

**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:** BG04-267

**Date of submission to IRB:**

**Principal Investigator:** Brigitte Miller, MD

Name

**SIGNATURE:** \_\_\_\_\_

**Protocol Amendment** - Amendment #6

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. Page i: Added "Attn: Debby Cherry, RN" to Goldsboro site information;
2. Page ii: added Holston Valley Hospital site information; changed Dr. Sharp's email address from [sasharo@gamewood.net](mailto:sasharo@gamewood.net) to [sasharp@gamewood.net](mailto:sasharp@gamewood.net); changed Gina Enevold's fax number to 716-6275
3. Page iii: deleted all previous NCI version dates and added "May 20, 2005"; added "Amendment #6" to bottom of page; changed "Responsible Research Nurse" to "Robin Rosdhal" and updated contact information accordingly
4. Page v, last arrow, 6<sup>th</sup> bullet: changed Creatinine parameters to " $\leq 1.5$  x institutional upper limit of normal"
5. Page vi, second bullet from end: combined bullets two and three and deleted sentence "Pregnant women ... or abortifacient effects."
6. Page 10, section 3.1.8: changed Creatinine parameters to " $\leq 1.5$  x institutional upper limit of normal"; combined sections 3.1.11 and 3.1.12 and deleted sentence "Pregnant women ... abortifacient effects."; renumbered remaining section accordingly
7. Page 11, section 3.2.9: deleted text "Pregnant women are excluded ... treated with depsipeptide." And renumbered remaining sections accordingly.
8. Page 13, section 3.5: deleted first paragraph and added text: "All patients entered on a CCCWFU trial ... Monday through Friday."
9. Page 14, section 4.1.3: added "within 1 hour" to line two
10. Page 15, section 4.2.2, third line line: changed "> 4.0 mmol/L" to " $\geq 4.0$  mmol/L"; fifth line, changed "> 4.0 mmol/L" to " $\geq 4.0$  mmol/L"; 8<sup>th</sup> line: changed ">2.0 mg/dl" to " $\geq 2.0$  mg/dl"; 10<sup>th</sup> line: changed ">2.0" to " $\geq 2.0$ "; paragraph following last bullet: added "during course 1"
11. Page 17, table 5.1.1, Creatinine section, middle column, second line: changed "< 1.5 x ULN" to " $\leq 1.5$  x ULN"
12. Page 26, Study Calendar table: added new row for "Phosphorus" and placed X's in columns for Pre-study, Wk1, Wk5, and Wk9; added new row for "LDH" and placed X in Pre-study column; added new row for "Magnesium" and placed X in all columns; "Physical exam" row: removed X in Wk3, Wk7, and Wk11 columns; "Vital signs" row: added X to Wk2, Wk6, and Wk10 columns; "Weight" row: added X to Wk2, Wk6, and Wk10 columns; "Performance status" row: removed X in Wk3, Wk7, and Wk11 columns; "B-HCG" row: removed "(e)" footnote beside X in "Pre-Study" column; end of table, footnote (b): deleted "(Must include Mag++ level)."; footnote (c): deleted existing text and added "Serum Creatinine  $\leq 1.5$  x institutional normal limits or Creatinine clearance  $\geq 60$  ml/min/1.73 m<sup>2</sup> for patients with Creatinine levels > 1.5 x institutional normal."; footnote (h): added "(more frequently per doctor's discretion)"
13. Page 34, deleted section 10.3.2 "AdEERS is programmed ... other e-mail recipients." per NCI recommendation; renumbered remaining sections accordingly.
14. Page 36, section 10.4.1.2: deleted existing text and added "Online Registration Header" and accompanying text "The registration forms will be faxed ... 336-713-6476."
15. Page 36, section 10.4.1.3, last line: changed number to read "713-6476"

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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.

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| 1. Page header: Changed “2005 Annual Renewal Version” to “Amendment 6 version”; added “Renewal w/ updates 06/06/05”  |
| 2. Page 6, under section “What About Confidentiality?”: deleted “Efforts will be made ... Fujisawa pharmaceuticals.” And added text “By taking part in this research study ... research study records until the end of the study.”                                 |
| 3. Page 8, under section “Who is Sponsoring the Study?”: removed Gloucester Pharmaceuticals and modified the first sentence to read “This study is being sponsored by the National Cancer Institute and Wake Forest University Research Base.”                     |
| 4. Page 9: deleted first paragraph “Should you experience ... 716-3467.” And added new paragraph “Should you experience ... 716-3467.” This change was made to reflect the change in WFU insurance company (from Steadfast to Endurance Specialty Insurance, Ltd.) |
| 5. Page 9: added new section “Information Regarding the Storage of your Tissue Samples”.   |
| 6. Pages 9 and 10: removed blank spaces for local physician’s name and hospital name; Page 9, second paragraph: “Changed last two lines to read “...illness, adverse event, or injury you should contact the study investigator, Brigitte Miller MD...”            |
| 7.   |

Amendment requests for approved protocols and consent forms may be submitted at any time. All amendments must be reviewed at a convened meeting by Full Board review.
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