From: OC GCP Questions
To: [redacted]
Subject: RE: Inc/exc
Date: Monday, March 06, 2017 11:35:00 AM
Attachments: [redacted]

Dear [redacted] -

Thank you for your question. The answer to your question is dependent on what the IRB-approved protocol requires. If the protocol requires the PI to confirm post-menopausal status from potential female subjects via medical records, then on inspection, an FDA investigator would expect to see that the PI is following the protocol.

FDA has Compliance Program Guidance Manuals (CPGMs), which essentially are instructions to our FDA investigators to assist in conducting inspections of the various regulated entities. We make these documents available to the public on our web site at https://www.fda.gov/ICECI/ComplianceManuals/CompliancePrograManual/ucm255614.htm. The CPGM for inspection of a clinical investigator can be found at https://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/ucm133773.pdf. Section III – Inspectional gives a nice overview of the type of information the FDA investigator will be looking for on an inspection, including that the PI follows the protocol and maintains the appropriate human subject records.

If the protocol in question is not specific about what type of documentation a PI is required to collect to support the inclusion/exclusion criteria, I suggest you contact the sponsor of the study to confirm that the PI is adhering to the sponsor's expectations. A well-written protocol should provide clear information about what is expected of the PI.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

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From: [redacted]
Sent: Friday, March 03, 2017 3:06 PM
To: OC GCP Questions
Subject: Inc/exc

Happy Friday!

If the FDA audited a study that had an inclusion that required female subjects to be post menopausal for at least 3 years and the PI writes in her notes that the subject's last period was in 2000, would that be sufficient documentation? Would medical records from the subject's GYN be required to support statement?

In other words, if all we had was the PI's statement, would that be considered a finding due to lack of sufficent evidence?