From: OC GCP Questions
To: [redacted]
Subject: ICF question
Date: Monday, October 26, 2020 1:22:00 PM

Good afternoon -

Thank you for your email. FDA regulations regarding clinical studies do not define a screening failure. This is also not discussed in any guidance document I am aware of. FDA's interest in knowing about all potential subjects who were screened is to ensure that there was no bias in choosing the subjects who actually participated in the subject. To that end, if potential subjects were identified by review of patient charts, maintenance of a log of those screened and the rationale for failure to follow up with certain subjects as to their willingness to participate is information that would be value. There is no requirement to do so, however, though the study sponsor might require retention of this information.

Additionally, a subject signing the informed consent form indicates that the subject is entering research and may be referred to as "enrolled." In many studies, the selection criteria necessitates procedures be performed that are done solely for the purpose of determining eligibility for the study. Such procedures may only be performed after the subject has consented to participate in research. When such procedures are performed, the subject's participation in research has begun although whether the subject actually meets the selection criteria for the study has not been determined.

For data analysis purposes, subjects who signed the consent form but were screening failures are often not counted as "enrolled" for purposes of data analysis. Identification of which subjects are included in data analyses is usually detailed in the statistical plan for the study.

If the subject is considered a screening failure, we assume that the subject failed the enrollment eligibility criteria and data after the failure should not be part of the study but maintained as described above. Please note that how to handle "screening failures" would probably be mentioned in the protocol.

Please see FDA information sheets on screening tests. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/screening-tests-prior-study-enrollment

Kind regards,

Doreen M. Kezer, MSN
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Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

-----Original Message-----
From: [redacted]
Sent: Friday, October 23, 2020 2:46 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Fwd: ICF question

> Hello,

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> I am a clinical research nurse and I have a question about following a “screen fail” patient. If a patient signs the ICF, enters screening, and it is determined that she is ineligible for the study based on failing to meet eligibility criteria, is it ever acceptable to continue following the patient and submitting data? I appreciate your guidance.
>
> Thank you,
>
> [redacted]
>
> Sent from my iPhone