UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN SUBJECTS PROGRAM
FACT SHEET

Human Subjects Literature Monitoring Program

Background

The UCSD Human Subjects program is responsible for ensuring that all research involving human subjects is conducted in an ethical manner, and complies with federal regulations and University policies which protect the rights of research subjects. Research involving human subjects must be reviewed and approved by one of UCSD's Institutional Review Boards (IRBs) if it is conducted by or under the direction of any employee or agent of UCSD or using any property or facility of UCSD.

Current events and those of the recent past involving UCSD faculty investigators have demonstrated poignantly that noncompliance with human subjects regulations has institutional effects which can be dramatically disproportionate. An FDA audit triggered by a single adverse event on a single clinical trial in 1994 caused a federally-imposed temporary suspension of all UCSD human subjects research, affecting the research activities of over 400 UCSD faculty investigators. Recent events also suggest that failure to have human subjects research reviewed and approved by an IRB, and failure to adequately document the informed consent of human subjects may generate legal liabilities to the University.

During an external audit commissioned by UCSD in 1995, a key finding was UCSD's inability to assure that all human subjects research was being reviewed by an Institutional Review Board. Although the Human Subjects Office offers individualized assistance to help faculty, staff and students understand and comply with human subjects regulations, its services require the initiation of contact by the investigator.

The literature monitoring program

As part of the response to the external audit report, the UCSD Human Subjects Program, in consultation with the chairs of the UCSD IRBs, UCSD Internal Audit, and the Chancellor's office, proposed a program of computer-assisted literature monitoring. This program was incorporated into the UCSD management response to the audit report and implemented beginning in February, 1996.

The program works as follows. A broad search profile of the Melvyl Medline database is stored on the UC Library Automation computer system. This profile automatically retrieves the titles, authors, and abstracts of all newly-entered literature citations indexed by the Medical Subject Heading "Human" and originating from UCSD.

Human subjects research is identified by abstracts which contain phrases such as "A cohort of *nn* experimental subjects..." or "*nn* consecutive patients with [disorder x]". These literature citations are analyzed by a computer algorithm which assigns a similarity score to a citation and related project descriptions contained in the Human Subjects office database of approximately 9700 research projects conducted at UCSD since 1986. Similarities are based on a matches between a citation author and a project P.I. or co-investigator, as well as matches which occur on the words of the citation and the human subject project record descriptions. The computer-assisted match process results in a computer display of a list of possible matching projects ordered by decreasing similarity scores; the actual selection of a project to match is done by a protocol analyst in the Human Subjects office, not by the computer. Thus it is based on the

substantial knowledge of the staff regarding investigators and their projects.

When a likely match is selected by the protocol analyst, the system generates an individualized letter to the investigator commending them on their publication and asking confirmation whether the office has correlated the citation to the correct research project. If no match can be found, the system generates a letter which embeds the citation and asks the investigator to contact the human subjects office.

What are the implications of this for me as a UCSD researcher?

Once matches are recorded, the link between the literature citation and the human subjects protocol record allows the citation to be displayed online within the human subjects office as part of the cumulative research project record. We expect that such a link will assist protocol analysts in understanding the nature and results of the research protocols they review, so that they can better communicate with and understand the concerns of UCSD researchers; because the same system is used to record "online" the deliberations of IRB meetings, the availability of relevant abstracts may also assist the IRBs to understand better the context for requested protocol amendments and adverse event reports.

What happens if my publications don't "match up" to Human Subjects office records?

The staff of the Human Subjects Program appreciate that the applicable regulations are subject to interpretation, and that some faculty simply may not be aware of their responsibilities in this area. As well, there is not always a clear and obvious relationship between a publication describing research involving human subjects, and its corresponding UCSD project description; this is why all links between projects and published literature will be subject to the confirmation of the researcher. In cases where a

researcher receives a letter from the human subjects office asking for clarification of the relationship of a particular publication to the research project records, it is the intent of the program office to work in good faith with any UCSD researcher to help him/her comply with all applicable federal and University regulations. If a researcher refuses to communicate with the office, the matter will be referred to a UCSD IRB. The IRB may choose the course of action, if any, it believes most appropriate to the situation.

UCSD IRBs, which are constituted in accordance with federal regulation, are largely made up of faculty members, chaired by faculty members, and empowered to prevent human subjects research from proceeding without IRB approval by section 45 of the Code of Federal Regulations, Part 46.113, which states "An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements...". In addition, 45 CFR 46.112 states that "Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB." As an institution, UCSD has specifically committed to abiding by these federal regulations for over 25 years.

What kinds of projects need IRB review?

Federal regulations define research as "a systematic investigation designed to develop or contribute to generalizable knowledge"; such activities, when they involve human subjects or information about human subjects, need prior review and approval by an IRB. For assistance with an IRB application, and when in doubt as to whether a particular project or activity needs IRB review, please call the UCSD HRPP at (858) 657-5100.