From: OC GCP Questions
To: [redacted]
Subject: Data and Safety Monitoring
Date: Monday, May 18, 2015 11:41 57 AM

Good morning --

Please see the guidance below -- Establishment and Operation of Clinical Trial Data Monitoring Committees

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127073 pdf

Please also see FDA's draft guidance "Safety Reporting Requirements for INDs and BA/BE Studies" (available at http://www.fda.gov/downloads/Drugs/.../Guidances/UCM227351.pdf). This draft guidance was issued in concert with FDA's final rule, which published on September 29, 2010, "Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products." Information on this final rule is available at the following link:

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226358 htm

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

Kind regards,

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Office of Good Clinical Practice

Office of the Commissioner, FDA

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: Friday, May 15, 2015 3:29 PM
To: OC GCP Questions
Subject: Data and Safety Monitoring

To whom it may concern:

Please provide direction on where I could go for guidance and tools for appropriate data and safety monitoring for investigator-initiated sponsored clinical trials, particularly use of Data and Safety Monitoring Boards/Committees, and/or Safety Monitoring Committees.

Please also direct me to the FDA OGCP BIMO (bioresearch monitoring).

Thank you-

[redacted]