From: OC GCP Questions
To: [redacted]
Subject: 21 CFR 50, 56 vs 45 CFR 46
Date: Thursday, May 07, 2015 11:12:49 AM

Good morning –

You will need to contact the Center for Devices (CDRH) to determine if the study you describe requires an IDE. Their email address is DICE@fda.hhs.gov. Also you might want to contact the Office for Human Research Protections' website below as they follow 45 CFR 46.

Office for Human Research Protections (OHRP) | HHS.gov

I hope this information is helpful.

Kind regards,

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

From: [redacted]
Sent: Thursday, May 07, 2015 7:22 AM
To: OC GCP Questions
Subject: 21 CFR 50, 56 vs 45 CFR 46

A respected person in the IRB world suggested that you are a most helpful and responsive resource at FDA.

We are trying to determine whether a study should be reviewed under 21 CFR 50, 56 or under 45 CFR 46.

The study compares a group that receives four exercise interventions with a control group that receives only parental education on promoting psychosocial development.

The study hopes to see if increasing physical activity in infants (who are a risk for obesity) can prevent obesity when they become toddlers. The investigator describes the intervention as a modification of the environment and the infant's daily activities, to help the child increase their level of physical activity, in order to see if they will have a healthier body size as they grow.

However, one of the exercise interventions is an infant treadmill. FDA considers treadmills to be Class I devices (890.5380). The study is being done to see if the interventions can prevent obesity. We acknowledge that any effect may not be able to be sufficiently attributed to any one of the

interventions.

Our questions

1) Would FDA consider this to be a clinical investigation of a device to determine safety and effectiveness (21 CFR 812.2(a))?

2) If so, would it qualify as an "Exempted investigation" under the provisions of 21 CFR 812.2 (c), since Class I devices don't have labeling requirements?

3) If FDA would consider this to be an exempted investigation of a device would review under 21 CFR 50, 56 be required, rather than review under 45 CFR 46?

Thanks very much for your consideration of these questions. As someone who once worked for FDA I know what a daunting task you have to address all the things you cover with the budget you get.

Sincerely,

[redacted]