From: Hommel, Carolyn - OC
Sent: Friday, September 24, 2004 4:13 PM
To: [Redacted]
Subject: FW: regulatory question

-----Original Message-----
From: Hommel, Carolyn - OC
Sent: Friday, September 24, 2004 4:10 PM
To: [Redacted]
Cc: Stith-Coleman, Irene (OS)
Subject: RE: regulatory question

Dear Ms. [Redacted] :

Your e-mail to Irene Stith-Coleman at the Office for Human Research Protections was forwarded to me for a response.

Generally, the clinical investigator who conducted the study would have copies of any IRB records that are relevant to the study, so it's not clear why the sponsor has not contacted that clinical investigator for the documents.

In any case, in response to your question, there is nothing in the regulations of the Food and Drug Administration (FDA) that would require your IRB to provide copies of the IRB's records to the outside physician.

You may also wish to consult with your institution's legal department for a legal opinion on releasing these records, as it may raise confidentiality or privacy issues.

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

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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: Tuesday, September 21, 2004 2:56 PM
To: Stith-Coleman, Irene
Subject: regulatory question

Hello,

I called the 800 number for OHRP today, and explained the situation I am dealing with, and was given your email address. I am an IRB Manager for [Redacted].

[Redacted] has been approached by another physician (who is not affiliated with us)who is asking to receive copies of IRB submission and regulatory documents on a study that was initiated and completed by a [Redacted] Principal Investigator. The title of the study was [Redacted]. The IND number was [Redacted] . It was closed at [Redacted] in [Redacted] 2002.

The pharmacetical company who supplied the drug [Redacted] at that time has been bought out several times by different companies and now [Redacted] is the supplier of [Redacted].

The outside physician (not affiliated with [Redacted]) is requesting (basically a copy of the IRB file and I believe copies of case report forms from the local PI at this site). I requested that the outside physician send the [Redacted] IRB a written request outlining an explanation as to why he feels he is entitled to the IRB file documentation.

His letter explained that "[Redacted] is in the process of filing a new drug applicaition with the FDA for use if [Redacted] in [Redacted] ." And that "the FDA regulations require that complete data sets be provided in support of a new drug application."

He has also indicated that the above referenced study was conducted under an IND ([Redacted]) that was opened by another physician and himself.

He also stated the consent form indicates that representatives of the [Redacted] study group, the supplier (which is now [Redacted]) and the FDA may inspect records related to the study. [Redacted].

So, my question is - does the [Redacted] IRB have the authority to turn over IRB related and study related documents to this outside physician? Thank you in advance for your assistance.

[Redacted]