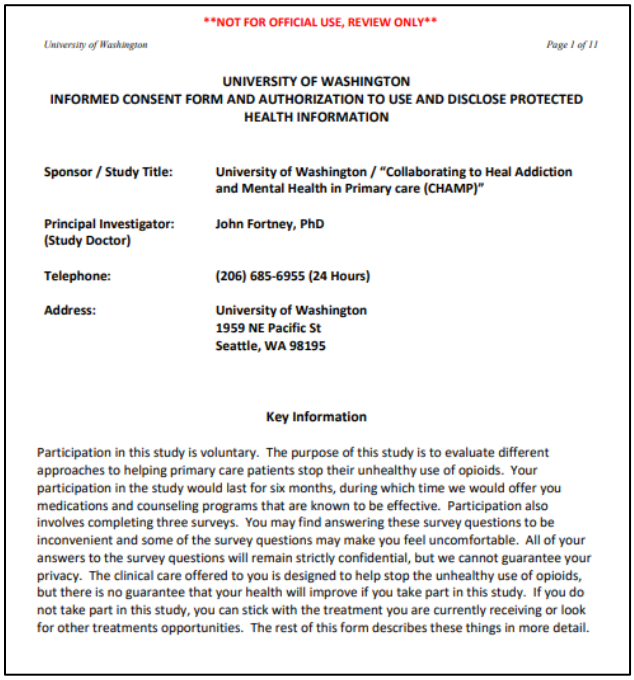
No – Can you tell me what your concerns are?
Address the concerns if possible.
If refuse, record concern.

Yes – If you decide to participate, you will be asked to complete a survey over the phone or on the Internet. The survey will take about an hour and will ask questions about your health and use of health services. You will then be asked to complete two follow-up surveys 3 and 6 months later. To show our appreciation for your time, you will receive $50 after completing the first survey, $50 after completing the 3-month survey and $50 after completing the 6-month survey for a total of $150. If you decide later that you don't want to be in the study, you can quit at any time.

If you are still interested, I'll need to obtain your informed consent. Basically, I need to make sure you understand the study, and exactly what is involved. First, I'll need you to read a description of the study and then I will answer any questions you have. I would also be happy to read the description to you if you would like.

E-CONSENT FOR REVIEW

To help facilitate the e-consenting process, **a PDF version of the e-consent** is available to review with the patient. This version is not for signing and review only. Consents can only be signed in-person or through the electronic version of the consent as a REDCap link sent out from the **Consent Tracking Form**. You can find the PDF version of the consent here.



NOT FOR OFFICIAL USE, REVIEW ONLY

University of Washington *Page 1 of 11*

UNIVERSITY OF WASHINGTON
INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title: University of Washington / "Collaborating to Heal Addiction and Mental Health in Primary care (CHAMP)"

Principal Investigator: (Study Doctor) John Fortney, PhD

Telephone: (206) 685-6955 (24 Hours)

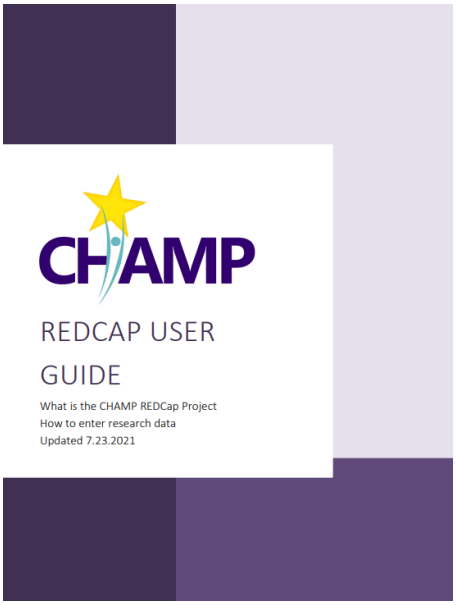
Address: University of Washington
1959 NE Pacific St
Seattle, WA 98195

Key Information

Participation in this study is voluntary. The purpose of this study is to evaluate different approaches to helping primary care patients stop their unhealthy use of opioids. Your participation in the study would last for six months, during which time we would offer you medications and counseling programs that are known to be effective. Participation also involves completing three surveys. You may find answering these survey questions to be inconvenient and some of the survey questions may make you feel uncomfortable. All of your answers to the survey questions will remain strictly confidential, but we cannot guarantee your privacy. The clinical care offered to you is designed to help stop the unhealthy use of opioids, but there is no guarantee that your health will improve if you take part in this study. If you do not take part in this study, you can stick with the treatment you are currently receiving or look for other treatments opportunities. The rest of this form describes these things in more detail.

REDCAP USER GUIDE

If you need specific information on what to enter into REDCap and where, there is an in-depth REDCap User Guide located on the CHAMP website here.



CHAMP WEBSITE AND QUICKLINKS

You can find clinical and research related resources on our CHAMP website here: https://champ.psychiatry.uw.edu