From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, September 30, 2004 8:30 AM
To: [Redacted]
Cc: [Redacted]
Subject: RE: 1488 Referral by [Redacted]

Dear Ms. [Redacted]:

Your e-mail was forwarded to me for a response, and I apologize for the delay in getting back to you.

There isn't enough information in your e-mail to provide you with a definitive answer, and in fact, your e-mail raises numerous questions, the answers to which might help to determine what type of review your research should undergo. For example:

--Are the specimens publicly available?

--Has the identifying information been removed from the specimens, such that the patients who provided the specimens cannot be identified, directly or through identifiers that are somehow linked to the subjects?

--At the time the specimens were collected, what were the patients told about the specimens? Were they informed that the specimens would be held in a repository and possibly made available to researchers in the future? Is it possible that the patients have already given their consent to allow additional research on the specimens?

--Is it possible that at some future date, the results of the research might be submitted to the Food and Drug Administration (FDA) to support a marketing or research permit or to change the labeling or advertising of the drug products involved in the research?

--Does the institution from which you are obtaining the specimens or the institution where you are going to conduct the study (if they are not the same) have any specific requirements with respect to the conduct of such research?

My recommendation would be for you to develop a research protocol describing the materials and procedures that you plan to use, as fully as possible, and submit the protocol to the IRB at the institution that is providing the samples for review, and, if different, the IRB for the institution where you intend to actually conduct the research. The IRB(s) could then determine if the proposed research is exempt from IRB review, or might be reviewed using expedited review procedures, or in fact, should undergo review by the full IRB(s).

I hope this is helpful to you.

Sincerely,

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

Telephone: 301/827-3340
Fax: 301/827-1169

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: Friday, August 20, 2004 9:00 AM
To: Falcone, Marie T
Subject: 1488 Referral by [Redacted]

I was referred to you by [Redacted] from [Redacted]. I inquired with [Redacted] concerning a question I had with some a research project I am currently working up. This research involves the synergistic effects of two drugs as opposed to each one alone. This is bench research and is independent research and involves no granting, it will be privately supported by a physician nor a clinical trial. This research involves the determination of [Redacted] for two strains of bacteria. The question is if we use isolates obtained from clinical specimens submitted for culture at a hospital, would that require IRB approval, informed consent and a formal clinical trial protocol. I received my certification as a [Redacted] last January and I'm struggling with this and want to do the right thing but I'm getting conflicting opinions. Any thoughts on this would be greatly appreciated. Thank you.

[Redacted]