From: Brown, Sheila (OGCP)
To: [redacted]
Subject: RE: Eligibility
Date: Thursday, August 06, 2015 7:57:00 AM

Dear [redacted]

Eligibility checklists/worksheets are not addressed in the FDA regulations related to the conduct of clinical trials (21 CFR Part 312 for drugs and biologics and Part 812 for medical devices). How subject eligibility is documented depends on things like the sponsor's SOPs, protocol requirements, and Case Report Form design. You may want to discuss any protocol or study-specific issues with the sponsor.

Although eligibility checklists are not specifically addressed in FDA regulations, they are commonly used. When the regulations are silent, institutions and sponsors are free to develop their own standard operating procedures (SOPs) or policies to address a specific situation. If you have not done so already, you may want to consider developing an SOP to outline how eligibility checklists are used at your facility and to specify if they should be considered source documents.

Generally the data from the Case Report forms (CRFs) is what is submitted to FDA, and not source documents, although the source documents may be reviewed during an FDA inspection. FDA's guidance document, *Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects*, may be helpful to you. It can be found at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm187772.pdf

Also, ICH E-6 and ICH E-3 may be useful. They can be found at the links below.

ICH E-6
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf

ICH E-3
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E3/E3_Guideline.pdf

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
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Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Monday, August 03, 2015 4:36 PM
To: OC GCP Questions
Subject: Eligibility

Would the agency expect to see documentation by the PI stating the subject is eligibility with source documentation for the study or just a completed worksheet with PI signature and source documentation to support enrolling in clinical trial?
[redacted]