From: OC GCP Questions
To: [redacted]
Subject: FDA waiver to screen potential subjects prior to signing consent and enrolment
Date: Friday, March 31, 2017 12:09:00 PM
Attachments: [redacted]

Good morning –

It would be difficult for my office to answer this query. It is best to check with the sponsor or the regulatory project manager (RPM) of the IND to obtain their current advice. Generally FDA does not allow waiver of consent.

Please also see FDA's guidance on screening.

Search for FDA Guidance Documents > Screening Tests Prior to Study Enrollment - Information Sheet

If the sponsor wants to talk to potential subjects about all potential studies that may be available in the future, the sponsor does not need a consent form to do so. See excerpt below from the guidance document above:

For some studies, the use of screening tests to assess whether prospective subjects are appropriate candidates for inclusion in studies is an appropriate pre-entry activity. While an investigator may discuss availability of studies and the possibility of entry into a study with a prospective subject without first obtaining consent, informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research, including withdrawal from medication (wash-out). When wash-out is done in anticipation of or in preparation for the research, it is part of the research

Additionally, if the subjects were only screened during the initial procedures and not officially entered into an actual study, there is no study to which the FDA regulations could be applied (Title 21, Code of Federal Regulations - 21 CFR - Part 312 for drugs and biologics and 812 for medical devices). Therefore, there are no FDA reporting requirements to be met. However, it is possible that the sponsor is interested in the continuing medical history of these potential study subjects, to better determine their eligibility for the study and/or gather further information that might be related to the product being studied. If this is the case, however, the fact that you will be collecting data on the subjects during the time before their formal initiation into any future study would need to be explained in the informed consent document they sign. It would be difficult to see how you could even collect such information without such disclosure, as these individuals would otherwise not expect to be recontacted except to decide whether or not to participate in the study, should they prove eligible.

Kind regards,

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

From: [redacted]
Sent: Wednesday, March 29, 2017 4:25 PM
To: OC GCP Questions
Subject: FDA waiver to screen potential subjects prior to signing consent and enrolment

Hello:

I would like clarification on a regulatory issue involving informed consent. I am a CRA working currently on an IRB-approved study where the FDA has approved screening of patients prior to signing a consent form and being enrolled into the study. They can either screen fail at that time or screen fail and be eligible for rescreening once their medical condition meets the entrance criteria.

Is access to this pre-consent form screening data by the monitor also covered in this type of waiver for subjects who are never consented and enrolled because they could not meet the entrance screening criteria? Can the source documents for this pre-consent data be reviewed by the CRA and can this data be collected by the sponsor? or not? FDA considered it appropriate to provide this waiver because it would have been very difficult to do this study without this form of preliminary screening. It appears to me that the consent waiver to screen patients pre-consent applies only to the PI and his designated study personnel but not to the monitor or sponsor. I would like to verify whether not I am correct in this assumption or if it is actually permissible because the pre-consent screening waiver would also apply to the monitor and sponsor as well.

Can you please also provide references in the CFR in support of your response for reference?

Thank you.

Best regards,

[redacted]