**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Form FDA 1572 section 6 question: Surgeons in an oncology trial
**Date:** Tuesday, April 30, 2019 2:47:27 PM
**Attachments:** [redacted]
**Importance:** High

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Good morning –

I have consulted with the Center for Drugs (CDER) and given the description of the surgeon's role, they have advised me that the surgeon should be listed on the 1572 form. However, since your mentioned it was a phase 3 oncology study, it is best, you as the sponsor, to check with the FDA regulatory project manager of the IND at CDER.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA




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[redacted]
**Sent:** Friday, April 26, 2019 1:21 PM
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>
**Subject:** Form FDA 1572 section 6 question: Surgeons in an oncology trial

Hello,

I work in the [redacted] for a biopharmaceutical company that is about to start a global Phase 3 oncology study. I would appreciate the FDA's advice as to whether or not surgeons that will be performing tumor resection surgeries should be listed as a Sub-Investigator in box #6 of the Form FDA 1572? I am familiar with the FDA's 1572 FAQ Guidance Sheet (May 2010) that states an individual should be listed in section #6 if they "make a direct and significant contribution to the data" and "is directly involved in the performance of procedures required by the protocol, and the collection of data." For this study, cancer patients will receive investigational drug for a period of time and after which, will be evaluated to determine if they are eligible for surgery to remove their tumor. The surgeons performing the tumor removal surgeries will be doing so per their standard of care procedures and in accordance with their judgement/abilities. The surgeons will follow the patients after their surgery and report safety data back to the PI (for inclusion in the study database). The outcome of the surgery (e.g., tumor resection value R0, R1, R2) is an important endpoint for the study; however, the surgeon will not be determining resection outcomes, as this

will be done by a central pathology lab.

We are leaning towards not requiring the surgeons to be added to the 1572 (although they will be included on the Delegation of Authority Log and will be trained on the protocol, etc.). However, as the determination of whether or not the surgeons are making a "direct and significant contribution to the data" is very selective, we would appreciate the FDA's opinion as to whether or not the surgeons should be added to the 1572 as Sub-Investigators.

Much appreciation,

[redacted]