From: OC GCP Questions
To: [redacted]
Subject: RE: Do we need to register with ClinicalTrials.gov?
Date: Monday, May 11, 2015 7:56:00 AM

Good morning,

It appears from your message that you may be conducting studies with both drugs and devices. Unfortunately, the definitions of an "applicable clinical trial" differ for drugs and devices. The statutory requirements, including the definitions of applicable clinical trial can be found in the Food and Drug Administration Amendments Act of 2007.

Please be aware that the determination of whether a trial is an "applicable clinical trial" has to be made by the sponsor/responsible party associated with that trial and familiar with all aspects of the clinical trial. FDA cannot make that determination for any party. The NIH website does contain an Elaboration of Definitions document which can be referred to as well as various FAQs.

You may wish to consider the following, along with a review of the NIH Elaboration of Definitions document.

For drug studies: Is your study a clinical investigation, as defined under 21 CFR 312.3? Is it controlled? Is the study something other than a Phase 1 study? Is it being conducted in at least one site in the United States?

For device studies: Is the device subject to either 510(k), 515, or 520(m) of the Food Drug and Cosmetic Act? Is the study looking at a health outcome? Is the study looking at a prototype device or studying the feasibility of a device and not related to health outcomes? Does the study involve a control in human subjects?

The answers to these questions should help in making a determination of whether the trial is an "applicable clinical trial" and required to be registered with ClinicalTrials.gov.

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

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

From: [redacted]
Sent: Friday, May 08, 2015 12:31 PM
To: OC GCP Questions
Subject: Do we need to register with ClinicalTrials.gov?

I'm hoping to get your insight into our need to register research under ClinicalTrials.gov.

9 months ago we received an IRB for conducting sunscreen and sun protective fabric research in natural sunlight.
We are following the FDA's 2011 sunscreen final rule, except we're using natural sunlight, not a solar simulator.
We are confining our exposures to either 2 hours or 4 hours of natural sunlight exposure.
We are testing the hypothesis that indoor SPF and broad spectrum testing is more accurate and in general agreement with sun protection in natural sunlight.

Do we need to register with ClinicalTrials.gov? My assumption is no, given that we're testing OTC drugs or fabrics that are tested using a specific method, but that natural sunlight is estimated to be $1/20^{th}$ as potent as solar simulator UV exposure.

Can someone give me guidance if we're correct?
Can someone give me any other suggestions on our research?

Thank you,

[redacted]