From: OC GCP Questions
To: [redacted]
Subject: RE: Question on screening
Date: Wednesday, June 04, 2014 7:02:00 AM

Dear [redacted],

While the specific regulatory wording in 21 CFR part 312 (312.120(b))

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A sponsor shall not begin a clinical investigation subject to 312.2(a) until the investigation
is subject to an IND which is in effect in accordance with 312.40.
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does not as clearly state FDA's position as 21 CFR part 812 regarding what can be initiated when for a clinical investigation, the following citation from part 812 (812.110(a)) provides FDA's requirements for all clinical trials

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An investigator may determine whether potential subjects would be interested in participating in
an investigation, but shall not request the written informed consent of any subject to
participate, and shall not allow any subject to participate before obtaining IRB and FDA
approval.
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Therefore, both FDA and IRB approval must precede any procedure to an initiate a study, whether FDA approval for initiation is by direct correspondence or the lapse of the 30-day review time for IND approval. Also, as stated in FDA's guidance on subject recruitment (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm)

FDA considers direct advertising for study subjects to be the start of the informed consent and subject selection process

Therefore, even advertisement of a specific study prior to both FDA and IRB approval is not appropriate. Actual screening of potential subjects for a specific study, whether by general testing common to the practice of medicine or study-specific procedures, must definitely await both FDA and IRB approval. Sites are sometimes confused by the fact that an IRB may review and approve a study during FDA review. Regulations do not prohibit this but both FDA and IRB approvals are necessary before a study can be initiated. (It is always possible that FDA will require protocol amendments before allowing a study to start and then IRB review and approval of those changes must also precede study initiation, even if the IRB had reviewed and approved the initial study protocol.) However, it would be possible for a doctor or clinic to review patient files during FDA's review of an IND application to determine who might be a candidate for a study and let those individuals know that an appropriate study may be available shortly, as stated in 812.110(a) as cited above.

We also recognize that facilities regularly conducting Phase 1 drug studies are in a unique position. Therefore we would consider it appropriate for such facilities to do generic screening of individuals for studies on a particular disease or condition and maintain the information from that testing to review when specific study protocols are received. Such general screening would require IRB review and approval and the use of a general screening informed consent that has IRB approval.

Hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us once again 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.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Office of Good Clinical Practice
Office of the Commissioner, US FDA

From: [redacted]
Sent: Tuesday, June 03, 2014 12:02 PM
To: OC GCP Questions
Subject: Question on screening

Dear GCP staff:

Could you please provide a response to the following question:

Can invasive procedures (HIV tests, pregnancy tests, drug tests, etc.) for a Phase 1 healthy volunteer study take place prior to the end of the 30-day IND review period?

It is understood that they cannot receive the study drug, but can they be screened by the Phase 1 unit? (Assuming IRB approval has been granted and subjects have signed the informed consent form.)

Thank you,

[redacted]