From: Hommel, Carolyn - OC
Sent: Tuesday, January 06, 2004 8:37 AM
To: **[Redacted]**
Subject: RE: subject recruitment database

Dear **[Redacted]** ,

FDA regulations are silent on the issue of subject recruitment databases.

Thus, we would defer to OCR (with respect to how HIPAA might affect collection, storage, use, and sharing of such confidential, medical information about patients) and to the IRB, which may have established guidelines or policy as to how clinical investigators affiliated with the institution should collect, store, use, and protect such information.

Carolyn

-----Original Message-----
From: **[Redacted]**
Sent: Monday, January 05, 2004 5:24 PM
To: Carolyn.Hommel@OC.FDA.GOV
Subject: RE: subject recruitment database

Carolyn,

Thank you for your reply. Before i emailed, I read through the "Receptionist Script" section, which is what prompted my question. Through your response, it sounds like the appropriateness of maintaining a research recruitment database is determined by the IRB.

So does this mean, that with an IRB approval, the FDA allows the following:

1. Create a phone screener that lists several medical conditions.

2. Complete the phone screener (a bunch of check boxes) when potential subjects who respond to an ad for one study don't qualify for the study they responded to, but want to be contacted for future studies.

3. Keep this information along with the patient contact info on file so if a study comes along, the database can be queried for potential subjects with the required conditions.

Now my question is...how can you get IRB approval for something like this when it is not related to a specific study but to a practice? I had thought that you have to go to an IRB with a specific study in mind.

Thanks again for your help!
[Redacted]

Dear **[Redacted]**,

The Food and Drug Administration (FDA) does not have any specific regulations pertaining to subject recruitment databases. FDA's "Information Sheet" on subject recruitment addresses this issue somewhat indirectly, by suggesting that IRBs review the "methods and materials" used to recruit study subjects. The most pertinent section is "B. Receptionist Scripts," which states:

"The first contact prospective study subjects make is often with a receptionist who follows a script to determine basic eligibility for the specific study. The IRB should assure the procedures followed adequately protect the rights and welfare of the prospective subjects. In some cases personal and sensitive information is gathered about the individual. The IRB should have assurance that the information will be appropriately handled. A simple statement such as "confidentiality will be maintained" does not adequately inform the IRB of the procedures that will be used.

"Examples of issues that are appropriate for IRB review: What happens to personal information if the caller ends the interview or simply hangs up? Are the data gathered by a marketing company? If so, are names, etc. sold to others? Are names of non-eligibles maintained in case they would qualify for another study? Are paper copies of records shredded or are readable copies put out as trash? The acceptability of the procedures would depend on the sensitivity of the data gathered, including; personal, medical and financial."

(You may read the information sheet in its entirety at: http://www.fda.gov/oc/ohrt/irbs/toc4.html .)

Because the database may be maintaining confidential information about the individuals considered for the study, it is also possible that the Health Insurance Portability and Accountability Act (HIPAA) may have some bearing on this issue. HIPAA was developed "to maintain strong protections for the privacy of individually identifiable health information" and was "intended to provide consumers with ...assurances that their health information, including genetic information, will be properly protected. Under the Privacy Rule...health care providers must guard against misuse of individuals' identifiable health information and limit the sharing of such information, and consumers are afforded significant new rights to enable them to understand and control how their health information is used and disclosed."

The Department of Health and Human Services (DHHS), Office of Civil Rights (OCR) is responsible for enforcing the provisions of HIPAA. There are a number of guidance documents about HIPAA that are available on OCR's web site (http://www.dhhs.gov/ocr/hipaa/). Should the information on the website not answer your questions, you may e-mail OCR directly (ocrmail@hhs.gov) or call that office at (800) 368-1019.

Finally, I would also suggest that you contact the IRB that has responsibility for reviewing and approving your study(ies) for their guidelines or advice on how to handle the information.

I hope this is helpful to you.

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)
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-----Original Message-----
From: **[Redacted]**
Sent: Tuesday, December 30, 2003 6:50 PM
To: gcpquestions@oc.fda.gov
Subject: subject recruitment database

Can you please refer me to a document that spells out the GCP policy on set up and maintenance of subject recruitment databases?

Specifically, is it legal to enter potential subjects who call in response to an advertisement for one study into a database so they can be contacted for future studies.

Thank You
[Redacted]