

**Wake Forest University School of Medicine Institutional Review Board
Protocol Amendment Request Form**

Study Title: A Phase II Study of Single Agent Depsipeptide (FK228) in Recurrent, Platinum Sensitive Adeno-Carcinoma of the Ovary or Peritoneum

IRB Number: BG 04-267

Date of submission to IRB:

Principal Investigator: Brigitte Miller, MD

Name

SIGNATURE: _____

Protocol Amendment - Amendment # 5

CC: Megan Whelen, Protocol Info Office, PP2, Suite 401

Give a brief description of each change in the study protocol and rational (Additional pages may be used as needed):

1. Cover page: changed Dr. Mumber's institution name to "Harbin Clinic Radiation Oncology" and updated his email address to read "mmumber@harbinclinic.com"
2. Page iii: Changed "Responsible Research Nurse" to Laura Gilliam and updated contact information accordingly; changed Cissy Yates's fax number to 713-6476; Added "Amendment #5" to bottom of page
3. Page v, bottom of page: deleted mmol/L and mg/dL information for potassium and magnesium and added "within institutional normal limits"
4. Page viii, table of contents: renamed section 10.0 "Adverse Events: List and Reporting Requirements"; renamed section 10.1 "Comprehensive Adverse Events and Potential Risks List (CAEPR)"; deleted "X Expedited Reported Guidelines ... X Data Reporting" and added sections 10.2 through 10.6 to table of contents; updated page numbers throughout entire table of contents to reflect pagination of clean copy of protocol.
5. Page 10, section 3.1.9: deleted "> 4.0 mmol/L and a magnesium level > 2.0 mg.dl" and added "and a magnesium level within institutional normal limits"
6. Page 14, 1st paragraph under "Subsequent cycles": deleted text "If alertin findings were noted ... will be continued." and added text "After the 1st cycle of Depsipeptide, even if dose changes occurred, cardiac monitoring will be at the treating physician's discretion."
7. Page 14-15, section 4.2.2: Deleted text: "Suggested guidelines: For patients with a serum potassium ... supplemental infusions due to low levels." and added text: "Potassium level must be > 4.0 mmol/L before Depsipeptide can be given...and adequate levels achieved prior to Depsipeptide administration."
8. Page 19, section 6.2, 1st paragraph: added "cardiac ischemia/infarction" and "infection with normal ANC or Grade 1 or 2 neutrophils"
9. Page 19, section 6.2, 2nd paragraph: added following adverse events: sinus bradycardia, ventricular tachycardia, cardiac troponin T, sudden death, nail changes, constipation, nucositis/stomatitis (functional/symptomatic), taste alteration, wound infection, pneumonia, limb edema, increased alkaline phosphatase, cranial neuropathy, depression, sensory neuropathy, blurred vision, cataract, headache, joint pain, muscle pain
10. Page 26, section 8.0, table, last column: deleted "q 2 months" and added "(k)" beside "Off Study"; added new footnote "k" to end of table: "Every 2 months for 1 year ... until 5 years are completed."; "Physical exam" row through "Tumor measurements" row: replaced "X(e)" with "X(k)"; "Radiologic evaluation" row: added (k) beside "X(e)"; serum Ca125 row: added "X(e)" to last column
11. Page 31, section 10.0 through section 10.5: deleted all existing text and tabular information and replaced with NCI-required information per new NCI adverse event reporting guidelines (see attached copy of NCI template and adverse event reporting requirements); renumbered remaining sections accordingly (sections 10.6 and 10.7)
12. Page 26, paragraph before table, 1st line: changed "within 1 week prior to administration of protocol therapy" to "within 1 week prior to registration."

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Consent Form Changes

Give a brief description of each changes in the consent form and rational. Provide one copy of the consent form with the changes red lined and two clean copies of the revised consent form for IRB approval stamp.

1. None.
2.
3.
4.
5.

Amendment requests for approved protocols and consent forms may be submitted at any time. If only minor changes are requested, expedited review may be possible. Other amendments will be considered at a convened meeting of the full IRB.