From: OC GCP Questions
To: [redacted]
Subject: RE: Keeping the blind in double blind clinical trial
Date: Friday, November 09, 2018 1:24:00 PM
Attachments: [redacted]

Dear [redacted] -

Thank you for your question and your patience in our response. As I previously mentioned, I wanted to confer with other colleagues in FDA's Center for Drugs.

The regulations do not address your specific question. The answer to your question is not a simple yes/no response. As such, the answer to your question can vary and may depend on any number of considerations, such as the type of study, what the protocol says, the role of the Medical Monitor, whether the sponsor is utilizing a safety assessment committee, whether there is a Data Monitoring Committee, etc.

FDA has DRAFT guidance titled, "*Safety Assessment for IND Safety Reporting – Guidance for Industry*" that can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm477584.pdf. Although this guidance is Draft, section IV.C. addresses unblinding of safety data and may be helpful to you in discussing the role of the Medical Monitor for this particular study. The Draft guidance says that FDA recommends that those participating in the conduct or analysis of the study (e.g., study clinicians, statisticians, chief medical officers, clinical research associates) remain blinded to overall data, although in individual serious adverse event cases, appropriate medical care may require unblinding.

There is no regulatory prohibition against the Medical Monitor being unblinded or discussing relevant information with the investigator about the protocol, or medical related issues encountered during the study. This includes providing medical expertise for study oversight in an emergency situation.

We are not able to provide you with a yes/no response to your question; however, we suggest that you continue to discuss this issue with the sponsor of your study and together determine the best course of action for developing an SOP for the specific study in question.

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Monday, October 29, 2018 11:42 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: RE: Keeping the blind in double blind clinical trial

Dear Janet,

Thank you. I will wait for the response.

Best regards,
[redacted]

[redacted]

From: OC GCP Questions [mailto:gcpquestions@fda.hhs.gov]
Sent: [redacted]
To: [redacted]
Subject: RE: Keeping the blind in double blind clinical trial

Dear [redacted] -

I am conferring with other colleagues in CDER and hope to respond to your question soon. Thanks for your patience.

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: Wednesday, October 24, 2018 12:11 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Keeping the blind in double blind clinical trial

Dear All,

I am in the process of writing a study SOP. According to our Company SOPs the Medical Monitor assigned to a double blind study and being a "blinded" Medical Monitor has to remain blinded, but Sponsor insists that in case of emergency unlinding, Medical Monitor is unblinded and discuss treatment options with the investigator. Can you please provide your opinion? In addition according to my understanding of regulation MM cannot be involved in subjects treatment decisions.

Thank you in advance,

Best regards,