From: Toth-Allen, Jean
Sent: Tuesday, August 01, 2006 8:55 AM
To: [purged]
Subject: RE: Question regarding Recruitment Material - Testimonials

Dear Ms. [purged]:

Thank you for your inquiry regarding study subject testimonials as part of study recruitment materials.

The FDA Information Sheets address this subject broadly at http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting. The statements that you site as FDA guidance are contained within this information sheet, so it may indeed be the guidance you have already accessed. As noted in this guidance, FDA considers recruitment advertisement to be part of the informed consent process and, as such, cannot contain any statements that explicitly or implicitly make effectiveness claims about the investigational product. Testimonials, in general, advertise the product or procedure they discuss in the words of a "satisfied user" and so, by their very nature, are claiming success/improvement/effectiveness. Therefore, testimonials would not be appropriate in recruitment advertisement for an investigational study.

Hope this information is useful. If you need further information and/or have additional questions, please submit them once again 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.

From: [purged]
Sent: Monday, July 24, 2006 4:19 PM
To: OC GCP Questions

Cc: [purged]
Subject: Question regarding Recruitment Material - Testimonials

To whom it may concern:

We are requesting guidance concerning using testimonials as a part of recruitment materials for a research study.

An example would be if a subject completes a research study involving a study article, has a good result, and now his/her story about participation in the research study becomes a part of future recruitment materials.

As a central IRB, we have not received many requests for review and approval of testimonials as a part of recruitment materials, until recently.

Your guidance states that 'No claims should be made, either explicitly or implicitly, the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.'

Would the FDA consider a testimonial to be perceived as an implicit claim of efficacy for the study article?

I appreciate any feedback that you can provide.

Best regards,
[purged]