From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, February 07, 2006 2:19 PM
To: [purged]
Subject: RE: question

Dear [purged]:

Your e-mail was forwarded to me for a response. You asked whose responsibility it is to maintain a screening log, and if the agency has an opinion regarding "use of the IVRS system to maintain a screening log for all investigator sites."

Food and Drug Administration (FDA) regulations do not define or use the term "screening log," so there are no requirements pertaining to them. FDA's best guidance on this issue, the ICH E6, "Good Clinical Practice: Consolidated Guidance," recommends in Section 8.3.20 that the "subject screening log" be maintained in the investigator's/institution's files, and "where required" in the sponsor's files, "to document identification of subjects who entered pretrial screening."

Please note that in the U.S., the ICH E6 is guidance, and thus is not legally binding on the agency or industry, where provisions of ICH E6 are not otherwise contained within FDA regulations. Thus, the passage cited above represents FDA's best thinking on the topic and does not entail a "requirement" per se, but rather an approach that is fully compatible with FDA regulations.

I am not familiar with "the IVRS system," so cannot comment on whether it would be appropriate to use to maintain a screening log. In any case, FDA does not, nor can it appear to, endorse any particular product, firm, or organization.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
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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.

-----Original Message-----
From: [purged]
Sent: Wednesday, February 01, 2006 9:12 AM
To: OC GCP Questions
Subject: question

I would like to know the agency current thinking
regarding the use of the IVRS system to maintain a
screening log for all investigator sites. I thought
it was the responsiblity of the site to maintain a
screening log.
[purged]