From: OC GCP Questions
To: [redacted]
Subject: Clinical trial advertising on Craigslist
Date: Friday, January 19, 2018 1:15:00 PM
Attachments: [redacted]

Good afternoon –

FDA regulations are not specific as to how clinical trials are listed on the internet. Please see FDA information sheet below.

Search for FDA Guidance Documents > Recruiting Study Subjects - Information Sheet

To paraphrase the information in FDA's Information Sheet, "Recruiting Study Subjects," IRBs have the authority to review, approve, require modifications in, or disapprove all research activities covered by the IRB regulations. This includes the authority to review the methods and material that investigators propose to use to recruit subjects.

FDA has said that IRBs need not review listings of clinical trials on the internet if the database used precludes any information beyond the "basic trial information", e.g., study title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information. If the database system allows additional descriptive information to be included, however, then IRB review and approval may assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
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FDA U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Thursday, January 18, 2018 1:55 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Clinical trial advertising on Craigslist

Hello,

My name is [redacted] I was told by a couple

research locations that the FDA has guidelines as to where within [redacted] the recruitment and needs to be placed.

Our business has always followed the [redacted] "City Name: > Community > Volunteers

But I have heard from others that they place their ads on the job boards.

Can you advise us if you have such guidelines?

Many thanks,

[redacted]

[redacted]