DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
900 Madison Avenue Baltimore, MD 21201 410-962-3396	7/17,18,19,20,24, 8/3,16, 9/7/01
	FEI NUMBER 1120913

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: CHI VAN DANG, M.D. Ph.D. Vice Dean for Research

FIRM NAME	STREET ADDRESS
Johns Hopkins School of Medicine, IRB	720 Rutland Avenue, Suite 36
CITY, STATE AND ZIP CODE Baltimore, MD 21205	TYPE OF ESTABLISHMENT INSPECTED Institutional Review Committee

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

1. Failure to prepare and maintain adequate documentation of minutes for fully convened IRB meetings in sufficient detail for six (6) out of 21 meetings, occurring on 1/9/00, 1/23/00, 2/13/00, 3/13/00, 3/27/00, and 4/10/00.

2. Failure to prepare and maintain adequate documentation of IRB minutes in sufficient detail to determine if an IRB member, who had a conflicting interest in a project, participated in the initial review or voting for his project. For example, RPN #00-11-07-02 was approved by the fully convened IRB on 12/12/00. A co-investigator in that study, who was also an IRB member, was documented as being present at this meeting. There was no indication that this member did not participate in the initial review or voting.

3. Failure to follow written procedures for conducting the initial review of research. IRB guideline "IV. A. Full Board/Committee Review," provides that the protocol application packet, including the proposed consent document, will be distributed to all IRB members for review and comment. The procedure then requires that "significant issues, comments or questions" regarding the protocols be sent to the subcommittee and then forwarded to the investigator in writing for a response, prior to the fully convened IRB meeting. Some, but not all, comments or questions were forwarded to the investigator. For example:

   A. Study RPN #00-11-07-02

   (1) One (1) IRB member questioned in writing about the "sample size reasoning/calculation." This same IRB member commented in writing about including children in the study given the low risk of [redacted] There was no documentation to show that these concerns were sent to the clinical investigator in writing for a response.

   B. Study RPN #99-03-19-07

   (1) One (1) IRB member questioned in writing, "why start this study before the results of GOG [Gynecologic Oncology Group] #157 [another trial using different cycles of the study drug] are known?" There was no documentation to show that this concern was sent to the clinical investigator in writing for a response.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	J. Diann Shaffer Gerald W. Miller	J. Diann Shaffer, Investigator Gerald W. Miller, Compliance Officer	9/7/01

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: CHI VAN DANG, M.D., PH.D., VICE DEAN FOR RESEARCH

FIRM NAME	STREET ADDRESS
Johns Hopkins School of Medicine, IRB	720 Rutland Avenue, Suite 36
CITY, STATE AND ZIP CODE Baltimore, MD 21205	TYPE OF ESTABLISHMENT INSPECTED Institutional Review Committee

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

4. Failure to review research at fully convened IRB meetings at which a majority of IRB members are present, in that reviews are conducted by individual IRB members and/or in subcommittees at which only a minority of the IRB membership is present. Multiple studies, approved by the subcommittee, are approved by block vote at fully convened meetings of the IRB. The meeting minutes do not always document that the IRB discussed, considered, or determined whether the various issues, comments and questions raised by individual members were addressed or resolved. For example,

   A. Study RPN #00-11-07-02

   (1) On 11/10/00, one (1) IRB member documented that the "language could be simplified in the risk section." At the final subcommittee meeting on 12/11/00, the Pharmacy and Therapeutics Committee (P&TC) member documented that although the proposed consent document was changed, it was still too technical and not in lay terms, especially regarding risks. When the IRB convened on 12/12/00, it approved 26 protocols by a single block vote, but only (3) of these protocols were discussed. The P&TC member was not present, this protocol was not discussed, and there was no documentation in the written minutes or in the audio tapes to show that this issue was resolved.

5. Failure to require that information given to subjects as part of the informed consent minimizes the possibility of undue influence. the consent document emphasized the expensive nature of test articles provided to the subject(s) at no cost. For example: AI/AM CD

   On 4/14/98, the fully convened IRB reviewed and approved the consent form for RPN# 97-02-03-04. The consent form provided under "Benefits" that "you will receive treatment with an [redacted] which will be provided at no cost to you or your insurer (standard cost $[redacted] or [redacted] which is also expensive."

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	J. Shaffer Gerald W. Miller	J. Diann Shaffer, Investigator Gerald W. Miller, Compliance Officer	9/7/01