

ATTACHMENT C

POST-APPROVAL REVIEW FOLLOW-UP LETTER

To: Principal Investigator
Study Coordinator
OEQCR Director
HSRC Chair
HSRC Vice Chair

From: Name
Post -Approval Review Team

Date:

Subject: HSR # xx-xxxx: (title)

Thank you for your cooperation in the review of the above named protocol. Please review the enclosed observations and, if applicable, provide a written response by (DATE). Your response should address all requests. If corrective action is warranted, please outline all actions to be implemented.

Please send a copy of your written response to:
Office for Education and Quality in Clinical Research
c/o Mailcode S9.315

The Director of the OEQCR will review your answers and corrective plan(s) as applicable and determine if further action is necessary.

Please feel free to contact me with any questions or concerns. I may be reached at (PHONE #) or (EMAIL).

Sincerely,

(Signature)

(NAME)
Post-Approval Review Team