FW: Clinical Trials WebsiteFrom: Toth-Allen, Jean
Sent: Monday, August 28, 2006 2:19 PM
To: [purged]
Subject: RE: Clinical Trials Website

Dear Mr. [purged]:

Since this is already sent, I will just answer it right here. Please do use our query e-mail addresses for future questions, however.

Recruiting, also considered advertising for study subjects, is part of information that, in most cases, needs review and approval by the reviewing institutional review boards (IRB), as information contained therein is considered to be part of the informed consent process. The FDA Information Sheets do have a section in this regard. However, it has not been updated since 1998 and is very limited. It is accessible at http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting. It is not completely clear to me that the website you supplied complies with the exception from IRB approval included in this guidance as there is considerable specific information included on that site. I would therefore raise this issue with the reviewing IRBs. The main FDA concern is obviously with the message. Besides the Information Sheet referenced above the only other FDA guidance in that regard is a simple guidance with regard to the contents of recruitment materials for device studies available at http://www.fda.gov/cdrh/comp/2229.html.

(Sorry it took so long to respond that you had time to send a second message to our official e-mail account - the internet response is slow today on my computer and I wanted to ensure I gave you the correct link. I have deleted your second message so you will not be getting a duplicate answer at least!)

Jean

From: [purged]
Sent: Monday, August 28, 2006 1:33 PM
To: Toth-Allen, Jean
Subject: RE: Clinical Trials Website

Jean, I did get your very prompt reply and many thanks for your guidance.

Rather than the FDAMA website, I was really asking about the use of a website such as http://www.abatetrial.org designed to recruit patients into a specific clinical trial. I will send my question to the email address you provided. Thanks again. RMK.

From: Toth-Allen, Jean [mailto:jean.toth-allen@fda.hhs.gov]
Sent: Monday, August 28, 2006 12:28 PM
To: [purged]
Subject: FW: Clinical Trials Website

Dear Mr. [purged]:
Despite the fact that I copied and pasted your address from the e-mail you sent to Dr. Ball, my system apparently did not correctly capture it and I received an "undeliverable" message. Hopefully this one will reach you. Sorry for any inconvenience.
Jean

From: Toth-Allen, Jean
Sent: Monday, August 28, 2006 12:23 PM
To: [purged]
Subject: Clinical Trials Website
Dear Mr. [purged]:
Dr. Ball cced our office on her response to you as we provide a query service with regard to clinical studies. (See further information in that regard at the end of this e-mail.)
I am not completely sure what you mean by the "Clinical Trials Website." Are you perhaps referring to the clinical trials listing that the FDA Modernization Act of 1997 (FDAMA) required to be developed to assist the public in identifying on-going clinical trials for serious or life-threatening conditions? (It is mandated that studies related to serious and life-threatening conditions be listed here, but that does not preclude the listing of other on-going clinical studies.) While I would not personally consider this website as a method for "recruiting" trial subjects, I assume that individuals have found their way into appropriate studies in this way. There is an FDA website related to this FDAMA requirement and its implementation (http://www.fda.gov/oashi/clinicaltrials/section113/default.htm). There are links at that site to FDA draft and final guidance documents in this regard. If this clinical trials listing is not what you are referring to, please send your clarification to the e-mail address below.

Hope this information is useful.
If you need further information and/or have additional questions, please submit them to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.
Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US 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.