

NIAAA Data Access Application

The COMBINE Study A Multi-site Trial of Combined Pharmacotherapies and Behavioral Interventions for Alcohol Dependence

Title of Research Project:

Introduction

The COMBINE Study (often times referred to as COMBINE) is the largest pharmacotherapy trial conducted for alcoholism in the United States, recruiting 1383 alcohol dependent patients, 31% women and 23% ethnic minorities, from 11 sites. This double-blind, randomized placebo-controlled trial evaluated the efficacy of naltrexone and acamprosate, both alone and in combination, in the context of medical management with and without Combined Behavioral Intervention (CBI). CBI is a therapy that integrates aspects of cognitive behavioral therapy, motivational interviewing and 12-step facilitation. The duration of treatment was four months with follow-ups for one year post treatment. There were nine groups including a CBI only group with no pills and no medical management.

A more detailed overview of the study and main results can be found in the primary publication:

Anton RF, O'Malley SS, Ciraulo DA, Cisler RA, Couper D, Donovan DM, Gastfriend DR, Hosking JD, Johnson BA, LoCastro JS, Longabaugh R, Mason BJ, Mattson ME, Miller WR, Pettinati HM, Randall CL, Swift R, Weiss RD, Williams LD, Zweben A; COMBINE Study Research Group. Combined pharmacotherapies and behavioral interventions for alcohol dependence: the COMBINE study: a randomized controlled trial. *JAMA*. 2006 May 3;295(17):2003-17. doi: 10.1001/jama.295.17.2003. PMID: 16670409.

Data Access Application Procedure and Access Policy

The COMBINE data set contains individual level data and is categorized as a controlled access data set. Access to the data will only be granted to approved researchers by the NIAAA Data Access Committee (DAC).

To receive access to the COMBINE data, the Applicant Principal Investigator must: (1) complete this Data Access Application form and (2) obtain a fully executed Data Use Agreement (DUA). The DUA is designed to define the allowable uses of the data set and to protect the confidentiality of the COMBINE participants. The DUA must be signed by an authorized institutional official that can legally bind the Applicant Principal Investigator's institution. This is ordinarily someone from the Applicant PI's technology transfer office. Completed applications may be submitted by email to:

Email: niaaa-dac@mail.nih.gov

(Application starts on the next page)

COMBINE
Data Access Application

Title of Research Project:

Date of Application: _____

Applicant Principal Investigator (P.I.):

Name: _____

Affiliation: _____

Title _____

Address: _____

Telephone: _____

E-Mail: _____

Degree(s) Held: _____

Major Discipline/Field of Study: _____

May we contact you in the event that updates are made to the COMBINE data set and/or documentation? **Yes** **No**

Authorized Institutional Official

Name: _____

Affiliation: _____

Title: _____

Address: _____

E-Mail: _____

FWA # _____

I have read the notes on access below and will contact the DAC with any questions **Yes**

Notes on access to the COMBINE data:

- Only researchers who will be working on the **same Research Project under direct the supervision of the Applicant Principal Investigator (PI) at the Applicant PI's same institution** (including, but not limited to, graduate students, postdocs, data analysts, and investigators working under the Applicant PI for this project) **will be covered by this application and the DUA.**
- Researchers who will be working on the same Research Project in collaboration with the Applicant PI but are part of a **different institution** and will need direct access to the requested database are NOT covered by this application. These researchers must submit their own application and DUA to get access to the requested datasets.
- Researchers who are affiliated with the Applicant PI's institution but are working on a **separate research project** not described in this application should submit their own application and DUA.
- Individuals who may contribute to scientific papers and other works in collaboration with the Applicant PI, but do not have direct access to the requested datasets, do not need to submit an application or complete a DUA.
- If a student wishes to use this dataset in a thesis or dissertation, a faculty sponsor must submit this application and be listed as the Applicant PI.

Exhibit A

Research Project Description

Please briefly describe your research plan in the space below.

Exhibit A

Research Project Description

Continued - Extra Space