**From:** Hommel, Carolyn - OC on behalf of OC GCP Questions
**Sent:** Tuesday, September 02, 2003 10:15 AM
**To:** [Redacted]
**Subject:** RE: clinical trials
Dear Ms. [Redacted] :

Your e-mail was forwarded to me for a response. I have pasted your questions into this e-mail, and provided answers (in *italics).*

**Q1. Is there anywhere I can find an "absolute" list of duties for each the PI and the Research Coordinator (who is also a nurse)?**

*The responsibilities of clinical investigators are found in FDA's regulations for the conduct of clinical studies in 21 CFR 312. I would recommend that study site staff familiarize themselves with this section generally. You may wish to pay particular attention to 21 CFR 312.53(c), which includes the "Investigator Statement" (Form FDA 1572), and details the investigator's commitments to comply with specific FDA requirements pertaining to clinical studies, as well as the requirements described in 21 CFR 312.60 through 312.70.*

*Investigators are also required to comply with the requirements for obtaining informed consent (21 CFR 50), obtaining review and approval of their research from an institutional review board (IRB) that complies with 21 CFR 56, and providing information about their financial interests to the sponsor under 21 CFR 54.*

*FDA regulations do not specify the "duties" for study coordinators, nurses, or other staff members, nor am I aware of any guidance on this issue. However, study staff should be appropriately qualified by experience and training to perform the duties that the clinical investigator assigns to them.*

*While researching your question, I checked the ICH E6 Good Clinical Practice: Consolidated Guidance, but the guidance does not specify the duties that should be performed by various staff members. There are a few sections that are relevant, although not explicit. I have copied them into this e-mail for you:*

*Section 4.1.5: "The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties."*

*Section 4.2.4: "The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions."*

*Again, although the ICH does not list specific duties to be performed by the various study staff members, the expectation is clear that duties should be*

*assigned only to individuals who are well-qualified by training and experience to perform them.*

**Q2. Am I (the Coordinator) allowed to sign in the Physician's Progress Notes that I obtained informed consent for entrance into a study, HIPAA consent, etc.? It was explained by a drug company that the Physician should be documenting their actions and this brought up this question.**

*In 21 CFR 312.62(b), FDA's regulations for investigator recordkeeping and record retention, it states, "An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigaitonal dug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study."*

*Note that although informed consent must be documented, FDA's regulations are silent as to who should document that it was obtained. Some IRBs and sponsors, however, may require the clinical investigator to personally conduct the informed consent interview. Other IRBs and sponsors may leave the particulars of the consent process up to the clinical investigator, who in turn may assign this responsibility to one of the members of his/her study staff.*

**Q3. Where can I find a list of Phases that pertains to studies (including IIb, IIIb, etc. )?**

*21 CFR 312.21 describes the phases of an investigation.*

*You might also want to review "From Test Tube to Patient: New Drug Development in the United States," a series of excellent articles that appeared in the FDA Consumer magazine several years ago. One of the articles described the various phases of drug studies in some detail. The URL for that section is http://www.fda.gov/fdac/special/newdrug/testing.html. The rest of the series' articles discuss various aspects of this process, including drug testing from laboratory, clinician and patient perspectives, how FDA balances benefits and risks, and the role of FDA drug advisory committees and of FDA inspectors. FDA's responsibilities do not stop once a drug is approved, and this publication also examines the increasingly important area of postmarket surveillance. You may view the entire series on FDA's web site by pasting the following URL into your browser: http://www.fda.gov/fdac/special/newdrug/testing.html .*

*There is also information about Phase 4 studies in the regulations and guidance. 21 CFR 312.85 describes Phase 4 (post-marketing) studies. There is also a draft guidance document entitled "Reports on status of postmarketing studies - Implementation of Section 13 of FDA Modernization Act of 1997. You can find it by pasting the following URL into your browser: http://www.fda.gov/cder/guidance/index.htm. Then, in the index on the left, select "Procedural (Draft)", and select item #15. It's available in PDF or HTML formats.*

**Q4. Am I the coordinator allowed to obtain informed consent assuming the physician has already mentioned the study to the patient or family member?**

*Question 39 of "FDA's Information sheets for IRBs and Clinical Investigations," addresses this issue. I have pasted this Q/A into this e-mail for your convenience:*

> ***39. Who should be present when the informed consent interview is conducted?***
>
> *FDA does not require a third person to witness the consent interview unless the subject or representative is not given the opportunity to read the consent document before it is signed, see 21 CFR 50.27(b). The person who conducts the consent interview should be knowledgeable about the study and able to answer questions. FDA does not specify who this individual should be. Some sponsors and some IRBs require the clinical investigator to personally conduct the consent interview. However, if someone other than the clinical investigator conducts the interview and obtains consent, this responsibility should be formally delegated by the clinical investigator and the person so delegated should have received appropriate training to perform this activity.*

*You may view all of the information sheets on FDA's website: http://www.fda.gov/oc/ohrt/irbs/default.htm*

I hope this is helpful.

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

Phone: 301/827-3340
Fax: 301/827-1169

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
**From:** [Redacted]
**Sent:** Thursday, August 21, 2003 3:03 PM
**To:** 'gcpquestions@oc.fda.gov'
**Subject:** clinical trials

Now that I found this resource to ask my questions, I am afraid you might be hearing from me quite often!

But, that is better than the alternative! (Making a BIG mistake by not following GCP simply because of ignorance).

Anyway, my questions are:

Is there anywhere I can find an "absolute" list of duties for each the PI and the Research Coordinator (who is also a nurse)?

Am I (the Coordinator) allowed to sign in the Physician's Progress Notes that I obtained informed consent for entrance into a study, HIPAA consent, etc.? It was explained by a drug company that the Physician should be documenting their actions and this brought up this question.

Where can I find a list of Phases that pertains to studies (including IIb, IIIb, etc. )?

Am I the coordinator allowed to obtain informed consent assuming the physician has already mentioned the study to the patient or family member?

Thank you.
[Redacted]