



Human Research Protection Program HRPP Bulletin No. 16-23 – January-September 2009

Committee on Human Research
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Your Action Required: Sign Up for iMedRIS Access (September 2009)

iMedRIS, the CHR's online protocol submission and review system, is scheduled to go live in late 2009. Before iMedRIS is implemented, we need to add as many users as possible on to the system so they have immediate access to iMedRIS after it launches. Faculty members and students will have access by virtue of their payroll titles, and need take no further action.

However, we need help identifying UCSF staff who:

- Prepare CHR applications
- Check on the status of CHR applications
- Have access to CHR approval and expiration dates
- Need to receive CHR renewal notices
- Need access to CHR-approved consent forms
- Need any of the above for [GESCR](#)

If this applies to you, and you have a UCSF Employee ID, fill out a [User Information Form](#) by Friday, October 9th, so we can be sure to register you as an iMedRIS user before iMedRIS launches. If this applies to someone you know, please forward this email.

Again, this is not necessary for faculty or students.

What information will I need to provide?

When filling out the [form](#), you must provide us with all of the following information:

- **UCSF ID Number***
- **UCSF Department Code***
- **Your name**
- **Email address**

Be sure you have this information before you complete the form.

** If you do not know your Employee ID number or UCSF Department Code, ask your HR representative to provide you with this information before you fill out the form. Alternatively, both your employee ID number and home department*

number are listed on your UCSF earnings statement. The HRPP office will not be able to look up this information for you.

Who DOES NOT need to complete the form?

- **UCSF faculty members and students** – These individuals automatically will be given access to iMedRIS.
- **Individuals who are currently participating in User Acceptance Testing.**
- **Individuals who do not have a UCSF ID number** – They will be given the opportunity to sign up for iMedRIS access at a later date.

Who is receiving this notice?

This bulletin is being sent to all PIs, Co-PIs, and study contacts listed on active CHR studies at UCSF. Please forward this message to any other individuals who may need access to iMedRIS (excluding faculty members and students).

What will happen next?

Shortly we will send out regular announcements with more information on the iMedRIS implementation process, including training plans.

Where can I get more information?

For more information on iMedRIS, please visit the [iMedRIS Project website](#). If you have any questions about the form, please email the iMedRIS Project team at CHR.SystemProject@ucsf.edu.

Using a Current CHR Approval for a New Grant or Contract (September 2009)

The CHR must review and approve the use of an existing approved CHR protocol in support of new funding before Contracts and Grants may accept the new award. Accordingly, if you are adding a new funding source to an existing approved study protocol, you must add the new funding to the CHR application as part of a modification application. In many cases, this can be reviewed quickly by CHR Analysts as an administrative modification. Once reviewed and approved, the CHR will add the new award to the protocol record in Research Online. Note that the PI of the award must also be listed among the investigators on the CHR application.

To add the new funding, follow these steps:

1. Describe the new funding source in Section B, Summary of Modifications, in the [Modification Request for Minor and Administrative Changes Form](#). Be sure to include the grant title and PI, if applicable. Also, please explain if there are any significant discrepancies between the CHR application and the grant or contract, or if this is a training grant.
2. If you are adding federal funds and UCSF is the prime grant holder, you must submit one of the following:

- the Research Plan, including the Human Subjects, Section E of your NIH grant,
- for other federal proposals (contracts or grants), the section of the proposal describing human subjects work, OR
- the section of your progress report if it provides the most current information about your human subjects work.

3. If necessary, update the list of Key Personnel in the Application Form.

The CHR will review the modification and add your new funding source to Research Online. You and the Contracts and Grants administrators have access to this database and will be able to verify that the new funding source has been added.

Please note that a minor or major modification will be required if you are adding a new funding source and any of the following points are true:

- You are modifying the research and the changes do not qualify as [administrative modifications](#).
- You are changing the PI, Co-PI or anyone named on consent documents.

If you have any questions, please call 415-476-1814 and ask to speak with the Analyst of the Day or email us at chr@ucsf.edu.

Staffing for the Human Gamete, Embryo and Stem Cell Research Committee (August 2009)

The office of the Human Research Protection Program now provides administrative support for UCSF's Human Gamete, Embryo and Stem Cell Research Committee (GESCR). Since its founding in 2002, GESCR has provided scientific, ethical, and regulatory guidance and review for the research use of human reproductive tissues.

With new administrative support, GESCR review is more timely than in the past, and questions can be answered promptly by the GESCR Committee Coordinator.

California law requires that all research involving human stem cells be reviewed by a Stem Cell Research Oversight Committee (SCRO). As UCSF's SCRO, GESCR verifies that submitted protocols comply with all federal, state and University guidelines and regulations. In addition to formal review, GESCR advises the campus and individual researchers on the complex ethical and scientific issues that arise in this rapidly changing realm of research.

GESCR consists of bench scientists, clinicians, ethicists, and community members, and is chaired by Bernard Lo, MD. Meetings are held once a month.

For questions about application procedures, contact Denise Bernstein, GESCR

iMedRIS Project Update and Request for Additional Testers (August 2009)

Earlier this year, we asked for volunteers to help us test iMedRIS, the Human Research Protection Program's upcoming electronic submission and review system. We were overwhelmed by the wonderful response we received to our request and excited by the positive reaction to our announcement.

We already have recruited some of you to assist with early-stage testing and appreciate your hard work. However, testing is far from complete and we still need your help.

During August and September, we will conduct user-acceptance testing (UAT). If you participate in UAT, we will give you a brief overview of the iMedRIS system and then ask to use it to complete certain tasks, such as submitting a new study. You can complete the testing on your own or at one of the UAT open houses we are holding at various UCSF computer labs.

UAT requires a large number of testers, so if you are willing to participate and have not previously volunteered, please complete [our volunteer survey](#). If you have already volunteered, we will be in contact with you soon and you do not need to complete the survey again.

Thank you, and please email us at CHR.SystemProject@ucsf.edu if you have questions about the iMedRIS project or testing.

CITI Website Temporarily Offline Starting August 3rd (July 2009)

On Monday, August 3rd, the Collaborative Institutional Training Initiative (CITI) website will be taken offline for approximately five days for a system upgrade. Prior to Monday, please complete your work on CITI and print or save any completion certificates you may need.

Our office recently has received many questions about which CITI courses users should take. When you initially register on CITI, you will be asked to choose a Basic Human Subjects course. The Basic Human Subjects course will satisfy the human subjects training requirement that all UCSF investigators and Key Personnel conducting human research at UCSF or affiliated sites must complete. Later in the registration process, you will be prompted to select a curriculum, or Learner Group. Choose the Learner Group that best fits the type of research in which you are most often engaged.

You also will be asked if you wish to enroll in the Good Clinical Practice (GCP) and Responsible Conduct in Research (RCR) courses. These two courses are *optional* for most people. Some units on campus ask their staff to complete the GCP course. Also, some federal awards require that grantees undergo education in the responsible conduct of research, and the CITI RCR course is one way to meet this requirement. Please visit the [Contracts and Grants](#) website for additional information on the RCR course.

For more information on CITI and the registration process, please visit these sites:

- [CITI Site](#)
- [UCSF CITI FAQs](#)

You also can contact Melanie Mace, HRPP Education Coordinator, at 415-476-9839 or Melanie.Mace@ucsf.edu.

CHR Review of NIH “Just in Time”/ARRA Stimulus Submissions (April 2009)

The CHR expects to receive a large number of studies eligible for "Just in Time" (JIT) submission and the CHR is committed to reviewing these studies in timely fashion so the awards can be issued. However, it is important for investigators to do the following to help identify these submissions:

- Check “Yes” to the JIT submission question at the top of the CHR application form.
- Include a cover letter to explaining the special funding issues.

Please visit the CHR website for more information on the [CHR’s review of “Just in Time” submissions](#).

New iMedRIS System for CHR Reviews (March 2009)

We are excited to announce that later this year, the HRPP and OAAIS will launch iMedRIS, an online CHR submission and review system. The new system will expedite the CHR review and approval process and has numerous other benefits, including:

- Quicker communication of study status
- Study information at your fingertips
- Intuitive application
- No paper!

In order to make this project a success, **we need your help**. We are asking for volunteers to give us feedback about the system in a variety of ways, such as system testing and focus groups. We are looking for comments on the system's ease of use, look and feel, navigation, and application questions. If you would be willing to participate in one or more of these testing groups, please fill out [our volunteer survey](#). We will contact you when a group that meets your criteria is scheduled.

For more information about iMedRIS, please review the [project web page](#).

Reminder for March 1, 2009: New Human Subjects Education Training Requirement for all UCSF Key Personnel (January 2009)

We have replaced the UCSF Protecting Human Research Subjects online training with the nationally-recognized and widely-used online training program called the [Collaborative Institutional Training Initiative](#) (CITI). As of **March 1, 2009**, all UCSF Key Personnel conducting human research will be required to complete this online CITI training. The prior training will no longer be accepted.

Please refer to the [Frequently Asked Questions about Online Training Requirements](#) on the HRPP website for additional information about how to access and register for this training.

For other questions regarding this training, please contact Melanie Mace, CHR Education Coordinator (415-476-9839, Melanie.Mace@ucsf.edu).