From: OC GCP Questions
To: [redacted]
Subject: RE: IRB Inquiry
Date: Tuesday, September 23, 2014 5:03:00 PM

Dear [Redacted]-

Thank you for your question. FDA is responsible for protecting the public health by assuring that foods (except for meat from livestock, poultry and some egg products which are regulated by the U.S. Department of Agriculture) are safe, wholesome, sanitary and properly labeled; ensuring that human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective; protecting the public from electronic product radiation; assuring cosmetics and dietary supplements are safe and properly labeled; regulating tobacco products; and advancing the public health by helping to speed product innovations. FDA has basic information that you might find interesting on our web site at http://www.fda.gov/AboutFDA/Transparency/Basics/default.htm - look under the Main Topics tab in the middle of the page.

You may also be aware of the Office for Human Research Protections (OHRP) who provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research. More information about OHRP can be accessed at their web site at http://www.hhs.gov/ohrp/index.html.

Your question is very broad and not one that can be easily answered in an email message response. Based on the very limited information provided in your question, it appears that you may not be using an FDA-regulated product in your proposed research. While you may want to send your question to OHRP at OHRP@hhs.gov, I'm afraid that without more details, it will be difficult for OHRP to provide a simple yes/no response.

I recommend that you start by consulting the IRB at your institution [Redacted] for assistance in assessing your proposed research and determining whether or not your study requires IRB approval. I noticed on the [Redacted] web site at [Redacted] that you can also contact your [Redacted] with questions. Your [Redacted] office should be familiar with whether your institution holds a Federalwide Assurance (FWA) with OHRP, the status of your IRB registration, your institutional policies, etc.

The [Redacted] web site at [Redacted] also indicates that the Human Subjects Committee members at [Redacted] must complete extensive on-line training that covers many topics that may be helpful to you in learning about IRB review. You may want to talk to the [Redacted] staff about getting access to these on-line training modules to help in your education about IRBs.

I'm sorry that I can't be more helpful, but there are many components that require careful consideration when determining whether or not a study requires IRB review.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [Redacted]
Sent: Monday, September 22, 2014 9:49 AM
To: OC GCP Questions
Subject: IRB Inquiry

Hello,

I am a bit confused about IRB procedure. Does a private start up company need IRB approval if they are not receiving federal support? The reason I ask is because we want to conduct a product test with children between the ages of 8-13. The children would be testing out our new computer program, which [Redacted] and then they would give us their feedback. We would not share their personal information. Does this require an IRB?

Sorry for bugging you, but we have been looking for the answer everywhere and found no luck.

Thank you,
[Redacted]