

Instructions for Completing the Physical Exam Form

The Physical Examination form (PHE) is critical for documentation of the physical health of the prospective COMBINE participant at screening. Perform an abbreviated physical examination and record the findings. If indicated, a full exam can be conducted. If a problem is detected, clinical referral should be provided. Should any abnormal conditions be detected as a result of the examination, indicate the condition and degree of severity. Some abnormalities may be severe enough to exclude the participant from the study (see Chapter 2: Eligibility). Record a standard 12-lead resting ECG if there is any personal history of heart conditions, and note any abnormalities upon interpretation.

Baseline:

An abbreviated physical examination will be performed at the Screening Visit -1. At Visit 0, a physical checkup, including breath alcohol testing, vital signs and an ECG (as needed) will be performed.

Specific Guidelines for Conducting the Medical Evaluation

This visit will occur with the RN/Physician, usually 2 days after first screening visit so that lab results will be back.

- Begin the interview by asking the participant if he/she has any questions since last visit.
- Reinforce the participant's commitment and cooperation as well as their importance to the study.
- Orient the participant to what will occur in this visit as well as to the role of the physician/medical monitor.
- Complete the History and Physical
- Conduct an ECG (if indicated--see protocol). Review the results with the Medical Consultant if abnormal.
- Lab results within acceptable range for randomization will be discussed with the participant by the MM therapist.
- CBI-only participants lab results will be discussed with the participant in collaboration with MD, NP, or PC as determined by each site.
- Labs greater than 3x the upper limit normal will be discussed with the participant by the MD/NP, and referred to primary medical doctor as indicated. Retest as indicated. Consider Hepatitis C testing.
- Abnormal physical findings will be discussed with the participant during the physical exam and referred for follow up with primary care doctor.
- If eligible, review requirement of 4 days of abstinence. Problem-solve with participant about how to achieve this. Discuss potential for acute withdrawal symptoms and develop a plan in case this occurs.
- Attempt to schedule inclusion visit as soon as possible, considering the participant's preference for initiation of treatment.

Follow-up:

At each Visit 1 - 8, a physical checkup, including breath alcohol testing and vital signs will be performed.

If a participant does not have an underlying medical condition, has not reported any adverse events, and has not had any abnormal lab reports, the week-16 physical examination is optional. Each site will determine whether a physical should be completed.