From: OC GCP Questions
To: [redacted]
Subject: RE: Question
Date: Monday, March 24, 2014 9:01:00 AM

Dear [redacted],

Whether or not staff needs to be blinded for screening will depend on the specific study conditions. If how subjects are placed in a study arm is dependent on any parameters that would be determined during screening, then the screeners would need to be blinded, particularly if they will have any role in the actual conduct of the study. If subjects screened will be randomized to study arms by a system that is not dependent on any specific parameters related to the individual's health or condition, then there would not be a need for the screeners to be blinded. Whichever scenario fits the study in question, it would still be wise to consult with the sponsor to ensure they agree.

Hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us once again 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.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Office of Good Clinical Practice
Office of the Commissioner, US FDA

From: [redacted]
Sent: Thursday, March 20, 2014 9:46 AM
To: OC GCP Questions
Subject: Question

Goodmorning – I have a specific question that I need guidance with. We will be conducting a double-blind study in the near future. There will be blinded and an unblinded staff with specific assignments to each group. Our question relates to screening subjects prior to consent. I see that the guidelines state "A Double-blind trial is one in which neither the subject nor any of the investigator or sponsor staff involved in the treatment or clinical evaluation of the subjects are aware of treatment received. This includes any determining subject eligibility, evaluating endpoints, or assessing compliance with the protocol." What I need to know from this statement – does this literally exclude the blinded group from being able to screen subject information and or contact with the subject prior to signing the consent?

Thank you for your assistance/guidance with this matter,

[redacted]