[redacted]

**From:** OC GCP Questions
**Sent:** Thursday, April 21, 2016 7:54 AM
**To:** [redacted]
**Subject:** FDA Form 1572

Good afternoon -

Many individuals do not realize that one of the main purposes of the 1572 is to provide the sponsor with advance information about the clinical site(s) where the research will take place, the investigator's qualifications, and information about other facilities that will be performing protocol required tests. Providing this information to the sponsor allows the sponsor to establish and document that the investigator and site are qualified to conduct the study. The other main purpose of completing the 1572 is to obtain the investigator's commitment to comply with FDA's regulations for conducting the clinical investigation. Although it is not required, many sponsors commonly submit a copy of the 1572 to FDA for IND studies as the information it contains is required for an IND application. The 1572 is meant to supply site-specific information to the sponsor.

From an FDA standpoint, it is not against FDA regulations for the CI/site to send the 1572 to the IRB unless there is a specific contract or agreement in place between the sponsor and the CI/site.

That said you might want to consult your legal department at your institution to see if they agree or disagree as to whether the information on the 1572 from is proprietary.

I hope this information is helpful. Please contact us 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



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**From:** [redacted]
**Sent:** Wednesday, April 20, 2016 11:56 AM
**To:** OC GCP Questions
**Subject:** FDA Form 1572

Hello,
I am writing regarding the FDA Form 1572. I have read the related information (listed below) and was unable to find the answer:

a) Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs -Frequently Asked Questions Statement of Investigator (Form FDA 1572) DRAFT GUIDANCE
b) 21 CFR Part 56 - Institutional Review Boards
We normally send the completed FDA Form 1572 to our IRB with all of the other initial submission documents. A study Sponsor Monitor recently mentioned to me that submitting the completed 1572 to an

IRB is prohibited. He explained that since this is a contract between the investigator and FDA but is proprietary information of the Sponsor. Because it is proprietary information, he said the IRB is not privy to see it.

I think this is a lot of nonsense. We are sending it to the IRB – not posting it on the wall of the local Kroger for Goodness sake!

Can you please let me know if it is a problem to send the completed FDA Form 1572 to the reviewing IRB? Thanks again!

[redacted]