

How to Submit a Study to the FDA for an IND Consult.

To submit a study proposal to the FDA to receive an IND number, or to inquire if the study needs one is not really very complicated. The following steps will get you thru the process.

1. You must have a completed SUNY IRB application packet filled out for the study. *Make sure that you go to the IRB website (<http://www.upstate.edu/researchadmin/irb/>), so that you are using the most current version of the application.* This will serve as the protocol information for the FDA.
2. You must fill out an FDA form #1571 and form #1572 with information about the study, the Principal Investigator and the institution where you are doing the work (SUNY Upstate). The 1571 and 1572 form can be found at the FDA's website. You can either do a search for them, or go directly to the forms page at: <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>
3. The instructions for where to submit these materials, and how to fill out the forms, can be found at: <http://www.fda.gov/cder/forms/1571-1572-help.html>

Make sure to send these materials to the correct address listed on the bottom of page 1 of the instructions. **The address for a drug study is different than the address for a Biologic device study.**

4. Compose a cover letter stating what you are requesting, (either an IND number or an evaluation to see if the study needs an IND number), return address and contact information, and study title. Also include a BRIEF summary of the study and justification for doing it.

Here is a sample of a basic cover letter:

Dear FDA,

I am writing this cover letter to inform you that I would like to proceed with a study, "Xyrem for treatment refractory insomnia due to PTSD", where I will investigate how safe and effective sodium oxybate (Xyrem) is when used to treat patients with post traumatic stress disorder who cannot sleep despite multiple trials of other sleeping agents. Xyrem is one of the only medicines that can induce sleep but also improve sleep efficiency by promoting delta slow wave sleep (deep sleep). Most psychiatric medications, including those FDA approved to treat PTSD, degrade deep sleep.

I feel there is a distinct population of PTSD patients who cannot sleep due to this mental illness and furthermore cannot sleep due to our indicated treatments. If patients have failed to sleep on adequate trials of commonly used agents (antihistamines, antipsychotics, sedative-hypnotics), then I would like to offer 10 of these patients a trial

of Xyrem in an open label fashion as a pilot study. Attached is my proposal, IRB application, consent document, Forms 1571 and 1572. Please let me know if this study is IND exempt or if you would like to assign an IND number.

5. Send all of this material by certified carrier, (either UPS or FEDEX) so that you have a guaranteed date of delivery AND a receipt that states when you sent it and to who it was sent. Make sure you print a receipt to prove when you sent it. *You can also see who signed for the package in case there are any problems regarding delivery.*

6. **BE PATIENT.** The review process usually takes as long as 30 days from the time the FDA receives your materials.

7. **Make sure you save all shipping receipts, and all correspondence both to and from the FDA.** These should be placed in the regulatory binder of the study under a divider labeled "FDA Materials".

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