# Types and Examples of RNI and How They Should be Reported to the IRB



| RNI Category | Definition | Types | Examples |
|---|---|---|---|
| | | | |
| **Adverse Events** *(Local Only)* | 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<br>▪ Accidental Injuries<br>▪ 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:<br>▪ Results in death<br>▪ 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)<br>▪ Requires inpatient hospitalization or prolongation of existing hospitalization<br>▪ Results in persistent or significant disability/incapacity<br>▪ Results in a congenital anomaly/birth defect<br><br>In addition, an important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. |
| | | Unanticipated Adverse Device Effect (UADE) | Any serious adverse effect associated with a device. |
| **Non-Compliance** *(Local Only)* | 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)<br>▪ Failure to respond to IRB inquiries<br>▪ Engagement of new study personnel without IRB approval<br>▪ Change in PI without IRB Approval (without continuation of activities)<br>▪ Engagement of new study site without IRB approval<br>▪ Fail to maintain copies of regulatory approvals and documents |
| | | Serious Non-Compliance | ▪ Performing non-approved study procedures<br>▪ Change in PI without IRB Approval (with continuation of activities)<br>▪ Lapse in IRB Approval (with continuation of activities)<br>▪ Inappropriate destruction of study records or study samples<br>▪ Failure to follow safety monitoring plan<br>▪ Falsifying research or medical records |

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| | | Continuing Non-Compliance | ▪ Recurring non-compliance, protocol deviation, consent issue, etc. |
| | | Minor Consent/HIPAA Issues | ▪ Use of outdated/expired consent form<br>▪ Missing original signature page<br>▪ Missing subject signature, printed name, or date<br>▪ Missing consenter signature, printed name, or date<br>▪ Copy of consent not provided to subject |
| | | Major or Continuing Consent/HIPAA Issues | ▪ No documentation of informed consent process<br>▪ Consenting subjects without or during lapse of IRB approval<br>▪ Consenter not listed on IRB approval<br>▪ Recurring minor consent issues |
| **Protocol Deviation** *(Local Only)* | 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<br>▪ Study Visit outside of visit window<br>▪ Error resulting in drug dosage higher than approved but with no side effects<br>▪ Failure of subject to return study medication/device<br>▪ Failure to follow study protocol (no effect on subject safety) |
| | | Major Protocol Deviation | ▪ Intentional deviation from protocol in non-emergency setting<br>▪ Enrollment of subject(s) not meeting inclusion/exclusion<br>▪ Failure to follow study protocol (may affect subject safety)<br>▪ Any medication error involving dosing, administration<br>▪ Deviations by the study participant that may affect safety<br>▪ Missed Visit where safety outcomes are assessed |
| | | Emergency Deviation | ▪ Changes made to the protocol without IRB approval to eliminate immediate harm |
| | | Incarceration of Study Participants | |
| **Unanticipated Problems** *(Local Only)* | 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<br>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** | | Hold/Suspension/Termination | |

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| | Miscellaneous reportable new information that should be reported to the IRB but does not fit into the above categories. | Results of Audit/Inspection from 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 Medical Staff Action | |
| | | AEs, Non-Compliance, or PDs for Multi-site studies that DO NOT occur locally | |
| **Post-Approval Monitoring (PAM) Findings** | Any information including anything that falls into the RNI categories listed above that is discovered either by the study team or the IRB in the course of post-approval monitoring. | PAM Findings | |

*Types in blue text require prompt reporting. All other Types must be documented on the Event Tracking Log.*