VII. STANDING COMMITTEES

A. Academic and Student Affairs Committee

Amending the Board of Regents Governance, Standing Orders, Chapter 6, "Policy on Assistance for Human Subjects"

RECOMMENDED ACTION

It is the recommendation of the administration and the Academic and Student Affairs Committee that the Board of Regents approve the amendment of the *Board of Regents Governance*, Standing Orders, Chapter 6, "Policy on Assistance for Human Subjects."

BACKGROUND

The existing Standing Order was written in 1980. The purpose of the proposed modification is to provide a clear delegation from the Board of Regents to the President to establish terms and conditions of this no-fault program which are consistent with both applicable regulations and with the operating needs of the institution. The modification also aligns the content of the standing order to be consistent with other standing orders, by focusing on policy and delegation of authority rather than operations.

The University's human subjects assistance program, created in 1972, is widely respected as the premier model for such programs and has garnered recognition from the National Institutes of Health and the Presidential Commission for the Study of Bioethical Issues. Over the past forty years, payments made by the University have been quite modest, averaging $1,200 per claim for the 32 claims received. In addition, the University has provided free medical care to subjects in 95 cases, only 9 of which resulted in fee waivers of $50,000 or more. The program has been very valuable, however, both in providing some comfort and encouragement to those who volunteer as subjects and in underscoring the University's fundamental commitment to the well-being and ethical treatment of these individuals, who make such an important contribution to society.

While the University continues to value our voluntary research subjects, it is necessary to update the program due to changes in the regulatory environment, insurance coverage, the University's healthcare operations, and the University's growing emphasis on conducting research with partners outside the institution.

It is reasonable to assume that continued developments in the research environment will require additional updates to the program over time, hence the need for a clear delegation of authority to the President.

VII. STANDING COMMITTEES

A. Academic and Student Affairs Committee

Amending the Board of Regents Governance, Standing Orders, Chapter 6, "Policy on Assistance for Human Subjects" (continued p. 2)

REVIEW AND APPROVAL

The proposed amendment of Chapter 6 has been approved by the University President, the Vice Provost for Research, the Executive Director of Risk Management, and endorsed by UW Medicine and the Human Subjects Division.

Attachments

1. Proposed Board of Regents Governance, Standing Orders, Chapter 6, "Policy on Assistance for Human Subjects"
2. Current Board of Regents Governance, Standing Orders, Chapter 6, "Policy on Compensation for Adverse Effects to Human Subjects"

Policy on Assistance for Human Subjects

The University of Washington respects and values the volunteer human subjects who participate in University research, and recognizes that subjects may assume some risk by participating in research.

Consistent with the University's research mission, the University is authorized to maintain a no-fault human subjects assistance program to provide medical and other assistance to human subjects who, in the course of University-conducted research, suffer adverse effects. The terms and conditions of such a program will be determined by the President or the President's designee.

BR, June 1980; June 13, 2013.

Policy on Compensation for Adverse Effects to Human Subjects

1. Application of Program

The University's adverse effects compensation program is intended to apply to projects carried out by University personnel and under University sponsorship. To be covered, the project must also be one which has been approved in writing by the University's Human Subjects Review Committee. The program applies only to adverse effects resulting from the study procedure itself.

2. Scope of Compensation

Compensation under the program is intended to be on a "no-fault" basis (i.e., the claimant need not demonstrate University fault or negligence), and is designed as a substitute for the traditional tort system. It is voluntary from the viewpoint of the claimant, who must agree to give up his or her right to pursue a traditional tort action in order to receive the benefits provided under the program. The benefits to be provided are as follows:

A. All medical expenses immediately and directly associated with the adverse effect, up to a maximum of $10,000.

B. Such additional expenses or compensation as may be agreed to by the parties. If the claimant is unwilling to give up his or her right to sue, then the matter will be handled as a traditional tort claim and will be settled or defended on that basis.

3. Claim Procedure

If an investigator believes an adverse effect has occurred, the investigator shall immediately prepare a report summarizing the background, nature and result of the adverse effect. The report shall be submitted to the Human Subjects Office and the Office of Risk Management, who may consult with representatives of the Attorney General's Division and the Human Subjects Review Committee which reviewed the project involved, in making a determination as to the applicability of the compensation program. If the situation is one for which compensation is appropriate, the Office of Risk Management will arrange for paying the applicable benefits and securing a release from the subject.

If a subject believes an adverse effect has occurred, the subject may independently prepare a report containing the information mentioned above to be submitted to the Human Subjects Office and Office of Risk Management, and a determination as to applicability of the compensation program will be made. If compensation is appropriate, it will be arranged as described above; if it is not, the subject will be so notified. Any such report must be submitted within one year of the occurrence of the adverse effect.

BR, June 1980.

ATTACHMENT 2