From: OC GCP Questions
To: [redacted].
Subject: OTC pregnancy test used in clinical research
Date: Monday, May 23, 2016 9:59:00 AM

Good morning –

I asked multiple people to give suggested answers to your questions. Please see the information below.

If the study is being done under IND, FDA suggests that the person inquiring have the sponsor follow up with the relevant review division on those questions. FDA should not be commenting on the adequacy of any given type of pregnancy test or whether the test would need to be administered by someone who is licensed in some capacity.

I hope this information is helpful.

Kind regards,

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Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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.

From: [redacted]
Sent: Friday, May 20, 2016 8:40 AM
To: OC GCP Questions
Subject: OTC pregnancy test used in clinical research

Hello,

We currently have an imaging trial utilizing a PET-tracer under the auspices of an IND (held by a sponsor-investigator). Standard operating procedure at our institution mandates a pregnancy test prior to any research administered radiation. The PET tracer is deemed research administered radiation for the purposes of this imaging trial.

The study currently uses an over the counter pregnancy test, administered by a non-licensed staff member. The results of the test are not recorded in the subject's clinical chart / EHR, but are recorded in the research chart.

Upon review, the following questions were addressed:

- is it acceptable to use an OTC test and have it administered by non-licensed personnel, provided the PI (or an SOP) deems that staff qualified, and,
- what documentation should be noted in the research chart? I thought the name of the test, lot

number, and expiration date should be documented; however, other staff did not believe this was necessary

Thank you for your time,

[redacted]

[redacted]

[redacted]