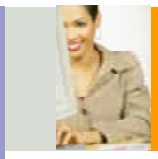







Volume I, Issue 2 Spring 2007

Committee for the Protection of Human Subjects

the protocol

WHAT'S INSIDE
Spring 2007

OFFICE LETTER

Use Web this "GAP Season"

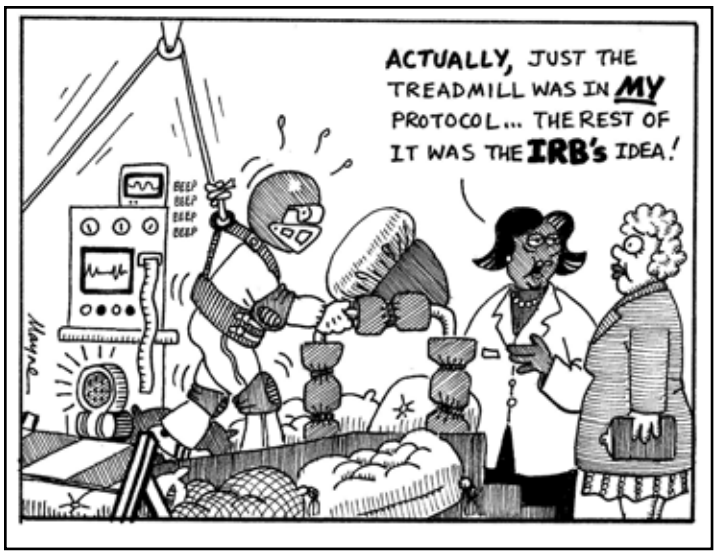
Thanks for your positive response to the first issue of The Protocol. We hope the second issue is equally informative.

As the graduate student world reels into another "GAP Season," we encourage all graduate advisors and coordinators to send students directly to the CPHS web site at www.sfsu.edu/~protocol. All forms have been updated. The protocol template now requests all the information the office needs to conduct a pre-review.

Old format protocols (dated before July, 06) will be sent back to the researcher, with a request to use the new template. Departments frequently pass around copies of old protocols for students to use as models, but this is now counter-productive. Please send students to the web site for the new templates.

For a description of what happens to a protocol once it has been turned in, see http://www.sfsu.edu/~protocol/human/process.htm. The same section, "Review Process," contains tips on how to avoid a lengthy review process.

Please address any comments or suggestions to protocol@sfsu.edu.



SFSU San Francisco State University

Changes for Spring '07:

IRB staff available for consultation, two committee meetings a month, closer links with ORSP, new guidelines for research using deception and research with prisoners, does YOUR research required review?, and everything else you need to know to get your research off to a good start this spring.

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

Two Committee meetings a month:

The CPHS will meet twice a month this semester, on the first and third Wednesday of February, March, April and May. Dr. Betsy Blosser of BECA will chair both committees.

The committee office usually schedules at least one summer meeting.

Closer Links with ORSP

Our office is working with ORSP's Pre-Awards staff and their Regulatory Compliance Office to check research grant proposals alongside human subjects protocols, to ensure consistency in title, procedures, risks and benefits.

We are also exchanging information with ORSP grants administrators and the Compliance Office on scheduled research start dates, expiration dates, faculty grant approvals through ORSP and faculty IRB approvals through CPHS.

Research using Deception

The protocol and consent templates have added questions to elicit more information from investigators planning to use deception in their research. Until the CPHS publishes an official policy on deception, we will be following the APA guidelines which require researchers to:

- Justify the use of deception in the research project
- Demonstrate that the deception is not physically or mentally harmful to participants
- Describe their method of debriefing participants.

Research with Prisoners

The federal Office of Human Research Protection (OHRP) has determined that if a research subject becomes incarcerated during the research study, the subject's participation in the study has to undergo re-review with the Prisoner Advocate present. Please Note: Research with prisoners will undergo two full committee reviews, the second with the Prisoner Advocate attending as a voting member of the committee.

Policy and Procedures:

This academic year, the CPHS has been rewriting a comprehensive set of policies and procedures, to be approved by the Academic Senate before publication on our web site. For information now, www.sfsu.edu/~protocol outlines the procedures necessary to apply for approval of research with human subjects, the criteria for approval, and provides forms and templates to gain approval for research projects.

Does Your Research Require IRB Review?

The IRB office has identified a number of activities that do not require review by our office. A general list appears on the web site at http://www.sfsu.edu/~protocol/human/review-required.htm.

More specific examples of "not the kind of research the IRB has to review" can be found at the very end of the web page, or click on Research that does not Require Review.

The "Research Categories" section on the web site also contains examples of non-exempt full committee review research and exempt research.

Staff Available for Consultation

Researchers are encouraged to telephone or email the office with any questions that surface during the protocol submission process.

IRB staff are available to go over a protocol draft before the investigator submits the final package. Phone the office for an appointment at 415: 338-1093 or email us at protocol@sfsu.edu.

Since January 3, 2007, the office has worked directly with eleven faculty members and twelve students, to resolve protocol pre-review issues, either in person or by telephone.

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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Quality Improvement Measures:
Survey Results are In

In fall, 06 we evaluated our own service to the campus community by sending out a survey to faculty researchers from all disciplines. We sent out 85 surveys to faculty members who had conducted research involving human subjects in the past three academic years. We received 36 back, a return rate of 42%.

The survey collected quantitative and qualitative data. In the quantitative section researchers were asked to rate the SFSU IRB as compared to their ideal IRB, in terms of the Committee's procedures for reviewing protocols. No significant differences were found between what researchers wanted from their ideal IRB and their experiences with the SFSU IRB. When researchers were asked for comments in the qualitative section, several mentioned not understanding the review process well enough to answer the questions in the quantitative section.

The qualitative data were more informative and gave clear indications of how we could improve our service to the campus community. In this section, researchers were asked three open-ended questions. The responses to these questions were coded for common themes. Each response was broken into meaningful units and given a code.

Not surprisingly, qualitative comments ran the gamut from "It's the most frustrating process I have experienced at SFSU," to "I appreciate all the work that faculty members put into this committee."

When asked, "What does the Office for the Protection of Human and Animal Subjects do well?" faculty researchers responded that we "provide detailed, specific feedback" and that we had a "timely return of reviews or need for clarification."

The most common themes in response to this question, "What do we do well?" were:

- Review research
- Respond quickly and respectfully in correspondence
- Remind researchers about renewal deadlines

To the second question, "What does the Office for the Protection of Human and Animal Subjects need to improve?" one researcher responded that we needed greater "understanding of social science research, especially interactive methods." Another researcher stated that we need to improve the "timeliness, consistency, clarity of applying exempt status."

The most common themes in response to this question "What needs improvement?" were:

- Necessity for understanding different research methods
- Scope of review—stop correcting typos, spelling, and grammar
- Improve speed of review

The third question was more general: "What are

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The Office for the Protection of Human & Animal Subjects

Spring Information Sessions

Protocols, Informed Consent, & More!

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 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

Seminar for Faculty

March 15

Join us Thursday, March 15, from 12:15 to 1 PM in ADM 460 for this Lunchtime Seminar

Seminar for Students

March 8
March 22

Join us Thursday, March 8 and Thursday March 22, from 12 to 1 PM in ADM 460 for this Lunch-time Seminar

Seminar for Evening Students

March 7

Join us Wednesday, March 7 from 6 to 7 PM in Burk Hall 125 for this Evening Seminar.

National 'Dings' for Human Subjects Research Violations

Former FDA Head Pleads Guilty

Washington, D.C. - Lester M. Crawford, a former Commissioner of the Food and Drug Administration (FDA) who held office for only two months before resigning "to spend more time with his family," pled guilty recently to two criminal charges: conflict of interest and making false financial disclosures to both the legislative and executive branches of the U.S. government.

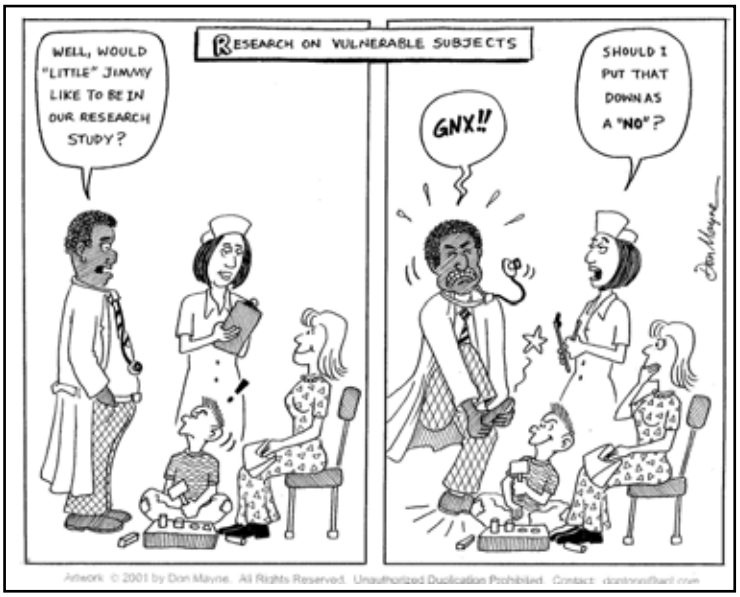
The conflict of interest charge stemmed from Crawford's ownership of Sysco and Pepsico stock while he served as Chairman of the FDA's Obesity Working Group (OWG).

Crawford's stock ownership was not disclosed to the government. He and his wife owned 1,400 shares of Pepsico stock, worth approximately $62,000, and 2,500 shares of Sysco stock, worth approximately $78,000. Both Pepsico (a leading manufacturer of soft drinks and snack foods) and Sysco (a leading manufacturer of food products) had obvious financial interests in the OWG's conclusions and recommendations.

Crawford's final OWG report contained such recommendations as encouraging manufacturers to simply re-label serving sizes for sodas.

Crawford entered his guilty plea to the two misdemeanors and was sentenced on February 27, 2007. He faced up to one year in prison on each count. He was fined $89,377, put on supervised probation for three years and must perform fifty hours of community service.

http://www.usdoj.gov/usao/dc/Press_Releases/2006_Archives/Oct_2006/06378.html



What Can Happen if a Researcher Gets Dinged

According to the Office of Research Integrity, the U.S. Department of Health and Human Services (HHS) may take the following administrative actions against respondents who have a finding of research misconduct made against them:

- debarment from eligibility to receive Federal funds for grants and contracts,
- prohibition from service on Public Health Service (PHS) advisory committees, peer review committees, or as consultants,
- certification of information sources by respondent that is forwarded by institution,
- certification of data by institution,
- imposition of supervision on the respondent by the institution,
- submission of a correction of a published article by respondent, and
- submission of a retraction of a published articles by respondent.

Which administrative actions, the number of administrative actions, and the length of the administrative actions depends on the seriousness of the misconduct, the impact of the misconduct, and whether the misconduct demonstrates a pattern of behavior. Administrative actions are usually imposed for 3 years, but have ranged from 1 year to life. http://ori.dhhs.gov/misconduct/admin_actions.shtml

~Suzanne Holguin

IRB Meetings

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**	12	13	14
15	16	17	18 **Third Wednesday** IRB Committee #2 meets	19	20	21
22	23	24	25 **Fourth Wednesday**	26	27	28
29	30	31				

The CPHS will meet twice a month in Spring, 07, IRB #1 on the first Wednesday and IRB #2 on the third Wednesday. Dr. Betsy Blosser will chair both IRBs in spring '07.

As always, we are looking

for a few good members, and for potential committee chairs.

For members, the time commitment now is approximately 4-5 hours per month:

- Two hours preparation prior to the meeting in protocol pre-review
- Two hours attendance at one committee meeting per month to discuss and vote on protocols from both faculty and students.
- We especially need good community members, who are not affiliated with the university as an employee, faculty members, staff person, or a spouse or close relative of any of the above. Retired people, grandparents, clergy, civil servants, neighbors–we have exhausted all of our own contacts and hope the campus can come up with a few.

For a chairperson, the commitment is 40% released time, which equals approximately sixteen hours per week. Chairs are expected to:

- Review protocols that require full-committee review, to determine if they are ready for committee.
- Consult with staff on problem protocols.
- Chair the two-hour committee meeting.
- Write revision letters to researchers after the meetings.
- Follow through on the post-committee revisions and final approvals.
- Approve exempt and expedited protocols with a final review if necessary.
- Conduct ongoing study of the regulations,
- Research literature or web sites as needed on issues such as post-review monitoring, international research requirements, or a human subjects research issue of interest to the chair.

Survey Results
continued from page 3

your perceptions of the IRB approval process?" Again, the responses varied from one end of the scale to the other. One researcher responded that it is "slow, laborious, tedious, staying with the rules to the nth degree" while another found that the process "clarified and improved my protocol." One researcher stated that the experience was "extremely positive;" another reported that the CPHS are "getting better all the time."

The most common themes on the perception of the approval process were:
• The process is a hurdle or impediment to research

• Improvements have been made in the past couple of years

• The process contains unexplained delays

In response to our survey, in the past few months we have made some changes:

• Exempt research is now reviewed less stringently than protocols requiring full committee review, in accord with federal regulations.

• Staff members are actively inviting faculty and students to come in to the office to discuss protocols before their official submission, to clear up problem spots before review.

• Staff send an email to researchers notifying them when their protocols are received in the office, when revisions have been received, when protocols are placed on an agenda for full committee review. Researchers also receive multiple notices prior to the protocol's expiration date, reminding them to submit a renewal application or a completion form.

• The office pre-review staff no longer ask researchers to change typos, spelling, or grammatical errors in the protocol, as long as we can understand what the researcher means, because the protocol is an internal document. We do request those changes on any forms that will out to the public, such as the consent forms, recruiting letters, flyers, etc., because these documents represent the students, faculty and SFSU to the general community.

• Mary Richards and Suzanne Holguin have registered for a teleconference on April 18, 2007 titled Community-Based Participatory Research Proposals and the Human Subjects Review Board," sponsored by the Tuskegee Institute for Bioethics in Research, and Community-Based Partnerships for Health.

~Amanda Foster

Campus Poll on Informed Consent Document

Faculty and student researchers, along with anyone who has participated in research as a human subject, are invited to respond to our question:

Should SFSU adopt a more user-friendly consent form?

Sample form at http://www.research.ucsf.edu/chr/HIPAA/_CF-behav-0205.doc.

Email your vote to us at protocol@sfsu.edu. Put "consent" in the subject line. A simple yes or no will do, but if you want to elaborate, go ahead.

CPHS Protocol

CPHS PROTOCOL
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