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

RNI Category	RNI	Description	*Recording/Reporting Methodologies if		Additional Comments
			UP: (Prompt Reporting)	**Not UP: (Not Prompt Reporting)**	
Adverse Events	**Adverse Event (AE)**	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.	• ETL • PRNI • MOD	• ETL • CR/SU	An AE encompasses both physical and psychological harms; most commonly occurs in the context of biomedical research, but can also occur in the context of social and behavioral research. An AE may be "Serious" (SAE); but even if it includes death, only SAEs that are also UP require prompt reporting.
	Unanticipated Adverse Device Effect (UADE)	Any serious adverse effect on health or safety, or any life-threatening problem or death that is either (1) caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan; **OR** (2) any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants.	• ETL • PRNI • MOD		
Non-adverse Events	**Non-adverse Event (NAE)**	An incident, experience, and outcome that may involve social or economic harm instead of the physical or psychological harm associated with an adverse event.	• ETL • PRNI • MOD	• ETL • CR/SU	Examples of UPs that do not involve adverse events but must be reported promptly the IRB are found **here**.

		Also includes an event that places subjects or others at increased risk of harm, but no harm occurs.			
	Breach of Confidentiality or Privacy	Examples: • Unauthorized disclosures of subject information • Access to information by an unauthorized individual or for unauthorized reasons • Theft or loss of a mobile device with unencrypted data, records or other private information • Computer viruses/malware	• ETL • PRNI • MOD		
Non-Compliance	**Non-Compliance**	A failure to comply with applicable laws, regulations, institutional policies pertaining to the protection of human subjects or with the requirements or determinations of an IRB; and/or an accidental or unintentional departure from the IRB-approved procedures without prior sponsor or IRB approval (i.e., protocol deviation); that, in the investigator's judgment, **DOES NOT** adversely affect the risk/benefit ratio of the study; the rights, safety, or welfare of the participants or others; or the integrity of the study/data.		• ETL • CR/SU	Some common examples of non-compliance & protocol deviations are found **here**.
	Serious Non-Compliance (SNC)	A failure to comply with applicable laws, regulations, institutional policies pertaining to the protection of human subjects or with the requirements or determinations of an IRB; and/or an accidental or unintentional departure from the IRB-approved procedures without prior sponsor or IRB approval (i.e., protocol deviation); that, in the investigator's judgment, **DOES** adversely affect the risk/benefit ratio of the	• ETL • PRNI • MOD (if applicable)		Some common examples of non-compliance & protocol deviations are found **here**.

		study; the rights, safety, or welfare of the participants or others; or the integrity of the study/data.			
	Emergency Deviation	Emergency deviations involve a planned or unplanned departure from the approved protocol to avoid an immediate hazard to the participant. Emergency deviations may occur without time for prospective IRB review and approval.	• ETL • PRNI		
	Continuing Non-Compliance (CNC)	**Continuing Noncompliance** is a pattern of noncompliance that indicates an inability or unwillingness to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB.	• RNIF • MOD (if applicable)		The PI is responsible for reviewing the ETL periodically to monitor compliance with the approved research. Frequent minor deviations of a similar nature should be reported to the IRB as a CNC. Also, at the time of CR, the ETL will be reviewed to determine if CNC has occurred.
			New or Increased Risk/ Deficiency	**NO New or Increased Risk/ Deficiency**	
Updated Study Information	**Report or Document with Finding of Deficiency, Risk, or Recommended Change(s)**	Any report or document from the sponsor, regulatory agency or other entity **WITH** at least one deficiency, evidence of new risk, OR recommendation for changes to the study.	• PRNI • MOD (if applicable)		Report or document may be AE/SAE Summary Report, Interim Data Analysis Report, Audit Report, IB, research publication, etc. Entity may be DSMB, Data Monitoring Committee, study monitor, state agency, etc.
	Report or Document without Finding of Deficiency, Risk, or Recommended Change(s)	Any report or document from the sponsor, regulatory agency or other entity **WITH NO** deficiency, **NO** increased or new risk, **AND NO** recommendations for changes to the study		• CR/SU	

Other	**Hold and/or Suspension**	• FDA clinical hold (21 CFR 312.42) • Sponsor imposed • DSMB imposed • Investigator self-imposed Administrative Hold • Institution imposed	• PRNI • MOD		Since there is a change in the study status, an amendment must be submitted concurrent with the RNI.
	Audit/ Inspection/ Inquiry by a Federal Agency	By FDA, DOD, NIH, etc. Regardless of finding.	• PRNI		
	New FDA Black Box Warning	The FDA can require a pharmaceutical company to place a boxed warning on the labeling of a prescription drug, or in literature describing it. It is the strongest warning that the FDA requires, and signifies that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects.	• PRNI • MOD		
	Significant or Unresolved Subject Complaint		• PRNI		
	Incarceration of a Study Participant	Participant is in a study not approved to involve prisoners	• PRNI		
	State Medical Board or Hospital Medical Staff Actions	Actions against a study team member	• PRNI • MOD (if applicable)		An amendment will be necessary to document any changes to the study team.

*Investigators are not required to submit RNIs to the LSUHSC IRB that occur at other research sites in multi-center research trials unless required by the sponsor. If a multi-center study is under the purview of a single IRB (either LSUHSC IRB or another IRB), submit RNIs, CRs and MODs to the Lead (Reviewing) IRB according to its instructions. Submit RNIs that meet the criteria for an UP to the LSUHSC IRB also if it is the Relying IRB.

- **CR/SU –** Submitting RNIs not requiring prompt reporting with Continuing Review application or Status Update report
- **ETL –** Recording RNIs on the Event Tracking Log

- **MOD -** Modification Application
- **PRNI –** Method for prompt reporting of RNI

More information about RNIs and their reporting requirements and procedures are available at the **IRB website**.