LSU HEALTH COORDINATOR COMPETENCIES

PROTOCOL COMPLIANCE

Reportable New Information (RNIs)

Objectives

- Define Reportable New Information (RNI)
- Define the different categories of RNI
- Discuss the reporting requirements for RNI
- Discuss the process for amending the study as a result of an RNI

What is Reportable New Information?

Any new information that may impact on the conduct of an IRB-approved, human subjects research study or the safety and welfare of the participants in that study.

RNIs must be reported to the IRB

RNIs are classified into one or more of the following categories:

- Adverse Events (AEs)
- Unanticipated Problems (UPs)
- Non-Compliance
- Protocol Deviations (PD)
- Other Information

Adverse Events (AE)

Definition	Types	Examples
Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.	Adverse Event (AE)	• Non-life-threatening reactions not mentioned as possible risks in the Consent • Accidental Injuries • Any other unexpected and related or possibly related (as determined by the PI) event that is normally not considered serious
	Serious Adverse Event (SAE)	Any untoward medical occurrence that meets any of the following criteria: • Results in death • Life-threatening (refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe) • Requires inpatient hospitalization or prolongation of existing hospitalization • Results in persistent or significant disability/incapacity • Results in a congenital anomaly/birth defect
	Unanticipated Adverse Device Effect (UADE)	Any serious adverse effect associated with a device.

Non-Compliance

Definition	Types	Examples
Failure to adhere to federal, state, or local regulations governing research, organizational policies, or determinations made by the IRB	Non-Compliance	• Lapse in IRB Approval (without continuation of activities) • Failure to respond to IRB inquiries • Engagement of new study personnel without IRB approval • Engagement of new study site without IRB approval • Fail to maintain copies of regulatory approvals and documents
	Serious Non-Compliance	• Performing non-approved study procedures • Lapse in IRB Approval (with continuation of activities) • Inappropriate destruction of study records or study samples • Failure to follow safety monitoring plan • Falsifying research or medical records
	Continuing Non-Compliance	• Recurring non-compliance, protocol deviation, consent issue, etc.

Non-Compliance Consent/HIPAA Issues

Definition	Types	Examples
Failure to adhere to federal, state, or local regulations governing research, organizational policies, or determinations made by the IRB	Minor Consent/HIPAA Issues	• Use of outdated/expired consent form • Missing original signature page • Missing subject signature, printed name, or date • Missing consenter signature, printed name, or date • Copy of consent not provided to subject
	Major or Continuing Consent/HIPAA Issues	• No documentation of informed consent process • Consenting subjects without or during lapse of IRB approval • Consenter not listed on IRB approval • Recurring minor consent issues

Protocol Deviations/Violations (PD)

Definition	Types	Examples
Unplanned excursion, either intentionally or non-intentionally, from the protocol, by either the study team or the subject, that is not implemented or intended as a systematic change.	Minor Protocol Deviation	• Exceeding approved sample size/enrollment goal • Study Visit outside of visit window • Error resulting in drug dosage higher than approved but with no side effects • Failure of subject to return study medication/device • Failure to follow study protocol (no effect on subject safety)
	Major Protocol Deviation	• Intentional deviation from protocol in non-emergency setting • Enrollment of subject(s) not meeting inclusion/exclusion • Failure to follow study protocol (may affect subject safety) • Any medication error involving dosing, administration • Deviations by the study participant that may affect safety • Missed Visit where safety outcomes are assessed
	Emergency Deviation	• Changes made to the protocol without IRB approval to eliminate immediate harm
	Incarceration of a Study Participant	

Unanticipated Problems (UP)

Definition	Types	Examples
An event that occurs in the research that may cause harm to participants (including physical, psychological, economic or social) and is: 1) unexpected; 2) related or possibly related to participation in the research; and, 3) potentially increases the risk of harm to the subject or others	Breach of Confidentiality or Privacy	• Non-encrypted laptop/flash drive containing identifiable participant data was stolen • Non-IRB approved person reviewing identifiable data
*Other reportable new information may also meet the definition of Unanticipated Problems. Any RNI that also falls into this category must be promptly reported to the IRB.		

Other Reportable Information

Definition	Types	Examples
Miscellaneous reportable new information that should be reported to the IRB but does not fit into the above categories.	Hold/Suspension/ Termination	
	Results of Audit/Inspection by Federal Government	• If audit results in the issuance of a 483
	New FDA Black Box Warning	
	Significant or Unresolved Subject Complaint	
	State Medical Board Hospital Staff Action	
	AEs and UPs for a Multi-Site study that DO NOT occur locally	

Reporting RNIs to the Sponsor

Adverse Events

- Once an adverse event becomes serious, the site should inform the Sponsor by submitting an SAE report. Typically, the Sponsor will provide the report form to use and inform the study team where and how to send the report.
- An SAE report should be submitted to the Sponsor no later than 24 hours after the site becomes aware of the event.
- As the site gains more information (i.e. admission records, hospital discharge summaries) updated SAE reports with the new information should be submitted to the Sponsor.

Protocol Deviations

- Sponsors will specify at the beginning of the study how they would like to handle protocol deviations.
- Minor deviations are usually recorded in the case report forms and tabulated by site at the end of the study.
- Major deviations are often report to the Sponsor in a timelier fashion.
- In the case where a site needs a deviation in order to enroll a patient, a Sponsor will request a planned protocol deviation be filed requesting permission from the Sponsor for the site to enroll the patient.

Reporting RNIs to the IRB

PROMPT REPORTING

Time Frame: 5 business days of becoming aware

Method: Reportable Event Application (Kuali)

RNIs that Require Prompt Reporting

- Serious AEs
- Unanticipated Adverse Device Effect
- Serious or Continuing Non-Compliance
- Major or Continuing Consent/HIPAA Issues
- Major Protocol Deviations
- Emergency Deviations
- Incarceration of Study Participant
- Breach of Privacy/Confidentiality
- Hold/Suspension/Termination
- Results of Audit/Inspection by Government
- New FDA Black Box Warning
- Significant/Unresolved Subject Complaint
- State Medical Board Hospital Staff Action

**Local only*

NON-PROMPT REPORTING

Time Frame: Next Renewal or Closure

Method: Event Tracking Log

RNIs that Do Not Require Prompt Reporting

- Unexpected and related/possibly related AEs
- Minor Non-Compliance
- Minor Consent/HIPAA Issues
- Minor Protocol Deviations
- AEs and UPs that DO NOT occur locally

Event Tracking Log Example

Event Tracking Log

This document is a cumulative tracking log for the life of the study.

IRB Study Number:	
Study Title:	
Principal Investigator:	

Ref #	Subject ID	Event Date	Date Identified	Brief Description of Event, Incident or Problem (including assessment of the net effect on Risk/Benefit)	Event Type	Corrective Action Taken to Avoid Recurrence
1					Choose an item.	
2					Choose an item.	
3					Choose an item.	
4					Choose an item.	
5					Choose an item.	
6					Choose an item.	
7					Choose an item.	
8					Choose an item.	
9					Choose an item.	

Amendments as a Result of RNIs

Submit, as soon as practical, a request for study modification if the RNI elicits, in the judgement of the PI, a change in the study status, protocol, procedures or documents such as the consent form or recruitment material.

***TIP**: UPs generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.*

The IRB may require additional/different changes as a result of its review even if the PI has concluded that no changes are warranted.

LSU Health Coordinator Competencies

- ✓ Onboarding
- ✓ Ethical Standards
- ✓ Protocol Compliance
- ❑ Informed Consent
- ❑ Patient Recruitment & Retention
- ❑ Management of Patients
- ❑ Documentation & Document Management
- ❑ Data Management & Information Technology
- ❑ Financial Stewardship
- ❑ Leadership & Professional Development