From: OC GCP Questions
To: [redacted]
Subject: RE: clinical trials and ordering of tests
Date: Wednesday, December 17, 2014 12:02:00 PM

Dear [Redacted]-

Thank you for your questions. If I understand your first question correctly, I think you are asking about the "timing" of informed consent and the conduct of protocol-specific tests. I will try to address this question below. However, I do not understand what you are asking in your second question regarding blood being drawn and run by research or in-house staff so I am not able to provide a response to that question.

The FDA regulations about informed consent can be found at 21 CFR part 50 (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50). Specifically, the regulations at 21 CFR 50.20 state:

> *Sec. 50.20 General requirements for informed consent.*
>
> *Except as provided in 50.23 and 50.24,* ***no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. [emphasis added]*** *An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.*

The ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance – see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) also addresses the timing of informed consent and study tests in section 4.8.8:

> *4.8.8* ***Prior to a subject's participation in the trial,[emphasis added]*** *the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.*

The clinical investigator is responsible for protecting the rights, safety and welfare of subjects during a clinical investigation, and for ensuring that legally effective informed consent is obtained from each subject **before** that subject takes part in the clinical investigation. Informed consent must therefore be obtained prior to enrollment in the study (i.e., prior to performance of any study related tests and administration of the test article).

FDA has many resources that are available to you for questions. You may find the information at the following web page to be helpful regarding where to send future questions:

http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm134476.htm

As stated on this particular web page, contact the Office of Good Clinical Practice (at gcp.questions@fda.hhs.gov) if you have:

- general questions about FDA good clinical practice regulations and policy
- general questions about the FDA clinical Bioresearch Monitoring Program, and specifically clinical investigator, Institutional Review Board (IRB), sponsor, monitor, and contract research organization programs
- questions about or suggestions related to FDA's Information Sheets for IRB's and Clinical Investigators2
- questions about reports made pursuant to 21 CFR 56.108(b) and 56.113 involving an FDA-regulated product if you do not know which FDA Center has jurisdiction (e.g., drug, medical device, biological product), including:
  - unanticipated problems involving risks to subjects [21 CFR 56.108(b)(1)]
  - serious or continuing noncompliance by an investigator with FDA regulations or with the IRB's determinations [21 CFR 56.108(b)(2)]
  - suspension or termination of IRB approval of a protocol [21 CFR 56.108(b)(3)]

If you have questions about human subject protection (HSP) regulations related to a specific product type (e.g., drug, biologic, device), or if you have FDA inspection questions, you can contact the appropriate Center Bioresearch Monitoring contacts listed on this same web page (see contacts for Biological Products, Drug Products, Medical Devices, CFSAN-regulated products, New Animal Drugs).

If you are already working with a specific product review division/office at FDA (e.g., the Division of Cardiovascular Products), you should contact that review division directly with specific questions related to your study.

If you have more general product questions, or if you are not sure which product review division/office you should contact, you can contact the appropriate general Center contacts as follows:

CDER – Information Also Available at http://www.fda.gov/Drugs/default.htm

Contact FDA

Human Drug Information
Division of Drug Information (CDER)
Toll Free (855) 543-3784, or (301) 796-3400
druginfo@fda.hhs.gov

CBER – Information Also Available at http://www.fda.gov/BiologicsBloodVaccines/default.htm

Contact FDA
Consumer Affairs Branch (CBER)
Division of Communication and Consumer Affairs
Office of Communication, Outreach and Development
(800) 835-4709
(240) 402-8010
ocod@fda.hhs.gov

CDRH – Information Also Available at http://www.fda.gov/MedicalDevices/default.htm

Contact FDA
CDRH-Division of Industry and Consumer Education (DICE)
Office of Communication and Education
1-800-638-2041
301-796-7100
Fax:301-847-8149
DICE@fda.hhs.gov

CFSAN – Information Also Available at http://www.fda.gov/Food/default.htm

Contact FDA
1-888-SAFEFOOD
1-888-723-3366
10 AM- 4 PM EST
Outreach and Information Center
Inquiries: Submit Your Question - https://cfsan.secure.force.com/Inquirypage
Center for Food Safety and Applied Nutrition

CVM – Information also available at http://www.fda.gov/AnimalVeterinary/default.htm

Contact FDA
240-276-9300
AskCVM@fda.hhs.gov
Center for Veterinary Medicine
Communications Staff (CVM)

CTP – Information also available at http://www.fda.gov/TobaccoProducts/default.htm

Contact FDA
1-877-CTP-1373
1-877-287-1373
(9am EST-4pm EST)Tobacco
For General Inquiries:
AskCTP@fda.hhs.gov
Center for Tobacco Products Food and Drug Administration

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [Redacted]

Sent: Monday, December 15, 2014 11:41 AM
To: OC GCP Questions
Subject: clinical trials and ordering of tests

Good Morning,

Is it necessary for a physician to place an order for a lab or radiographic test for a study subject after consent has already been obtained and the test is already specified in a research protocol? Alternatively, can the blood be drawn and run by research or in-house staff?

Is there a source where I can ask research compliance questions in the future?

Thank you,
[Redacted]