OTHER REPORTABLE NEW INFORMATION

P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
4.04	09.13.2022	5.17	02.08.2020

In addition to unanticipated adverse events, unanticipated problems, major or continuing non-compliance, and major protocol deviations, there are other miscellaneous events that constitute reportable new information that should be promptly reported to the IRB via a Reportable Event submission.

- Suspension, hold or termination of a research protocol
- Results of an audit, inspection or inquiry from the Federal Government
- New FDA Black Box Warning(s)
- Significant or Unresolved Subject Complaint(s)
- State Medical Board Hospital Medical Staff Action
- AEs and UPs for Multi-site studies that DO NOT occur locally