

UCLA

**Town Hall Meeting:
Human Research
Protection Program
Improvements
Overview**

**Human
Research
Protections
Program**

Thursday, April 23, 2009
9:00 to 10:30 am
Louis Jolyon West Auditorium

Improvements in Six Areas

- ✓ Human Research Website
- ✓ Policies and Guidance
- ✓ Forms and Applications
- ✓ Post Approval Reporting
- ✓ Quality Improvement Program
- ✓ Education and Training

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**Human
Research
Protections
Program**



- ✓ Revised and Improved and Human Research Website

<http://www.oprs.ucla.edu/>

OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS

The Office for Protection of Research Subjects (OPRS) serves as the administrative arm for federally mandated compliance committees responsible for reviewing all research protocols that involve the use of human and animal subjects. Charged with implementing University policies that are based on federal regulations and State laws, the committees are composed of faculty, community representatives and consultants representing special subject populations. The committees work in partnership with the OPRS to maintain the federal assurances that govern the use of human and animal subjects in research conducted by UCLA investigators and students, handle special problems, and participate in audits.

Human Research Protection Program

➤ **CONTACT HRPP**

- **Program Feedback**
- **IRB Staff**
- **Campus Consults**

➤ **WHAT'S NEW**

- **Human Research News**

➤ **FOR RESEARCHERS**

- **Meeting Calendars**
- **Forms**
- **Policies and Guidance**
- **Investigator Survey**
- **Other Resources**
- **Participants Bill of Rights**
- **Certification and Education**

➤ **FOR & ABOUT IRB MEMBERS**

- **Meeting Calendars**
- **IRB Member Rosters**
- **Checklists for Members**

➤ **FOR RESEARCH PARTICIPANTS**

- **Información para Participantes**
- **Participant Survey**

Animal Research Committee

- **About**
- **Applications**
- **Certification**
- **Inspections**
- **Veterinary Care**
- **Resources**
- **Contact**

✓ Updated HRPP Guidance, Procedures and Policies

- **#1** UCLA Policy 991: Protection of Human Subjects in Research
- **#2** Determining which Research Activities Require UCLA OPRS/IRB Review
- **#29a** The Use of Legally Authorized Representatives or Surrogate Consent
- **#36** Emergency Use of a Test Article

✓ Updated Guidance, Procedures and Policies (continued)

- **#37** Genetics Research
- **#39** Research Collection, Use, and Secondary Analysis of Human Data and/or Specimens
- **#40** Data and Specimen Repositories
- **#41** Data Safety Monitoring Plan
- **#43** Data Security in Research

√34 More Translations of Research Participants Bill of Rights

- Amharic/Ethiopian
- Arabic
- Bengali
- Bosnian (also use for Croatian and Serbian)
- Burmese
- Khmer (Cambodian)
- Chinese (Simplified)
- Chinese (Traditional)
- Farsi
- French
- German
- Gujarati
- Hebrew
- Hindi
- Hmong
- Indonesian
- Japanese
- Korean
- Laotian
- Polish
- Portuguese
- Punjabi
- Romanian
- Russian
- Spanish
- Tagalog
- Thai
- Turkish
- Ukrainian
- Urdu
- Vietnamese

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√ARRA (American Recovery and Reinvestment Act) IRB Pre-Assignment Request Form

1. **Complete** this form as soon as you find out that you will receive ARRA funding.
2. **E-mail** the form to: Alison Orkin or Alisa Irwin
3. **Use** “IRB Pre-Assignment Request for ARRA” in the subject line of the e-mail.
4. When you do submit your IRB application, **attach** a copy of this form to the front of your application.
5. The IRB will use this to **pre-assign** your study for IRB review.

✓ New and Revised Forms

✓ PI Self Certification Form

- For Non-Human Subject Research Determination
- Decision Tree

✓ Exempt Certification Forms

- Subject Contact
- No Subject Contact

✓ No Subject Contact Application

- For studies accessing or studying data and/or human biological specimens with identifiers
- Replaces previous HS-7 Medical Records Review



✓ Application for the Involvement of Human Participants in Research

- Replaces HS-1
- Two types:
 - Social Behavioral, Education and Health Services or
 - Biomedical
- Place to indicate if study qualifies for expedited review (identify expedited review category)
- Requires use of Application Supplements

✓ Application Supplements

These supplements are to be used with primary application:

- **Investigator**

- Disclosure of Financial Interests

- **Populations**

- Inclusion of Children and Minors

- Inclusion of Prisoners

- Inclusion of Pregnant Women, Fetuses, Fetal Tissue

- Inclusion of Neonates

Application Supplements continued

■ **Consent**

- Waiver of Informed Consent . . .
- Surrogate Consent
- Emergency Medical Research Waiver of Informed Consent

■ **Methods and Procedures**

- Genetic Analysis
- Investigational Device
- Investigational Drug
- Multi-Institutional Research
- Data and/or Specimens Repositories

- ✓ **Surveys** posted to elicit feedback from
 - ✓ Researchers
 - ✓ Research Participants



May Preview



⇒ **IRB approval packets** available
on line on the **Office of Research
Portal**

<http://portal.research.ucla.edu/>

√ **Post-Approval Reporting**

What Are the Types of Post-Approval Reports?

- Adverse Events
- Protocol Violations, Deviations and Incidents
- Updated Study Safety Information

Note: See Guidance #57: Post Approval Reporting Requirements for Investigators

Goals of Post-Approval Reporting

- Protect the safety, rights and welfare of research subjects
- Evaluate the risk/benefit of the research
- Ensure that adequate safeguards are in place
- Inform subjects of any significant new information that may alter their decision to participate or continue participation

Adverse Event Reporting

- **Submission Criteria** – 2 and 10 working days
- **Continuation Review** – brief narrative summary

Internal Adverse Events

Report **within 10 working days**

- Unexpected; related/possibly related; and places subjects and others at greater risk of harm than previously known or recognized
- Expected and related but indicates a higher frequency of occurrence or greater severity

Internal Adverse Events continued

Report **within 2 working days**

- Subject death – interventional study, unexpected and related/possibly related to research participation

Report **at Continuation Review**

- Subject death – interventional study, expected and related/possibly related to research participation

DO NOT REPORT – subject deaths that occur in non-interventional studies

External Adverse Events

Report **within 10 working days**

- Unexpected; related/possibly related; and places subjects and others at greater risk of harm than previously known or recognized
- For studies where subjects have completed participation, any event that indicates a potential risk which requires notification of previously enrolled subjects

External Adverse Events continued

DO NOT REPORT

- Events that ***do not meet the criteria*** for submission to the IRB
- Events when all subjects at UCLA have completed participation and the event ***does not require notification of previously enrolled subjects***

Violations, Deviations and Incidents

- **Submission Criteria** – 5 and 10 working days
- **Continuation Review** – brief narrative summary and a list of non-reportable events (any event that does not meet the 5 or 10 day submission criteria)
- **Examples include:**
 - **Violations:** use of expired or incorrect consent documents; enrollment of ineligible subjects
 - **Incidents:** stolen laptop, breach of security

Violations, Deviations and Incidents continued

Report within **5 working days**

- Any emergent variance from the approved IRB protocol made without prior IRB review *in order to eliminate apparent immediate hazard to the research subject*

Report within **10 working days**

- Unexpected; related/possibly related; *and* places subjects and others at greater risk of harm than previously known or recognized

Updated Study Safety Information

- **Provides IRB** with necessary information to evaluate the risk/benefit of the research
 - in real time and
 - at the time of Continuing Review
- **Examples include:**
 - DSMB reports,
 - site monitoring/audit reports,
 - interim study results,
 - FDA Safety Alerts,
 - publication in the literature,
 - changes in the Investigator's Brochure,
 - sponsor imposed hold, suspension or termination

Updated Study Safety Information continued

Report within **2 working days**

- Any sponsor imposed hold, suspension or termination

Report within **10 working days**

- Any updated information that addresses risk or potential benefit

Report **at Continuation Review**

- Any reports not previously submitted
- Provide a brief narrative summary

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**Human
Research
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✓ **Quality Improvement
Program**

Quality Improvement Program

- **Routine Quality Improvement On-Site Reviews**
 - ✓ Protocol Adherence
 - ✓ Accurate, complete and current record keeping
 - ✓ Accurate, timely reporting to the IRB, FDA
 - ✓ Adequate subject records and source documents
 - ✓ Appropriate informed consent process

Quality Improvement Program

- **Directed/For-cause On-Site Review**
 - **Internal Requests**
 - University Officials, IRB, SOM, DOM, Audit & Advisory Services, Risk Management, Whistleblower, Participant Complaints or Injury
 - **Externally Initiated**
 - OHRP, FDA, NIH, DOD, DOE, DON
 - **Reports reviewed and approved by IRB**
 - Status of IRB Approval
 - Corrective Action Plan

Quality Improvement Program Activities

- Ensure the protection of human subjects participating in UCLA IRB approved research
- Provide ongoing support and internal oversight to research community
- Focus on biomedical research not monitored by other QA/QI programs on campus
- Emphasis on vulnerable populations [45 CFR 46.111(b)], regardless of sponsor

✓ Education and Training

Certification



- Collaborative Institutional Training Initiative (CITI)
 - Key Research Personnel
 - September 1, 2009*
 - FAQ's – see website

*Must complete training by this date when submitting new and/or continuing review applications.

Education and Training

➤ Education

- **Calendar to be posted**
 - Various Presentations
 - Monthly Workshops: first Thursday each month

➤ Campus Consults

<http://www.oprs.ucla.edu/human/campus-consultants>

➤ Training

- **OPRS website**
 - Training Request Form
 - *Human Research News:*
<http://www.oprs.ucla.edu/human/news/>

Questions???



IRBs:

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