

Office of Research
Institutional Review Board

MEMORANDUM

To: Brigitte E. Miller, M.D.
OB_GYN - GYN Oncology

From: Chairman, Board #4
Institutional Review Board

Date: July 27, 2005

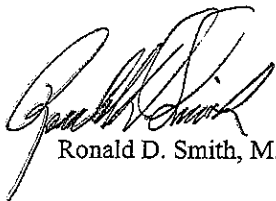
Subject: Human Protocol: BG04-267
A Phase II Study of Single Agent Depsipeptide (FK228) in Recurrent Platinum Sensitive
Adeno-Carcinoma of the Ovary or Peritoneum CCCWFU 83403 – Amendment #6

The Institutional Review Board voted approval of the amendments listed below at its meeting of July 27, 2005. This action of the full Board does not extend the term of approval for this protocol.

The amendment includes the following:

- Creatinine parameters changed to " ≤ 1.5 x institutional upper limit of normal."
- Section 3.1.11 and 3.1.12 combined and deletion of "Pregnant women...abortifacient effects."
- Section 3.2.9; deletion of "Pregnant women are excluded...treated with depsipeptide."
- Section 4.1.3; added "within 1 hour" to line two.
- Section 4.2.2: ">4.0 mmol/L" changed to " ≥ 4.0 mmol/L;" and ">2.0 mg/dl" changed to " ≥ 2.0 mg/dl."
- Study Calendar table updated.
- Administrative, editorial and clarifying changes.
- Consent form revised to reflect change of insurance carrier to "Endurance Specialty Insurance Ltd."

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.



Ronald D. Smith, M.D.

cc: Megan Whelen