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Ⅱ. プロトコル

プロトコル文書

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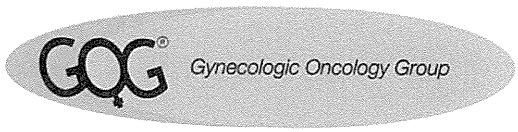

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TO: ALL PRINCIPAL INVESTIGATORS, NURSES AND DATA MANAGERS

FROM: KIA NEFF
PROTOCOL SECTION

DATE: SEPTEMBER 29, 2014

RE: PROTOCOL GOG-0213 – REVISION # 12

Protocol Title: "A PHASE III RANDOMIZED CONTROLLED CLINICAL TRIAL OF CARBOPLATIN AND PACLITAXEL (OR GEMCITABINE) ALONE OR IN COMBINATION WITH BEVACIZUMAB (NSC #704865, IND #113912) FOLLOWED BY BEVACIZUMAB AND SECONDARY CYTOREDUCTIVE SURGERY IN PLATINUM-SENSITIVE, RECURRENT OVARIAN, PERITONEAL PRIMARY AND FALLOPIAN TUBE CANCER. NCI-SUPPLIED AGENTS: BEVACIZUMAB (NSC #704865, IND #113912)"

NCI Version June 23, 2014

Study Chair: Robert L. Coleman, M.D., (713) 745-3357; email: rcoleman@mdanderson.org

IRB Review Recommendation:

( ) No review required
(X) Expedited review; however, site IRB requirements take precedence
( ) Full board review recommended because there have been changes to the Informed Consent and/or the risk information

*Although there is modified risk information for bevacizumab, CTEP has indicated that **the added risks are very similar to or associated with risks that were already included in the previous version of the CAEPR and would have been communicated to patients in the informed consent document (ICD)**. In this case, (1) watering eyes is associated with allergic rhinitis; (2) wound complication is a more general term and includes wound dehiscence; (3) dehydration is associated with other known AEs such as colitis, nausea, and vomiting; (4) infections, other (necrotizing fasciitis) is a specific type of infection, a previously identified risk; (5) an increase in frequency of neutrophil count decreased resulted in this risk being moved from less likely to likely, but this risk was previously identified; (6) an increase in frequency of platelet count decreased resulted in this risk being moved from reported but undetermined to less likely, but this risk is associated with bone marrow suppression which is already reflected in the increase in frequency of neutrophil count decreased.

When changes such as these are made to the ICD (i.e., changes as to how risk information is presented and/or additional clarifying information), it is not necessary to suspend enrollment of new subjects until a revised informed consent

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document is reviewed and approved by the Investigational Review Board (IRB). For this requested amendment, patient enrollment may continue before the IRB reviews and approves such changes to the informed consent; however, changes to the ICDs cannot be implemented until they are approved by the IRB. **Please note that there will be no Action Letter.**

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SUMMARY OF CHANGES

The following changes are being submitted in response to an RA from Dr. Helen Chen (Helen.chen@nih.gov):

For Protocol Revision #12 to:

NCI Protocol #: GOG-0213
Local Protocol #: GOG-0213

NCI Version Date: June 23, 2014
Protocol Date: June 23, 2014

#	Section	Page(s)	Change
1.	Title Page	1	NCT# 00565851 has been added. NCI version date has been updated. Includes Revisions #1-12. Lead Institution and Participation Organizations have been added. Heather Lankes has replaced Kathleen Darcy as Translational Research Scientist. Revised footer has been added.

	4.36	32-37	A Revised CAEPR (Version 2.3, August 1, 2013) has been inserted.
			• Added New Risk:
			  • Less Likely: Dehydration; Wound complication
			  • Rare But Serious: Infections and infestations – Other (necrotizing fasciitis)
			  • Also Reported on Bevacizumab Trials But With the Relationship to Bevacizumab Still Undetermined: Acidosis; Activated partial thromboplastin time prolonged; Agitation; Alopecia; Anxiety; Arachnoiditis; Arterial injury; Arthritis; Ascites; Ataxia; Atelectasis; Atrioventricular block complete; Atrioventricular block first degree; Back pain; Bladder spasm; Blood antidiuretic hormone abnormal; Blurred vision; Bone marrow hypocellular; Bone pain; Breast pain; Bruising; Burn; Carbon monoxide diffusing capacity decreased; Cardiac arrest; Cataract; CD4 lymphocytes decreased; Central nervous system necrosis; Cerebrospinal fluid leakage; Chelitis; Chest wall pain; Cholecystitis; Chronic kidney disease; Cognitive disturbance; Colonic stenosis; CPK increased; Cystitis noninfective; Death NOS; Depressed level of consciousness; Depression; Dermatitis radiation; Dry eye; Dry mouth; Dry skin; Dysesthesia; Dysphagia; Dysphasia; Ear and labyrinth disorders – Other (tympanic membrane perforation); Edema face; Edema limbs; Edema trunk; Electrocardiogram QT corrected interval prolonged; Encephalopathy; Enterocolitis; Erectile dysfunction; Esophageal pain; Esophageal stenosis; Extraocular muscle paresis; Extrapyramidal disorder; Eye disorders – Other (blindness); Eye disorders – Other (conjunctival hemorrhage); Eye disorders – Other (corneal epithelial defect); Eye disorders – Other (floaters); Eye disorders – Other (ischemic CRVO); Eye disorders – Other (macular pucker); Eye disorders – Other (transient increased IOP > or = 30 mm Hg); Eye disorders – Other (vitreous hemorrhage); Eye pain;