OPRS Human Research Protection Program: AAHRPP Site Visit and HRPP Improvement Plan Update

Sharon K. Friend, MS, CIP
Director of OPRS Operations
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The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) promotes and recognizes high quality Human Research Protection Programs—worldwide.

To earn accreditation, organizations must provide tangible evidence — through policies, procedures, and practices — of their commitment at all levels of the organization:
- not only to protect rights and welfare of research participants
- but also to promote and advance human research more efficiently and effectively
Benefits of AAHRPP Accreditation

- Development of more effective and efficient review processes through the self-assessment and continuous quality improvement process
- Enhancement of UCLA’s HRPP reputation and the quality of our human research
- Reduction of review inconsistencies as a result of written policies, guidance and procedures
- Ability to more easily develop reciprocal IRB review agreements with other AAHRPP-accredited institutions
- Expanded educational outreach
Other Accredited Institutions

**In CA:**
- UC San Francisco
- UC Irvine
- UC Riverside
- USC
- Cedars-Sinai
- Stanford
- VA Greater LA
- VA San Diego
- VA San Francisco

**Outside CA:**
- Johns Hopkins
- Harvard
- Duke
- Vanderbilt
- U of Washington
- U of Michigan
- U of Minnesota
- Washington U
- **Pfizer**
Where is UCLA in the process?

- Conducted a detailed self-assessment of HRPP:
  - Reviewed processes to assure we achieve desired outcomes of accreditation standards
  - Revised and updated policies, guidelines, procedures, forms and processes as needed

- Preparing for second on-site evaluation visit (April 29 – May 1): Two Site Visitors will
  - Review program SOPs, protocols and minutes
  - Interview various IRB members, staff, PIs and research staff as well as key organization officials (for a total of 63 people)
HRPP Improvement Plan Rollout Update

✓ Improved OPRS Human Research website
✓ Updated guidance and policies posted
✓ 34 more translations of Bill of Rights posted
✓ Elimination of the requirement for IRB “administrative” approvals
✓ ARRA IRB Pre-Assignment Request Form
Updated and Revised Application and Reporting Forms Posted

✓ PI Self Certification Form for Non-Human Subject Research Determination + Decision Tree
✓ Exempt Certification Forms (2 types)
✓ No Subject Contact Application (for studies accessing or studying data and/or human biological specimens with identifiers)
✓ Application for the Involvement of Human Participants in Research—formerly HS-1:
  ✓ Social Behavioral, Education and Health Services
  ✓ Biomedical
  ✓ Place to indicate “expedited review category”
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
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
Improvements Rollout continued

- **Revised post approval reporting forms** and decision trees: adverse events, violations and incidents, other updated safety information

- **Surveys** posted for Researchers and Research Participants to elicit feedback

- **Collaborative Institutional Training Initiative (CITI)** on-line human research training initiated

- **Town Hall Meeting** to go over improvements
  - Thursday, April 23, 2009
  - 9:00 to 10:30; here
May Preview

- Dedicated IRB staff for expedited processing of studies that qualify for expedited review
- Posting of IRB approval packets on the Office of Research Portal