From: OC GCP Questions
To: [redacted]
Subject: Question about News Media Policy
Date: Wednesday, May 03, 2017 6:21:00 AM
Attachments: [redacted]

Good morning –

After reviewing the guidance, I believe your interpretation is correct. IRB review is not required for new stories.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, May 02, 2017 12:46 PM
To: OC GCP Questions
Subject: Question about News Media Policy

Hello –

[redacted] communications specialist from FDA regulatory affairs in Detroit, gave me this email address and I'm hoping you can help. I'm [redacted] director of media relations for [redacted] Because I'm still fairly new to [redacted] I am learning everything I can about the policies and protections surrounding our clinical trials programs. In talking with our Institutional Review Board about the possibility of doing news stories regarding various clinical trials going at [redacted] they sent me the following link regarding FDA regulations: https://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

I am particularly interested in this paragraph from that link:

Direct advertising for research subjects, i.e., advertising that is intended to be seen or heard by prospective subjects to solicit their participation in a study, is not in and of itself, an objectionable practice. Direct advertising includes, but is not necessarily limited to: newspaper, radio, TV, bulletin boards, posters, and flyers that are intended for prospective subjects. **Not included** are: (1) communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting for study subjects), (2) news stories and (3) publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

That said, I want to make sure I am understanding this correctly. This policy seems to suggest that the FDA requires hospital IRB's to review and approve any marketing and advertising materials regarding clinical trials, but does NOT require them to review or approve of our participation in stories done by news media. Is that correct? I want to make sure all members of our PR and media team know and adhere to this policy. Any insight you could provide would be great. I'm happy to discuss this in more detail if you'd like.

Thanks so much.
[redacted]

[redacted]

[redacted]