From: OC GCP Questions
To: [redacted]
Subject: Form FDA 1572
Date: Friday, September 12, 2014 1:14:57 PM

Good afternoon –

Please see the guidance link below on the 1572 Form
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf It states --

3. When must this form be completed and signed by an investigator?
Whenever a sponsor selects a new investigator to participate in a clinical investigation that is being conducted under an ***investigational new drug application (IND)*** **[Emphasis added],** *the sponsor must obtain a completed and signed 1572 before permitting the investigator to begin participation in the clinical investigation (21 CFR 312.53(c)). The investigator should sign the form only after being given enough information to be informed about the clinical investigation and to understand the commitments described in Section #9 of the 1572. Having enough information about the study typically means that the investigator has received copies of, has read, and understands the protocol and investigator's brochure (if required2), and is familiar with the regulations governing the conduct of clinical studies.*

The investigator's signature on this form constitutes the investigator's affirmation that he or she is qualified to conduct the clinical investigation and constitutes the investigator's written commitment to abide by FDA regulations in the conduct of the clinical investigation.

I cannot tell whether the study you describe needs an IND. Please contact the Center for Drugs (CDER) to determine if your study needs an IND. If it does, than an1572 form must be completed by the investigator.

Questions about whether a product is subject to IND regulations:
Call 301-796-3400
Druginfo@fda.hhs.gov

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Thursday, September 11, 2014 3:42 PM
To: OC GCP Questions
Subject: Form FDA 1572

I have a question regarding FDA 1572. I have an investigator who states he doesn't need a 1572. The

trial involves 2 arms, one that gets radiation and the other is surveillance. Both arms have induction chemotherapy and subjects can receive surgery or another chemo while on surveillance. All drugs used are commercially available and are standard of care.

Does he need a FDA 1572? Our policies are a little vague to me.

Thanks
[redacted]