

## **3. Chapter 3: Recruitment and Pre-Screening**

### **3.1 Overview of Recruitment and Screening**

The final overall number of participants will be 1375 men and women. Each site has a fixed recruitment goal of 125 participants.

- Sites will be expected to use a standardized phone screen and consent procedures.
- If someone decides not to participate at any point during the screening process, the reason(s) should be documented on the Reasons for Not Wanting to Participate form (RNP). If s/he is not able or willing to complete the form, and the research staff is aware of the reason(s), they should document this on the form and note that staff completed the form.

### **3.2 Recruitment and Screening Principles**

Here are some screening and recruitment principles to follow as a general approach for the study:

•The primary goal is to eliminate non-eligible participants at cheapest cost while minimizing loss of potential participants by:

- assuming eligibility until ruled-out,
- excluding the obviously ineligible before face-to-face encounter, &
- applying sensitivity early and specificity later

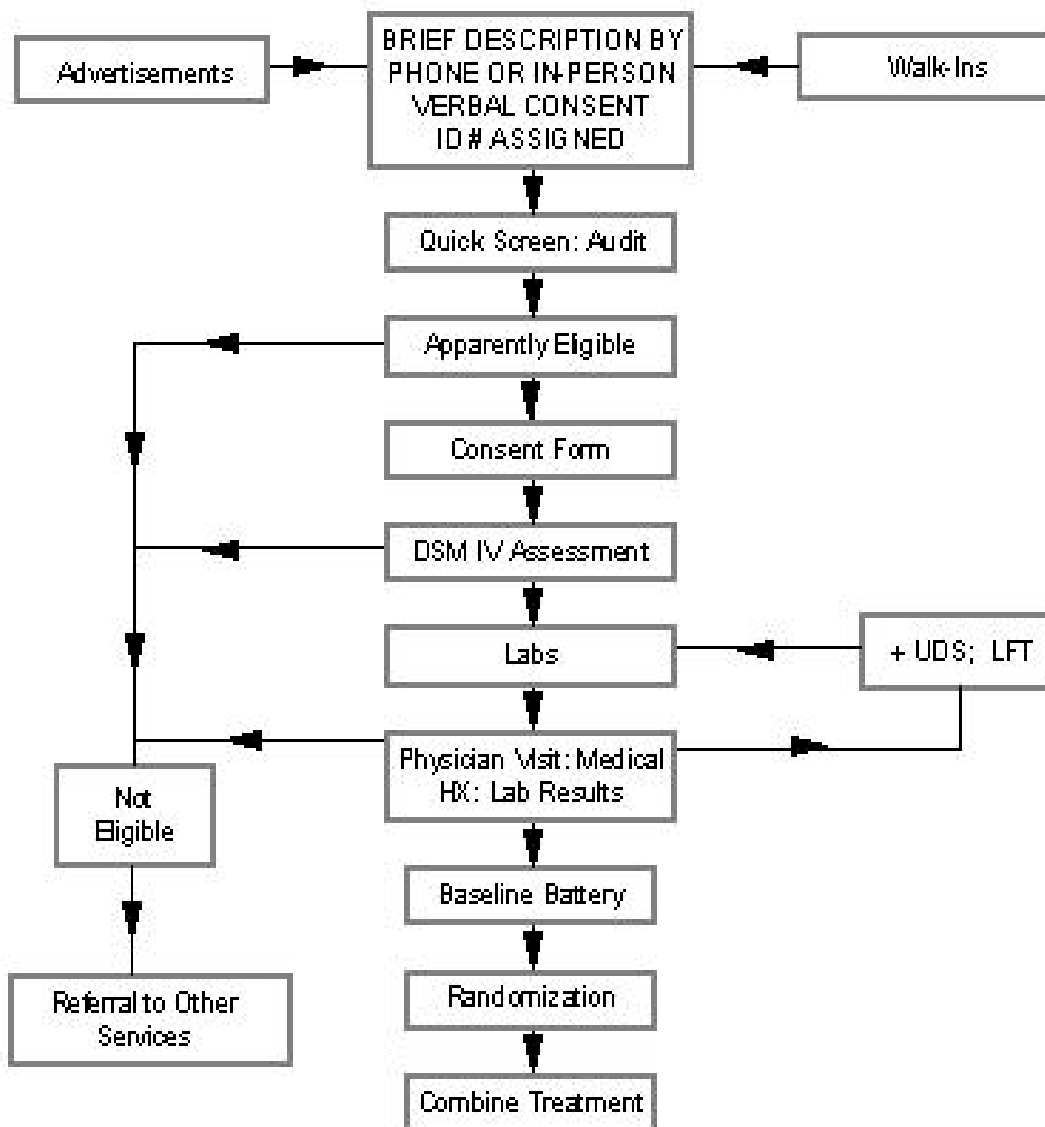
•Screening levels include

- “Gross exclusions” at initial in-person or phone contact:
  - e.g. age; pregnancy; obvious medical; alcohol severity; “permanent” address
- “More specific” psychiatric, medical, & legal issues:
  - e.g. CIWA; opiate use; IND or other disallowed meds; Axis I & II questions
- “Most detailed” physical evaluation & blood results

•Data collection, compliance and retention begins with initial contact

A flow chart of the screening process appears on the following page. Each center may need to adapt this flow in order to meet local staffing and organizational structures. The chart is intended as a model of one logical way to order procedures and may not work in every instance.

### Steps From Screening Through Randomization



### **3.3 Screening Visit (pre-baseline)**

After providing verbal informed consent, potentially eligible participants will be given a Screening Identification Code and evaluated for study admission. Participants requiring medicated detoxification will be referred for medical detoxification if not already in the process, and screening visit evaluations (as well as the assignment of the Screening Identification Code) will be deferred until medicated detoxification has been completed. Once someone is assigned a Screening ID Code, that code should remain with him or her throughout screening even if s/he becomes ineligible or does not wish to participate at that time (s/he may come back to the site to be re-screened at a later time).

The presence of the previously enumerated inclusion criteria and the absence of the previously enumerated exclusion criteria will be verified if someone decides to continue with the screening process.

#### **3.3.1 Evaluations**

##### **3.3.1.1 Telephone Quick Screen**

The Telephone Quick Screen (TQS) was adapted from Project MATCH, and includes the AUDIT. This form is administered prior to the baseline battery. The TQS should be completed for all potential participants. If some information is unknown, leave those items blank and enter those items as permanently missing in the data management system.

##### **3.3.1.2 Determinants of Participation**

If, after completing the TQS, the person is not interested in participating in the study, s/he will be asked to complete the Reasons for NOT Wanting to Participate Questionnaire (RNP). If the participant wants to participate, s/he will be asked to complete the Reasons for Wanting to Participate Questionnaire (RWP) during the baseline-screening phase.

#### **3.3.2 Definition of a Screen**

The process of screening varies considerably across sites as some sites screen for several studies at any given time. For standardization purposes, a screen will be defined as completion of the Telephone Quick Screen (TQS). Recruitment and Screening reports generated by the Coordinating Center will be based on the TQS data that is entered at the site and transferred to the Coordinating Center.

#### **3.3.3 Screening Failures**

A screening failure is defined as someone who completes the TQS who does not meet the eligibility criteria. This information should be captured in the site's screening log (described in section 3.4.2).

Research staff can inform the participant as to why they are ineligible but should use good judgement when doing so.

### **3.4 Recruitment and Screening Logs**

#### **3.4.1 Recruitment Sources**

It is recommended that each site record the number of phone contacts received and the sources of referrals as this will determine the rate of contact and the most fruitful recruitment source. This

information can be shared across sites to enhance recruitment for sites that experience difficulties or slow periods.

### **3.4.2 Screening Logs**

The screening log will incorporate information about screen failures (those who complete a TQS but are ineligible) and will keep track of people in the screening phase and people who have been randomized.

A screening log should be kept on location with an ID number designed to identify individuals in screening but not yet randomized. The screening failure log will assist with identification of potential participants' characteristics and evaluation of generalizability. The log will include basic demographic information such as: 1) participant ID; 2) gender; 3) race; 4) age; 5) reason for ineligibility and 6) referral source .