Effect of Changes in Human Exposure Regulations on Quality Assurance

A New Paradigm of Field QA

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Learn to QA that which cannot be QA’d
• QAE Officers?

• Quality Assurance & Ethics
  – Check Worker Consent
    • No coercion
    • Can opt out at any time
    • Meet minimum requirements
      – Experience
      – Age
  – Monitor Working Conditions
    • Heat Stress/Dehydration

Excerpt from Feb 2007 NAICC Presentation
New Rule

- 40 CFR, Part 26: Protection of Human Subjects
  - Subpart A: Basic EPA Policy for Protection
  - Subpart B: Prohibition of Research
  - Subpart C: Observational Research - Women
  - Subpart D: Observational Research – Children
  - Subpart K: Basic Ethical Requirements
  - Subpart L: Prohibition of Third-Party Research
  - Subpart M: Requirements for Submission
  - Subpart O: Actions for Noncompliance
  - Subpart P: Review of Research
  - Subpart Q: Ethical Standards
People to Know

• Human Studies Review Board (HSRB)
  – Advisory panel to EPA
  – Appointed by Congress
  – Must review all proposed research involving human subjects (except “observational” studies)

• Institutional Review Board (IRB)
  – Private Companies
  – Membership made up of cross-section
  – Must review all proposed research
    • Protocols
    • Informed consent forms
    • Any information given to workers
Timeline

• Sponsor Develops Study Plan
• Protocol Prepared
• All documents undergo IRB review
• All documents submitted to EPA/HSRB
• With approval, study may begin….
• Otherwise, revisions will be necessary and whole process starts over.
• This adds at least 6 months lead time to starting a field study
QA Concerns

Pre-study Issues (Subpart K):

- §26.1115(a)(1): All materials submitted to an IRB
- §26.1115(a)(2): Minutes of IRB meeting(s) documented
- §26.1115(a)(6): SOPs submitted to IRB
QA Concerns

Protocol Issues (Subpart K):
– §26.1125(a)(2): Measure taken to reduce risk
Protocol Issues (Subpart K):

- §26.1125(b): All info/documents reviewed by an IRB
- §26.1125(c): Recruitment procedures
- §26.1125(d): Description of Methods of Presenting Information (consent process)
- §26.1125(e): Documentation of correspondence
- §26.1125(f): Official notification from an IRB has been received
QA Concerns

Field Research (Subparts B, K, & M):

– §26.203: Prohibitive Research
  • Assure that female participants are not pregnant
  • Assure that no participants are under 18 years old

– §26.1117: Documentation of Informed Consent
  • Can’t be present during consent
  • Can only review signed confidential consent forms

– §26.1303: Submission of Information
  • Assure that all appropriate ethical documentation is complete
What This Really Means

• More Paperwork
  – Protocol size has almost tripled (15 pgs – 40+ pgs)
  – Final Reports will also have increased sections
  – New SOPs are needed to meet HSRB requirements
    • Recruitment of Participants
    • Consenting Processes
    • Language Requirements
    • Mitigation of Risks
    • Handling Confidential Personal Information
  – Flexibility for QAUs to be able to assure compliance without being able to audit everything
AHETF SOPs

- Personnel Responsibilities – Ethics Training
- Procedure for Recruiting Study Participants
- Archiving Confidential Worker Information
- Ethical Requirements for Studies
- Recruiting Volunteers
- Worker Health Status
- Pregnancy Testing
- Pesticide Safety Precautions
- Adverse Events Reporting for IRB
AHETF SOPs

- Identification and Control of Heat Stress
- Emergency Procedures for Human Subjects
- Language Considerations
- Informed Consent of Study Volunteers
- Compiling Lists of Potential Growers
- Compiling Lists of Potential Applicators
- Recruiting Eligible Growers/Applicators
- ???

15 New SOPs with 14 revisions in past 12 months
Developing the Process

• Only Audited Three Studies
  – One was an “Observational” Study
    • Not scripted, but purely watching workers do a normal daily routine
    • Samples still collected as usual
  – Two were typical field Worker Exposure Studies
    • Applicator Only
    • One worker per day
    • Some workers were randomly selected at time of study

• Plans for Conducting Future Audits
  – Still Developing this Process
  – Policy in place to review all consent forms immediately after consenting process completed
  – QAU to have taken certified ethics course, as all study team members are required
In Conclusion

• Standard GLP Audits Still Conducted
  – Documentation
  – SOPs
  – Protocols

• Adapt new Ethical Regulations to QA Policy
  – Be able to assure that the intangibles are met
  – Assure researchers are following ethical rules
  – Verify what little documentation is associated

• It’s a learning process that will take some time to get completely assimilated. Just like the GLPs 20 years ago!