

**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 # 4

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. Cover page: changed Dr. Brigitte Miller's phone and fax numbers to 716-6673 and 716-4334, respectively   |
| 2. Page ii: added the following participating institutions w/ appropriate PI contact information: High Point Regional Hospital, Bay Area Tumor Institute, Hugh Chatham Memorial Hospital, Kentuckiana Cancer Institute, Danville Regional Medical Center                        |
| 3. Page iii: Deleted "Rhonda Kimball" beside 'Responsible Data Manager' and added "Cissy Yates"; updated contact information (phone, email, etc.) accordingly; added "January 4, 2005" beside 'NCI Version Date'; added "Amendment #4" to bottom of page                        |
| 4. Page iv, last line before "Eligibility Criteria" section: deleted "Day 1 before and after ... as outlined in Appendix L." and added "Day 1 EKG within ... administration of depsipeptide."   |
| 5. Page 13, section 4.1.3: added "within 1 hour" to 3 <sup>rd</sup> line  |
| 6. Page 14, section 4.2.2: added new paragraph to end of section "If patient requires ... administration of depsipeptide."  |
| 7. Page 21, section 7.2: added text "*Please contact Andrea Rice ... to enrolling patients."  |
| 8. Page 25, parameter table, footnote "i": deleted "EKG pre-study ... study C1D15." and added "EKG within 1 hour prior to administration of depsipeptide and immediately after treatment on C1D1. EKG within 1 hour prior to administration of depsipeptide on C1D8 and C1D15." |

**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.       |
| 3.       |
| 4.       |
| 5.       |

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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.