

**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 # 3

CC: Megan Whelen, Protocol Information Office

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

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| 1. Page iii: changed "Protocol Version Date" to "NCI Version Date" and added "September 21, 2004"; added "September 2, 2004" beside "Activation Date"; added "09/22/04" beside "Amendment #2"; added "Amendment #3" |
| 2. Page v, 1 st line: deleted comma from "Patients, who have not received..." |
| 3. Page ix, added appendix N "NIH Form 986"; renamed Appendix M "VEG-F and Tissue Sample" |
| 4. Page 9, section 3.1.3, 2 nd paragraph, last line: added "prior to protocol entry."; added last paragraph: "Patients may not have received ... platinum compound and/or taxanes." |
| 5. Page 12, section 3.4. 13 th line: deleted ", PTT" |
| 6. Page 17, table 5.2: added last two rows "Troponin I*..." and "LVEF..." |
| 7. Page 19, section 6.2, 1 st paragraph, last line: changed "PTT, INR." to "PT/INR" |
| 8. Page 24, section 8, Study Calendar: changed all superscripts to the following format: (a), (b), (c), etc...; under "Off Study" column header in far-right column, added "q 2 months"; deleted superscript "d" beside "Urinalysis" on 16 th row; 15 th line of table: deleted ", PTT" from first column of table; 14 th and 15 th rows: added "X" in every column; 16 th row: added "X" in first column ("Pre-Study column"); rows 6 through 8 and 10 through 15, and row 18: added "(e)" beside each "X" in "Off Study" column; footnote b: added text "(Must include Mag++ level)"; footnote i: added text "(Additional EKG's per Toxicity Guidelines)" |
| 9. Page 32, section 10.2.3, 2 nd line: changed "(Appendix G), the Tumor Response Form (Appendix H) and Treatment Completion Form (Appendix I)" to "(Appendix G), and the Tumor Evaluation Form (Appendix H) ..."; 3 rd line: changed "after each treatment or" to "after each cycle or"; 4 th line: changed "submitted within 2 months" to "submitted within 2 weeks"; 5 th line: changed "examination was done. All forms will be sent to Rhonda..." to "examination. All forms will be sent to Rhonda..." |
| 10. Page 32, section 10.2.4, 3 rd line under 'Data Forms': deleted "Flow" and added "Addenda"; last line under 'Submission Schedule': changed "Within two weeks after exam" to "Within two weeks after follow-up exams" |
| 11. Appendix L "Cardiac Monitoring Guidelines": deleted entire appendix except for "A. Dose Modification in Case of Cardiac Toxicity" and accompanying table, and "ST Change / Degree of Change / Score" table. |

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.

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| 1. None. |
| 2. |

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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.