

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: RE: IRB which does not fulfill its mandated service.
Date: Friday, January 11, 2019 10:50:00 AM
Attachments: [REDACTED]

Dear [REDACTED] -

Thank you for your email message. FDA has a web page that includes information about where to report complaints related to FDA-regulated clinical trials – see

<https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ComplaintsrelatingtoClinicaltrials/default.htm>. Since it was not clear from your email message what type of FDA-regulated product was involved as part of the study-in-question, I am providing you the link, so you can forward your email to the appropriate FDA Center (i.e., CDER for drug studies, CDRH for medical device studies, etc.).

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: Wednesday, January 09, 2019 12:48 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>; [REDACTED]
Subject: re: IRB which does not fulfill its mandated service.

i participated on an IRB board [REDACTED]

i have resigned the board

i reviewed a study which did involve bad medical practice and did not protect the rights of patients...

the administrator took control of the meeting and basically forced an approval.

this is not good clinical practice...

is there any action which i should take

[REDACTED]