

Managing a Scientific Laboratory

Research Ethics & Integrity

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Office for the Protection of Human
Subjects (OPRS)



USC



"You are completely free to carry out whatever research you want, so long as you come to these conclusions."

Office for the Protection of Human Subjects (OPRS)

- Reports to Vice President of Research
- Remain at national forefront of exemplary Human Subjects Protection Program
- Promote and enforce regulatory and ethical requirements for all USC human subjects research activities
- Maximize opportunities for better human subjects protections
- Maintain accreditation of USC Human Subjects Protection Program through sound policies & procedures

Responsible Conduct of Research (RCR)

- RCR is an expectation that research will be conducted ethically, results will be fair and accurate, and funds will be used wisely
- The scientific community, fund givers, the public and academic institutions expect that research be conducted following RCR principles.
- RCR practices vary by discipline and country

Nine Areas of RCR (Federal Expectations)

1. Animal Welfare
2. Conflicts of Interest and Commitment
3. Data Acquisition, Management, Sharing and Ownership
4. Mentor/Trainee Responsibilities
5. Collaborative Research
6. Publication Practices and Responsible Authorship
7. Peer Review
8. Research Misconduct
9. Human Subjects



Misconduct Uncovered by Office of Research Integrity

Assistant Professor at Kansas University
Found Intentionally Plagiarizing

Voluntary two-year settlement agreement :

- Supervision on any PHS-supported research
- Annual summary from the institution/employer certifying the contents of all PHS grant applications, manuscripts
- Exclusion from serving PHS in any capacity

KU Lab Director of a engaged in research misconduct by ***approving publication of three articles and one abstract he knew contained plagiarized text...***

Received same settlement terms as KU researcher who plagiarized

Grad Student Caught *Falsifying Data* at NYSU

Voluntarily three years agreement:

- ✓ Regular research supervision
- ✓ Institution /employer will certify all data submissions to ORI
- ✓ Exclusion from serving in an advisory capacity on PHS research

Scientists Behaving Badly *

Top Ten Bad Behaviors

1. Falsifying or “cooking” research data
2. Disregard for major aspects of human-subject requirements
3. Not properly disclosing conflict of interest (COI)
4. Exploiting subjects, clients, students
5. Plagiarizing
6. Unauthorized use of confidential information
7. “Cherry picking” data/own previous research/withholding details
8. Poor study design/poor record keeping
9. Less rigor expected towards students/colleagues on research
10. Unauthorized changes to study

Who must have RCR training?*

- **Public Health Service (PHS) has requirements for all trainees and certain grant categories**

****National Institute of Health (NIH) does not have specific requirements**

- **National Science Foundations (NSF) requires RCR training for every student on NSF \$**

***Beyond these requirements, all PI's and lab directors should mentor and train students and staff in RCR**

Human Subjects Protection Program

- Protect the rights, welfare, and safety of research subjects
- Evaluate regulatory permissibility and scientific value of proposed studies
- Determine if a subject's participation places him/her at personal risk or harm
- Establish an administrative infrastructure to manage, unify, and support these efforts



What is Human Subjects Research?

◎ **Research*:**

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

◎ **Human subject^{*} :**

Living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

◎ **Benefit:**

A valued or desired outcome; an advantage.

◎ **Risk:**

The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

^{*}as defined in 45 part 46 / policy on the protection of human subjects

What is an Institutional Review Board?

IRB



- An oversight committee charged with reviewing research involving human subjects
- Functions as a surrogate human subjects advocate
- IRB members can be faculty, staff or students of the institution and local community members
- USC has 3 health science IRBs, 1 social behavioral IRB

IRB Submissions

- **Full Board** – greater than minimal risk
reviewed by a full committee e.g. drug study/domestic violence study
- **Expedited** – minimal risk (9 categories)
IRB Chair/designee reviews e.g. blood draw / alcoholism
- **Exempt** – not greater than minimal risk (6 categories)
IRB Chair/designee/staff reviews e.g. blood pressure / educational tests
- **Continuing Review**
For full or expedited review, annually
- **Amendments**
Changes to a study require amendments
- **Not Human Subjects Research**
IRB Chair/designee/staff reviews e.g. doesn't meet the federal definition or is coded data

Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Office for Human Research Protections



- OHRP is the federal office overseeing the system that protects the rights, welfare, and well-being of subjects involved in research with the regulations described at 45 CFR part 46 or its equivalent at other agencies.
- OHRP focus is compliance, education, regulation, and policy setting.

www.hhs.gov/ohrp

U.S. Food and Drug Administration



- The FDA is responsible for protecting the public health by assuring the safety and efficacy of human biological drugs and devices.
- Research studies involving human subjects must comply with federal regulations. (Title 21) of the FDA.

www.fda.gov

Privacy Rule/ HIPAA (Health Insurance Portability and Accountability Act)

Protected Health Information (PHI)

- Identifies or could be used to identify an individual
- Created or received by a healthcare provider, health plan, or healthcare clearinghouse and
- Relates to the past, present, or future physical or mental health or condition of an individual
- Confusion about HIPAA makes certain research difficult to do. All HIPAA makes lawyers rich

*Administered by Health and Human Services (HHS)/Office of Civil Rights (OCR)



We've run out of lab rats,
Henderson... Put this on
and come with us.

search.ID: jmcn7

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Privacy and Confidentiality

- **Privacy** is about personal information that is not readily apparent. It also applies to setting.
- **Confidentiality** is about data; how its obtained and protected
- Discuss some privacy issues
- Some confidentiality issues
- Potential risks of each



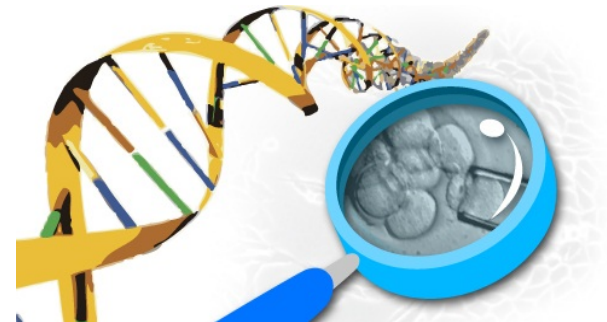
Technology vs. Privacy/Confidentiality

- Internet
- Social Networking
- Data security measures



“Hot Science vs. Privacy/ Confidentiality”

- Biobanking
- Stem cells
- Electronic Medical Records
- Genetics



Who are Vulnerable Populations?

- ◎ **Vulnerability can be situational and individual**
 - Pregnant Women/Fetuses*
 - Comatose patients
 - Prisoners*
 - Cognitively impaired
 - Children*
 - Employees/Students
 - Homeless
- ◎ **Vulnerability is a power differential**
- ◎ **Vulnerable subjects MUST receive extra protections**



International/Ethnic Research

- **Protections must equal protections required in the US**
- **Obtain local permission / ethics board approval**
- **Consent and recruitment documents must be in a language that is understood by the subjects**
- **Cultural Sensitivity must be learned and practiced by investigator**
- **Guidelines available at OHRP's website www.hhs.gov/ohrp/international/**
- **International research concerns may also apply to local ethnically diverse neighborhoods, such as Los Angeles**



Online Human Subjects Education

CITI

- Required for all “Key Personnel” conducting human subjects research at USC.
- Two tracks—Biomedical and Social & Behavioral
- Specific user groups—Investigators, Staff, IRB members, Students
- Modules and quizzes for review
- Available 24/7 from any computer
- Certificate valid for three years & uploaded to USC IRB Application System (iStar)
- CITI Helpdesk: **citi@usc.edu** or 213.821.5272
- CITI FAQs:
www.usc.edu/oprs/citi

CITI Homepage: www.citiprogram.org

CITI Collaborative Institutional Training Initiative

Forgot username or password?

How do I use the new **Lab Animal Course**?

See how your institution can become a CITI participant

Welcome

CITI Login and Registration Page

i The CITI Program is a subscription service providing ethics education to all members of the research community. To participate fully, learners must be affiliated with a CITI participating organization.

The CITI course is a protected site. If you are a new learner at a participating organization you must register to create your own username and password and gain access to the site.

i **New Users** [Register Here](#)

i **Already Registered?** [Login Below](#)

Username

Password

Submit

[Forgot username or password?](#)

Announcements and FAQ

The CITI Program offers Public Access Courses to individuals and research organizations. Take the:

i Public Access Course in [Responsible Conduct of Research \(RCR\)](#) (includes access to the course, "Essentials for IACUC Members")

i Public Access Course in [Health Information Privacy and Security Course](#)

i Public Access [CITI International Course](#) Site

i Laboratory Animal Welfare Course is now available to CITI participating organizations

What is iStar?

- ❖ iStar (Online IRB application submission system)
- ❖ Three participating IRBs: (HSIRB, UPIRB, CHLA)
- ❖ To request a user account, send email to istar@usc.edu and include your Last Name, First Name, division and department, email address, user role & phone number



The screenshot shows the iStar website home page. At the top left, there are logos for USC and iStar. The top right corner has a 'Login' link. Below the logos, there are navigation tabs for 'Home' and 'System Information'. A left sidebar contains a menu with categories like 'General Information', 'Training Resources', and 'Contacts'. The main content area features the iStar logo, the university and hospital names, and the title 'IRB Submission Tracking And Review system'. A login form is on the right with fields for 'User Name' and 'Password', and a 'Login' button. A red banner at the bottom contains an important news message. Two green boxes with arrows highlight the 'Sandbox' link in the sidebar and the 'LOGIN HERE' text in the main content area.

USC **iStar** Login

Home System Information

Home

Sandbox

General Information

- Obtaining an iStar Account
- Browser Support
- Help Using iStar
- FAQ
- iStar Training
- Information for Committee Members

Training Resources

Contacts

- IRB - CCI
- IRB - HSIRE
- IRB - UPIRE
- iStar Technical Support

iStar

University of Southern California &
Childrens Hospital Los Angeles

IRB Submission Tracking And Review system

Login with your iStar Username and Password:
[\(Click here for information on obtaining an iStar account\)](#)

Version 2.1

LOGIN HERE

Login as...

User Name:

Password:

Remember me

[Forgot password?](#) [Forgot user name?](#)

After signing into this site, you are bound by the terms and conditions set forth when you received your account.

Important News

Please note that every Sunday between 3am and 8am iStar is not available due to system maintenance.

Federal Offices

- Office of Research Integrity (ORI)
<http://ori.hhs.gov>
- National Institute of Health (NIH)
www.nih.gov
- Public Health Service (PHS)
www.usphs.gov
- National Science Foundations (NSF)
www.nsf.gov



Resources:

OPRS/IRB Websites, booklets, videos:

<http://oprs.usc.edu/education/>

Sample studies, consent templates / information sheets:

<http://oprs.usc.edu/review/forms/>

Human Subjects Research Booklets:

<http://oprs.usc.edu/education/booklets/>

Obtaining an iStar Account:

<http://oprs.usc.edu/review/istar/>

RCR Training:

<http://oprs.usc.edu/education/rcr/>

Who Can I Contact for Help?

www.usc.edu/oprs

Institutional Review Boards

University Park Campus

3720 S. Flower Street
Credit Union Building # 301
Los Angeles, CA 90089
Tel: (213)821.5272
Fax: (213)821.5276
E-mail: upirb@usc.edu
<http://oprs.usc.edu/upirb/>

Health Sciences Campus

General Hospital, Suite 4700
1200 North State Street
Los Angeles, CA 90033
Tel: (323)223.2340
Fax: (323)224.8389
E-mail: irb@usc.edu
<http://oprs.usc.edu/hsirb/>

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