From: OC GCP Questions
To: [redacted]
Subject: IRB Review Requirement for Non-treatment Development Project
Date: Friday, August 01, 2014 10:52:03 AM

Good morning --

It appears that you may need IRB review and approval especially if you are using an ICF, compensating subjects, and the information will be used for future clinical trials.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, 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: [redacted]
Sent: Thursday, July 31, 2014 6:13 PM
To: OC GCP Questions
Subject: IRB Review Requirement for Non-treatment Development Project

Dear GCP office,
I'd like to find out if IRB review is required for a development project in which no treatment will be administered. Volunteers will be photographed and, from these photographs, visual scales will be created depicting specific features. The scales will then be validated by physicians who will rate the features of live volunteers vs. the photo scales. The volunteers will sign a release/ICF prior to participation, will be compensated, and may provide contact information, but will not provide health information or undergo any tests or procedures.

The completed and validated photo scales would be used as measurements for future clinical trials.

Your assistance with this would be appreciated.

Kind Regards,

[redacted]