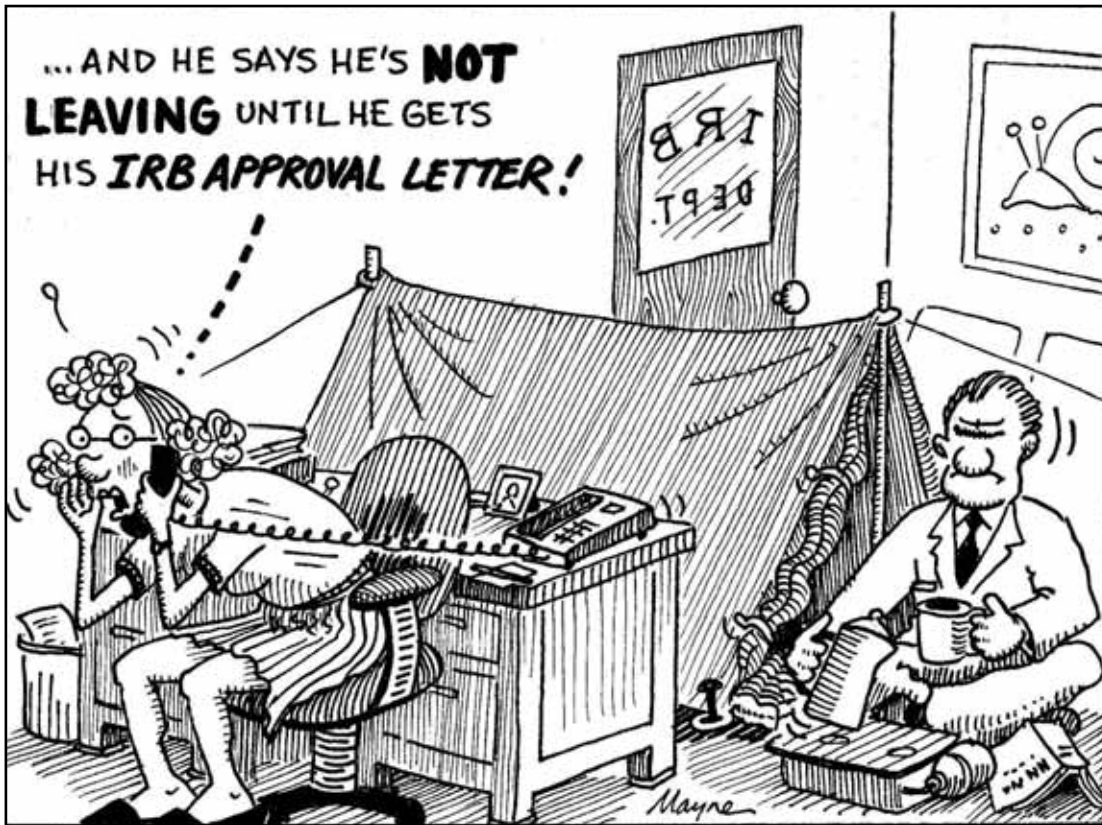




Volume II, Issue 1 Fall 2007

Committee for the Protection of Human Subjects

the protocol



OFFICE LETTER

Welcome back! We hope you had a relaxing and/or productive summer.

This issue of *The Protocol* includes 2 new sections:

· **National News and Resources** provides information on determining conflict of interest, a round-up of informed consent resources and a recap of stem cell research to date.

· **Hot Links!** directs you to websites you will need as a researcher, faculty advisor or research methods instructor.

Contact us with questions or comments at protocol@sfsu.edu.

We hope you find *The Protocol* useful and informative.

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Fall 2007



SAN FRANCISCO STATE UNIVERSITY

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

CITI Research Training Course Offered

Starting this fall, researchers will be able to take the CITI (Collaborative Integrative Training Initiative) research training course as evidence of training in human subjects research ethics. The animal subjects research training course is also available at the CITI site.

A certificate, valid for 3 years, will be issued on completion of the CITI courses. (An up-to-date NIH course completion certificate is still acceptable as proof of human subjects research training.)

Researchers working with human subjects must take either the biomedical or the social/behavioral/educational module of the CITI course. Each module contains 7 required sections and 3 electives needed to complete the course, along with optional sections for special interests. Elective sections include HIPAA, international research, and internet research, among others. Instructors may demo the course from the home page.

The lab animals course and the human subjects courses will be available

on September 17, 2007. To register for the courses go to <http://www.citiprogram.org/>. Go directly to "New Users Register Here." You will choose either the human or animal courses in the process of registration.

Occupational Health Program in Place

Starting this fall, SFSU will implement

Qualified Medical Evaluator in Internal and Occupational Medicine. He provides occupational health training and assessment for a variety of institutions in the Bay Area, and has extensive experience in occupational health consultation for laboratory animal handlers.

Dr. Rinker will serve as a consultant to SFSU in

Changes for Fall '07:

CITI research training course offered, occupational health program implemented, staff available for consultation, Jason Bell serves as IRB prison advocate, closer collaboration with faculty affairs, help for harried researchers, new office database, graduate studies faculty site more accessible, and everything else you need to know to get your research off to a good start this fall.

its Occupational Health Program for Individuals with Animal Contact as required by OLAW (the federal Office of Laboratory Animal Welfare).

The SFSU UACUC has contracted with Jordan Rinker, M.D., M.P.H. to provide their occupational health assessment for animal handlers. Dr. Rinker is Board Certified in Preventive Medicine and Internal Medicine and is a California State licensed

matters of occupational health and safety, and will provide training to laboratory animal handlers.

Graduate Studies Faculty Site: More Accessible

Do you need to know:

- what's expected of a graduate advisor?
- graduation paperwork deadlines?
- the name of a departmental graduate coordinator?

· how to calculate a student's GPA?

The Grad Studies office has simplified access to the graduate web portal at

<http://www.sfsu.edu/~gradstdy/login.htm>

Click on the red "Log In" button at the top of this page, and enter your email address (without the @sfsu.edu) and the password grad.

Prisoner Advocate

Jason Bell, an SFSU alum (Sociology, 06), current MA student and director of Project Rebound, will serve as the prisoner advocate for the SFSU IRBs again this year. Jason reviews research protocols involving prisoners from the standpoint of the prisoners' welfare and rights.

Researcher Outreach: Closer Collaboration with Faculty Affairs

In close collaboration with Dr. Pamela Vaughn, Associate Dean for the Center for Teaching and Faculty Development, the Office for the Protection of Human and Animal Subjects worked with scholars receiving funding from the Office of Faculty Affairs this spring and summer. Our office proactively contacted researchers to help them determine if IRB or UACUC review was needed for their projects involving human or animal subjects.

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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

Office for the Protection of Human & Animal Subjects
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San Francisco, CA 94132

415 338 1093

National 'Dings' for Human Subjects Research Violations

Findings of Scientific Misconduct from the Office of Research Integrity

(3 cases adapted for *The Protocol* from the PRIM&R newsletter)

Precious Bodily Fluids Department:

An Oklahoma phlebotomist working with TEAL (Tribal Efforts Against Lead), a research project supported by NIH and NIEHS (Nation-

al Institute of Environmental Health Sciences) was found to have substituted her own blood for the blood samples of 10-15 children participating in the TEAL study.

<http://ori.dhhs.gov/misconduct/cases/Bryant.shtml>

A UCLA research associate in a substance abuse project funded by NIH "falsified and fabricated" multiple interviews, urine samples and records of human participants, and entered the false data into the study's database.

In a study of gender differences among opiate users in California, the researcher claimed he conducted face-to-face follow-up interviews with 20 subjects. However,

in subsequent contacts, the subjects stated that they had not been interviewed. The researcher also falsified the urine specimens for 20 subjects, and entered false data for 11 subjects. His situation was aggravated by the theft of \$5180 for incentive payments to subjects and travel expenses.

[Federal Register: July 23, 2007 (Volume 72, Number 140)]

Both of the above researchers have been banned from conducting research with federal funds and from participating in any advisory capacity to the Public Health Service for the next three years.

The Feds Beg to Differ:

Unreported Accidental Exposure

Texas A&M University officials said this week that researchers there did not violate federal rules when they failed to report that three laboratory workers had been accidentally exposed to a microbe that is regulated as a potential biological-warfare agent. Federal officials disagreed.

In an unprecedented step, the Centers for Disease Control and Prevention ordered the university's College Station campus on Saturday to halt all research on any such organisms because of two cases of accidental exposure, neither of which the university reported until a year after discovering them.

National Research News and Resources

New Web Site Offers Guidelines to Deal With Financial Conflicts of Interest in Research

The Federation of American Societies for Experimental Biology (FASEB) opened a Web site on Friday with guidelines for researchers, universities, scientific societies, research publications, and industry to manage and disclose financial relationships that could give rise to conflicts of interest.

The Web site, which the federation dubbed a COI Toolkit, is based

on the premises that scientists should do their research objectively, work transparently, and be accountable.

The site provides sets of principles for each group involved in potential conflicts of interest. Some policies have already been adopted by organizations or institutions; others are recommendations. The toolkit will allow groups and individuals to find a ready reference to consult as they formulate their own approaches to the issue.

The NIH Clinical Research Policy Analysis and Coordination Program (CRpac) has released a compendium of current, publicly available NIH resources on informed consent.

The CRpac program has compiled a list of informed consent resources available online from the National Institutes of Health's Institutes and Centers. Among the resources are informed consent templates, frequently asked questions, guidance created by specific ICs, and other relevant materials.

Resources on Informed Consent

History and Current Status of Stem Cell Research Enhancement Act, June 20, 2007.

The Stem Cell Research Enhancement Act would have required the federal

government to conduct and support embryonic stem cell research, regardless of the date on which the stem cell lines were derived and provided that the embryos used were: originally created for in vitro fertilization; would otherwise be discarded; and were donated by fully informed, consenting individuals. Current policy limits federal funding of stem cell research to stem cell lines created without harming or destroying an embryo or those embryonic stem cell lines that were created before August 9, 2001.

The proposed legislation was passed by the House and the Senate, but vetoed by President Bush on June 20, 2007.

About Us: Office News

Staff to Present a Session at National PRIM&R Conference

In December, Mary Richards and Suzanne Holguin will present a didactic session at the national Public Responsibility in Medicine & Research conference in Boston. The workshop is entitled "Raise your Voice and Improve your Human Research Protection Program."

The presentation, accepted for the Professional Development track,

encourages HRPP staff to use evidence-based practice techniques to define their own roles and enhance their institutions' human research protection programs.

UC Davis Conference

Mary Richards has been asked to serve on the steering committee for the February, 2008 regional conference in Sacramento, sponsored by OHRP (Office of Human Research Protections) and UC Davis. The conference title is "Thinking Outside the Box: Addressing the Challenges of Human

Subjects Research in 2008." The conference will focus on both biomedical and social/behavioral/educational research, and is designed for researchers and human subjects committee members as well as administrators and committee chairs.

Staff Spotlights:

As of September 1, Suzanne Holguin is now a full-time Senior Protocol Analyst in the Office for the Protection of Human and Animal Subjects. She came on board as a graduate student assistant in the fall

of 2003, while working on an MA in Geography, and after graduation stayed on as an hourly worker. Suzanne recently qualified as a Certified IRB professional (CIP), a designation claimed by only 700 IRB staffers internationally (including Mary Richards, who earned a CIP in 2004).

The certification verifies that the recipient has passed a four-hour examination on the regulations covering federal research (including clinical trials, biomedical and social/behavioral/educational studies) and the applicant's ability to apply the regulations to specific research situations. The CIP exam also assesses knowledge of administrative policies and procedures, correct documentation of records, and the history of human research subject protections.

We are proud to have two CIPs in our very small IRB office!

Kara Gall, our web and newsletter designer, also began working with us in the Fall of 03, while typing her way to an MA in Creative Writing. Kara, who currently lives in Lincoln, Nebraska with her daughter, is a special consultant for the IRB office. Kara works with small businesses and non-profit organizations as a web designer and editor, while continuing her own writing and web publishing.

(We're also proud of our retention statistics!)

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The Office for the Protection of Human & Animal Subjects

Fall Information Sessions

Information Sessions on the Protocol Submission Process
scheduled on the following dates:

Your research awaits.

Before you begin any human subjects research at SFSU, you must first submit a protocol to be approved by the Committee for the Protection of Human 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, and much more. 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

For Faculty Advisors

Thursday, October 4, 2007

12 to 1 PM
ADM 460

Dr. Linda Blackwood

For Graduate Students

Wednesday, October 10, 2007

7 to 8 PM
BUS 202
IRB Staff

Thursday, October 11, 2007

12 to 1 PM
ADM 460
IRB Staff

Thursday, October 24, 2007

12 to 1 PM
ADM 460
IRB Staff

IRB MEETING SCHEDULE

In Fall, 2007 the CPHS will meet on the first and third Wednesday of every month. Dr. Betsy Blosser, BECA, will chair both IRB #1 and IRB #2 meetings.

Only non-exempt protocols are reviewed by the full committee. Determination of this review category is made by the office staff and chair. Exempt and expedited categories are reviewed in the office.

The CPHS will meet on the following dates:

- September 5 and 19
- October 3 and 17
- October 31 Joint Policy meeting (no protocols will be reviewed)
- November 7 and 28
- December 5 and 19

The CPHS tries to schedule at least one meeting during the January intersession, depending on the number of protocols to be reviewed and the number of members available to meet.

Please note that all protocols submitted to the committee go through a pre-review process and a revision cycle before being ready to copy for the meeting. A complete packet goes out to committee members the week prior to every meeting with the protocols to be discussed so members will have time to review them before the meeting.

IRB COMMITTEES

IRB COMMITTEE #1

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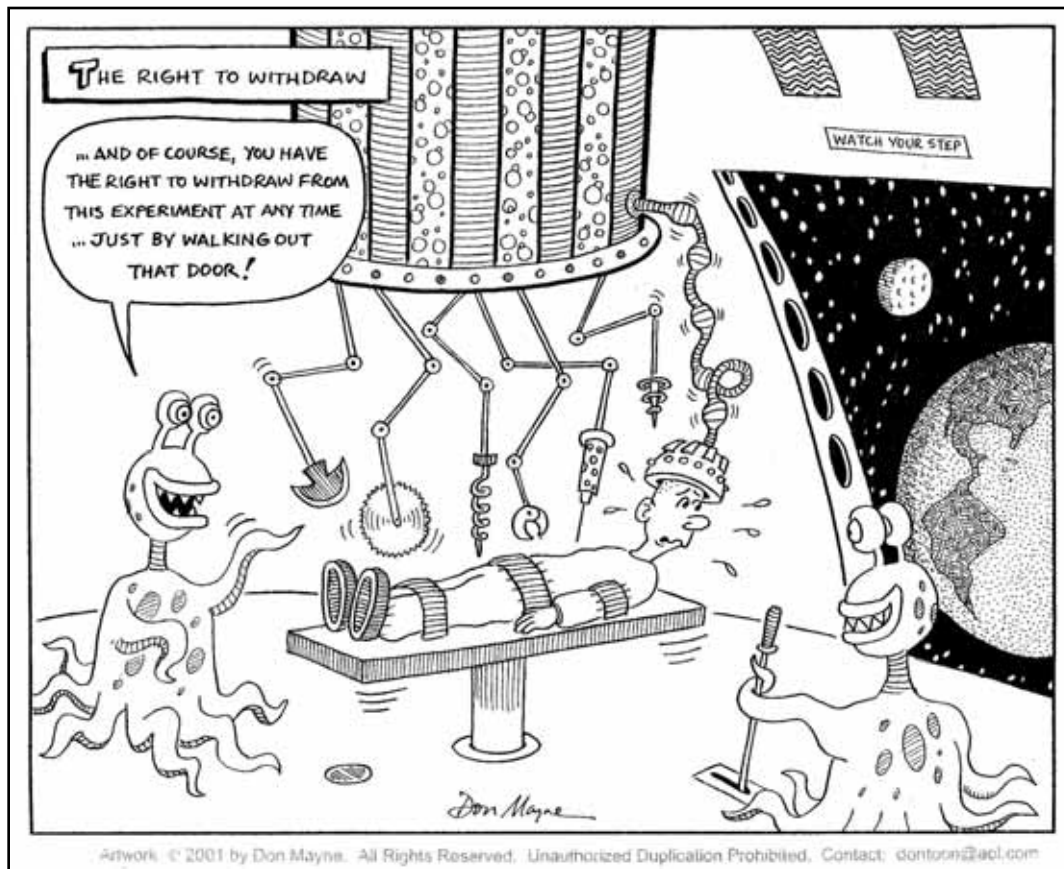
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edu/
~protocol](http://www.sfsu.edu/~protocol)

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In addition, Office Coordinator Dr. Linda Blackwood spoke at the New Faculty Orientation this year on the IRB and UACUC processes at SFSU.

Office Switches to Filemaker Pro database

The IRB office is working with a former IRB administrator turned database developer to design a more user-friendly database to eliminate repetitive tasks and ensure more accurate records.

Filemaker Pro will automatically generate approval letters, expiration notices and other researcher correspondence, and document email messages.

Help for Harried Researchers

IRB staff members are available for consultation with faculty researchers prior to protocol submission and review. We can help you:

- Get started on the process
- Write approvable protocols

- Edit consent forms
- Troubleshoot “hot spots” you may not have noticed in your study design

Bring your final draft to our office, or we can come to yours. Phone 338-1093 or email protocol@sfsu.edu for an appointment with a qualified staff member.

The best place to start is with our website, www.sfsu.edu/~protocol. Staff will also work with student researchers referred by advisors.

HOT LINKS!

Office for the Protection of Human and Animal Subjects
www.sfsu.edu/~protocol

Attention Researchers! These hot links are for YOU:

Does your research require human subjects review?
<http://www.sfsu.edu/~protocol/human/review-required.htm>

Full committee review? Expedited review? Exempt review? For a description of these categories, see <http://www.sfsu.edu/~protocol/human/categories.htm>

Find the official “Criteria for Approval” from the federal code at
<http://www.sfsu.edu/~protocol/human/criteria-for-approval.htm>

A description of possible outcomes for full board review of a protocol can be found at
<http://www.sfsu.edu/~protocol/human/decisions.htm>.

Attention Faculty Advisors! These hot links are for YOU:

Check out <http://www.sfsu.edu/~gradstdy/login.htm> for graduate advising. (Click on the Log In button, add your email name without the @sfsu.edu, and add the password “grad” without the quotation marks).

After you have advised your student researchers, send them to our website for instructions and templates on how to write a protocol and informed consent form at <http://www.sfsu.edu/~protocol/human/forms.htm>

CPHS Protocol

CPHS PROTOCOL
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