Problems that arise that are unexpected and are NOT Adverse Events that require reporting to IRB are a) unexpected b) related to participation and c) place subject or others at greater risk

Examples:
- Breach of confidentiality
- Loss of data
- Unresolved participant complaints
- Wrongful dose
- Interim findings

Was problem unexpected?

Was problem related to research?

Does the problem place the subject or others at greater risk or harm? (Socially, economically)

REPORT to IRB WITHIN 5 DAYS on Unanticipated Problem Form

For more information, contact the NSU Institutional Review Board at (954) 262-5311