DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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April 15, 2009

John C. Elkas, M.D., J.D.
Partner
Northern Virginia Pelvic Surgery Associates
3289 Woodburn Road Suite 320
Annandale, VA 22003

RE: Human Research Protections Under Federalwide Assurance FWA-13356

Research Project: A Phase III Trial of Carboplatin and Paclitaxel Plus Placebo vs. Carboplatin and Paclitaxel Plus Concurrent Bevacizumab, Followed by Placebo, vs. Carboplatin and Paclitazel Plus Concurrent and Extended Bevacizumab, in Women with Newly Diagnosed, Previously Untreated, Stage III (Suboptimal) and All Stage IV, Epithelial Ovarian or Primary Peritoneal Cancer
Principal Investigator: Dr. John C. Elkas
HHS Protocol Number: Gynecology Oncology Group (GOG) -0218

Dear Dr. Elkas:

Thank you for your March 17, 2009 report in response to our February 19, 2009 request that Northern Virginia Pelvic Surgery Associates (NVPSA) respond to determinations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). In our February 19, 2009 letter, we made the following determination, among others:

> The complainant alleged that the informed consent documents reviewed and approved by the institutional review board (IRB) that approved this study on behalf of NVPSA did not include an accurate description of any additional costs to the subject that may result from participation in the research, as required by HHS regulations at 45 CFR 46.116(b)(3). In specific, the complainant alleged that she is now being asked to pay the co-pay for the visits to infuse Bevacizumab/placebo, even though the informed consent document states "In the case that the costs of administering Bevacizumab/placebo are not covered by your health plan or insurance company, you will not be held personally responsible for covering these costs" and she had been previously told the costs of those visits in which she received an infusion were "written off and you will not be charged a co-pay for these types of visits going forward." We determined that the informed consent documents reviewed and approved by the IRB for this study failed to include an accurate description of any additional

costs to the subject that may result from participation in the research, as required by HHS regulations at 45 CFR 46.116(b)(3).

Corrective Action: We acknowledge that the informed consent document has been revised to clarify that subjects are responsible for all insurance co-payments and deductibles. This corrective action, and the corrective action described in your September 25, 2008 response adequately address the determination and are appropriate under your FWA.

At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

We appreciate the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina C. Borror, Ph.D.
Director
Division of Compliance Oversight

cc:

Ms. Sheila D. Whitt, Research Coordinator, Northern Virginia Pelvic Surgery Associates
Dr. Annette Bicher, Northern Virginia Pelvic Surgery Associates
Commissioner, FDA
Dr. Joanne Less, FDA
Dr. John E. Niederhuber, Director, National Cancer Institute
Dr. Maureen Kavanah, Chair, Adult NCI Central IRB
Ms. Jacquelyn Goldberg, IRB Administrator, NCI Central IRB
Dr. Sherry Mills, NIH
Mr. Joseph Ellis, NIH