

**From:** OC GCP Questions  
**To:** [REDACTED]  
**Subject:** RE:ICF/Protocol question  
**Date:** Wednesday, February 08, 2017 9:56:00 AM  
**Attachments:** [REDACTED]

---

Good morning --

I checked with our ethicist here in OGCP. We suggest you ask the review division responsible for the IND this question, assuming you are the sponsor that is asking the question. The response might depend on what is presently in the protocol which the review division should know. If I have not adequately answered your question, you may contact the Center for Drugs (CDER) directly at [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)

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:** [REDACTED]  
**Sent:** Tuesday, February 07, 2017 1:51 PM  
**To:** OC GCP Questions  
**Subject:** RE:ICF/Protocol question

Dear Sir/Madam,

A local ethics committee has requested that we add the word "vasectomy" in the pregnancy section of the ICF and this request has been complied with. Do we have to prepare a local protocol amendment to have the inclusion criteria in line with ICF birth control/pregnancy ICF section.

Thank you.

Kind regards,

[REDACTED]