

NIDA Clinical Trials Network

0068P (ENR)

Web Version: 1.0; 1.00; 03-08-17

Date of verbal consent:(*STARTDT*)

(*mm/dd/yyyy*)

Pre-Screening Interview (PSF)

Segment (PROTSEG): P

Visit number (VISNO):

Section A: Pre-Screening Interview

1. How did you hear about this research?

If multiple sources, which one most influenced you to call?(PSFINDOT)

- 1-Treatment program staff
- 3-Poster/flyer/brochure
- 2-Clinicaltrials.gov
- 4-Another study participant
- 5-Friend/family/acquaintance (not in the study)
- *Additional Options Listed Below

If "Other", specify:(PSFINDSP)

2. How old are you?

[Must be between 18-65 years old.](PSAGE)

 (xx) years old

3. Are you male or female?(PSSEX)

1-Male 2-Female

4. If female, are you pregnant or currently breastfeeding?

[Must not be pregnant or breast feeding.](PSPREG)

0-No 1-Yes

5. Which substances are you using?

Check all that apply.

[Must report methamphetamine use.]

a. Alcohol:(PSALCHL)

0-No 1-Yes

b. Cocaine:(PSCOCANE)

0-No 1-Yes

c. Opioids:(PSOPIATE)

0-No 1-Yes

d. Methamphetamine:(PSMETHAM)

0-No 1-Yes

e. Amphetamine/other stimulants:(PSAMPHET)

0-No 1-Yes

f. Marijuana:(PSMARJNA)

0-No 1-Yes

g. Benzodiazepines:(PSBENZO)

0-No 1-Yes

h. Other substances:(PSUSEOT)

0-No 1-Yes Specify:(PSUSESP)

6. Which substance do you consider the biggest problem for you right now?

If more than one substance reported, ask potential candidate to indicate the substance that is most problematic.(PSPRMSUB)

- 1-Alcohol
- 2-Cocaine
- 3-Opioids
- 4-Methamphetamine
- 5-Amphetamine/other stimulants
- *Additional Options Listed Below

If "Other", specify:(PSPRMSP)

7. Are you interested in reducing or stopping your methamphetamine use?

[Must say yes.](PSTRTMET)

If "Yes", as of today, is your goal to:(PSTRTGOL)

0-No 1-Yes

0-Not use methamphetamine at all 1-Reduce methamphetamine use

8. Have you used methamphetamine in the past 30 days?

[Must say yes.](PSMET30D)

a. If "Yes", how many days have you used methamphetamine?(PSMETDAY)

0-No 1-Yes

 (xx)

b. If "Yes", when did you last use methamphetamine?(PSMETDT)

 (mm/dd/yyyy)

9. Are you able to refrain from opioid use for at least 7 days before being given study medications?

[If currently using opioids, must say yes.](PSNOOPTD)

0-No 1-Yes 96-Not applicable

10. Have you been in a prior study of pharmacological or behavioral treatment for methamphetamine use disorder within the past 6 months?

[Must say no.](PSMETSTY)

0-No 1-Yes

11. Are you currently taking an investigational drug in another study?

[Must say no.](PSINVSTY)

0-No 1-Yes

12. Have you been prescribed and taken naltrexone (Vivitrol) or bupropion (Wellbutrin) within the last 30 days?

[Must say no.](PSTKN30D)

0-No 1-Yes

13. Do you have any medical or mental health conditions that require ongoing monitoring, care, or medication? 0-No 1-Yes

Inform potential participant that you will need to speak with the study medical clinician about any medical conditions that s/he reported.(PSPSYCH)

If "Yes", specify:(PSPSYHSP)

14. Are you taking medication(s) for any ongoing medical or mental health problem? 0-No 1-Yes

Inform potential participant that you will need to speak with the study medical clinician about any medical conditions that s/he reported. [May be ineligible if s/he will require therapy with opioid-containing medications (e.g., analgesics) or any medications that could interact adversely with study medications during the study period.](PSMEDS)

If "Yes", what medications are you taking and what are they for?(PSMEDSP)

15. Are you currently enrolled in formal addiction treatment services? 0-No 1-Yes

[Must not be receiving formal behavioral or pharmacological addiction treatment. Mutual support groups are okay.](PSADDTRT)

If "Yes", where are you receiving these services?(PSTRTSRV)

16. Have you been mandated by a court of law to attend treatment?(PSMANDTE) 0-No 1-Yes

If "Yes," are you currently in jail, prison, or any inpatient overnight facility as required by a court of law?

0-No 1-Yes

[If yes, meets OHRP definition of prisoner; participant ineligible. Skip to #19 and complete Pre-Screening Interview.](PSJAILIN)

17. Are you attending outpatient treatment as required by a court of law?(PSOUTPNT) 0-No 1-Yes

If "Yes", must you be escorted to and from outpatient treatment and/or wear a monitoring device?

0-No 1-Yes

[If yes, may be considered a prisoner; recommend deeming participant ineligible. Skip to #19 and complete Pre-Screening Interview. Alternatively, OHRP can be consulted prior to enrollment.](PSOUTESC)

18. Are you currently awaiting trial, on probation, or under house arrest?(PSTRLPRB) 0-No 1-Yes

If "Yes", must you be currently escorted to treatment or, upon discharge from treatment, will you be escorted to jail, prison, or any inpatient overnight facility as required by law?

0-No 1-Yes

[If yes, meets OHRP definition of prisoner; participant ineligible. Complete Pre-Screening Interview.](PSTRLESC)

19. Do you have a personal smartphone?(PSCCELL) 0-No 1-Yes

20. Smartphones are often used to help monitor and improve health. Would you agree to use a smartphone app to take a video of yourself when taking daily oral study medication? 0-No 1-Yes

[Must say yes.](PSUSEAPP)

21. Are you willing and able to attend the clinic two times a week during the 12 week treatment period? 0-No 1-Yes

(e.g., no transportation problems, legal problems, or plans to move out of the area)

[Must say yes.](PSCLNC2X)

22. This study will give injections every 3 weeks and daily oral medication. You will get either long-acting naltrexone, an injectable medication, and oral bupropion or you will get a placebo injection and oral placebo. Are you interested in a study where you will get 4 injections and a daily oral medication for 3 months? 0-No 1-Yes

[Must say yes.](PSXRNTX)

Section B: Eligibility

The question below is for the Research Assistant (RA).

23. Is this person eligible to continue with in-person screening?(PSELIG) 0-No 1-Yes

IF ELIGIBLE GIVEN RESPONSES IN SECTION A:

Thank you for your willingness to answer our questions. Based on the answers you provided, you may be eligible to participate in this study. I'd like to schedule you for a face-to-face meeting with research staff so they can explain the study to you in more detail and, if you are still interested, they will obtain your written permission to begin the study screening process. Completing this process will in no way require you to participate in this study. You may choose not to participate or change your mind about participation at any time.

24. Are you interested in scheduling an appointment?(PSSCHED) 0-No 1-Yes

If "Yes", complete the Pre-Screen Contact Form and set appointment date and time.

a. If "Yes", in-person screening appointment date:(PSAPTDT)

 (mm/dd/yyyy)

b. If "No", are any of the following reasons why?

1. Declined to schedule:(PSDEC SCH)

0-No 1-Yes

2. Not interested in study:(PSNOSTUD)

0-No 1-Yes

3. Doesn't want the study medications:(PSNOMED)

0-No 1-Yes

4. Other:(PSSCHOTH)

0-No 1-Yes

Specify:(PSSCHSP)

IF INELIGIBLE GIVEN RESPONSES IN SECTION A:

Thank you for your willingness to answer our questions. Based on the answers you provided, unfortunately you are not eligible to participate in this study. Would you like referrals to other treatment programs in this area? *(Provide referrals as requested.)*

CLOSING - FOR ELIGIBLE AND INELIGIBLE PERSONS

Do you have any questions about this pre-screening or the research? I am going to give you a couple of telephone numbers to call if you have any questions later. Do you have a pen?

If you have questions about the research screening you may call (provide local information here).

If you have any questions about your rights as a research subject, please call the (provide institution's name and IRB or other appropriate local office) at (provide local number).

Thanks again for your time and interest in this study.

Comments:(PSFCOMM)

Additional Selection Options for PSF

How did you hear about this research?

If multiple sources, which one most influenced you to call?

6-Newspaper/magazine ad

7-TV

8-Radio

9-Referral from another agency or medical/mental health provider

10-Craigslist

99-Other

Which substance do you consider the biggest problem for you right now?

If more than one substance reported, ask potential candidate to indicate the substance that is most problematic.

6-Marijuana

7-Benzodiazepines

99-Other