From: OC GCP Questions
To: [redacted]
Subject: Request for IRB advice
Date: Monday, July 21, 2014 2:59:45 PM

Good afternoon --

I am not sure what you are asking. However, a number of physicians or clinical investigators perform research on a similar or same medical conditions based on their medical specialty or interest -- for example, oncologists or cardiologists

For disclosure questions we have a guidance on financial disclosure that should be helpful to you. Please see the link below.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf

Additionally we have other guidances that you should review. Please see the links below.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM328855.pdf

Guidances > Institutional Review Boards Frequently Asked Questions - Information Sheet

Guidances > Sponsor - Investigator - IRB Interrelationship - Information Sheet

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf

I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

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.

-----Original Message-----
From: [redacted]
Sent: Saturday, July 19, 2014 4:12 PM
To: OC GCP Questions
Subject: Request for IRB advice

My name is [redacted] and I am a member of [redacted]

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While I haven't practised for many years, I am a lawyer by training and accustomed to turning to people who have faced problems similar to my own and relying on precedents when I have a problem. I am hoping you will provide that kind of help as I have been unable to find anything on the internet that provides assistance. I did make this request of the OHRP, and while they provided some helpful thoughts, they suggested that you were the proper people for me to ask.

Some of our doctors have multiple studies underway focused on the same disease. The issues this involves were highlighted lately when we were asked to approve a study which made the drug pirfenidone available to some patients with idiopathic pulmonary fibrosis. As I understand it, this drug has been approved in several foreign countries, and some expect FDA approval in the future. The same doctor has other studies going for the same disease, and, as I understand it, success at slowing the disease are less proven in those situations.

I would love to have advice as to how an IRB should handle this sort of situation. Many questions are presented like is disclosure required, if so what needs to be disclosed (e.g., the amount of payments to the doctor by the manufacturers of the various drugs), what about patients already on another study, etc.

I would appreciate any help you can give me by pointing me in the direction of written advice on this subject or giving me advice yourself. Is there a procedure I should follow?

Incidentally, I do not doubt the honestly and decency of the doctor or any drug company, but I feel as an IRB member that I cannot ignore what is obviously an ethical problem

Thank you very much for any help you can give me.

[redacted]