OPRS Quality Improvement Program

Judith L. Brookshire, Director
Quality Improvement Program (QIP)

- On-site review of human research studies
- Research participant’s experience report
- Review and assessment of HRPP operations and procedures
- Evaluation of IRB member and IRB staff performance
HRPP QIP Coordination

- Coordinates Activities with other Quality Assurance/Improvement Units on Campus
  - UCLA School of Medicine Quality Assurance Program
  - UCLA Office of Compliance and Privacy
  - Jonsson Comprehensive Cancer Center Internal Quality Assurance Program
  - Department of Medicine Clinical Trials Compliance Office
  - GCRC Office of Research Participant Advocacy
On-Site Review of Human Research Studies

- QI On-Site Routine (not for cause) Review
  - PI’s understanding and compliance with regulations and policies
  - Effectiveness of resources
  - Identification of current trends in practice
  - HRPP educational program

- QI On-Site Directed (for cause) Review
  - Determinations necessary to protect subjects
  - HRPP educational program

- QI Reports to the IRB
  - Determinations to correct deficiencies
  - HRPP educational programs
New Guidance and Procedures

- Consolidates previous policies addressing biomedical adverse event reporting, violations and incidents
- More definitive submission criteria for reporting adverse events, violations and incidents
- New reporting requirement of updated study safety information
HRPP Collaborative Institutional Training Initiative (CITI)

- Nationally recognized
- Online web based training program
- Education modules and quizzes relevant to research and discipline
- Replaces current online training and certification requirements
- April 1, 2009 implementation
- September 1, 2009 all key research personnel must complete
- HRPP/OPRS training and education
Animal Research Oversight Quality Improvement Program (QIP)

- ARC/DLAM Educational Meetings
  - Review ARC policies and DLAM procedures
  - Increased communication
  - Decrease in number of serious noncompliance

- ARC QIP Site Visits
  - Post approval onsite (not for cause) review of animal research protocols and facilities
  - Assure that experiments conducted in the lab match those described in the approved protocol
  - Identify/Correct “protocol drift”
  - Reports may go to the ARC if deficiencies are found
  - QIP Site Visits do not replace semiannual facility inspections
ARC Collaborative Institutional Training Initiative (CITI)

- Online web based ARC General Certification course and quiz
- Replaces current didactic ARC General Certification requirement
- April 1, 2009 implementation
  - By September 1, 2009, all personnel listed on protocols must be recertified if more than 3 years, and
  - September 1, 2009 all previously exempted personnel must be certified
- ARC/OPRS training and education
OPRS Office Hours at Outreach Campus Locations

- **MIRB**: Mondays, noon to 4PM: Center for Health Sciences (CHS) Building, Room 14-214K. (contact Michele Carter, mcarter@oprs.ucla.edu)

- **ARC**: Fridays, 10:00am to noon: Center for Health Sciences (CHS) Conference Room B3-143. (contact Kathy Wadsworth, kwads@oprs.ucla.edu)

- **GIRB**: To be announced (contact Alison Orkin, aorkin@oprs.ucla.edu)