THE REPORT OF THE PROJECT REVIEW PANEL

(Please type)
Name of Principle Investigator: _____

Title of Project:_____

1. Type of Proposal or Activity
   ( ) New
   ( ) Renewal - Date of Last IRB Approval:
   Renewal is required every 12 months. Should there be changes to the protocol before expiration of the 12 month period, an amendment should be required.

2. Indicate concurrence or non-concurrence with the human subjects protocol prepared by the investigator:
   ( ) Concur
   ( ) Non-concur If non-concur, explain reasons in an addendum.

3. Date of Project Review Panel approval of the project :_____

4. Did the full Project Review Panel meet personally in a face-to-face conference with the principal investigator of this project?
   Yes___ Date of meeting :_____
   No ___ If no, why not?
   It is a requirement of the IRB that the Panel members meet face-to-face with the investigator. Although the IRB may waive this requirement under certain circumstances, the investigator risks deferral of his protocol for failure to meet personally with the panel.

5. If the research is to involve children (defined as persons under age 19) please answer the following questions, otherwise skip to question 6.
   For research involving children, please indicate into which of the following four categories you would recommend that the proposed research be placed:

____ Research not involving greater than minimal risk. Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
   Research in this category requires both assent of the child and permission of at least one parent or guardian.

____ Research involving greater than minimal risk but of possible direct benefit to the child, in which the risk is at least as favorable to the subject as that presented by available alternative approaches. This requires both the assent of the child and permission of at least one parent or guardian.

____ Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the disorder or condition, in which the risk is minor relative to the potential improvement in knowledge to be applied to general understanding. Permission must be obtained from both parents unless there is only one reasonably available parent. Guardian consent should be substituted for parental under appropriate legal constraints.

____ Research not meeting the specifications above, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children. This category is considered so serious that it must be submitted to a ruling by the secretary of DHHS following consultation with an appropriate panel of experts. Permission must be obtained from both parents unless there is only one reasonably available parent. Guardian consent should be substituted for parental under appropriate legal constraints.

6. Will human subjects be at greater than minimal risk? Minimal risk means that the risks of harm anticipated in the proposed research are not ordinarily encountered in daily life or during the performance of routine, physical or psychological examinations or tests.

_____ Yes If yes, answer the following questions
_____ No If no, skip to number 7

A. Are the risks to the subject so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept those risks?

Yes ___ No __

B. Will the rights and welfare of any subjects be adequately protected?
Yes ___ No __

C. Will the proposal be acceptable in terms of:
Organizational commitments and regulations?
Yes___ No___
Standards of professional conduct and practice?
Yes___ No___
Community attitudes?
Yes___ No___

D. Comment on the risk-benefit ratio regarding human subjects.

E. What benefits, if any, may accrue to the public at large?

7. Will effective informed consent be obtained by adequate and appropriate means?
Yes___ No___

8. Does the consent form for this project include the basic elements as required by the IRB?
Yes___ No___

9. Is adequate provision made to preserve subject confidentiality?

Yes___ No___

10. If this project is a renewal or a continuing application, indicate any changes proposed.

11. What is the significance of the project?

12. Does the Panel have any recommendations for the investigator relative to human use?

Please type panel member's names and provide signatures.

1. _____ Physician's Signature

2. _____ Physician's Signature

3. _____ EAMC Pharmacist's Signature

4. _____ EAMC Vice-President's Signature

5. _____ IRB Chairperson's Signature

DATE: