INFORMED CONSENT TRAINING

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Three stage process

1. Recruitment
2. Eligibility Assessment
3. Informed Consent

Assessing Eligibility

To be eligible for CHAMP, a patient **MUST** meet all 3 Inclusion Criteria and none of the Exclusion Criteria.

https://champ.psychiatry.uw.edu/

What is informed consent?

- Informed consent is the *process* through which the research team obtains the legal permission of a person to participate in a research study.

- Informed consent is achieved when a prospective research participant:
  - Receives full disclosure of the research plan and intent
  - Understands all of the information that is disclosed to him or her
  - Voluntarily consents to participate in the study

It is NOT just signing the form!

- The research participant's signature provides documentation of agreement to participate in a study, but is only one part of the consent process.
- The consent document must not serve as a substitute for discussion.
- The consent document is to be used as a guide for the verbal explanation of the study.
- The consent document should be the basis for a meaningful exchange between the consenter and the potential research participant.
- The documentation of informed consent (i.e., signing of the consent form) is the last step in the informed consent process.

Who may obtain informed consent?

- If someone other than the Principal Investigator obtains informed consent, the Principal Investigator should formally delegate this responsibility.
- The consenter is required to complete a web-based educational course on the protection of human subjects in research (CITI).
- The consenter should have received appropriate training to obtain inform consent.

Basic elements of Informed Consent

- **Purpose and Description:**
  - Explain the purpose of the study, the length of time expected for the subjects' participation, the process to be followed during the study, and the procedures.
- **Risks:**
  - Describe any reasonably foreseeable harms, inconveniences, or discomforts to the participant
- **Benefits:**
  - Describe any benefits to the prospective participant or to others that may reasonably be expected to result from the research.
- **Alternatives:**
  - Disclose any appropriate alternative treatments that might benefit the prospective participant.

Basic Elements of Informed Consent

- **Confidentiality:**
  - Tell the prospective participant whether his or her individual record will be kept confidential and explain the level of confidentiality to be maintained.
- **Greater Than Minimal Risk:**
  - For research involving more than minimal risk, provide an explanation of whether any compensation is available and whether medical treatments are available if injury occurs.
- **Contact Information:**
  - Provide information about whom the potential research participant may contact with questions about the research.
- **Voluntary Participation:**
  - Explain that participation is voluntary.

Additional elements of Informed Consent

- **Costs and Compensation:**
  - Tell the potential research participant what costs might be involved and how much they will be compensated.
- **Withdrawal:**
  - Explain the consequences of deciding to withdraw and describe the withdrawal procedures.
- **Source of Funding:**
  - State that this study is being funded by the National Institute of Mental Health.

Informed Consent Steps

Explaining the Study

- The person considering participation in research needs to know:
  - Nature, duration and purpose of the study
  - The method and means by which it is to be conducted
  - All inconveniences, costs and risks to his/her health which may possibly come from participation in the research study.

Assessing Comprehension

- Potential research participant should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an understanding and enlightened decision.
- The person considering participation in a research study should have legal capacity to give consent.

Informed Consent Steps Cont.

Ensuring Voluntary Choice

- Potential research participant should be able to exercise free power of choice without any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of coercion.

Explaining the Study

- Explain the study to the potential subject verbally, providing all pertinent information:
  - Purpose
  - Procedures
  - Risks
  - Benefits
  - Alternatives to participation
  - Confidentiality
- Investigators must educate potential subjects to ensure that they can reach a truly informed decision about whether or not to participate in the research.
- Informed consent must be based on a clear understanding of what participation involves.
- Must allow the potential subject ample opportunity to ask questions.

Reading the Consent Form

- The potential subject should be provided with the written or e-consent form and afforded sufficient time to consider whether or not to participate in the research.
- Offer to read the consent form to the patient.

Current Consent forms

Current consent forms are available to download on the CHAMP Website.

- CHAMP Website Resources Page: https://champ.psychiatry.uw.edu/
  - **NOTE:** University of Wisconsin Health has its own consent form.

Spanish Speaking Patients

- COMING SOON
  - Informed Consent Form will be translated into Spanish.
  - If consenter does not speak Spanish, arrange for a translator.

Commonly Asked Questions and Answers

- An essential part of the informed consent process is being able to adequately answer every question presented by the person considering participation in the research study.
- Informed consent may not be obtained until you have adequately answered all the questions asked by the person considering participation in research.
- If the Principal Investigator designates someone else to conduct the informed consent process, a list of commonly asked questions and answers must be provided.

CHAMP FAQ

COMING SOON

https://champ.psychiatry.uw.edu/

Assessing Comprehension

- The responsibility of ensuring that a potential subject understands the research and the risks and benefits involved falls upon the consenter and not upon the potential research participant.
- It is critical to the consent process that the consenter not only answers questions but also asks questions.
- Asking open-ended questions can:
  - Further the discussion
  - Elicit questions from the potential research participant
  - Prompt the potential research participant to think more carefully about the study
  - Help the consenter decide whether the person has adequately understood the study

Assessing Comprehension, cont.

- In contrast, closed-ended questions do not further discussion and tend to bring it to a stop, so they should be avoided. Examples of closed-ended questions are:
  - "Do you understand?“
  - "Do you see that there are some risks to participating?“
- Useful questions will be open-ended and non-directive.
- Potential research subjects should **NOT** be enrolled if they cannot comprehend the study protocol, despite repeated attempts to explain the details.

Assessing Comprehension, cont.

Element of Consent	Comprehension Assessment Question
Overall	"It's my job to explain things clearly. To make sure I did this I would like to hear your understanding of the research project.“
Purpose and Description:	"Tell me in your own words about what will happen to you if you agree to be in this study.“
Risks:	"What risks would you be taking if you joined this study?“
Benefits:	"What do you expect to gain by taking part in this research?“
Alternatives:	"What happen to you if you refuse to be in this study?“
Confidentiality:	"Who will be able to see the information you give us?“
Contact Information	"What should you do if you have any questions or concerns about this study?“
Voluntary Participation	"What should you do if you agree to be in the study but later change your mind?“
Correct any misinformation	"Let's talk about the purpose of the study again because I think I may have not explained it clearly.“ “This is complex material. It is not your fault that you didn’t understand all of it the first time.”

Coercion

- You must assure that at no time do potential research participants feel forced to participate.
- You are required to make sure they understand that participation is completely voluntary, and that they may withdraw at any time.
- They must also understand that whether or not they participate in the research study, it will not affect their normal standard of care or their health insurance benefits.
- Make sure their Primary Care Providers have not coerced them into participation.
- If a patient reports coercion, our IRB may shut down the study.

Barriers and Facilitators

- The informed consent process has some challenges:
  - Mistrust of researchers in general
  - Clinical uncertainty about why the patient is being asked to participate
  - Patient does not want treatment
  - Complex legal language in consent document

- Potential research participants should be encouraged to discuss participation with providers, family members, or other trusted advisors.

Informed Consent Checklist

1. Print and hand, email, or text consent form to patient
2. Choose a private setting to conduct the informed consent process where others can not hear the conversation.
3. Confirm the patient is eligible for the study.
4. Confirm that the patient has the capacity to consent.
5. Describe the informed consent form and its purpose.
6. Explain the study to the patient using simple language.
7. Allow the patient plenty of time to read the consent form and offer to read the consent form to the patient.

Informed Consent Checklist, Cont.

8. Confirm that the patient understood what has been disclosed in the consent form.
9. Give the patient an opportunity to ask questions and answer them to the best of your ability.
10. Witness consent:
    - Paper Consent – watch the patient sign and date the consent form
    - E-Consent – sign the e-consent form **BEFORE** the patient signs
11. Make sure the patient has a copy of the signed and dated consent form.
12. If using a paper consent form, scan and upload the signed/dated paper consent form to the CHAMP Consent Tracking Form.
13. Store the signed/dated paper consent form in a locked file cabinet with other consent forms.

THANK YOU

Assessing Eligibility

To be eligible for CHAMP, a patient **MUST** meet all 3 Inclusion Criteria

Inclusion Criteria

1. Positive screen on NIDA-modified ASSIST within the last 6 months; a positive screen is a score of ≥ 4 for prescribed **and/or** street opioids.
2. Meeting ≥ 2 DSM-5 Diagnostic Criteria for OUD
3. Positive screen on either the PHQ-9 **or** GAD-7 **or** PC-PTSD-5 within the last 6 months; a positive screen on the PHQ-9 is a score of ≥ 10, a positive screen on the GAD-7 is a score of ≥ 10, a positive screen on the PC-PTSD-5 is a score of ≥ 3.

Assessing Eligibility

To be eligible for CHAMP, a patient **CANNOT** meet any of the 9 Exclusion Criteria

Exclusion 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.
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).

Assessing Eligibility

To be eligible for CHAMP, a patient **CANNOT** meet any of the 9 Exclusion Criteria

Exclusion Criteria Continued

4. Patient enrolled in CoCM for MHD and OUD for more than 14 days.
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