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