From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, December 07, 2006 2:56 PM
To: [purged]
Subject: RE: IRB and patient registries

Dear [purged],

From your description below, that is, it's a patient registry for an approved product, with information collected solely for treatment purposes in an anonymous form, it would not be human subjects research and, thus, would not be regulated by FDA or by OHRP under the Department's human subject protection regulations. I checked with Julie Kaneshiro at OHRP (that's the Office for Protection from Research Risks)--from your description it does not sound as though you are doing research.

I hope this is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, 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: [purged]
Sent: Monday, December 04, 2006 10:47 AM
To: OC GCP Questions
Subject: IRB and patient registries

We would like to develop a patient registry for a FDA approved product.
All we want to do is follow the patient and gather data that would fall
under "normal standard of care". In other words we will not be performing
any additional tests or procedures and would only use the data collected
during normal follow up visits. Does this type of registry need IRB
approval if we are not taking away any PHI? This will be completely
anonymous. Thank you
[purged]