OPRS Human Research Protection Program: Revised Post IRB Approval Reporting Requirements

Sharon Friend
Director of OPRS Operations
May 14, 2009
Overview

- Why the Change?
- What’s Required
- What and When to Report
- Case Studies
Why the Change?

- Revised Federal Guidance
  - OHRP
  - FDA Guidance

- Association for the Accreditation of Human Research Protection Programs (AAHRPP) Guidance
What’s Required

Federal regulations require the “prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any unanticipated problems involving risk to subjects or others”

45 CFR 46.103(b)(5)
21 CFR 56.108(b)
What’s an Unanticipated Problem?

Any event, experience or outcome that meets *all* of the following criteria:

- Unexpected
- Related or possibly related to participation in the research
- Suggests that the research places subjects or others at greater risk of harm than was previously known or recognized
What happens beyond reporting of unanticipated problems?

An unanticipated problem usually requires consideration of modifications to:

- the research protocol,
- informed consent documents, or
- other corrective action to protect the safety, welfare, or rights of subjects.
What is different now?

- **Focus** in on the unexpected events
- **IRB Guidelines** now require both
  - Fewer adverse event and violation reports and
  - Additional updated safety reports
- **New Forms** for reporting
  - Adverse Events (Internal and External)
  - Protocol Violations, Deviations and Incidents
  - Other Safety Reports
What is the goal of reporting?

- Protect the safety, rights and welfare of human research subjects
- Ongoing evaluation of the risks and benefits of the research
- Ensure that adequate safeguards are in place
- Inform subjects of any significant new information that may alter their decision to participate in the research
What to Report

❖ The following if events meet the definition of unanticipated problems:
  - Protocol Violations or Deviations—intended or accidental
  - Protocol Incidents, including subject complaints
  - Adverse events

❖ Updated Safety Reports (DSMB Reports, Audit Reports, Revised Investigator Brochure, Notification of Sponsor Suspension…)}
Unanticipated Problems (UPs)

Violations
Deviations
Incidents

Unanticipated Problems

Adverse Events

Updated Study Safety Information
When to Report

- **10-day** Reporting Requirements
  - Adverse Events that are UPs
  - Protocol Violations or Incidents that are UPs
  - Updated Safety Information

- **5-day** Reporting Requirement
  - Protocol change to eliminate immediate hazard to subjects
When to Report (continued)

- **2-day** Reporting Requirements
  - Internal on site death PI determines to be unexpected and related or possibly related

- **Continuing Review**
  - Violations, deviations or incidents that are not unanticipated problems
  - Brief narrative summary of adverse events

- See *Summary Sheet* on website
Case #1: Should this be reported to the IRB?

A subject is enrolled in a trial evaluating an investigational device versus standard of care for carotid artery stenosis and recent transient strokes. After the device placement the subject suffers a stroke. The consent form lists a 5-10% chance of stroke as a risk. The DSMB attributes the event to the study device. To date 2 out of 20 subjects have suffered a stroke.
Case #2: Should this be reported to the IRB?

The PI is notified by the study sponsor that the dose used in one of the study arms is found to cause increased toxicity to subjects. The sponsor instructs the PI to immediately transfer subjects to another study arm and to perform additional safety tests.
Case #3: Should this be reported to the IRB?

An investigator conducting social-behavioral research on college students collects personal identifiable sensitive information. The data is stored on a laptop. The computer is stolen.
Case #4: Should this be reported?

A researcher is conducting a study that involves surveys of sexually risky student behavior. On the evening of the survey, one of the students who participated in the study experiences an asthma attack requiring a visit to the ER.
Questions? More Information?

- See OPRS Human Research website at http://www.oprs.ucla.edu/ for guidance (#57) and forms and summary sheet.
- Call Bette Okeya at 310-206-2040
- E-mail bokeya@oprs.ucla.edu
- E-mail gcirb@oprs.ucla.edu