

Compliance and Coordinating Research

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Overview

- ◆ Defining noncompliance
- ◆ Common findings of noncompliance
- ◆ Common situations for noncompliance
- ◆ Avoiding noncompliance
- ◆ Asking for help

What Is Noncompliance?

- ◆ In the conduct of human research, an act or event which does not conform to the IRB- approved protocol, other IRB requirements, institutional policies, code of conduct, or state, federal, or local laws, and/or regulatory requirements.
- ◆ Noncompliance covers a broad spectrum of events – from record keeping errors to subject safety concerns
- ◆ May or may not be serious, but is always reportable to the IRB

Common Noncompliance Findings

- ◆ Not following the protocol and or IRB and regulatory requirements:
 - Performing research without IRB review
 - Implementing changes (not to eliminate immediate hazard to subjects) without prior IRB review and approval
 - Inadequate supervision of study team members

Common Noncompliance Findings

- ◆ Informed consent oversights:
 - Not documenting (or inadequate documentation of) informed consent
 - Not obtaining legally effected informed consent
 - Using the wrong consent document
 - Not using currently approved version
 - Using consent document for a different study
 - Using consent document modified without prior IRB review and approval

Common Noncompliance Findings

- ◆ Enrolling subjects who do not meet eligibility criteria without prior IRB and, if appropriate, sponsor approval

Common Noncompliance Findings

- ◆ Not maintaining adequate source documentation:
 - Incomplete, inaccurate, or illegible
 - Discrepancies in documented findings
 - Documentation not signed and dated
 - Source documentation destroyed before end of study

Common Noncompliance Findings

- ◆ Not submitting required reports to IRB:
 - Adverse events, unanticipated problems, noncompliance, suspensions, and terminations
 - Not submitting progress reports (continuing review) within the designated timeframe and/or to all IRBs overseeing the study

Common Noncompliance Findings

- ◆ Poor record keeping:
 - Not keeping complete files of all versions of all study documentation
 - Not keeping correspondence with IRB and, if appropriate, sponsor on file
 - Not maintaining activity logs
 - Not keeping other relevant documentation on file (e.g., training certificates, CVs, CLIA certification)

Common Situations for Noncompliance

- ◆ Study coordinator/staff turnover
- ◆ Investigator-initiated studies without a sponsor protocol
- ◆ Coordinating centers for multi-site studies
- ◆ New investigators and/or study coordinators/staff

Common Situations for Noncompliance

- ◆ Poor communication among research team members
- ◆ Overburdened research team members
- ◆ Inadequate training of research team members

Avoiding Noncompliance

- ◆ Have good and consistent recordkeeping practices everyone on the study team knows
- ◆ Follow the IRB-approved protocol
- ◆ Each research team member should know the expectations and requirements regarding the conduct of research in addition to roles and responsibilities

Avoiding Noncompliance

- ◆ Conduct periodic QA check
- ◆ Be familiar with and adhere to IRB and sponsor reporting requirements
- ◆ When in doubt, ask

Asking for Help

- ◆ Be sure you and everyone on your study team has the required training
- ◆ Consult with successful, experienced coordinators
- ◆ When coordinating multi-site studies, be sure recordkeeping practices are consistent
- ◆ Don't be afraid to talk with your IRB
