From: OC GCP Questions
To:

Subject: 1572 Box 3 Question

**Date:** Thursday, November 13, 2014 11:06:49 AM

## Good morning -

From the limited information in your email it appears you are correct. Please see FDA's guidance document on the 1572 form.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf It states -

20. What address should be entered into Section #1?

The address where the investigator can be reached by mail or in person should be entered in Section #1 of the 1572. Usually, this corresponds to the investigator's work or business address.

I hope this information is helpful. Please contact us again at <a href="mailto:gcp.questions@fda.hhs.gov">gcp.questions@fda.hhs.gov</a> 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.

From: OYXUMYXQ

Sent: Wednesday, November 12, 2014 1:49 PM

To: OC GCP Questions

Subject: 1572 Box 3 Question

Good Afternoon,

The sponsor for a study that we will be participating in just sent my 1572 back to me and requested that I add the following to my address in box 3. "IP shipment and Urine pregnancy test location."

We only have one research facility so I was under the impression that IP shipment and urine pregnancy test location fall under the heading of clinical investigations and since there are no separate addresses is such a clarification necessary?

As always I greatly appreciate any assistance that you could provide!

Best Regards, ltgf cevgf\_