

Faculty Senate Agenda Item

Number: **09-14**

SUBJECT: Change to Appendix IV (Human Subjects Research Policy) of the Faculty Handbook.

DESCRIPTION: The Institutional Review Board (IRB) is a committee established according to federal regulations and charged with the protection of human research subjects. The purpose of an IRB review is to assure that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. All research involving human participants conducted by Washburn University students, faculty, and staff must be reviewed and approved prior to the initiation of research.

Between 2001 and 2005, the IRB received and reviewed an annual average of 53 applications. In 2006, 2007, and 2008, the IRB received 98, 113, and 107 applications, respectively, with approximately 93% of the applications being reviewed during the Fall and Spring semesters. The amount of work is burdensome for everyone including the external reviewer (an individual with no affiliations with Washburn University). In response to the increased number of submissions, it is requested that the size of the IRB be increased. Increasing the number of IRB members would result in a decrease in member workload. Increasing IRB membership will also provide researchers with additional sources of information about the IRB process and policies.

In the Fall of 2008, the IRB moved to an electronic submission and review process. Using the Washburn University email system, IRB applications were submitted and distributed for review. This move was expected to make the application and review process easier for applicants and reviewers. It was also expected to decrease the amount of time needed to review applications.

Increasing the membership of the IRB and the acceptance of electronic submissions of IRB applications requires modification of certain sections of Appendix IV (Human Subjects Research Policy) of the Faculty Handbook (see attachment).

Finally, according to the Faculty Handbook (IV.D.2.d.), IRB membership is term limited. The ability to accurately review an IRB application requires extensive experience. For this reason, it is requested that this section be deleted.

FINANCIAL IMPLICATIONS: None.

RECOMMENDATION: It is requested that Faculty Senate approve the following modifications of Appendix IV of the Faculty Handbook.

Appendix IV: Human Subject Research Policy

D. Institutional Review Board (IRB); Establishment and Membership

1. The Institutional Review Board shall consist of at least seven appointed members. The President and VPAA ~~Provost~~ will serve as ex officio members.
2. Membership
 - c. Membership shall include the following:

1. **At least one** member shall be appointed from each of the five major academic areas. **The number of members from one academic area may not vary by more than one from any other area.**
2. **At least one** member shall be appointed who is not affiliated with the University, nor is related to anyone affiliated with the University.
3. **At least one** member shall be appointed who is a full-time upper-division or graduate student with a 3.0 grade point average or better.
- d. ~~Members shall serve for a term of two (2) years; except for three initial appointees to the Board who shall have one (1) year appointments so that membership will be staggered.~~

F. Institutional Review Board; Reports and Documentation

The Institutional Review Board shall prepare and maintain adequate documentation of its activities including:

2. ~~Minutes of IRB meetings reflecting attendance at the meetings;~~ **Records (written or electronic) of** actions taken; the vote on actions approving or disapproving research proposals, including the number of members voting for, against, and abstaining; the basis for requiring changes in, or disapproving, research; and a ~~written summary~~ **record** of the discussion of controversial issues and a resolution;

H. IRB Review of Application and Approval

2. Normal review process.

~~The IRB meets the first Monday of each month. The Investigator is to submit nine (9) **hard** copies **or one (1) electronic copy** of the application to the Chairperson of the IRB. Proposals should be sent to the IRB two (2) weeks before the regular monthly meeting for review. Proposals received less than two weeks before a regular meeting may be subject to delay, however, every effort will be made to accommodate the Investigator.~~ The application will be assigned a number, recorded and distributed to IRB members for review. The application will be evaluated, recorded and an "IRB PROPOSAL EVALUATION" form will be returned to the Principle Investigator or the Faculty Supervisor. The IRB keeps the original application on file along with a copy of the IRB PROPOSAL EVALUATION.

3. Expedited review process.

If the Investigator requests an expedited review, he/she must submit three (3) **hard** copies **or one (1) electronic copy** of the application. The Chairperson of the IRB and one other committee member will make the evaluation and return the IRB PROPOSAL EVALUATION. If either one or both decide that the proposal requires full committee review then the Investigator is notified with a request for six (6) more **hard** copies of the proposal (**assuming hard copies of the application were originally submitted**) and it will follow the normal review procedure.

Originated by: Mike Russell, IRB Chair

Date: October 12, 2009