

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Site-Created Form 1572
Date: Thursday, July 31, 2014 2:57:42 PM

Dear [redacted] –

I checked with the Center for Drugs (CDER) the Center where the 1572 form was created. Please see their answer below.

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: CDER DRUG INFO
Sent: Thursday, July 31, 2014 2:23 PM
To: OC GCP Questions
Subject: RE: Site-Created Form 1572

Doreen,

I would advise them to use the form on our Forms webpage:
<http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>

From: [redacted]
Sent: Thursday, July 31, 2014 1:52 PM
To: OC GCP Questions
Subject: Site-Created Form 1572

Hi,

I've received an unusual Form 1572 from a study site and was wondering if you could let me know if this is allowable. Attached

I don't believe that I've seen a site create their own version of the form before.

Would this be acceptable?

Your input would be greatly appreciated.

Thanks,
[redacted]