COMPLIANCE TRENDS

Post Approval Reporting and Quality Improvement Monitoring

Judith Brookshire, Director
Office for Protection of Research Subjects
August 13, 2009
Post-Approval Reporting (PAR)

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

OPRS HRPP Guidance #57
Revised Guidance & Procedures

- Consolidated previous policies
- Redefined submission criteria
- New reporting requirements
- Study safety information
- Developed new forms for reporting
PAR changes – Better Information Upfront

- Protect the safety, rights and welfare of subjects
- Evaluate risk/benefit
- Ensure adequate safeguards
- Inform subjects of significant new information
Refined Focus

- Focus on unexpected events
- Fewer adverse event and violation reports
- Additional updated safety reports
- Enhanced risk assessment
Adherence to new PAR Guidance – April 2009

- Post Approval Reports: 58
- 24 Violations (41%)
- 31 Information (31%) (Revised Investigator’s Brochure, DSMB Report, Sponsor notification and/or Closure)
- 03 Adverse Events (5%)
Adherence to new PAR Guidance – May 2009

- Post Approval Reports: 69 Total
- 11 Violations (16%)
- 38 Information (55%) (Revised Investigator’s Brochure, DSMB Report, Sponsor notification and/or Closure)
- 20 Adverse Events (29%)
Adherence to new PAR Guidance – June 2009

- Post Approval Reports: 63 Total
- 11 Violations (17%)
- 28 Information (44%) (Revised Investigator’s Brochure, DSMB Report, Sponsor notification and/or Closure)
- 24 Adverse Events (38%)
Adherence to new PAR Guidance – July 2009

- Post Approval Reports: 84 Total
- 18 Violations (22%)
- 33 Information (39%) (Revised Investigator’s Brochure, DSMB Report, Sponsor notification and/or Closure)
- 33 Adverse Events (39%)
Quality Improvement Program (QIP)

- Routine Quality Improvement On-site Reviews
- Directed/For-cause On-Site Reviews
QIP Review

- Protocol Adherence
- Accurate, complete and current record keeping
- Accurate, timely reporting to IRB, FDA
- Adequate subject records and source documents
- Appropriate informed consent process
QIP Scope and Purpose

- Vulnerable populations, investigator-initiated research
- Biomedical research not monitored by other QA/QI programs
- Ensure protection of human subjects participating in UCLA IRB approved research
- Provide ongoing education and internal oversight
QIP: January – July 2009

- 25 On-Site Reviews
  - 19 Routine
    - Investigator Initiated: 17
    - Pharma Sponsored: 2
  - 6 MIRB Referred
    - Investigator Initiated: 3
    - Pharma Sponsored: 3
Current Trends

- Number of Studies with Protocol Violations *not* reported to the MIRB in Required Timeframe:  6

- Number of Studies with ICF Violations:  5
Current Trends

- Number of Studies with a lapse in MIRB Approval: 2
- Number of Studies without documentation of California Experimental Subjects’ Bill of Rights: 2
Recommendations for Further Education

- QA self-review guidance tool
- DSMB Requirements for investigator-initiated studies
- Clinicaltrials.gov registry
- OPRS HRPP Website
- Updated PAR Requirements
  - HRPP Policy & Guidance #57
Recommendations for Further Education

- Informed Consent checklists
- CITI IRB Training and Certification
- Recommendation for further education/training
- New Application forms
Future Trends

- Enhanced education and training opportunities may provide a clear direction for future on-site visits.
- Increased availability of on-line education, lectures, and didactic sessions should impact both PAR and QIP trends
HRPP Education & Training

- Fall 2009 Lecture Series
- Lunch-time “Brown Bag” Sessions
- Medical Research Coordinator Workshop
- MIRB and GIRB Consults
- Discipline/Department Specific Presentations
Fall 2009 Lecture Series
Louis Jolyon West Auditorium

- History and Ethics in Human Subjects Research
  - September 16th, 10-11:30

- An Overview of the Consent Process
  - September 24th, 10-11:30
Fall 2009 Lecture Series
Louis Jolyon West Auditorium

- How to Assess Risk: The R&B’s of IRBs
  - September 24th, 10-11:30

- Good Clinical Practice
  - October 28th, 10-12pm
Lunch-time “Brown Bag” Sessions

- First and third Thursday of the Month, noon to 1:00pm
- Kinross 210 Conference Room
Medical Research Coordinator Workshop

- September 29th
  - 210 Kinross
  - 2:00-4:00pm

- Interactive workshop geared to new research coordinators and first time submitters
MIRB Consults

- Center for Health Sciences Room 17-187 CHS
- Mondays noon to 4:00 pm & Thursdays 9:00 am to 11:00am
- Appointment Requests: MIRB@oprs.ucla.edu
General Campus Consults

- Wednesdays, 10am - 1pm

- Appointment Requests: GCIRB@oprs.ucla.edu
Collaborative Institutional Training Initiative (CITI)

- September 1, 2009
Collaborative Institutional Training Initiative (CITI)

- All Key Research Personnel must complete the online CITI Training Program prior to IRB approval of a new or continuing review application.
Human Research Protections Program