From: OC GCP Questions
To: [redacted]
Subject: Prescreening info
Date: Thursday, April 20, 2017 5:58:00 AM

Good morning -

FDA's regulations do not specifically discuss "prescreening". When the regulations are silent, IRBs, institutions, sponsors, investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met. As you state this is a gray area. An internal SOP explaining where the prescreening data is kept would be helpful.

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

-----Original Message-----
From: [redacted]
Sent: Wednesday, April 19, 2017 12:01 PM
To: OC GCP Questions
Subject: Prescreening info

I have a question regarding pre-screening as we did get IRB approval and moved on with the approved prescreening. Then we did get IRB approval for a sponsors Protocol and moved on with that. We routinely have captured all this screening information in both our regulatory binders in subject source and subject chart binders. My question is what is the expectation of the pre-screening info being in the source docs charts and binders for the records of the sponsors protocol. We keep this information but in a separate binder from the sponsors protocol driven activities. Seems to be a gray area so looking for guidance on where to keep any prescreening data.

Regards
[redacted]