Good morning –

The Center for Drugs (CDER) updates the form and they tell me they don't know when the new form will be completed. You can however use the expired form. You can email CDER directly to check in the future at druginfo@fda.hhs.gov

It is probably best to check both boxes for phase 1 and 2 studies. However you might want to check with the sponsor to see what preference they have since the sponsor submits the 1572 form to FDA.

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

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.

Hello,

I hope all is well!

I the following questions regarding the Form FDA 1572:

1) A study that I am working on just changed its study design, along with the protocol title, from Phase 2 to Phase 1/2. The previous 1572s for the sites have the checkbox "For Phase 2 or 3 investigations…" in Section 8 checked. Since the study is now a Phase 1/2, should both checkboxes ("For Phase 1 investigations…" and "For Phase 2 or 3 investigations…") be checked?

2) When do you expect the new version of the 1572 to be available since the current version (7/13) expired 30 April 2015?

If you could please send me the answers to the above at your earliest convenience, I would be most

grateful.

Many thanks for your help!

Kindest Regards,

█████████