From: OC GCP Questions
To: [redacted]
Subject: Query regarding obtaining medical history for clinical trials
Date: Monday, September 08, 2014 3:49:24 PM

Good afternoon –

You question relates to screening and documentation of eligibility of the subject. Your IRB should be provided with the screening process for their review. The FDA Information Sheet "Screening Tests Prior to Study Enrollment" (available at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm116332.htm) states, "Clinical screening procedures for research eligibility are considered part of the subject selection and recruitment process and, therefore, require IRB oversight."

In general, the information maintained on individuals screened for a study should be sufficient to demonstrate that the study screening was appropriately conducted per the investigational plan and or protocol and that adequate medical history and screening was completed to make sure that the potential subject met inclusion/exclusion criteria. Of course, for individuals who pass screening, records demonstrating that the screening criteria are met would be part of the case histories required to be maintained for the study. Please refer to 21 CFR 312.62 for drug and biologic studies and 21 CFR 812.140(a) for device studies for the regulatory requirements. How the information is documented is up to the sponsor and the IRB. Generally a subject's medical history records would suffice however, it is possible that the subject provided the information verbally and this information was documented in the study records and this information would be transferred to the case report forms.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Saturday, September 06, 2014 9:51 AM
To: OC GCP Questions
Subject: Query regarding obtaining medical history for clinical trials

Hello,

I am [redacted] and am working in the capacity of a Research Coordinator. I had a question regarding obtaining medical history of subjects participating in a clinical trial. As per GCP or other regulations are there any specific guidelines of how much information is to be obtained??

In case there is no specification in the protocol about obtaining medical history, how far in a subject's age can we go to procure the history?.

Should history of tattoos, wearing eye glasses (myopia), wisdom tooth extraction, fractures in childhood which have resolved, ceasarian sections in case of women be captured? Should any such medical history which has resolved years back and there is no residual effect ongoing should those information be captured??

As per my understanding too much information which is not relevant too falls

out of the purview of GCP. Is there any defining criteria how much information is too much?

Will be greatly obliged if you could clarify this for me.

Thanking you for your time and cooperation

With Kind Regards,
[redacted]