MessageFrom: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, December 16, 2005 9:37 AM
To: [purged]
Subject: RE: IND submission questions

Dear Ms. [purged],

If you are submitting an IND, then, based on 21 CFR 312 (Investigational New Drug Application regulations), a Form FDA-1572 (1572) is required to be prepared and signed by the clinical investigator. All phases of IND studies (e.g. phases 1 through 4) are discussed in this regulation. There are very limited instructions for completing the 1572 on FDA's On-line Forms web page (see http://www.fda.gov/opacom/morechoices/fdaforms/cder.html). If you have specific questions about completing this form, I would be happy to address those questions. Please feel free to submit a question to our office of the CDER's Division of Drug Information (by e-mail: druginfo@cder.fda.gov; by phone: 301-827-4570) for further advice.

Thanks for your inquiry. I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD
20857
Telephone: 301-827-3340

-----Original Message-----
From: [purged]
Sent: Tuesday, December 06, 2005 1:45 PM
To: gcpquestions@oc.fda.gov
Subject: IND submission questions

We are preparing an IND submission for an FDA approved drug, in a new population. The instructions for completing the 1571 are very clear, however the 1572 limits to Phase 1,2 or 3 and I don't think this fits. Could I get

some clarification before I send this IND application for review? Is there another site I need to explore that will help me in correct form completion? Thank-you for taking the time to address my questions.
[purged]