

Office of Research

Institutional Review Board

**MEMORANDUM**

To: Brigitte E. Miller, M.D.  
OB\_GYN - GYN Oncology

From: Chairman, Board #3  
Institutional Review Board

Date: April 20, 2005

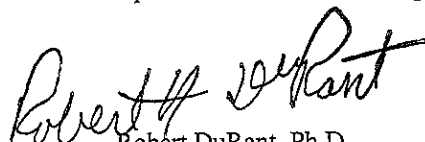
Subject: Human Protocol: BG04-267  
A Phase II Study of Single Agent Depsipeptide (FK228) in Recurrent Platinum Sensitive  
Adeno-Carcinoma of the Ovary or Peritoneum CCCWFU 83403 – Amendment #5

The Institutional Review Board voted approval of the amendments listed below at its meeting of April 20, 2005. This action of the full Board does not extend the term of approval for this protocol.

The amendment includes the following:

- Section 3.1.9: deletion of "> 4.0 mmol/L and a magnesium level > 2.0 mg.dl" and addition of "and a magnesium level within institutional normal limits."
- Subsequent cycles: deletion of "If alertin findings were noted...will be continued" and addition of "After the 1<sup>st</sup> cycle of Depsipeptide, even if dose changes occurred, cardiac monitoring will be at the treating physician's discretion."
- Section 4.2.2: "suggested guidelines; for patients with a serum potassium..." deleted and addition of "Potassium level must be > 4.0 mmol/L before Depsipeptide can be given...and adequate levels achieved prior to Depsipeptide administration."
- Section 6.1: addition of cardiac ischemia/infarction and infection with normal ANC or Grade 1 or 2 neutrophils.
- Section 6.2: addition of sinus bradycardia, ventricular tachycardia, cardiac troponin T, sudden death, nail changes, constipation, mucositis/stomatitis (functional/symptomatic), taste alteration, wound infection, pneumonia, limb edema, increased alkaline phosphatase, carnial neuropathy, depression, sensory neuropathy, blurred vision, cataract, headache, joint pain and muscle pain.
- Section 10.0-10.5: existing text and tabular information replaced with NCI-required information per new NCI adverse event reporting guidelines.
- "Within one week prior of administration of protocol therapy" changed to "within one week prior to registration."
- Administrative and editorial changes.

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.

  
Robert DuRant, Ph.D.

cc: Megan Whelen

*Wake Forest University Health Sciences*