UCSF Human Research Protection Program

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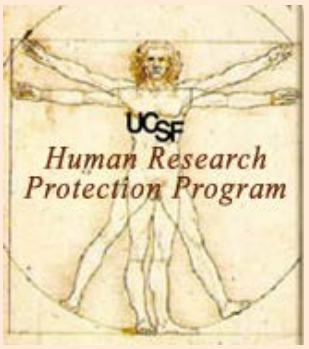
HRPP Bulletins in 2012



Bulletin Topics

Relying on Western IRB (December)

UCSF will rely on Western IRB (WIRB) review for some clinical trials. To be eligible for WIRB review and reliance, studies at UCSF must meet the following criteria (see exceptions):

- Phase III or Phase IV clinical trial
- Industry-funded
- Industry-authored
- Have approval from a UCSF scientific review committee:
    - Cancer Center Protocol Review Committee
    - CTSI Advisory Committees

The PI will be responsible for submitting the study to the CHR, WIRB, and a UCSF scientific review committee. See our website for more information.

WIRB is an independent IRB that provides fast and efficient IRB services for academic and non-academic institutions. Many industry-funded clinical trials have already been approved by private IRBs like WIRB before being submitted to UCSF.

If you have questions about IRB review reliances, please contact our office at 415-476-1814 or CHR@ucsf.edu.

Research Online to Be Decommissioned December 31, 2012 (November)

Prior to the implementation of iMedRIS, researchers could access CHR study information through a website called Research Online. That database is now obsolete and will be decommissioned on December 31, 2012.

Research Online contains an online summary sheet for each study that was approved before the implementation of iMedRIS in early 2010. The summary sheet lists the study's initial approval date, as well as the approval dates for modifications and continuing reviews.

If you wish, you can download a PDF version of a study's summary sheet prior to December 31, 2012. However, please note that you are not required to keep a copy of the summary sheet in your regulatory binder.

Questions? Please contact the Human Research Protection Program at 415-476-1814 or CHR@ucsf.edu. If you have forgotten your Research Online login information, follow the instructions on the Research Online sign-in page.

UCSF Treatment and Compensation for Injury Consent Form Paragraph Updated (November)

The Committee on Human Research (CHR) has updated the UCSF "Treatment and Compensation for Injury" paragraph in several of its consent form templates. This paragraph must be included in consent forms for studies involving more than minimal risk. The revised paragraph reads as follows:

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor *[sponsor name]*, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415- 476-1814.

New studies submitted on or after Dec. 10, 2012, must include this new language. Consent forms submitted before Dec. 10 do not need to be modified and subjects do not need to be re-consented.

Important Notes:

- The SF VAMC has different required wording. See the last page of the consent form template or the Treatment and Compensation for Injury Statement Background and Policy page for the standard SF VAMC wording.
- The statement must be used without changes. See the Background and Policy for more information.
- Do not highlight the updated language in your consent form.

Additional Consent Form Changes
The consent form templates also include the following changes:

- **Radiation Risks in the "What side effects or risks can I expect from being in the study?" section:** This section includes new standard risk language that should be included if you study involves radiation. These paragraphs were developed in consultation with the Radiation Safety Committee.

- **"Will my medical information be kept private?" section**: Now includes a blanket statement that the University of California may review the subject's records.

These additional changes should be included in new consent forms submitted after Dec. 10.

Please contact the CHR at 415-476-1814 or CHR@ucsf.edu with questions.

HRPP Holiday Schedule Announcement (October)

The Human Research Protection Program (HRPP) office will be closed over the following dates for the Thanksgiving and winter holidays:

Holiday	Office Closure
Thanksgiving	November 22-23
Winter and New Year	December 24-January 1

Please note that due to the holidays, there are fewer CHR meetings than usual in November and December. Please address questions regarding the holiday closures to John Heldens, HRPP Director, at john.heldens@ucsf.edu.

Upcoming Education Opportunities (October)

The Human Research Protection Program (HRPP) is offering several classes for researchers and staff in the upcoming months. Register using the links provided and contact Melanie Mace with questions at melanie.mace@ucsf.edu or 415-476-9839.

Can't make it to a class? We can come to you! We offer personalized trainings for groups of 4 or more people. For additional information or to schedule a group training session, please visit our website.

NEW! Submitting Post-Approval Events
Wednesday, October 17, 1:30-3 pm

Register Here: http://redcap.ucsfopenresearch.org/surveys/?s=mEezkc
Location: Parnassus, Health Sciences West, Room 301

Presenter: Beth Shields, HRPP Quality Assurance Coordinator

Class Description: This class will explain the different types of post approval event report submissions (Protocol Incidents/Violations, Adverse Events, Reporting Forms, and Study Close-outs) and how to best prepare these submissions.

Consent and HIPAA Training
Friday, November 2, 1-3pm
Register Here: https://redcap.ucsfopenresearch.org/surveys/?s=vaotX4
Location: Parnassus, School of Nursing Building, Room N-225

Presenters: Melanie Mace, HRPP Education Coordinator, and Vicky Kirby-Martin, PhD, CHC, CHP, Associate Privacy Officer, Operations Manager, UCSF Privacy Office

Class Description: In this class, we'll discuss the purpose of consent forms and when they are necessary. We will practice writing techniques to improve clarity and readability, and share resources that will help you write a stellar consent form. We'll also cover consent issues for special subject populations – such as children or non-English speakers – and talk about how to conduct and document the consent process.

This class will include a special presentation from the Privacy Office about why/when subjects need to sign a HIPAA authorization form.

Ongoing iMedRIS Training
Please check the HRPP home page for a list of upcoming intro and advanced iMedRIS classes. Each session includes hands-on practice in a computer lab setting. Pre-registration is required.

New! Add or Remove Research Support Staff or Study Contacts Without Submitting to CHR (September)

You can now add or remove research support staff or study contacts who are not **Key Personnel** without submitting a modification to the CHR. To add or remove the research support staff or study contacts in iMedRIS, someone already listed on the study should follow these steps:

1. Open the study via My Studies.
2. From the Submissions page, click on the "Study Management" tab.
3. Click on the "Key Study Personnel" link.
4. Add or remove the study staff and click "Save Access to the Study."

IMPORTANT NOTES:

- **DO NOT** add or remove the Principal Investigator, Other Investigators, or other Key Personnel* in the Study Management tab. You must update sections 3 and 4 in the CHR Application and submit a modification to the CHR to change these individuals.

- **DO NOT** update sponsor, drug/biologic/chemical agent, or device information in the Study Management tab. You must update the Drug or Device section in the CHR Application and submit a modification to the CHR to make these changes.

Making changes to these sections in the Study Management Tab without submitting a modification may result in a PROTOCOL VIOLATION.

Another Way to Add/Remove Research Support Staff or Study Contacts

Submit an administrative modification: You can submit an administrative modification to the CHR to add or remove research support staff or study contacts. The CHR will acknowledge this modification but will not issue an approval letter.

Update to UCSF Key Personnel Definition

The CHR has updated and simplified its definition of Key Personnel as follows:

> **UCSF Key Personnel* are defined as all individuals who contribute in a substantive way to the scientific development or execution of the study at or on behalf of UCSF or affiliated institutions. In addition, the CHR considers individuals who obtain informed consent to be Key Personnel.

CITI training is only mandatory for Key Personnel. However, the CHR recommends that anyone involved with human subjects complete CITI training or similar human subjects protection training.

Questions?

Visit the CHR website for more information, or contact the CHR at 415-476-1814 or CHR@ucsf.edu with questions.

iMedRIS Reminder: Do Not Share Your MyAccess Login Information (August)

This is a reminder to all iMedRIS users to not share your MyAccess ID and password or allow others to work in iMedRIS using your account. All individuals working in iMedRIS must use their own accounts. The HRPP website explains how to get an account if you do not have one. Note that HRPP has recently simplified the process for granting access for affiliates.

Sharing your MyAccess credentials constitutes a violation of UCSF's electronic security policy. In addition, by sharing your credentials you may inadvertently be giving others access to systems that contain your personal and sensitive data, such as your email account, financial, and employment records. Allowing someone else to use your account also invalidates the audit history for your CHR study, jeopardizing CHR compliance with electronic security regulations, and making it difficult to serve you best.

Case: Dr. Smith is busy writing a new CHR application for a Just-in-Time NIH award. One of his approved studies is going to expire soon, but Dr. Smith also has to go on clinical service. He gives his MyAccess ID and password to a visiting student and asks her to submit the continuing review to the CHR.

The student is unfamiliar with the iMedRIS system, and she accidentally deletes Dr. Smith's nearly-complete CHR application for the NIH award. Dr. Smith is unaware of the deletion until he goes to submit the new study a few days later. He ends up missing the NIH deadline and loses out on important funding.

If the student had been using her own ID and password, she would not have been able to

delete the draft study since only the individual who creates a study can delete it.

In addition, Dr. Smith uses the same password for his email account and for the University of California "At Your Service" site, which has Dr. Smith's payroll and benefit information. Therefore, the student also had means to log into Dr. Smith's email account and At Your Service account.

Errors:

- Dr. Smith shared his ID and password for MyAccess.
- The student was not trained on using iMedRIS.

Best practices:

- If new staff or affiliates need access to iMedRIS, request access as soon as possible.
- Encourage new users to receive iMedRIS training, either through in-person classes or by using quick guides.
- Do not share IDs and passwords.
- Keep your MyAccess password unique and do not use that password on other Internet sites.

Revised PHS Conflict of Interest Regulations Go Into Effect August 24, 2012 (August)

This message was sent on behalf of Associate Vice Chancellor, Ethics and Compliance Elizabeth Boyd*

REMINDER

This is a reminder that the revised Public Health Service Conflict of Interest regulations go into effect on August 24, 2012. The revised regulations, available at http://grants1.nih.gov/grants/policy/coi/index.htm, impose several significant changes that will apply to all Investigators on PHS-funded grants. Here is a quick summary of important requirements:

Who: The revised regulations apply to all Investigators *supported by PHS-funded grants or agreements*.

- Investigators are those individuals with *responsibility for the design, conduct, and reporting of the research results.*
- These requirements apply *only* to Investigators supported on PHS-funded grants or agreements. PHS includes all National Institutes of Health (NIH) grants, Centers for Disease Control (CDC), Food and Drug Administration (FDA), among others.

What: Investigators must disclose all significant financial interests *related to their Institutional Responsibilities* – including teaching, research, clinical care, and professional activities.

A Significant Financial Interest is:

- Income exceeding $5000 from a *publicly* traded entity
- Equity ownership exceeding $5000 from a *publicly* traded entity

- Equity ownership of any value from a *non-publicly* traded entity
- Intellectual property rights and interests exceeding $5000 – *excluding* royalties paid by the Regents of the University of California
- Travel reimbursements of any value paid by any entity – *except* federal, state, and local governments, institutions of higher education, and academic medical centers/hospitals/research institutes

Additionally, all Investigators must complete *training* in the new requirements prior to the release of PHS funds. The University of California Office of the President has created a special online training module, available through the Learning Management System. You will be receiving notification of this on August 6th.

When: Investigators must disclose at least annually, with new proposals, and whenever their significant financial interests change.

How: To make this process as easy as possible, we are implementing an electronic reporting system, COI-Smart. It will be accessible through UCSF Single Sign On beginning in mid-August. It is straightforward and easy to use. To attend a short webinar demonstrating the system, see http://or.ucsf.edu/osr/coi/Webinars.html.

We know that this change will be difficult, and we are doing all that we can to make the transition as easy as possible. Please contact Eric Mah (eric.mah@ucsf.edu) or Elizabeth Boyd (elizabetha.boyd@ucsf.edu) if you have questions or concerns.

iMedRIS Tip: Only Open iMedRIS in One Window, Tab, or Browser (July)

Working in more than one active session of iMedRIS can cause you to lose your work or create other problems, so please do not open iMedRIS in more than one window, tab, or browser.

It is OK to allow pop-ups generated by the system – such as printer-friendly windows, document downloads, or document comparisons.

As always, if you have questions about iMedRIS or encounter difficulties when working in the system, please call the HRPP at 415-476-9839 or email chr@ucsf.edu.

Example: James is filling out the CHR Application for a new study when his co-worker asks him a question about an existing study. James opens a new window of iMedRIS and looks up the information his co-worker is requesting. When he goes back to work on his new study, James realizes that the CHR form is no longer open and he has lost some of his work. To prevent this, James should have saved his work first, gone to the home screen, looked up the information his co-worker requested, and then returned to his CHR application.

COI Update: Revised PHS Regulations Effective 8-24-12 (July 2012)

This message was sent on behalf of Associate Vice Chancellor, Ethics and Compliance, Elizabeth Boyd

Dear Colleagues:

Last summer the US Department of Health and Human Services and the Public Health Service (PHS) issued revised regulations on the "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." These regulations establish new standards that must be followed by institutions, such as UCSF, that apply for or receive support from PHS agencies, including the National Institutes of Health (NIH). This memo is the first in a series of communications to let you know about the new regulations and UCSF's approach to implementing them.

The revised regulations are intended to increase accountability, add transparency, enhance effective management of financial conflicts of interest, and strengthen governmental compliance oversight. They go into effect on August 24, 2012.

These regulations differ in many ways from the existing rules for disclosure and review of personal financial interests related to PHS-funded research. They also place increased burdens on the University to oversee the reporting process. Thresholds for disclosure of financial interests have been reduced to $5000, while review and reporting obligations have been expanded. Also included are new requirements that include:

- Mandatory education/training
- Disclosure of all outside interests related to institutional responsibilities
- Disclosure of travel reimbursements
- Public accessibility of information
- Monitoring of conflict of interest management plans

The 2011 revised regulations and recently updated FAQs prepared by the NIH can be accessed at: http://grants1.nih.gov/grants/policy/coi/index.htm.

We have launched several initiatives designed to make compliance with these new requirements as efficient as possible. They include:

- Development of a web-based disclosure system and "smart" forms;
- Multiple opportunities for satisfying the training requirement;
- Development of a campus implementation policy that aligns with the regulatory requirements.

Despite our efforts, we are well aware that these new regulations increase the bureaucratic burden on PHS-supported investigators. We are committed to minimizing that burden to the greatest extent possible and appreciate your patience and cooperation.

In the weeks ahead, please look for additional communication from us. We will work to address these new federal requirements together.

If you have any immediate questions please do not hesitate to contact me or Senior Director of Research Compliance Eric Mah (eric.mah@ucsf.edu) at 502-0284.

Cordially,

Elizabeth Boyd, PhD
Associate Vice Chancellor, Ethics and Compliance

Upcoming Education Opportunities (July)

The Human Research Protection Program is hosting some exciting education opportunities for researchers and staff in the upcoming months. Please register using the links provided and contact Melanie Mace with questions at melanie.mace@ucsf.edu or 415-476-9839.

Submitting Modifications and Continuing Reviews
Thursday, July 12, 10-11:30 am, Parnassus, HSW-301
Register Here: http://redcap.ucsfopenresearch.org/surveys/?s=e8uozq

Presenter: Michael Thomas, CIP, CCRP, CHR Review Unit Manager
Description: Confused by administrative vs. minor vs. major modifications? In this class, Michael will describe the changes that fall into each category and how the CHR reviews the modifications. He also will explain what the CHR considers during continuing review and common problems with these submissions.

Findings From Routine Site Visits Conducted by the Quality Improvement Unit (QIU)
Tuesday, August 7, 9:30-11 am, Parnassus, HSW-301
Register Here: http://redcap.ucsfopenresearch.org/surveys/?s=IRqTzq

Presenter: Beth Shields, CIP, CCRP, QIU Quality Assurance Coordinator
Description: Beth will describe the purpose, goals, selection, and procedures of the HRPP's Routine Site Visits (RSVs). She'll also review common RSV findings and provide suggestions for immediate action investigators can take to ensure compliance.

For more information on education or to schedule a group training session, please visit our website: http://www.research.ucsf.edu/chr/Train/chrTrain.asp

Updates on Consenting Non-English Speakers (May)

Change #1: HIPAA Authorization Form Available in 15 New Languages
The UCSF HIPAA Authorization form is now available in a total of 19 languages. A non-English speaking subject should sign a translated form whenever possible. An interpreter does not need to sign the translated form, but should be available to speak with the subject about the form. Please also document in the research file that an interpreter was available.

If the language you need is not available or you are conducting research at the SF VAMC or another institution, follow these instructions.

Change #2: Witness Can Sign Instead of Interpreter With Short Form Consent Method
With prior CHR approval, the short form consent method can be used for the occasional and unexpected enrollment of a non-English-speaking subject. Using this method, an interpreter orally presents the consent form information to the potential subject and facilitates the consent discussion.

The CHR previously required that the interpreter sign both the consent form and the Experimental Subject's Bill of Rights as a witness that the consent discussion took place. However, interpreters often work over the phone and are unavailable to sign these documents in person. As such, the CHR is revising this guidance to clarify that **another witness can sign these two forms if the interpreter is unavailable.**

Who can sign as a witness?
The witness is signing to document that an oral presentation in a language the subject can understand took place. The witness can be the interpreter or another person (other than the person obtaining consent) who witnesses the involvement of an interpreter.

What if my currently approved consent form includes a "Translator" signature line?
The CHR suggests that you modify your consent form to remove this signature line. In the meantime, you can add a "Witness" signature line and date line by hand to the consent

form when you consent a non-English speaker using the short form method. See the consent form templates for witness signature line wording.

Who should serve as an interpreter?
Although it may be necessary in *very rare* cases to have a bilingual family member serve as a medical interpreter, this practice is strongly discouraged. The medical and technical information discussed during the consent process and throughout the study can be very complex and should be communicated through an interpreter with training and understanding in medical terminology**.** As such, medical interpreters *or* investigators – or perhaps knowledgeable Key Personnel – who are fluent in English and the language in question should conduct the consent form translation.

Updated: Short Form Method Documentation Chart

English-Language Informed Consent (CHR Approved)	**Experimental Subject's Bill of Rights** (Download in the subject's language)
Signatures required: 1. Witness 2. Person obtaining consent Document in the research file that an interpreter was used. Give a signed copy to the subject.	**Signatures required:** 1. Subject or legal surrogate 2. Witness Write a statement on the Bill of Rights that the elements of consent were presented orally. Give a signed copy to the subject.

More Information

- CHR Guidance on Consenting Subjects Who Do Not Read, Speak, or Understand English: http://www.research.ucsf.edu/chr/Guide/chrG_SpSpeakWrite.asp
- Quick Guide on Consenting Non-English Speaking Subjects: http://www.research.ucsf.edu/chr/Guide/Non-English_Consent_Quick_Guide.pdf
- HIPAA Authorization Forms: http://www.research.ucsf.edu/chr/HIPAA/chrHIPAA.asp#Forms

Town Hall Meeting
We'll be discussing these updates and several other exciting changes at the Human Research Protection Program Town Hall Meeting on May 31st from 9:30-11 am in N-225. Please RSVP if you plan on attending.

Obtaining and Using PHI for Research (May)

UCSF researchers should remember that research use of Protected Health Information (PHI) from UCSF health records is governed by several policies listed at the end of this message. These policies specify procedures that departments must follow to protect PHI and require a formal request to release protected information for research use.

The HIPAA Privacy Rule allows use of PHI for research purposes only when study participants have signed an Authorization form, unless a board like the Committee on Human Research (CHR) has approved a Waiver of Authorization.

Several sections of the CHR application ask what PHI will be gathered, stored, protected and shared with other researchers in the course of a study.

- For studies *with subject contact*, branching questions (marked with a red asterisk) in the "Recruitment" and "Informed Consent" sections of the CHR application call up additional questions that may allow the CHR to waive the requirement to obtain HIPAA Authorization, either for a complete study ("Waiver of Consent/Authorization for Minimal Risk Research") or to allow researchers to use PHI to identify and approach prospective subjects who will then be asked to sign an Authorization form during the consent process ("Waiver of Consent/Authorization for Recruitment Purposes").

- For studies involving *no subject contact*, the relevant section within the CHR application is "Waiver of Consent/Authorization for Minimal Risk Research."

CHR approval letters (sent by e-mail through the iMedRIS system) include comments indicating whether Authorization must be obtained or has been waived. Researchers should be sure that they follow the determinations included in the approval letter or contact the CHR if the comments seem to contradict the researcher's plans. In addition to substantial fines for researchers found to be in violation of the Privacy Rule, the IRB may suspend the research study and the researchers may lose their right to access and use the research data.

Additional Resources:
Policy 5.01.06 specifies procedures that departments must follow to protect PHI and recommends use of the Integrated Data Repository (IDR). The Health Information Management Services (HIMS) Data Request Process specifies the procedure for Information/Data Requests. These Medical Center approval processes are necessary to ensure that requests are both appropriate and necessary and meet regulatory requirements, and to provide accurate release of any patient information. The Clinical Research Resource HUB provides links for accessing APeX and STOR and provides additional guidance and resources related to data access, data management, and data protection in research.

Relevant Policies
- 6.07.11, Patient Participation in Research Protocols
- 5.01.06, Control and Access to and Release of Information from UCSF Medical Center Information Systems for Research Purposes
- 5.02.01, Confidentiality, Access, Use and Disclosure of Protected Health Information and Patient Privacy
- HIMS Data Request Process Policy/Procedure

Exempt Research Changes (May)

Starting May 2012, the Committee on Human Research (CHR) is making some changes to the way it handles exempt research. This bulletin describes these changes and how they may affect you.

As a reminder, the CHR does not approve exempt research, but does review the study and certify that it qualifies for exemption. Investigators cannot self-certify a study as exempt.

Change# 1: Fewer Restrictions on Exempt Research
The CHR will now exempt research that involves the following, provided that the research fits into one or more of the exempt categories:

a. **Contact with outpatients** at UCSF or an affiliated health care facility.

   Exclusion: Research involving inpatients does not qualify for exemption.

b. Review of **medical records** or other uses of Protected Health Information (PHI) – only if the data was collected prior to the research and the investigator does not record any identifiers (exempt category 4).

   Exclusion: If you are **collecting PHI** – even for recruitment purposes – your study does not qualify for exemption and will require expedited or full committee review.

   Important Note: Research that involves access to PHI and qualifies as exempt under the common rule (45 CFR 46) is *not* exempt from HIPAA. Therefore, these submissions will also receive appropriate privacy board review and documentation.

How This Change Affects You: Some educational, survey or interview research that includes outpatients and does not involve the collection of PHI may qualify for exemption.

In addition, some retrospective chart reviews may now qualify for exemption under exempt category 4. In order to qualify, the data must have been collected *prior* to the research for a purpose other than the proposed research. In addition, the investigator must record the data in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Change #2: Some Modifications Allowed Without CHR Approval
For exempt research only, researchers can make *minor* changes to the study without notifying the CHR. However, significant changes – such as changes in procedures, new subject populations, or new funding – must be submitted and reviewed by the CHR. The CHR website has a complete description of the types of changes that must be submitted to the CHR.

How This Change Affects You: You no longer need to submit modifications for minor changes to exempt studies.

Change #3: Exempt Research Consent Guidance and Templates Available
If your exempt study involves interaction with subjects, there generally should be a process to ask subjects to participate and confirm their agreement. However, *signed* consent is not required for exempt research. Also, the consent process and documents can be much simpler than those required for non-exempt research.

The CHR has created several short consent templates that you can use for exempt research projects. A sample verbal consent script also is available.

How This Change Affects You: The new templates make it easy to create a short and acceptable consent document for an exempt study.

Questions?
Please contact the CHR at 415-476-1814 or chr@ucsf.edu with questions about these changes.

Important Links
- UCSF Exempt Guidance: http://www.research.ucsf.edu/chr/Guide/chrExemptApp.asp
- Exempt Consent Templates and Guidance:

http://www.research.ucsf.edu/chr/Recruit/ExemptConsent.asp

Town Hall Meeting
We'll be discussing this new policy and several other exciting changes at the Human Research Protection Program Town Hall Meeting on May 31st from 9:30-11 am. Please visit our website for details and to RSVP: http://www.research.ucsf.edu/chr/TownHall.pdf

Extended Approval for Minimal Risk Research Not Subject to Federal Oversight (May)

Background
UCSF's Federalwide Assurance (FWA) allows some flexibility in applying human subjects federal regulations to non-federally supported research.

As such, the UCSF Human Research Protection Program has implemented a procedure for granting approval for up to 3 years for research projects that:

a) involve no more than minimal risk to participants (as defined by 45 CFR 46.102) **and**
b) are not subject to federal oversight.

Studies Not Eligible for Extended Approval
Research Subject to Federal Oversight: Projects that receive federal support, that are implemented at the direction of federal agencies, or otherwise subject to federal oversight are excluded from this policy.

Examples of federal oversight include:

- Federal sponsorship, directly or indirectly, including federal training and program project grants
- Research directed or overseen by a federal agency that has signed on to the Common Rule, including every agency within Department of Health and Human Services
- Student projects when the faculty sponsor uses federal funding for the student's project
- Federal no-cost extensions
- Studies subject to FDA oversight
- Studies seeking or obtaining Certificates of Confidentiality (which are granted by NIH)
- Studies where the CHR is serving as the IRB of record for an institution that applies the federal standards to all research regardless of source of funding. This includes:
    - San Francisco VAMC
    - Northern California Institute for Research and Education (NCIRE)
    - Lawrence Berkeley National Laboratory
    - San Francisco Department of Public Health
    - Ernest Gallo Clinical and Research Center
    - J. David Gladstone Institutes
    - The Jewish Home
    - Institute on Aging
    - Blood Centers of the Pacific

- Blood Systems Research Institute

Other Exceptions and Exclusions: Studies that involve greater than minimal risk are excluded from this policy. In addition, studies that involve the following also are excluded from this policy:

- Studies with contractual obligations or restrictions that preclude eligibility in this policy, e.g., the nonfederal sponsor or funder of the research requires an annual review
- Studies in which UCSF is serving as IRB of record for an institution not mentioned above that requires annual review
- Studies involving prisoners or parolees as subjects
- Studies funded by the California Institute for Regenerative Medicine

The HRPP reserves the right to make exceptions to this policy, and inclusion/exclusion of any research project under this procedure will be at the HRPP's discretion.

Post-approval Submission Requirements

Studies that are granted an extended approval period will continue to have the same post-approval submission requirements. PIs continue to be responsible for submitting:

- modifications to the study, which must receive CHR approval before they are implemented;
- reports of adverse events, protocol violation/incidents, and other safety information meeting HRPP reporting criteria;
- a continuing review submission at least 6 weeks prior to the study's expiration date, if the study is still active; and
- a closeout report when the study is complete.

Important: If new federal funding is secured during the approval period, the PI is responsible for promptly submitting a modification to notify CHR.

If the study becomes ineligible for an extended approval period because of new federal funding or other changes, the CHR will issue a new approval letter with a shortened approval period.

More Information

- http://www.research.ucsf.edu/chr/Guide/ExtendedApproval.asp

HRPP Town Hall Meeting

We'll be discussing this new policy and several other exciting changes at the HRPP Town Hall Meeting on May 31st from 9:30-11 am. Please visit our website for details and to RSVP: http://www.research.ucsf.edu/chr/TownHall.pdf

HRPP Town Hall Meeting: Time-Saving Improvements, May 31, 9:30am-11am, N-225

The Human Research Protection Program (HRPP) is implementing some major changes this spring that should lead to less work for investigators:

- HRPP is granting 3-year approvals for minimal risk research projects that have no federal oversight.

- HRPP lifted some restrictions on research that can qualify as exempt, and no longer requires investigators to submit minor changes for approval for exempt studies. In addition, we published 11 exempt consent templates, which make it easy to create a short (e.g., half-page) and acceptable consent document for an exempt study.

- HRPP is piloting a system to allow investigators to use Western IRB for review of some industry-funded Phase III and IV studies.

- Last but not least, HRPP is modifying procedures to make it easier to comply with rules for enrolling non-English speakers.

We will discuss these changes, answer your questions, and solicit your feedback at the HRPP Town Hall Meeting on Thursday, May 31, from 9:30-11 in N-225 (map).

We are excited about these updates and look forward to sharing them with you at this meeting. **If you plan on attending, please RSVP at http://j.mp/IldJVE.**

Upcoming Education Opportunities (May)

The Human Research Protection Program is hosting some exciting education opportunities for researchers and staff in the upcoming months. Please register using the links provided and contact Melanie Mace with questions at melanie.mace@ucsf.edu or 415-476-9839.

Recruitment: What Methods Are Appropriate?
Friday, May 4, 1-3 pm, Parnassus, HSW-303
Register Here: https://redcap.ucsfopenresearch.org/surveys/?s=hZNdBx

Presenter: Laurie Herraiz, RD, CCRP, Quality Assurance Coordinator
Description: The goals of this class are to understand the various recruitment methods, discuss in detail the more complex methods, practice writing recruitment materials, and discuss the use of technology in recruitment.

Submitting Modifications and Continuing Reviews
Thursday, July 12, 10-11:30 am, Parnassus, HSW-301
Register Here: http://redcap.ucsfopenresearch.org/surveys/?s=e8uozq

Presenter: Michael Thomas, CIP, CCRP, CHR Assessment Team Manager
Description: Confused by administrative vs. minor vs. major modifications? In this class, Michael will describe the changes that fall into each category and how the CHR reviews the modifications. He also will explain what the CHR considers during continuing review and common problems with these submissions.

Findings From Routine Site Visits Conducted by the Quality Improvement Unit (QIU)
Tuesday, August 7, 9:30-11 am, Parnassus, HSW-301
Register Here: http://redcap.ucsfopenresearch.org/surveys/?s=IRqTzq

Presenter: Beth Shields, CIP, CCRP, QIU Quality Assurance Coordinator
Description: Beth will describe the purpose, goals, selection, and procedures of the HRPP's Routine Site Visits (RSVs). She'll also review common RSV findings and provide suggestions for immediate action investigators can take to ensure compliance.

For more information on education or to schedule a group training session, please visit our website: http://www.research.ucsf.edu/chr/Train/chrTrain.asp

Case Study for Clinical Investigators (March)

This is a message to all clinical investigators as a reminder of your responsibilities to ensure that participants fulfill eligibility requirements and have the necessary evaluation prior to enrollment.

The University of California recently had a substantial settlement of a case as a result of:

- A missed test result, and
- Miscommunication about the clinical status of the research participant.

To disseminate lessons learned, the following generalized case study is being distributed for your review and careful consideration:

Case: A patient with an unusual condition is referred to UCSF for enrollment in a clinical study. The study protocol includes clear eligibility criteria. Confirmatory clinical testing is required for those criteria necessary to ensure the safety of the participant. Some of the criteria may be confirmed by chart review while some require additional studies to confirm eligibility. All required tests are performed but one criterion is not confirmed by chart review. The PI documents that the participant meets all eligibility criteria. The participant completes the study without incident, but the study treatment is ineffective. The participant returns to the care of the referring physician. The referring physician inquires about the screening test results performed for the study and is told via email that the participant met all eligibility criteria. However, one clinical test had not been performed, and the referring physician is led to believe the test was "negative". Subsequently the patient receives a therapy that (had the test been done and the results known to the referring physician) is contraindicated.

Errors:

- The participant was enrolled into the study without confirming all eligibility criteria had been met. Even if this does not pose an immediate risk, it may have resulted in enrollment of an ineligible subject.

- The communication to the referring physician was vague, and implied that the participant had been carefully screened for and met all eligibility criteria when, in fact one of the exclusion criteria was not confirmed. As a result, the referring physician assumed that a clinical test had been performed and the results were normal. In fact it had not been performed and, as a result, the patient was treated with a medication that was contraindicated.
- Best practices:

- Always ensure that research participants meet all eligibility criteria.

When other care providers inquire about the results of tests performed as part of clinical research, respond precisely, refer to documentation in the clinical records or, if necessary, indicate to the referring physician that some studies were either not completed or the results are pending. The referring physician will then be aware of the required follow-up before initiating further treatment.

Upcoming Education Opportunities (March)

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Preparing a New CHR Application
Thursday, March 8, 2012, 2-3:30 pm, Parnassus N-225
Register Here: http://redcap.ucsfopenresearch.org/surveys/?s=jWgkoF

Presenter: Michael Thomas, Manager, CHR Review Unit
Description: In this class, we'll talk about when you need to submit to the CHR, how to complete the CHR Application, what attachments to submit, what the committee considers during its review, and tips for navigating the submission process.

Post-Approval Event Reporting Class and an Overview of UCSF's Subject Injury Program
Wednesday, April 11, 9:30-11:30 am, Parnassus, N-225
Register Here: https://redcap.ucsfopenresearch.org/surveys/?s=QHwcy9

Presenters: Beth Shields, HRPP Quality Assurance Coordinator, and Carroll Child, Clinical Research Risk Manager
Description: Beth will cover important information on the submission and review of post-approval events, which include adverse events, protocol violations/incidents, other safety information, and study close-out reports. This class will be followed by a special presentation on the Subject Injury Program from 11-11:30 am.

Recruitment: What Methods Are Appropriate?
Friday, May 4, 1-3 pm, Parnassus, HSW-303
Register Here: https://redcap.ucsfopenresearch.org/surveys/?s=hZNdBx

Presenter: Laurie Herraiz, RD, CCRP, Quality Assurance Coordinator
Description: The goals of this class are to understand the various recruitment methods, discuss in detail the more complex methods, practice writing recruitment materials, and discuss the use of technology in recruitment.

Reminder: FDA-Mandated Consent Form Language About Clinical Trial Registration (January)

As a reminder, the following paragraph must appear in consent forms for all clinical trials approved on or after March 7, 2012:

> A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The mandatory language only needs to be entered if the study meets the FDA's definition of a *clinical trial*.* The paragraph should appear in the **"Who can answer my questions about the study?" section** of the consent form and must be used verbatim. The CHR added the required language to the Biomedical (regular and cancer) consent form templates last February.

The FDA will not retroactively apply this requirement. Consent forms *approved* before March 7, 2012, do not need to be amended and subjects do not need to be re-consented.

*** FDA Definition of a *Clinical Trial:***

- For any trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation.
- For trials of biomedical devices: controlled trials with heath outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-

market surveillance.

Reminder about Clinical Trial Registration:
In addition to the FDA, The International Committee of Medical Journal Editors (ICMJE) also requires registration of clinical trials in order for results to be published in member biomedical journals. ICMJE adopted a broader definition of a clinical trial, as follows:

"Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."

For more information, please visit the following sites:

- FDA Informed Consent Elements Final Rule
- UCSF Clinical Trial Registration Information can be found on these sites:
  - The HUB
  - Office of Ethics and Compliance website

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Preparing Consent Documents and the Consent Process
Note: This class is being held at Parnassus on 2/1 and at SFGH on 2/8.

- **Parnassus: Wednesday, February 1, 2012, 1:30-3:30 pm in HSW-301**
  Register Here: http://redcap.ucsfopenresearch.org/surveys/?s=SPZN6K

- **SFGH: Wednesday, February 8, 2012, 1:30-3:30 pm in the CARR Auditorium, Building 3**
  Register Here: http://redcap.ucsfopenresearch.org/surveys/?s=THKWDI

Presenter: Melanie Mace, Education Coordinator
Description: The goals of this class are to understand the purpose of consent forms, practice writing techniques, go over tips for conducting the consent discussion, and points to consider when consenting special subject groups, such as non-English speakers or children.

Preparing a New CHR Application
Thursday, March 8, 2012, 2-3:30 pm, in Parnassus N-225
Register Here: http://redcap.ucsfopenresearch.org/surveys/?s=jWgkoF

Presenter: Michael Thomas, Manager, CHR Review Unit
Description: In this class, we'll talk about when you need to submit to the CHR, how to complete the CHR Application, what attachments to submit, what the committee considers during its review, and tips for navigating the submission process.

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Description: Beth will cover important information on the submission and review of post-

approval events, which include adverse events, protocol violations/incidents, other safety information, and study close-out reports. This class will be followed by a special presentation on the Subject Injury Program from 11-11:30 am.

Switching to the Human Study Debit Card Program Payment (January)

The Controller's Office recently introduced a new program called the Human Study Debit Card Program, through which researchers can pay subjects with prepaid debit cards. If you decide to switch from cash or check to debit card payment, please read the information below on modifying your CHR submission.

I want to pay subjects via debit card. How and when should I modify my study with the CHR?

Timing: The CHR is aware of the new debit card program. You are not out of compliance if you pay subjects via debit card before you modify your consent form and CHR Application. However, you must modify your study *during the next continuing review* (renewal).

Optional: You can choose to modify your CHR submission before the next continuing review if you are actively enrolling subjects on the study. Submit the changes as an administrative modification.

What to Modify: You must update the consent documents and you may need to revise the CHR Application.

1. **Consent Form:** Please insert the highlighted sentences in your consent form and remove information on the outdated payment method. Do not remove any information about pro-rating or bonuses.

   Will I be paid for taking part in this study?
   In return for your time, effort and travel expenses, you will be paid *[$XXX]* for taking part in this study. We will give you a prepaid debit card worth [$XXX] at [each visit, the end of the study, etc.]. We will give you separate instructions on how to use the card.

   Important Note: If debit card payments total $600+/calendar year, you must collect the subjects' social security numbers and addresses for IRS reporting purposes. The consent form should include this information, and the CHR website has sample wording.

2. **CHR Application:**
   - ***If subjects were previously paid with cash*:** No changes are necessary.
   - ***If subjects were previously paid by check or another form of payment besides cash:***
     - "Confidentiality and Privacy" section, 4th question: Uncheck any identifiable information that you no longer need to collect to process the subject's check request, such as social security number and address.

       Exception: If payment is over $600/year, you must continue to collect this information for IRS reporting purposes.

     - "Financial Considerations" section, 1st question: Deselect "Check" and check

	“Cash.” **Reminder:** You should not share personal information about the subjects with JP Morgan Chase Bank, which issues the debit cards. The electronic system will prompt you to enter information like Social Security number, but you will be trained to enter alternate information. **Additional Information** Please visit the following sites for more information on the Human Study Debit Card Program: • Controller’s Office Website • HRPP Website: Payment of Research Subjects and Accounts Payable Procedures sections