From: OC GCP Questions
To: [redacted]
Subject: RE: Clinical Trials.gov
Date: Wednesday, July 26, 2017 2:58:00 PM
Attachments: [redacted]

Good afternoon,

The HHS regulations for registration and submission of clinical trial information to ClinicalTrials.gov (42 CFR part 11) are quite complex and it would be important to review the language of the regulations. Discussions of the applicability of the HHS regulations are found at 42 CFR 11.4. You also may wish to review the definitions under 42 CFR 11.10, particularly the definition of "applicable device clinical trial" and "applicable drug clinical trial." Please see the regulations here https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission

The National Library of Medicine/NIH has developed a checklist to assist in determining whether a trial meets the definition of an "applicable clinical trial." This checklist may be found at http://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf The ClincialTrials.gov website also has additional resources related to the requirements for submitting information required by the HHS regulations.

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.
Senior Health Policy Analyst

Office of Good Clincial Practice
U.S. Food and Drug Administration

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: Wednesday, July 26, 2017 11:38 AM
To: OC GCP Questions
Subject: Re: Clinical Trials.gov

Thanks so much. Does this mean it only applies to federally funded studies and not commercial sponsors?

[redacted]

On Jul 26, 2017, at 3:45 AM, OC GCP Questions <gcp.questions@fda.hhs.gov> wrote:

> Please note this is NIH's Final Rule not FDAs.
>
> ---
> **From:** OC GCP Questions
> **Sent:** Wednesday, July 26, 2017 6:05 AM
> **To:** [redacted]
> **Subject:** Clinical Trials.gov
>
> Good morning --
>
> Please see the links below.
>
> Federal Register :: Clinical Trials Registration and Results Information Submission
>
> ClinicalTrials.gov Final Rule Information
>
> Kind regards,
>
> Doreen M. Kezer, MSN
> Senior Health Policy Analyst
> Office of Good Clinical Practice
> Office of the Commissioner, FDA
>
> [redacted]
>
> 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.
>
> -----Original Message-----
> From: [redacted]
> Sent: Tuesday, July 25, 2017 8:59 PM
> To: OC GCP Questions
> Subject: Clinical Trials.gov

I understand the requirements for registering trials were updated or clarified in Jan 2017, but I cannot find this as a Guidance Document.

Can you please provide me this reference?

Thank you -

[redacted]