REPORTABLE NEW INFORMATION

December 7, 2022

Agenda

- What is RNI?
- Categories of RNI
- Reporting RNI
- Amendments as a Result of 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)

<table>
<thead>
<tr>
<th>Definition</th>
<th>Types</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>Adverse Event (AE)</td>
<td>Any non-life-threatening reactions not mentioned as possible risks in the Consent</td>
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<td>• Any other unexpected and related or possibly related (as determined by the PI) event that is normally not considered serious</td>
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<td>Serious Adverse Event (SAE)</td>
<td>Any untoward medical occurrence that meets any of the following criteria:</td>
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<td>• Results in death</td>
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<td>• 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)</td>
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<td>• Requires inpatient hospitalization or prolongation of existing hospitalization</td>
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<td>• Results in persistent or significant disability/incapacity</td>
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<td>• Results in a congenital anomaly/birth defect</td>
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<td>Unanticipated Adverse Device Effect (UADE)</td>
<td>Any serious adverse effect associated with a device.</td>
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## Non-Compliance (NC)

### Definition

Failure to adhere to federal, state, or local regulations governing research, organizational policies, or determinations made by the IRB

### Types

- Non-Compliance
- Serious Non-Compliance
- Continuing Non-Compliance

### Examples

- **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.

### 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 (PD)

<table>
<thead>
<tr>
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<th>Examples</th>
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<tbody>
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<td>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.</td>
<td>Minor Protocol Deviation</td>
<td>• Exceeding approved sample size/enrollment goal</td>
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<td>• Study Visit outside of visit window</td>
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<td>• Error resulting in drug dosage higher than approved but with no side effects</td>
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<td>• Failure of subject to return study medication/device</td>
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<td>• Failure to follow study protocol (no effect on subject safety)</td>
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<td>Major Protocol Deviation</td>
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<td>• Intentional deviation from protocol in non-emergency setting</td>
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<td>• Enrollment of subject(s) not meeting inclusion/exclusion</td>
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<td></td>
<td></td>
<td>• Failure to follow study protocol (may affect subject safety)</td>
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<td>• Any medication error involving dosing, administration</td>
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<td>• Deviations by the study participant that may affect safety</td>
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<td>• Missed Visit where safety outcomes are assessed</td>
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<td>Emergency Deviation</td>
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<td>• Changes made to the protocol without IRB approval to eliminate immediate harm</td>
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<td>Incarceration of a Study Participant</td>
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### Unanticipated Problems (UP)

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<tr>
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<tr>
<td>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</td>
<td>Breach of Confidentiality or Privacy</td>
<td>• Non-encrypted laptop/flash drive containing identifiable participant data was stolen</td>
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<td>• Non-IRB approved person reviewing identifiable data</td>
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*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 Information

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

**PROMPT REPORTING**

- **Time Frame:** 5 business days of becoming aware
- **Method:** Reportable Event Application

**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

**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
Amendments as the 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.

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

**NOTE:** 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.

Save the Date!

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/11/2023</td>
<td>12:00PM</td>
<td>Emergency Preparedness in Research</td>
</tr>
<tr>
<td>02/01/2023</td>
<td>12:00PM</td>
<td>Informed Consents &amp; HIPAA Authorization</td>
</tr>
<tr>
<td>03/01/2023</td>
<td>12:00PM</td>
<td>Expanded Access Use of a Test Article</td>
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Resources

- IRB Website – Reportable New Information: [https://www.lsuhsc.edu/administration/academic/ors/irb/reportable_new_information.aspx](https://www.lsuhsc.edu/administration/academic/ors/irb/reportable_new_information.aspx)

- Types & Examples of RNIs (HRP-2631): [https://www.lsuhsc.edu/administration/academic/ors/irb/docs/HRP-2631_RNI%20Table%20for%20Study%20Personnel_v2.0_09.12.22.pdf](https://www.lsuhsc.edu/administration/academic/ors/irb/docs/HRP-2631_RNI%20Table%20for%20Study%20Personnel_v2.0_09.12.22.pdf)

- Event Tracking Log (HRP-2220): [https://www.lsuhsc.edu/administration/academic/ors/irb/education_guidance_instructions.aspx](https://www.lsuhsc.edu/administration/academic/ors/irb/education_guidance_instructions.aspx)