screening logs for clinical trialsFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, April 03, 2006 1:46 PM
To: [purged]
Subject: RE: screening logs for clinical trials

Dear [purged]:
Your e-mail was referred to me for a response. I apologize for the delay in getting back to you.
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," only mentions screening logs in one place: Section 8.3.20. In that section, ICH E6 recommends 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."
Because there are no specific regulatory requirements, sites have the flexibility to develop and implement their own procedures related to screening study subjects.
Sincerely,
Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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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.

From: [purged]

Sent: Tuesday, March 14, 2006 3:28 PM
To: OC GCP Questions
Subject: screening logs for clinical trials

Hello:
Please clarify what is expected with regard to screening logs for Phase 1-4 pharmaceutical clinical trials. When should a subject be listed on this log? When the subject shows initial interest in a single study or at a stage thereafter? Thanks in advance for your guidance. Please reference the pertinent regulation, if applicable.
Regards,
[purged]