From: OC GCP Questions
To: [redacted]
Subject: RE: Question regarding Data Monitoring Committees
Date: Tuesday, May 02, 2017 2:53:00 PM
Attachments: [redacted]

Dear [redacted],

FDA has no explicit regulatory requirement for DMCs/DSMBs except in the case of research conducted under 21 CFR 50.24 (a)(7)(iv), in which the informed consent requirement may be waived. There is also no regulatory requirement for establishment of a CEC.

What is described in your email does not appear to be in violation of any FDA regulation; however, an individual's participation with both groups, or a blended group combining the functions of a DMC and CEC, may have the potential to introduce bias into the study. For example, participation on the DSMB may provide access to un-blinded data that would not necessarily be available to members of the Clinical Events Committee.

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.

We recommend that the study sponsor discuss the establishment of a DSMB and/or CEC with the appropriate FDA review staff prior to initiation of the study. The facility at which the study will be conducted may also have a policy regarding DSMBs or CECs for clinical trials; the sponsor may also want to contact the facility or IRB to determine whether there are any local policies or requirements for DSMBs/CECs.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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: Thursday, April 27, 2017 4:38 PM
To: OC GCP Questions
Subject: Question regarding Data Monitoring Committees

Hello,

My understanding from reviewing the FDA's Guidance "The Establishment and Operation of Clinical Trial Data Monitoring Committees for Clinical Trial Sponsors" is that a Data Monitoring Committee (sometimes called a Data Safety Monitoring Board) (DMC/DSMB) is typically distinct from a Clinical Events Committee (CEC) because their roles are distinct; members and functions would not overlap. Are there circumstances in clinical research studies (IND or IDE) where it would be acceptable for a committee/board to serve both of the typical functions of a DSMB and CEC, i.e., to review cumulative safety data and provide recommendations to the sponsor to continue, modify or terminate a study (DMC/DSMB's role), and to also provide adjudication of individual adverse events (CEC's role)?

Please let me know if my question is unclear or if you need further information. Thank you for any clarification you can provide.

Kind regards,

[redacted]