Non-Industry and Investigator Initiated Studies

Adverse Event Occurs

PI completes real-time review for RNI, PSI, and SI*

If no to ALL, no additional OHSU Reporting Required

Event Meets RNI Criteria

Report to IRB per institutional policy

Event requires PSI report

Report through PSI Portal

Event is a SI

Report to Risk Management

NOTES:
*Reporting for SI, RNI, or PSI is NOT mutually exclusive. You may need to submit some or all reports depending on the event, and as more information becomes available.

Abbreviations:
PI– Principal Investigator
PSI– Patient Safety Intelligence see Patient Safety Intelligence page on O2
RNI– Reportable New Information see Reportable New Information (Quick Guide) on the IRB Policies and Forms page
SI –Subject Injury see Research Injury Reporting on CRBO forms and policies page