March 8, 2002

To: Dean Paul Ramsey
    Associate Dean Albert Berger
    Dean Sid Nelson
    Acting Dean James Steiner
    Associate Dean Timothy DeRouen
    Dean Nancy Woods
    Associate Dean Pamela Mitchell
    Dean Patricia Wahl
    Associate Dean David Eaton
    Dean Dorothy Van Soest
    Dean David Hodge
    Divisional Dean Julie Stein
    Divisional Dean Susan Jeffords
    Divisional Dean Craig Hogan
    Dean Patricia Wasley

Re: Alvin L. Kwiram
    Vice Provost for Research

Re: Policy Prohibiting Use of Enrollment Incentives in Human Subjects Research

The use of enrollment incentives in research involving human subjects in general and in clinical trials in particular has become increasingly problematic in recent years. We are not referring to reasonable payments made to subjects for their participation in research or to the actual costs researchers incur in enrolling subjects. The concern is with practices in which sponsors provide payments, gifts, or other benefits that go beyond the actual costs, of enrolling subjects, incurred by the researchers. These often take the form of extra-contractual payments made directly to researchers and their staff.

Enrollment incentives were banned in clinical trials in the University of Washington School of Medicine starting in December 1999. After consultation with the Human Subjects Division, the UW Conflict of Financial Interest Advisory Committee and other groups, we are now promulgating the attached policy for use with human subjects research of all types at the University of Washington.

c: Lee Huntsman
    Helen McGough
    Carol Zwiches
    Malcolm Parks
    Patricia Kuszler
Policy Prohibiting Use of Enrollment Incentives in Human Subjects Research

The use of special enrollment incentives in research involving human subjects creates an unacceptable potential for conflicts of interest. We are not referring to reasonable payments made to subjects for their participation in research or to the actual costs researchers incur when enrolling subjects. We are referring to the use of special incentives, bonuses or other similar forms of compensation provided to institutions or investigators as a mechanism for enrolling subjects in research, including clinical trials. Such incentives create conflicts of interest. They may have an adverse effect on human subjects because they may erode the informed consent process and increase the likelihood that ineligible persons are enrolled as subjects in the research. Some enrollment incentives may also be contrary to Washington’s Ethics in Public Service Act, RCW Chapter 42.52.

It is the University of Washington’s policy that it will not participate in any human subjects research involving use of enrollment incentives and that neither the University, its investigators, its collaborators, its intermediaries, nor its subcontractors shall accept enrollment incentives in connection with human subjects research.

For purposes of this policy, the following definitions shall apply:

“Clinical trial” means human subjects research whose purpose is to assess the safety or efficacy of drugs, devices, diagnostics, treatments, or preventive measures.

“Enrollment incentive” means any form of direct or indirect inducement offered or received in exchange for enrolling subjects in human subjects research: (i) that is paid as reimbursement in excess of the reasonable cost of utilizing human subjects, or (ii) that is paid extra-contractually, including any bonus, reward, award, grant, gift, benefit, or other quid pro quo, or (iii) that creates a financial incentive that the University determines is contrary to the best interests of human subjects participating in the research.

“Human subjects research” means a systematic investigation designed to develop or contribute to generalizable knowledge that utilizes humans as research subjects and includes clinical trials.

The following is a non-exclusive list of examples that are not permitted in human subjects research under the foregoing policy:

- Entering into a human subjects research agreement that contains an enrollment incentive provision.
- Acceptance of or a request for an enrollment incentive by the University, its investigators, or subcontractors.
- Fees that exceed the actual costs of recruiting human subjects.
• Excessively high fees paid to subjects in exchange for participating in human subjects research.

• Bonuses, milestones, or similar forms of additional payments for timely, early, or over-enrollment of human subjects, for retention of human subjects, or for timely or early IRB approval.

• Use of per subject payment rates that vary based only upon the number of human subjects enrolled, including increased per subject rates paid for over-enrollment of subjects.

• Extra-contractual benefits such as unrestricted research gifts, medical or office equipment, authorship rights, journal subscriptions, educational stipends, payment of conference fees, software, personal gifts, favors, or similar inducements provided in exchange for enrolling human subjects.

• Payment of referral or finder’s fees in exchange for the referral by a professional of the professional’s patients or clients as potential subjects in human subjects research.

• Obtaining human subjects through recruitment firms or persons whose practices are not consistent with this policy.