

Date Entered: _____

Staff Initials: _____

COMBINE ELIGIBILITY CHECKLIST (ELG ver. B)

| | | | | |
|--------|---------------|----------------------|----------|----------|
| Center | Participant # | Participant Initials | Week | Sequence |
| | | | | 0 1 |
| | | Date | | |
| | | / | | |
| mo. | | | da. | |
| | | | | |
| | | yr. | | |
| | | | Staff ID | |
| | | | | |

Instructions: Use information collected during the screening visit to complete this global assessment of participant eligibility. Checklist must be completed before randomization of each participant so that verification of both inclusion criteria, and exclusion criteria can be made.

- | A. INCLUSION CRITERIA | Yes | No |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|
| 1. Age of participant is ≥ 18 years. | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Participant meets DSM-IV alcohol dependence criteria. | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. The participant has signed a witnessed informed consent form. | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. CIWA-Ar score < 8 prior to randomization. | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Minimum drinking level on average of ≥ 14 drinks/wk (females) or ≥ 21 drinks/wk (males) on average per week over a consecutive 30-day period in the last 90-day period prior to initiation of abstinence, and have two or more days of heavy drinking (4 drinks/females, 5 drinks/males) in the 90-day period prior to initiation of abstinence. | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Participant has been abstinent for last 4 (96 hours) - 21 days (maximum). | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Participant is able to speak and understand English. | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. No planned absences by participant during active treatment period ≥ 21 consecutive days. | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Participant is able to identify at least one "locator" person. | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | | |
|----------------------|----------------------|----------------------|----------------------|----------------------|
| Center | Participant # | Participant Initials | Week | Sequence |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| | | | | 0 1 |
| | Date | | Staff ID | |
| | <input type="text"/> | <input type="text"/> | <input type="text"/> | |
| | mo. | da. | yr. | |

B. EXCLUSION CRITERIA

- | | <u>Yes</u> | <u>No</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|
| 10. Other DSM-IV Axis I diagnoses requiring pharmacotherapy are present. | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Participant is taking medications that may pose safety issues with study drugs. | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Drug dependence on drugs other than alcohol, nicotine, caffeine, or marijuana. [Person can be retested after the metabolic interval appropriate to that drug. If second screen is positive, the person is excluded] | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Urine drug screen is positive for opioids. (no retest) | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Participant meets DSM-IV criteria for opiate dependence or abuse with the past 6 months, chronic treatment with any opiate-containing medications during the previous month, or urine positive for opioids. | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Significant medical disorders present that increase potential risk or interfere with study, and/or a major medical illness present (e.g., cancer). | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. Participant has a history of sensitivity to drug as evidenced by adverse experiences, especially with narcotic containing analgesics, opioid antagonists, or acamprosate. | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. Liver function tests are > 3 times above upper limit of normal (AST or ALT) or elevated bilirubin (above 10% of ULN). [Tests can be repeated if initial results are out of range] | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. Participant took naltrexone or acamprosate, or other drug which may influence drinking outcome within 1 month of enrollment. | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. Positive serum β -HCG pregnancy at intake | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. The participant is either pregnant or breast feeding, or refuses to use birth control. | <input type="checkbox"/> | <input type="checkbox"/> |
| 21. Participant intends to engage in additional formal treatment for alcohol related problem, or intends to continue in current treatment for alcohol-related problems during the active treatment period. | <input type="checkbox"/> | <input type="checkbox"/> |
| 22. Participant has had more than 7 days of inpatient treatment for substance use disorders in the 30 days prior to randomization. | <input type="checkbox"/> | <input type="checkbox"/> |
| 23. Participant requires further medicated detoxification [may re-screen when completed with detoxification]. | <input type="checkbox"/> | <input type="checkbox"/> |

C. OUTCOME OF BASELINE ASSESSMENT

- | | | |
|----------------------------------------------------------|--------------------------|--------------------------|
| 24. Participant did not show up for baseline assessment. | <input type="checkbox"/> | <input type="checkbox"/> |
| 25. Participant dropped out of baseline assessment. | <input type="checkbox"/> | <input type="checkbox"/> |
| 26. Baseline assessment was completed. | <input type="checkbox"/> | <input type="checkbox"/> |

D. ELIGIBILITY CERTIFICATION

- | | <u>Yes</u> | <u>No</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|
| 27. If the answer is YES to all Inclusion criteria, and NO to all Exclusion criteria then the participant is eligible for randomization into the main trial. | <input type="checkbox"/> | <input type="checkbox"/> |

Signature of Principal Investigator (or designate): _____