UCSF Human Research Protection Program

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HRPP Bulletins in 2013

Bulletin Topics

HRPP Holiday Schedule 2013-2014 (November)

The office of the Human Research Protection Program (HRPP) will be closed over the holidays on the following dates:

Holiday	Office Closure
Thanksgiving Holiday	November 28-29
Winter and New Year Holiday	December 24-January 1

Please note that due to the holidays, there are only 7 CHR meetings in November and 6 in December instead of the usual 8 meetings per month.
Questions regarding the closure of the HRPP should be addressed to John Heldens, Director HRPP at john.heldens@ucsf.edu.

Entering CHR Studies in iRIS, New Security Policy Reminder and iRIS Browser Compatibility Issue (October)

Users working in the wrong form:
A number of users have been accidentally entering their CHR applications in the eProposal form. Please make sure you are working in "Study Assistant" when you are preparing submissions for CHR or GESCR.

New Security Policy page:
Users logging in to iRIS after Tuesday night will see a new landing page reminding them not to share passwords. Please review all the information on the page before accepting the security policy and proceeding into iRIS. You will not see this page again.

Internet Explorer 10 (IE 10) is not compatible with iRIS:
UCSF ITS is recommending that users DO NOT upgrade to IE 10, as it is incompatible with iRIS and many other campus web-based systems. Contact your Desktop Support analyst if you need to be downgraded to IE 9.

Upcoming Education Opportunities (September)

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

Quality Improvement Unit Routine Site Visit Findings
Friday, October 4, 10:30 am-noon – Register Here

Parnassus, Medical Sciences Building, Room S-214
Presenter: Laurie Herraiz, Quality Assurance Coordinator

This class covers the following information:

- Discuss the Routine Site Visit (RSV) purpose/goals, selection, and procedures
- Review RSV findings, including:
  - Common examples of those findings
  - Suggestions for immediate action your team can take to ensure compliance

Preparing a New CHR Application
Tuesday, November 19, 10:30 am-noon – Register Here

Parnassus, Health Sciences West, Room HSW-300
Presenter: Kate Nolan, CHR Parnassus Committee Coordinator

This class will cover the following topics:

- When to submit to the CHR
- How to complete the CHR Application and what attachments to submit
- Demystifying the CHR review process
- Tips for speeding up CHR approval

Ongoing iRIS Training
Various Dates, Laurel Heights Computer Lab

Please check the HRPP site for a list of upcoming iRIS classes. Each session includes hands-on practice in a computer lab setting. Pre-registration is required.

Welcome to the New Release of iRIS (September)

Yesterday, we launched the new release of iRIS, the system formerly called iMedRIS. We are excited to share the system with you, which includes a number of enhancements you requested, such as:

- New look and feel
- Tools that make it easier to submit to Committee on Human Research (CHR), including:
  - Embedded text boxes
  - Streamlined navigation
  - Simplified document revision
  - Linked stipulations
  - Ability to copy past submission forms
- *Significantly* fewer clicks
- Time-saving tools for CHR staff and IRB members
- Implementation of the pre-award module called eProposal (Note: Do not use this module until you are given approval to do so.)

If you missed the webinar we gave about these improvements on 9/13/13, you will find a link to the recorded presentation in the Help section of iRIS. The Help section also includes updated quick guides that have step-by-step instructions on how to use the new features in the system. A link to the Help section is in the upper right-hand corner of the system.

Please be sure to review the list of CHR-iRIS Pending Fixes (below and in the Announcements section in iRIS). These issues have been reported and the vendor is working to resolve them.

We welcome your feedback on the new release of iRIS. Please send your comments or questions to CHR@ucsf.edu or call 415-476-1814.

CHR-iRIS Pending Fixes List

Study Assistant Module

- **System Help area**: links to help documents and guidance may not open. Users should call the CHR office at 476-1814 for troubleshooting help.
- **Key Study Personnel area**: new CITI Training record check feature may incorrectly flag users for needing additional training. The only CITI training required for CHR is the UCSF “Human Subjects Protection Training” (any stage) or the SFVAMC “Human Subjects Protection and Good Clinical Practices” training. (Note: Users can still check CITI records on the CHR website.)

- **Study Application and submission forms**: for XP/IE8 users plain text boxes may not be editable. Users should click the refresh button on the browser to activate the windows.
- **Sponsor details section**: currently doesn't allow users to enter the P number or the A number from within the Application form section. Users should save and close the window, and edit the information to add the P or A number.
- **Sponsor and Drug details sections**: pop-up window scrollbars may not scroll properly in Firefox. Users should switch to another browser.
- **Study document upload**: document name field doesn't auto-populate as it does for consent documents.
- **Study document revision**: previously submitted documents can be resubmitted.
- **Study Application form compare**: changes to personnel are not identified, and purple highlighting randomly appears where no changes have been made. Users should disregard purple highlights.

Training on the New Version of iRIS (Formerly Called iMedRIS) (August)

As we announced earlier this month, UCSF will launch a new and improved version of iRIS (the system formerly known as iMedRIS) on September 16th. The new version of the software includes numerous functionality improvements that will make it easier to submit a study to the Committee on Human Research.

We are offering a variety of training opportunities for you to learn more about the enhancements, including:

- Town Hall meeting on September 6th,
- Webinar presentation on September 13th, and
- In-person training labs on various dates.

Registration links and details about these opportunities are included below and our website.

NOTE: All of the training opportunities will cover similar information, so you do not need to register for multiple events.

Town Hall Meeting
Friday, September 6, 10:30 am-noon, Parnassus, N-225
At the Town Hall meeting, we will demo several of the system improvements and talk about other exciting projects the HRPP has tackled recently. Register here.

iRIS System Improvements Webinar
Friday, September 13, 9:30-11 am
During the webinar, we will demo several of the system improvements. Click here to register. Login information is available on our website.

If you cannot attend, we plan to record the webinar and make the archived presentation available.

In-Person Training Labs
Laurel Heights, Room 307

If you would prefer hands-on training instead of a webinar, attend one of our many lab training sessions. We will practice using some of the new system enhancements.

IMPORTANT NOTE: If you have not used the system before, please attend the "Intro to iRIS" class instead (see the training calendar on the home page).

Pre-registration is mandatory and spaces are limited. Click on the date to register:

- Thursday, September 12, 2-3:30 pm
- Tuesday, September 17, 9:30-11 am
- Friday, September 20, 10-11:30 am
- Wednesday, September 25, 1:30-3 pm
- Tuesday, October 1, 2-3:30 pm
- Wednesday, October 16, 10-11:30 am

Please contact Melanie Mace, Education Coordinator, at Melanie.Mace@ucsf.edu or 415-476-9839 with questions.

Coming Soon: New and Improved Version of iRIS (Formerly Known as iMedRIS) (August)

On September 16th, UCSF will launch a new and improved version of iRIS, the system formerly known as iMedRIS.

The new version of the software includes a more modern interface and numerous functionality improvements requested by the UCSF campus community. Thank you for your valuable input.

Some of the enhancements include:

- Faster navigation
- Significantly fewer clicks
- Simplified document revision – no more check-in/checkout!

These improvements will make it easier to submit a study to the Committee on Human Research. We will send more details on the other exciting upgrades and training opportunities later this month.

In September, the iRIS system also will introduce a new module – the eProposal pre-award system. eProposal is UCSF's new web-based software to support the full life cycle of proposal preparation.

eProposal will be rolled out to a small pilot group first and then released to the entire campus community by the end of the year. Please do not use the eProposal system until you have permission to do so. Stay tuned for more information on eProposal from the UCSF Office of Sponsored Research.

If you have questions about the upcoming iRIS release, please contact the Human Research Protection Program at 415-476-1814 or CHR@ucsf.edu.

Phlebotomy Related Safety Alert and Advisory for Clinical Investigators and Other Research Personnel (August)

This message was sent on behalf of the UCSF Subject Injury Group.

Safety Alert: Within the last 12 months, researchers at University of California, San Francisco have reported a series of adverse events related to research phlebotomy (blood draw) procedures. The following practices are intended to help address these concerns in all research settings where blood draw procedures are performed.

Required:

- All non-licensed personnel performing phlebotomy procedures *must* be currently certified as a phlebotomist by the California Department of Public Health Phlebotomy Program *before* they can draw blood. For specific information about certification requirements, training programs and FAQs check here.

- Personal Protective Equipment (e.g., lab coat, gloves, etc.) *must* be worn by phlebotomy site research personnel.
- Research personnel *must* complete the online UCSF Bloodborne Pathogens Training annually and enroll in the UCSF Health Surveillance Program (e.g. HBV vaccine, etc.). Principal Investigators must maintain training and completion records for all relevant training modules.
- If accidental exposure occurs, research personnel must call UCSF Exposure Hotline at 353-7842 and follow their instructions.
- All serious adverse events and other significant incidents must be reported to the HRPP/CHR within 10 working days, and all such events involving a possible or definite research injury should also be reported to UCSF's Subject Injury Program.

Recommended:

- Query participants about past or current problems with blood draws such as fainting or pre-syncope symptoms (significant anxiety, light headedness or dizziness, etc.). If problems are reported, implement additional safety precautions during the procedure (e.g., offering to draw the subject in a lying position and more closely observing the participant before and after drawing bloods) and a "phlebotomy alert" should be indicated in the subject's medical record.

- Maintain and follow standard operating procedures for responding to emergency situations that, at a minimum, include an algorithm for activating an emergency response and procedures to provide immediate supportive care to study participants who experience a loss of consciousness event. For an example of this sort of SOP, see the UCSF Clinical Laboratory's *Adverse Patient Reaction* procedures check here.

- Consider the safety of the research phlebotomy setting and how well it accords with clinical care blood draw settings (e.g., easily cleaned room; no cloth chairs, carpet, or rugs in phlebotomy sites; available hand washing facilities or use of hand sanitizer; use of phlebotomy chairs, medical waste and sharps containers; etc.).

- Offer and provide to donors, rapid carbohydrate and fluid replacement (e.g.,

cookies, fruit juices) *esp. following fasting blood draws*.
- Exercise extra caution when large amounts of whole blood[1] [2] are drawn (e.g., checking for recent hemoglobin, close post-draw monitoring of subjects).

For questions about this advisory, please contact: *EH&S for laboratory safety guidance; CHR for protocol requirements and Risk Management for phlebotomy certification guidance.*

1. UCSF Clinical Laboratories general policy for phlebotomist
2. CHR/HRPP Expedited Review Blood Sampling guidance

Formal Review Comment: Proposed UCSF Policy on Clinical Trial Registration and Results Reporting (July)

This message is sent on behalf of the Office of Ethics and Compliance.

CALL FOR COMMENT: Draft Campus Administrative Policy 100-36 Clinical Trials Registration and Reporting

UCSF is committed to complying with NIH and FDA regulations regarding clinical trial registration and results reporting, and ensuring clinical trials are publishable under the ICMJE standards. In order to ensure compliance this policy is proposed for formal adoption.

Investigators and/or other interested parties are encouraged to review the draft policy and to submit comments, if they have any, via the webform. Comments will be accepted for 30 days after posting: from July 1 to July 31. Questions may be directed to travis.flynn@ucsf.edu.

Upcoming Education Opportunities (June)

The Human Research Protection Program (HRPP) is offering several classes for researchers, staff, and students 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.

Post-Approval Event Training
Thursday, July 18, 10:00-11:30am

Parnassus, Medical Sciences Building, Room S-214 (map)
Presenter: Laurie Herraiz, Quality Assurance Coordinator

Register Here

In this class, Laurie will discuss the following issues:
- Types of post-approval events
- What and how to submit to CHR
- CHR/QIU role in review of events
- Using iMedRIS to submit reports

Preparing Consent and Assent Forms and the Consent Process
Wednesday, August 21, 9:30-11:30 am

Parnassus, School of Nursing Building, Room N-217 (map)
Presenter: Melanie Mace, Education and Training Coordinator

Register Here

This class covers the following information:

- Understand the purpose of consent forms and when they are needed
- Practice writing techniques for clarify and readability
- Discuss unique consenting issues for vulnerable populations and special situations
- Review consenting process
- Share resources available to help write consent forms

Ongoing iMedRIS Training

Please check the HRPP site 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.

IRB Review Fees for Industry- and Affiliate-Funded Research (June)

As of July 1, the UCSF Committee on Human Research (CHR) will increase its IRB review fees . The increase is necessary to accurately reflect operating costs, and the new rates remain in line with national standards. Please start to work these rates into any new budgets.

The revised rates are as follows:

Initial Full Committee Review:
Internal: $2,700
External (affiliated institutions or non-UCSF organizations): $4,500

Continuing Review, Full Committee:
Internal: $1,200
External: $2,000

Expedited Review, Initial Review and Continuing Review:
Internal: $700
External: $1,200

As a reminder, the CHR charges an IRB fee for the review of the following types of human research:

- Clinical Trials funded by private industry and conducted by UCSF
- All studies submitted on behalf of UCSF-affiliated institutions (e.g., NCIRE, the Gallo Center, the Gladstone Institutes)

Investigator-initiated studies: These studies also are subject to these rates, so please budget accordingly. However, if an investigator believes there are special circumstances, he or she may request a waiver in writing. These requests will be considered by the Director of the Human Research Protection Program.

Western IRB (WIRB): Studies that use the WIRB will be charged the expedited review rate ($700) and should be budgeted into the clinical trial agreement.

The CHR website has more information. Please direct questions about IRB fees to Judy Der at 415-502-2180.

Important Announcement Regarding Coverage Analyses for New Clinical Trials (May)

Sent on behalf of Eileen L. Kahaner, Director – Clinical Enterprise Compliance Program, and Susanne Hildebrand-Zanki, Associate Vice Chancellor of Research

After a soft launch in July 2012, effective June 1, 2013, UCSF will require a comprehensive Coverage Analysis for all new clinical trials in which there are patient care services. We recognize this Coverage Analysis mandate is a change for some departments and research teams. This approach is best practice at leading research institutions because of the financial and compliance benefits for subjects, sponsors, and research institutions. We appreciate your support and cooperation as we implement this best practice at UCSF.

Please see this Memorandum for further instructions and background information. Please make sure this information is disseminated to all relevant staff.

ClinicalTrials.Gov Event Registration (April)

This message is sent on behalf of the Office of Ethics and Compliance.

Navigating clinicaltrials.gov can be time-consuming and frustrating.

Please join us as we host Heather Dobbins PhD, lead results analyst with clinicaltrials.gov and learn how you can accurately and efficiently enter clinicaltrials.gov results.

Dr. Dobbins will be here May 13-15, 2013 to inform and assist UCSF faculty and staff with their clinicaltrials.gov results reporting.

Please complete a **survey** to help us meet your needs during her visit.

For more information, please email: marlene.berro@ucsf.edu.

Updated Charge Master Available in Help Section of iMedRIS (April)

This message was sent on the behalf of the Office of Research and the Medical Center. Please contact Susanne Hildebrand-Zanki, AVC, Research, with any questions.

In order to assist clinical coordinators and staff who prepare clinical trial budgets, a complete and updated charge master is available in the iMedRIS Help section. The charge master now has the current research pricing as well as the pricing for industry-sponsored trials by CPT codes, including the ones most frequently used in trials. For multiple year budgets, a 10% inflation factor should be applied. The industry rates which were approved back in December of 2011 should be budgeted now and will go into effect

in APeX as of July 1, 2013 for trials **starting after** that date.

Going forward, the charge master will be updated yearly in July.

For assessments or tests not listed in the spreadsheet, please contact the Medical Center for the appropriate charge.

Research Billing Compliance: Addressing Common Operational Challenges Webinar (April)

Tuesday April 9, 2013, 11:00 am PDT
Register Here: http://forteresearch.com/webinar-signup/3096857/338030168

Webinar Description
Institutions have become increasingly aware of the need to maintain a successful billing compliance program, but complex operational challenges still remain. Go beyond the basics in this intermediate-level webinar, "Research Billing Compliance: Addressing Common Operational Challenges." This webinar will explore common issues facing clinical research institutions today.

It will be presented by experts Ryan Meade, JD, and Julie Colasacco of Aegis Compliance & Ethics Center, LLP.

Who Should Attend
Individuals that have an understanding of current research billing requirements and would like to learn how to apply them more effectively at their institutions.

Questions?
Please contact Jennifer Kellen (Jennifer.Kellen@ucsf.edu) or Jacquie Eichhorn (Jacquie.Eichhorn@ucsf.edu).

Upcoming Education Opportunities (March)

The Human Research Protection Program (HRPP) is offering several classes for researchers, staff, and students 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
Tuesday, March 19, 10:00-11:30am
Parnassus, School of Nursing, Room N-217 (map)
Presenter: Michael Thomas, Manager, CHR Review Unit

Register Here: https://redcap.ucsfopenresearch.org/surveys/?s=gXyxhf

In this class, Michael will discuss the following issues:

- How and when to submit modifications and continuing reviews
- How to determine if you're submitting an administrative, minor or major modification
- Common problems and how to avoid them

CHR Introductory Training
Friday, April 12, 10:00-11:30am

Parnassus, Room S-214 (map)
Presenter: Melanie Mace, Education and Training Coordinator

Register Here: https://redcap.ucsfopenresearch.org/surveys/?s=uRnPWF

This class covers the following information:

- When to submit to the CHR
- How to submit to the CHR
- Demystifying the CHR review process
- Tips for speeding up CHR approval

Study Recruitment: Which Methods Are Appropriate?
Tuesday, May 21, 10:00-11:30am
Parnassus, HSW-300 (map)
Presenter: Laurie Herraiz, Quality Assurance Coordinator

Register Here: https://redcap.ucsfopenresearch.org/surveys/?s=kCnBGo

In this class, Laurie will talk about the following topics:

- Regulatory issues affecting recruitment
- Different types of recruitment methods – what is acceptable and what is not
- Challenges and solutions for recruiting participants
- iMedRIS Application tips and instructions

Can't Make It to Class?
We will 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 or contact Melanie Mace at 415-476-9839.

Making CHR Applications Easier - Volunteers Still Needed (January)

The CHR has been working with a small group of faculty to simplify the CHR application form for chart review research. Dr. Amy Gelfand is conducting a research study to see whether the new application form is easier to use than the current one. We are seeking a few more volunteers to test the new CHR application form — specifically we are looking for individuals who are planning new, retrospective chart-review research studies for which they would like to apply for CHR approval.

If you choose to be in the study:

- You will be given a log-in and password to access the new CHR application form online. You will complete this application form at your convenience instead of the current expedited application form in iMedRIS and it will be submitted to the CHR for review.

-The CHR will contact you if any revisions are needed on your application, just like they would under the current system.

-After your study is approved by the CHR, you will be asked to complete a short survey. This survey will take about 5-10 minutes to complete and will ask you about your experience using the new form and going through the CHR review process of your study application.

-Once your study is approved by the CHR you can begin working on your study, although the study will not immediately appear in iMedRIS.

-Once you have completed your participation in the study, you will receive a $25 Amazon.com gift card to thank you for your time.

Being in this study is optional. Please contact Dr. Amy Gelfand at GelfandA@neuropeds.ucsf.edu to find out more or to sign up for the study.

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The Human Research Protection Program (HRPP) is offering several classes for researchers, staff, and students 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.

Preparing a New CHR Application
Thursday, January 24, 1:30-3:00 pm
Parnassus, Medical Sciences, Room S-214 (map)
Presenter: Michael Thomas, Manager, CHR Review Unit

Register Here: https://redcap.ucsfopenresearch.org/surveys/?s=mrEpsC

This class will cover the following topics:
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