From: OC GCP Questions
To: [redacted]
Subject: 1572 for prescreen protocol
Date: Monday, October 28, 2019 11:10:57 AM
Attachments: [redacted]

Good morning –

Thank you for your email. Please see FDA's 1572 Form Guidance.
https://www.fda.gov/media/78830/download Specifically question # 3.

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), 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.

Since the CIs (PIs) are performing blood draws and collecting samples for a particular study, I believe a 1572 form needs to be completed if the study is under an IND.

Additionally, FDA's regulations do not specifically discuss "prescreening". A physician may review his/her patients' charts to determine if there are any patients who may be eligible to participate in a study and may discuss the availability of studies and the possibility of entry into a study with a prospective subject without first obtaining consent. Informed consent must be obtained, however, prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research. However, just to be sure, I would recommend that you contact the IRB to determine the preferred method of screening.

Also, you might find the link below helpful. It is an information sheet regarding "Screening tests Prior to Study Enrollment". www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm

Another information sheet -- Recruiting Study Subjects -- should also be helpful to you.
www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

If I have not adequately answered your question, you may contact the Center for Drugs (CDER) at druginfo@fda.hhs.gov as they answer IND questions.

I hope this information is helpful.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Friday, October 25, 2019 4:14 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: 1572 for prescreen protocol

Hello,

Does the FDA require 1572 of PIs who are conducting pre-screening protocols for sponsors? There is no drug administered. There is a blood draw to determine a bio marker presence and a urine sample. Outside of that there is only collection of minimal information such as age, gender, ethnicity etc.

What would the expectation be in this case, please?

Thank you,
[redacted]