From: OC GCP Questions
Sent: Friday, March 21, 2014 10:21 AM
To: [redacted]
Subject: Research assistance

Good morning –

Please see my answers below.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Thursday, March 20, 2014 9:58 AM
To: OC GCP Questions
Subject: Research assistance

Dear FDA,

We are doing some research relating to clinical trials and have a few questions if you would help please.

1. Do all clinical trials relating to drugs have to be approved by the FDA?
   Not all research is FDA-regulated research. Please see the links below for more information.
   https://research.missouri.edu/cirb/files/DeterminingWhenHumanSubjectResearchActivitiesareFDARegulated.pdf
   Educational Materials > Comparison of FDA and HHS Human Subject Protection Regulations

2. Do all clinical trials require a form 1572 to be filled out?
   The Form FDA 1572 (the 1572), while an official FDA form, is meant to provide full information about a study site to the study sponsor and to serve as a commitment to compliance with the investigational plan and pertinent regulations by the clinical investigator signing it. There is no requirement that the form be submitted to FDA, though most study sponsors do so, as it is a quick way to provide much of the information required for an IND. As an official agreement between the clinical investigator and the sponsor, as with most such agreements, the sponsor should keep the original form since once signed it represents a contract between the clinical investigator and the sponsor to adhere to the investigational plan and pertinent regulations.
   Please see the guidance below that describes the 1572 form.
   http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf

3. Are all clinical trials conducted listed on the website www.clinicaltrials.gov? If not which ones are and which ones are not?
   In order for a trial to be registered with CT.gov it must meet the definition of an "applicable clinical trial" (ACT) and therefore would be required to register with ClinicalTrials.gov. You may wish to review to the Elaboration on Definitions document available on the CT.gov website to help determine whether this trial meets the definition of an ACT (http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf). There is more information which might be useful for them in making the determination of whether it is an ACT.

   FDA has a guidance document related to the requirements at 21 CFR 50.25(c). This document indicates that ACTs conducted outside the US must contain the required statement (please see item 21. in the guidance). http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf

   FDA's also webpage related to ClinicalTrials.gov (http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/FDAsRoleClinicalTrials.govInformation/default.htm) which has some additional information and has a link to the documents I mentioned above.

3. We have been told there are two levels of clinical trials. Is this true, what are the different levels called?
   There are phases of drug trials. I am unclear as to what you mean as "levels". Please see the link below that describes drug phases.
   CFR - Code of Federal Regulations Title 21
   CFR - Code of Federal Regulations Title 21

4. Is there a way to find out the amount of money paid to doctors involved in a clinical trial?
   FDA is not involved in payment to doctors in clinical trials.

5. Is there a way to find out the amount of money paid for the drugs used in a clinical trial?
   FDA is not involved in money paid for drugs in clinical trials.

Any assistance you can provide would be greatly appreciated.

Thank you

[Redacted]