

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Section 6 of Form 1572  
**Date:** Tuesday, August 20, 2019 12:31:44 PM  
**Attachments:** [REDACTED]

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Good afternoon –

Please see FDA's 1572 form guidance. <https://www.fda.gov/media/78830/download>

**31. Who should be listed as a subinvestigator in Section #6?**

*FDA's regulation at 21 CFR 312.3(b) states: "In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. 'Subinvestigator' includes any other individual member of that team." 21 CFR 312.53(c)(1)(viii) requires the investigator to provide "a list of the names of the subinvestigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s)."*

*The purpose of Section #6 is to capture information about individuals who, as part of an investigative team, will assist the investigator and make a direct and significant contribution to the data. The decision to list an individual in Section #6 depends on his/her level of responsibility (i.e., whether he/she is performing significant clinical investigation-related duties). In general, if an individual is directly involved in the performance of procedures required by the protocol, and the collection of data, that person should be listed on the 1572. For example, if the protocol notes that each subject needs to visit a specified internist who will perform a full physical to qualify subjects for the clinical investigation, that internist should be listed in Section #6.*

See also question 32.

It appears that the individuals who perform the biopsies might be needed to be listed on the 1572 form but maybe not as sub-investigators. Perhaps instead of listing all the names, just list the name and address of the clinic where the biopsies are performed.

If you are still unsure, please contact your FDA representative of the IND.

Kind regards,

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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:** Monday, August 19, 2019 6:54 PM  
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>

**Subject:** Section 6 of Form 1572

Hello,

I'm from a research dedicated site and we contract our certain procedures for different protocols. For example, if our site was conducting an endometriosis study that required endometrial biopsies we would contract the procedure out to a women's health clinic. Would those providers need to be listed as Sub-Investigators?

Thank you in advance for the help.

Best Regards,

