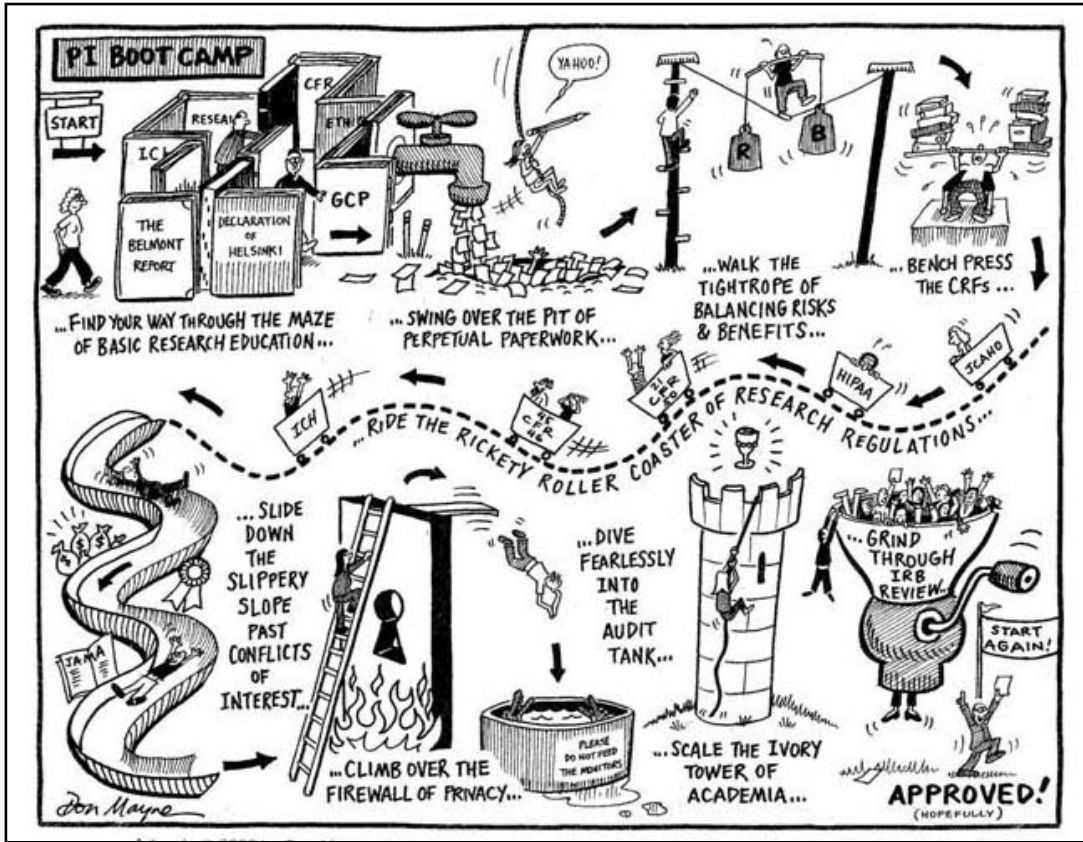




Volume III, Issue 1 Fall 2008

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 a new section. The **Member Profile Page** presents information about some of the committee members, and includes their comments about serving on the Committee for the Protection of Human Subjects.

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](http://www.sfsu.edu/~protocol). All forms have been updated and many have been made more "user-friendly."

Contact us with questions or comments at [protocol@sfsu.edu](mailto:protocol@sfsu.edu).

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

**Changes for Fall:**  
 Letter of Permission Required  
 New QA Program  
 Staff Guidance on Exempt Review  
 New IRB Chairs  
 Forms & Template Web Page  
 NEW!! Member Profile Page

**About Us: IRB Member Profiles**  
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WHAT'S INSIDE

Fall 2008



SAN FRANCISCO STATE UNIVERSITY

# Changes for Fall '08:

New forms available for download from the OPHAS website, letters of permission required for protocol review, new QA program, staff guidance on exempt review, IRB Member Profiles, and everything else you need to know to get your research off to a good start this fall.

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

## 1. Letter of Permission Required before Protocol Review Begins:

This semester the IRB office will not start protocol review until the signed letter of permission from the research site has been turned in. Last year, several researchers were denied permission by schools or agencies at the last minute, after a lot of office time had already been spent on their projects.

*Please note:* the letter of permission to recruit participants and/or conduct research should be on letterhead stationery if the organization has it, and should be signed by the principal, director, or the person who has authority to grant permission.

## 2. New Quality Assurance Program: Research Site Visits

The main purpose of a site visit is to confirm that a protocol is being carried out as approved by the IRB. It is also an opportunity to educate researchers, if needed, on the ethical principles that should underlie human subjects research.

The IRB may recommend a site visit for research studies that are sensitive or highly complex, or that involve vulnerable populations. A site visit may also occur if a serious adverse event has occurred or a complaint has been registered, or there is history of investigator non-compliance.

Complete details of the program, including investigator check lists, will be posted on the website prior to program initiation in mid-fall semester.

## 3. Staff Guidance on Review:

At Graduate Council meeting last year, the Associate Dean of Education asked us to suggest ways for students to alter research projects so their protocols would not require full committee review. Many students include procedures that may not be necessary to answer the research question. If a student is open to it, we will suggest ways to make the protocol reviewable in the office, which is usually a faster process for those with tight deadlines.

The IRB office is now clear on which projects do not require human subjects review, including oral history, class projects, needs assessments, and content expert interviews. We encourage researchers

to consult with us since the issues are sometimes complicated. The office will document the no-review-needed determination in writing and students should attach a copy to their culminating experience proposals.

## 4. Our Forms and Templates

page on the web site has added forms for reporting adverse events and protocol deviations or violations.

## 5. New Chairs for each IRB and the UACUC

Grace Hardie, Associate Professor of Nursing, will chair IRB 1, and Ellen Hines, Associate Professor of Geography, will chair IRB 2. Lynne Dowdy, Biology, will chair the University Animal Care and Use Committee.

## REMINDERS

Human subject recruitment, data collection or analysis **may not begin** without an approved protocol on file in the IRB office. Data collected without IRB approval cannot be used.

No extensions are allowed for expired protocols. Once a protocol has lapsed no data collection or analysis may take place. Filing a protocol deviation form with the IRB office may lead to resolution of the issue.

Repeat/serious offenders risk report to the AVP of Research or the Dean of Graduate Studies.

## 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  
SFSU, ADM 254J  
San Francisco, CA 94132

**415 338 1093**

# About Us: IRB Member Profiles

**Grace Hardie**, PhD, RN, has been a member of the CPHS since 2003, and will serve as Chair of IRB #1 this semester. An Associate Professor in the School of Nursing, Dr. Hardie has been a faculty member for nine years, and her research interests include asthma and ethnic differences in bronchoconstriction, word descriptors, and airway physiology; and health disparities and access to health care. Her research is conducted at UCSF, where she received her PhD.

Dr. Hardie says about her service on the committee: "Participation in the CPHS has been professionally a very rewarding experience for me. The members of this committee are not only very dedicated individuals but they are also a very collaborative and fun group to work with."

**Richard Harvey**, Assistant Professor of Health Education/Holistic Health, has taught at SFSU for the past three years. His PhD was earned at UC Irvine, and his research interests include personal courage in high-risk youth, psychophysiology (mind-body) methods for health and stress reduction.

About serving on the committee, Dr. Harvey writes: "Consistently one of the meetings I look forward to."

**Evelyn Ballard**, MD, has been a member of the committee since the fall of 2002. She is a Professor Emerita, and served as medical director of the SFSU Student Health Service from 1946-1977. She received her MD from Stanford University School of Medicine.

About her committee service Dr. Ballard writes: "I have thoroughly enjoyed my participation in the IRB Committee. I feel I have been able to contribute to its function and have also learned much over the past seven years."

**John Stenson**, staff member, received his BS in Business Administration from SFSU, and has been Student Services Coordinator in the Psychology Department for the past three years. John also has been involved in research projects as a participant. He has been a member of the committee for the past two semesters, and writes about his service: "This is one of the most difficult, yet enjoyable and rewarding positions I have ever committed to."

**Deborah Cohler**, Associate Professor in Women Studies, has been on the SFSU faculty for six years. She received her PhD in English Literature from Brown University and her research interests include the cultural

politics of gender and sexuality in wartime. About her committee service, Dr. Cohler writes: "I enjoy learning about the varied and exciting research projects being undertaken at SFSU."

**Jamal Cooks**, Associate Professor in Secondary Education, received his PhD in Language, Literacy and Culture from the University of Michigan. He has been a faculty member for eight years. Research interests include African American vernacular English, sports literacy, expository writing, and improving the teaching and learning of urban students.

Dr. Cooks writes: "Serving on the IRB/Human Subjects committee has been a great honor. I am happy to provide a constructive critique of the human subjects research we review, and to work with researchers—both students and faculty—to design and conduct interesting and ground-breaking research."

**Rita Melendez**, Research Associate at the Center for Gender and Sexuality and Chair of Human Sexuality Studies, is beginning her fifth year as a faculty member at SFSU. Her PhD was awarded by Yale University, and her research interests include HIV among women, and the evaluation of community research projects. Dr.

Melendez writes: "Serving on the IRB keeps me up to date on the latest research methodologies and helps inform my own research."

**Matt Lee**, Associate Professor in Kinesiology, received his PhD in Exercise Physiology in 2001 from Louisiana State University and has been a faculty member at SFSU for seven years. His research interests include clinical exercise physiology, autonomic nervous system control of the cardiovascular system and the validity/reliability of new technologies in the field of exercise science.

About the CPHS, Dr. Lee says: "Serving on this committee has made me aware of the wide variety of quality research being done at SFSU."

**Rae Doyle**, community member, graduated in 1995 from SFSU with a BA in History. She is recording secretary and editor of The FogCutter, the newsletter of the Greater West Portal Neighborhood Association. She is also secretary to the West of Twin Peaks Central Council, an umbrella organization of seventeen West of Twin Peaks neighborhoods. Rae is a reporter for West Portal Monthly and writes about issues that are discussed at the meetings of these organizations.

## NATIONAL 'DINGS' FOR HUMAN SUBJECTS RESEARCH VIOLATIONS

### Well-Known Researchers Fail to Report Full Payment from Drug Companies

Harvard psychiatrists whose research supports the use of powerful anti-psychotic drugs in children have been called to task for not reporting the full extent of their consulting fees from drug companies.

Drs. Joseph Biederman and Timothy Wilens belatedly reported earning \$1.6 million each from 2000-2007, after being pressed by investigators for Senator Charles Grassley (R-Iowa), who claims their earnings may have violated conflict of interest rules.

Dr. Biederman reported no income from Johnson and Johnson in a university disclosure report for 2001. When Grassley's investigators pressed him

to check again, he said he'd earned \$3,500. But Senator Grassley discovered Johnson and Johnson's records showed they had paid Biederman \$58,169 in 2001.

Dr. Biederman emailed a statement to the New York Times in which he said his interests "were solely in the advancement of medical science through rigorous and objective study" and that he "took conflict of interest policies very seriously."

The Harvard researchers' consulting arrangements with drug makers were already controversial because of their advocating unapproved uses of psychiatric medicines in children. In the past ten years, Dr. Biederman and his colleagues have maintained that bipolar disorder, once thought restricted to adults, has been "underdiagnosed" in children and could be treated with powerful anti-psychotic drugs invented to treat schizophrenia. As a result of the aggressive diagnosis of childhood bipolar disorder, "500,000 adolescents and children were given an antipsychotic drug in 2007, including 20,500 children under 6," according to Medco Health Solutions, a pharmacy benefit manager.

The Harvard group published the results of drug trials from 2001 to 2006, but experts say the studies were "so small and loosely designed that they were largely inconclusive."

Top psychiatrists are concerned about the loss of credibility contingent on disclosures of researchers accepting large amounts of money from drug trial sponsors. A Harvard spokesperson said the information had been turned over to a university conflict of interest committee.

Source: *New York Times*,  
June 8, 2008.

The Office for the Protection of Human & Animal Subjects

# Fall Information Sessions

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

## For Students

**Thursday, October 16, 2008**

12 to 1 PM  
ADM 460

**Wednesday, October 22, 2008**

5:15 to 6 PM  
ADM 460

**Thursday, October 23, 2008**

4 to 5 PM  
ADM 460

## For Faculty / Advisors

**Wednesday, October 15, 2008**

3 to 4 PM  
ADM 460

**Thursday, October 16, 2008**

4 to 5 PM  
ADM 460

**Wednesday, October 22, 2008**

4 to 5 PM  
ADM 460

**Thursday, October 23, 2008**

3 to 4 PM  
ADM 460

**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 above 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](mailto:protocol@sfsu.edu).

## NATIONAL IRB NEWS

### Blood substitutes tied to higher risk of heart attack and death.

In an article published May 21, 2008 in the Journal of American Medical Association (JAMA) a senior scientist at the NIH reported that randomized clinical trials of a number of blood substitutes completed as long as 12 years ago “raised concerns about the products’ safety and showed no clinical benefit.”

Dr. Charles Natanson’s study pooled data from 16 clinical trials of 5 products involving 3711 patients, and found 164 deaths among the patients who got the blood substitute versus 123 deaths among the control groups—an increase in mortality of over 30 percent.

There were also 2.7 times as many heart attacks (59) among the patients treated with the HBBS (hemoglobin-based blood substitutes) as those in the control group (16).

Natanson’s research team also discussed the regulatory process that permitted repeated trials with these agents despite persistent safety concerns. The data reported by sponsors to the FDA are not made public by the FDA unless the product is approved or an advisory committee is convened to discuss the product. “The cumulative mortality analysis ... indicates that prompt meta-analyses of the HBBS trials

by the FDA most likely would have demonstrated significant risks by 2000. Had the agency placed a moratorium on trials at that point, product-related deaths and [heart attacks] in subsequent trials most likely would have been prevented. However, such data were not available to scientists, the public, institutional review boards, or competing HBBS manufacturers,” the authors write.

Natanson suggested that researchers should return to laboratory-based work to improve products before beginning any more studies that involve human subjects.

He said he could not see any justification for clinical trials already in progress to continue.

*Sources: Journal of the American Medical Association early news release 4/28/08, Chronicle of Higher Learning (6/16/06, 4/28/08), CNN.com (<http://www.cnn.com/2008/HEALTH/4/28/blood.substitutes>)*

### Ethical Approaches to Adolescent Sexual Health Research

In an article for the Journal of Adolescent Health this month, Canadian researchers report that youth are disproportionately affected by sexually transmitted infections, owing to a number of biological, social, developmental and behavioral factors. By the eleventh grade, 51.4% of teenagers are sexually active, despite their lack of information about safe sex

practices and pregnancy prevention.

However, investigators often hesitate to include adolescent youth in studies because of the exigencies of the ethical review process; at the same time, youth don’t want to seek health services or consent to sexual health research if parental consent is required

The authors, who conducted the Toronto Teen Survey, make the case that requiring parental consent for adolescent participation in sexual health research is

- unwarranted, because a number of studies have demonstrated that youth as young as 14 have the cognitive capacity to make the same level of informed decisions as adults of 25;
- confusing, because of the wide differences that exist in states’ and provinces’ decisions about adolescents’ ability to consent to medical consultation as opposed to related research in a related field;
- inconsistent with the principles of justice and inclusiveness, and
- may silence those whose voices most need to be heard.

To improve their ethical access and research processes with youth, the researchers have several recommendations. First, they situated the research in a community context, and included

- community-based participatory research

techniques to address health disparities.

- youth-friendly protocols and consent procedures, on the recommendations of a Youth Advisory Committee (YAC), recruited from community-based organizations.

Second, once the YAC was set up:

- Survey content, length, format, and administration were heavily influenced by the youth
- They asked that the consent form be written in Q &A format, use accessible language and be read aloud to accommodate participants with literacy problems.
- They felt it was unethical to survey participants without an educational component to follow the survey. Participants wrote questions down and they were pulled from a hat. (An adult member of the research team was on hand to assist and ensure the information was correct.)
- The youth said they were more likely to participate if the surveys were distributed and explained by peers, in a community setting, rather than at school.

Researchers successfully made the case for a waiver of parental consent. In conclusion, they recommend that other investigators

- Pay maximum attention to confidentiality and anonymity in administering the surveys, and use of the data.

*Continued on page 6\**

## IRB COMMITTEES

### IRB COMMITTEE #1

Grace Hardie  
Nursing, Chair  
ghardie@sfsu.edu

Evelyn Ballard, MD  
Community Member

Jamal Cooks  
Secondary Education  
jcooks@sfsu.edu

Rae Doyle  
Community Member

Mark Geisler  
Psychology  
mgeisler@sfsu.edu

Humaira Mahi  
International Business  
hmahi@sfsu.edu

Rita Melendez  
Human Sexuality  
rita.melendez@gmail.com

John Stenson  
Psychology Department /  
Staff / Non-Scientist  
jstenson@sfsu.edu

### IRB COMMITTEE #2

Ellen Hines  
Geography, Chair  
ehines@sfsu.edu

Deborah Cohler  
Women Studies / Non-Scientist  
dcohler@sfsu.edu

Susan Courey  
Special Education  
scourey@sfsu.edu

Rick Harvey  
Health Education  
rharvey@sfsu.edu

Matt Lee  
Kinesiology  
cmlee@sfsu.edu

Ed Luby  
Museum Studies  
emluby@sfsu.edu

Judy Ott  
Non-Scientist  
jaott@sfsu.edu

Uschi Simonis  
Chemistry  
uschi@sfsu.edu

## IRB MEETING DATES

### IRB COMMITTEE #1

September 3

October 1

October 29: Joint Policy Meeting  
(no protocols will be reviewed)

November 5

December 3

### IRB COMMITTEE #2

September 17

October 15

October 29: Joint Policy Meeting  
(no protocols will be reviewed)

November 19

December 17

*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. 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. 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.*

*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.*

# CPHS Protocol

CPHS PROTOCOL

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CPHS

ADM 254J

San Francisco State

University

1600 Holloway Avenue

San Francisco, CA 94132

415 338 1093

415 405 2474 Fax

protocol@sfsu.edu

IRB ADMINISTRATIVE STAFF

Linda Blackwood, PhD.  
Coordinator

Mary Richards, M.A., CIP  
IRB Administrator

Suzanne Holguin, M.A., CIP  
Senior Protocol Analyst

Jessica Ramirez  
Protocol Analyst  
M.A. Ethnic Studies — In Progress

STUDENT ASSISTANT

Rhiannon Condon  
Protocol Analyst  
Post Bac, Biology

WRITER/EDITOR

Mary Richards, M.A., CIP  
415 338 1093  
mrich@sfsu.edu

GRAPHIC DESIGN/EDITOR

Kara Gall  
402 840 3204  
kgall@inkstage.com

CARTOONIST

Don Mayne  
<http://www.irb-irc.net/donmayne.htm>

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*Continued from page 5*

- Value youth participation appropriately, based on suggestions from the YAC (they requested informational resources and condom distribution, along with a movie gift certificate.)
- View their institutional review boards as partners, consulting with them during the protocol and consent development, and arranging face-to-face meetings during the review process. Study researchers were “ultimately applauded for their thorough and thoughtful approach to the consideration of the ethical aspects of their research.”

*Source: Flicker S, Guta A. “Ethical Approaches to Adolescent Participation in Sexual Health Research.” Journal of Adolescent Health. January 2008; 42.*

**Note:** A copy of the Toronto Teen Survey “youth friendly” consent is available from the IRB office at [protocol@sfsu.edu](mailto:protocol@sfsu.edu)

visit us online at:

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