



UNIVERSITY OF MARYLAND
SCHOOL OF PHARMACY

MEMO

TO: Bruce Jarrell, MD
Vice Dean for Research, UMB SOM

FROM: Magaly Rodriguez de Bittner, PharmD
Chair, Pharmacy Practice and Science Department

DATE: July 17, 2008

RE: **PPS PROCEDURE FOR INTERNAL SCIENTIFIC REVIEW**

All projects involving human subjects' research at UMB must undergo internal scientific review (ISR) prior to IRB submission, in accordance with UMB Research policies.

The procedure for ISR within the PPS Department will be carried out as follows:

1. The Department Chair serves as the Signature Authority (SA) for the PPS Department. The Department Chair has designated the Vice-Chair of Research and Scholarship (VCRS), Dr. Thomas Dowling, to conduct PPS Departmental ISR. Dr. Dowling has over 12 years experience with the design and conduct of clinical trials and has previously served a 3-year term as a regular IRB member at UMB. Both the SA and VCRS must have reviewer access to all PPS protocols.
2. The ISR will be conducted in accordance with Good Clinical Practice guidelines, and will address each of the following items related to the protocol, including but not limited to:
 - Is the research question meritorious?
 - Is the study design sound/valid?
 - Is the study design able to answer the proposed questions and is it likely to result in significant new information for the field?
 - Is the sample size adequate to answer the major scientific questions in the project?
 - Have all potential risks been identified?
 - Does the protocol incorporate all possible mechanisms for reducing risks?
 - Are there adequate resources (i.e., adequate number of qualified staff, adequate facilities, availability of medical or psychological resources that participants may need as a consequence of the research, and adequate access to patients/participants) to carry out the study and ensure the safety and welfare of all participants?
 - Are all investigators aware of their individual responsibilities with respect to this

study?

- Does the principal investigator have adequate time and expertise to supervise the study appropriately?
- Have the financial implications of the research been considered and deemed acceptable to the department?
- Have ethical principles AND CONFLICT OF INTEREST ISSUES been appropriately addressed?
- Confirmation that the protocol has been reviewed and approved at the unit level for scientific value, validity of study design, and feasibility.

3. The VCRS will forward recommendations to the Department Chair (SA) for consideration as follows:

- A. Approve – Can be submitted to IRB in current form.
- B. Contingent – Requires modification by PI, and may require second ISR.
- C. Deferred – Requires meeting between VCRS, Department Chair and Principal Investigator to discuss weakness of project and develop a contingency plan.

4. The PI will follow-up with VCRS and Department Chair regarding status of IRB review, and appropriate actions will be taken based on the changes made by the PI.