

**From:** OC GCP Questions  
**To:** [REDACTED]  
**Subject:** 1572 Form Completion  
**Date:** Thursday, July 21, 2016 7:17:00 AM

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Good morning –

Please note that block #3 on form 1572 provides a place to identify facilities where the investigation will be conducted. This is intended to include all facilities where subjects will be seen and study procedures performed (including liver biopsies). If you are still unclear whether the facilities should be listed, please consult the study sponsor.

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.

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**From:** [REDACTED]  
**Sent:** Wednesday, July 20, 2016 2:33 PM  
**To:** OC GCP Questions  
**Subject:** RE: 1572 Form Completion

Hi Doreen,

Thank you for our response. I did have one additional question, do sites performing liver biopsies have to be listed under section 4? Most of these procedures are performed at imaging centers but some are performed at other facilities. Please clarify.

Thank you.

Regards,

[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]