Institutional Review Board End-of-Year Report to Faculty Senate April 27, 1999

The Institutional Review Board (IRB) entered the 1998-1999 academic year charged with 1) Monitoring protocols and maintaining records for research involving human subjects. 2) Establishing and maintaining a presence on the World Wide Web. 3) Implementing the policy concerning the ethical care and use of animals in research and discuss the need for further intervention on the part of the Institutional Review Board.

This report will summarize the routine activities of the IRB as well as the board's progress in meeting each of these charges.

Routine Activities

As a Standing Committee, the IRB is responsible for monitoring research protocols, maintaining and managing records and drafting and considering policy for issues related to the protection of human subjects. The board evaluated and formally approved 20 new protocols and granted a renewal of one protocol during the 1998-1999 academic year. Individual department designates reported that they approved an additional 62 protocols which met the criteria for either exempt or expedited status according to the IRB Guidelines. Information regarding the approval of all protocols reviewed by the full board is kept on file in the Office of the Associate Deans. Information regarding protocols that were reviewed and approved by departmental designates is housed in the respective department offices.

Charge #1: Monitor protocols and maintain and manage records for research involving human subjects.

As the summary of routine activities above indicates, the IRB continues to receive and review protocols from both faculty and students in several departments. All protocols requiring full board review are reviewed by board members individually prior to meeting as a group. The board then discusses the protocols and comes to consensus as to whether the researchers have taken adequate measures to protect human subjects.

In instances where the board has questions or concerns, the board contacts the researcher(s) and asks for clarification or additional information before making a determination. Often, protocols are approved with modifications suggested by the board. The modifications are typically intended to clarify issues related to the protection of human subjects in the project description or the wording of the Consent Form. Written feedback is given to the researchers who must then revise and re-submit the protocols with evidence that the appropriate modifications have been made.

Charge #2: Establish and maintain a presence on the World Wide Web

The IRB established a presence on the World Wide Web in the Summer of 1998 (www.ups.edu/dean/irb/). At that time, the page consisted of the revised IRB Guidelines document with various forms for protocol preparation that could be downloaded and the IRB's Policy on the Ethical Care and Use of Animals which was adopted in the Spring of 1998.

During the Fall of 1998 and Spring of 1999 the contents of the Web Page was expanded to include links to the National Institutes of Health Office of Extra mural Research as well as some other on-line resources that the board believed might be useful to faculty or students interested in doing research. In addition, the page now also includes more information about the activities of the IRB on campus such as a roster of current board members and department designates, IRB meeting schedules and minutes, a list of frequently asked questions and an evolving list of resources regarding ethical issues in the conduct of research which the board has obtained for the University.

Based on the informal feedback that we have received, members of the university community are using the information posted on the Web Page to answer questions that they have concerning the function of the IRB as well as the guidelines for protocol preparation. The board is pleased that the Web Page has increased visibility of the IRB on campus and that it appears to be a useful resource.

Charge #3: Implement a policy concerning the ethical care and use of animals in research and discuss the need for further intervention on the part of the Institutional Review Board

The policy regarding the Ethical Care and Use of Animals which was adopted in the Spring of 1998 has been in place for a full year. (The policy is posted on the IRB Web Page.) The IRB is not aware of any instances in which student or faculty researchers have chosen to engage in animal research during this academic year. Given the apparent lack of individuals doing animal research on campus, the board has not discussed the need for further intervention.

Goals/Agenda Items for AY 1999-2000

Based on the progress made in addressing the charges given by the Faculty Senate this year, the Institutional Review Board has identified the following goals for the next academic year.

- 1) Continue to monitor protocols and maintain and manage records for research involving human subjects.
- 2) Seek out and obtain appropriate resource materials for the university regarding issues related to research involving humans.
- 3) Continue to maintain a presence on the World Wide Web by updating and enhancing the information contained on the IRB Web Page.

Respectfully submitted,

Ann M. Wilson Chair Institutional Review Board