# Letter of Interest Form:

# NIAAA Alcohol Pharmacotherapy Evaluation Program (APEP)

# Clinical Compound Testing

This form should be used to respond to NOT-AA-23-016. Please fill in the following information and submit this completed form to [falkde@mail.nih.gov](mailto:falkde@mail.nih.gov). Completed form should not exceed 4 pages in length. If you have any questions, contact Daniel Falk, Ph.D. at [falkde@mail.nih.gov](mailto:falkde@mail.nih.gov).

**Your Name** - *Click or tap here to enter text.*

**Affiliation/Position** - *Click or tap here to enter text.*

**Email and Phone number** - *Click or tap here to enter text.*

**Compound Name** - *Click or tap here to enter text.*

**Submitter’s relationship with compound** - *Choose an item.*

**Compound Type** - *Choose an item.*

**Primary Proposed Indication -** *Click or tap here to enter text.*

**Secondary Proposed Indication(s) (if applicable) -** *Click or tap here to enter text.*

**Known or theoretical mechanism/targets -** *Click or tap here to enter text.*

**Rationale for testing in Alcohol Use Disorder (AUD) -** *Click or tap here to enter text.*

**Investigational New Drug (IND) -** *Choose an item.*

* If yes,
  + Primary Indication - *Click or tap here to enter text.*
  + IND Status - *Choose an item.*
  + IND Sponsor’s name - *Click or tap here to enter text.*
  + IND number - *Click or tap here to enter text.*
  + Most Advanced Study Phase completed under IND - *Choose an item.*

*If compound has multiple IND approvals, please use space provided at the end of this form to provide the relevant information specified in the bullets above for each indication.*

* If no,
  + Has a pre-IND meeting/communication with the FDA occurred? *Choose an item.*
    - If yes, what was the outcome (i.e., what are the outstanding issues and studies needed to obtain an IND)? *Click or tap here to enter text.*
    - If no, is a pre-IND meeting/communication planned in the next 6 months? *Choose an item.*
      * If yes, please provide date. *Click or tap to enter a date.*
  + Have any IND enabling studies been completed? *Choose an item.*
    - If yes, list studies including a brief description and results if not already included in the Investigator’s Brochure (IB). *Click or tap here to enter text.*
    - If no, are any IND enabling studies planned to start or finish within the next year? *Choose an item.*
      * If yes, provide a brief description of each study including relevant dates. *Click or tap here to enter text.*
* **Alcohol Interaction Study Completed?** *Choose an item.*
* **IB or Package Insert?** *Choose an item.*
  + If yes, please attach to email
* **Intellectual Property (IP)**
  + Does IP exist? *Choose an item.*
    - If yes, provide the following:,
      * Link to patent (or attach patent summary to email if not available) - *Click or tap here to enter text.*
      * Name of owner - *Click or tap here to enter text.*
      * Patent Number - *Click or tap here to enter text.*
      * Patent Expiration Date - *Click or tap here to enter text.*
* **Plan for obtaining compound and placebo control for testing in NIAAA trials (e.g., license, Material Transfer Agreement, NIAAA “off the shelf” purchase, etc.)** *Click or tap here to enter text.*
* **Plan for future product development for AUD beyond NIAAA APEP trial (e.g., outside funding available for larger trial, Venture Capital interest, securing IP, etc.)** *Click or tap here to enter text.*

**Please Save Document As:** *Your Abbreviated Organization Name -Date of Document mm\_dd\_yyyy* **-***NIAAA-APEP-CCTForm* and email to [falkde@mail.nih.gov](mailto:falkde@mail.nih.gov)

**Additional IND approvals information:**

*Click or tap here to enter text.*