

Volume I, Issue 1

Fall 2006

Committee for the Protection of Human Subjects the protocol

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OFFICE LETTER

New semester, new newsletter

This is the first issue of **The Protocol**, an online newsletter to be published at the beginning of each semester by the Office for the Protection of Human Subjects.

We plan to include features on new IRB policies and procedures that will affect campus researchers whose studies involve human subjects. IRB membership rosters and staff updates will also be published every semester.

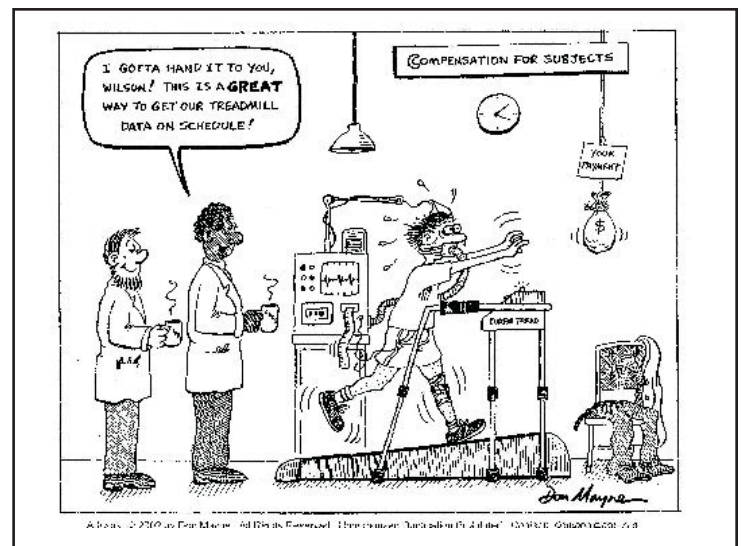
In this first issue, we invite faculty researchers

to take our Quality Improvement survey. Changes to be implemented in the fall semester are outlined, and national instances of non-compliance are presented.

And, we're including cartoons by Don Mayne, a Marin cartoonist and

IRB administrator turned consultant, for a look at the lighter side of regulatory compliance.

See the "What's Inside" navigation bar to the left for the contents of this semester's newsletter.



Following is an outline of Office for the Protection of Human and Animal Subjects changes for fall.

Protocol Approval Dates

Human subjects research protocols can be approved for a maximum period of one year.

For non-exempt protocols that undergo full committee review, the approval period will begin when the committee grants the protocol "contingent approval". "Contingent approval" means that the committee requires non-substantive changes to the protocol, which must be approved by the Office for the Protection of Human and Animal Subjects before research may begin.

Although the approval period begins on the date the committee grants contingent approval, research may not begin until full approval is awarded, so the actual period during which the research may occur can be less than 12 months.

For example, if the committee grants contingent approval on September 6, 2006 and revisions are not received until December 6, 2006 the protocol will still expire on September 6, 2007. The researcher will thus have only nine months to

conduct the research project before a renewal must be approved. In addition, to be approved by the expiration date, a renewal must be submitted two months prior to expiration.

Honestly, we have not been able to find a reason for this.

change will facilitate faster and more appropriate review of this lower-risk category of research.

Research protocols with no risk to subjects and no privacy or confidentiality issues may be eligible for a Certificate of Exemption.

Changes for Fall: Protocol Approval Dates

Collaboration with the College of Education, approval periods, updated forms to expedite your approval process, and everything else you need to know to get your research off to a good start this fall.

We suspect it has something to do with encouraging researchers to get their revisions in quickly after a committee review. However, to be compliant with the OHRP (Office of Human Research Protections) standards, we will start the new dating policy this fall semester.

Exempt Research

The IRB Office is changing its review process for exempt research. We hope that this

This means that the protocol does not need to undergo further review after the determination of exempt status, and will not be formally "approved" by our office. Instead, the researcher will receive a Notice of Exemption by email. This action is consistent with federal guidelines for low-risk research and is acceptable by journals and other publications.

All other exempt research will be reviewed with attention consistent with the level of risk involved in the project. Higher risk research will receive more careful scrutiny, while lower risk research will undergo less stringent review in the areas that do not directly affect subject protection. Higher risk includes research involving special areas of concern, such as:

- sensitive interview or survey topics
- power imbalance between researcher and subjects (teachers using their own students for research, employers surveying workers about job satisfaction)

For more information, see Issues of Special Concern on our Web site.

Also, in collaboration with the College of Education graduate committee, the IRB has identified and approved a list of commonly accepted educational practices which will now qualify for exempt review status under the 45 Code of Federal Regulations, part 46.101 (b):

"Research activities in which the involvement of human beings in one or more of the following categories are exempt from this policy:

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Our office is yours

IRB staff are available for consultation by telephone or email and in the office by appointment.

Our staff can help you:
write culminating experience descriptions
review your draft protocols
edit consent forms prior to formal submission

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(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.”

Click on Exempt Educational Practices for more details.

No Review Required

Protocols involving human participants which are determined to be program evaluation, needs assessment, curriculum development and self-improvement projects, which have no research elements (such as field testing), will receive an email stating that the research needs no further IRB review.

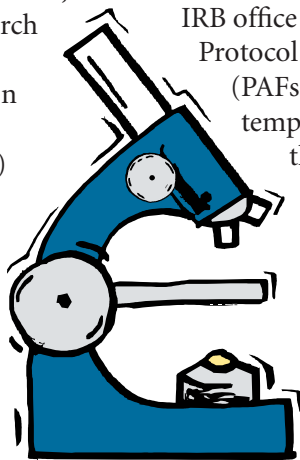
Research which involves human participants but as content experts or consultants, not research subjects, will also need no further review. In these cases, the participants answer questions only about their field of expertise, not about themselves.

For more information, see Does My Research Require Review?

Forms Update

After September 1, 2006 the IRB office will not accept Protocol Approval Forms (PAFs) and Protocol templates dated earlier than 6/06. They will be returned to researchers with a request to submit the most current versions found on our Web site. The forms have been updated to elicit the information

we need from investigators, and we expect the new forms and templates will facilitate protocol review and cut down on revision requests from this office.



In addition, the following new or revised forms are on the Forms and Templates page on our Web site (www.sfsu.edu/~protocol)

- Protocol Renewal Application
- Modification Request
- Protocol Deviation/ Violation (under construction)
- Adverse Event Report (under construction)

We urge researchers to check our website before beginning a new project, because forms and information are updated continually. Do not use old protocols or consent documents as a guide, because they may be outdated.

Fees

The IRB office will begin charging fees for IRB review to researchers unaffiliated with SFSU. Our new policy and fee schedule is posted on the Web site under **Unaffiliated Investigators**. Because of our highly diverse student population, many more researchers than in the past now seek to conduct studies here. We have been trying to accommodate them, but the volume of SFSU research has grown so that we need to limit the time and expertise we expend on reviewing outside research. Our primary responsibility is to the SFSU research community.

See IRB Policy and Fee Schedule for Unaffiliated Investigators on our website.

The Office for the Protection of Human & Animal Subjects

Fall Information Sessions

Protocols, Informed Consent, & More!

Seminar for Faculty

Sept. 20

Join us Wednesday, September 20, from 12 to 1 PM in ADM 460 for this Lunchtime Seminar

Seminar for Students

Sept 27

Join us Wednesday, September 27, from 12 to 1 PM in ADM 460 for this Lunchtime Seminar

Seminar for Students

Evenings

Locations and time will be announced after classrooms are assigned

Your research awaits.

Before you begin any scientific research at SFSU, you must first submit a protocol to be approved by the Committee for the Protection of Human and Animal Subjects.

Just what, precisely, does that mean? Join us for the informational sessions listed to the right for information about:

- Writing your protocol
- Forms you need to complete your protocol
- Tips for faster approval turnaround time
- For more information, contact the Office for the Protection of Human and Animal Subjects by telephone at (415) 338-1093 or by email at protocol@sfsu.edu

www.sfsu.edu/~protocol

National 'Dings' for Human Subjects Research Violations

University of Arizona Doctor Barred From Research on Humans

A cardiologist from the University of Arizona was permanently barred from conducting medical research on humans after the FDA found serious violations of federal rules to protect patient safety. The researcher considered his violations to be “simple clerical errors,” but the FDA says that he “failed to protect all human subjects from undue hazard or risk during the course of scientific investigations” and his violations put at risk up to a half-billion dollars in research funds.

While the researcher referred to his study as a success, examples of his violations include: failure to notify the IRB for six months that a subject had died (a serious adverse event should be reported within five days); failure to notify the IRB for a year and a half that a subject underwent a kidney transplant as a result of participating in the research (another adverse event); and allowing a physician who had not been approved as a study physician to implant a pacemaker device in three people. This physician had also “tried to implant a device in a fourth person.”

Assistant Research Scientist Pleads Guilty after Obtaining Salary Support for False Biographical Sketch

A now-former Assistant Research Scientist at the University of Iowa plead guilty in a state criminal case to scientific misconduct in NIH-supported research, in a grant proposal, and in obtaining salary support for postdoctoral training. Examples of her scientific misconduct include:

- fabricating interview records for at least six interviews of autism patient-families;
- falsifying her biographical sketches to include fabricated claims of a B.S. from the University of Northern Iowa, an M.S./ M.P.H. from the University of California at Berkeley and a Ph.D. in Epidemiology/ Biostatistics from the University of Iowa;
- using these falsified biographical sketches to receive salary support for three years of postdoctoral training.
- She also falsely claimed to be co-author of several published articles by simply inserting her name, or replacing another author’s name with her own, on 10 articles listed in her biographical sketch for four NIH grant applications.

As a result, she has entered into a Voluntary Exclusion Agreement, agreeing for a period of three years to exclude herself from contracting

or subcontracting with any agency of the U.S. government and from eligibility or involvement in non-procurement programs of the U.S. government. She will also exclude herself from serving in any advisory capacity to the U.S. Public Health Service. The report did not include the state criminal sanctions applied. (from Office of Research Integrity: <http://ori.hhs.gov/misconduct/cases/>)

UCLA Psychology Graduate Student Engaged in Scientific Misconduct

A now-former graduate student in UCLA’s Department of Psychology was found by both UCLA and the national Office of Research Integrity (ORI) to have engaged in scientific misconduct by falsifying or fabricating data and statistical results for up to nine pilot studies. The student was studying the impact of vulnerability on decision-making as a basis for her doctoral research. The graduate student has since been debarred for three years and is prohibited from serving in any advisory capacity to the US Public Health Service, in addition to incurring damage to her future career and academic reputation. (from ORI: <http://ori.hhs.gov/misconduct/cases/>)

OFFICE FOR THE PROTECTION OF HUMAN & ANIMAL SUBJECTS

IRB COMMITTEE #1

Mark Geisler, Chair
Psychology

Evelyn Ballard, MD
Community Member

Rosa Casarez-Levison

Jamal Cooks
Secondary Education

Rae Doyle
Community Member/Non-Scientist

Grace Hardie
Nursing

Rita Melendez
Human Sexuality

Jo Tomalin
Theatre Arts/Non-Scientist

Ann Hallum

Ken Paap

OFFICE FOR THE PROTECTION OF HUMAN & ANIMAL SUBJECTS

IRB COMMITTEE #2

Betsy Blosser, Chair
Broadcast & Electronic Communication Arts

Josie Arce
Elementary Education/ Language and Literacy

Victoria Chen
Speech and Communication/ Non-Scientist

Linda Juang
Psychology

Matt Lee

Ed Luby
Museum Studies

Judy Ott
Community Member/Non-Scientist

Pamela Wolfberg
Special Education

Ann Hallum

Ken Paap

Deborah Cohler
Women Studies
On Leave Fall, 06

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3	4 First Wednesday IRB Committee #1 meets	5	6	7
8	9	10	11 Second Wednesday IRB Committee #2 meets	12	13	14
15	16	17	18 Third Wednesday IRB Committee #1 meets	19	20	21
22	23	24	25 Fourth Wednesday IRB Committee #2 meets	26	27	28
29	30	31	IRB Meetings			

IRB #1 will meet on the first and third Wednesday of every month, beginning on September 6, 2006. IRB #2 will meet on the second and fourth Wednesday of every month, beginning on September 13, 2006. They will meet on November 29, instead of November 22, because of the Thanksgiving holiday. Both committees will meet once in December. An ad hoc committee meeting may be held during the January intersession.

Our busiest time of year is between November 1 and February 1, due to the high volume of graduate student protocols, which must be approved before the students can register for the culminating experience in spring.

Students are encouraged to submit their protocols before the deadline, and to return requested revisions in a timely manner, to avoid delays in approval.

MEET THE STAFF

Administrative Staff

The Office for the Protection of Human and Animal Subjects includes the following staff:

Linda Blackwood, PhD. IRB Coordinator

Mary Richards, M.A., CIP IRB Administrator

Suzanne Holguin, M.A. Protocol Analyst

Dr. Blackwood ends several years as chair of the Committee for the Protection of Human Subjects, and returns this fall to the Coordinator position she originally held. The Committee has accomplished a lot during

her tenure as chair, and the office has grown from one person to three staff members and two student assistants. Two IRBs have been established, each with a new faculty chair: Mark Geisler from Psychology chairs IRB #1, and Betsy Blosser from BECA chairs IRB #2.

Mary Richards is now IRB Administrator, and Suzanne Holguin, one of our original graduate assistants while she earned an M.A. in Geography, has recently been appointed staff Protocol Analyst.

Student Assistants

Bre-Lyn Cober Graduate Assistant (M.A. in progress—Museum Studies)

Amanda Foster Graduate Assistant (M.A. in progress—Psychology)

Both our graduate student assistants are staying with the IRB office for a second year while they complete their master's degrees. Beginning in Fall, 06, they will be available help graduate students write culminating experience descriptions, review draft protocols, and edit consent forms prior to formal submission.

IRB staff are available for consultation by telephone at (415) 338-1093 or email at protocol@sfsu.edu, and in the office by appointment.

Quality Improvement Measures Take our Survey!

IRBs are encouraged by federal regulators to gather empirical data regarding operations and ethics, on which to base quality improvement decisions. To this end, our office has developed a survey to determine how we can improve our efficiency and service to faculty researchers.

Click here to link to the survey.

Our office will send a link to the survey by email to faculty and staff researchers on August 23, 2006 and

again on September 13. This is your chance to let us know how you really feel.

The IRB office will also survey two groups of students this fall. The first survey is aimed at students who did not complete their protocols over the past three years, to investigate their reasons for non-completion. The second survey will be of students who did complete their protocols and received IRB approval. These surveys will measure student perceptions of and experiences with the IRB.

We hope to publish the results in a future newsletter.

Ask an auditor

Federal regulations require the IRB office to audit ongoing research to confirm that the human subjects pro-

cedures are being conducted as described in the approved protocol. We've not been able to undertake this function in the past.

However, this fall we are fully staffed for the first time, and will be able to begin the audit process. We are investigating how to implement an audit, and as soon we have finalized the system, our staff will explain the procedures to researchers.

We will also add a page to our Web site with a self-audit instrument to aid investigators in checking their own research procedures.

Please be assured that this process is not meant to be punitive, but rather informative, to help SFSU investigators maintain quality research.

CPHS Protocol

CPHS PROTOCOL

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