Industry Sponsored Studies

Adverse Event Occurs

- Report AE to Sponsor/Funder per Protocol and Contract

If no to ALL, no additional OHSU reporting required

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

- Event Meets RNI Criteria
  - Report to IRB per institutional policy
- Event requires PSI report
  - Report through PSI Portal

Event is a SI

- Event is a SI
  - Report SI to Sponsor/Funder per Contract **

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 re-evaluate as more information becomes available.
- ** Contract considerations – Is the sponsor financially responsible for subject injuries? Did OHSU cause/exacerbate injury?

Abbreviations:
- CTO – Clinical Trials Office
- CRBO – Clinical Research Billing Office
- PBS – Patient Business Services see the Patient Business Services page on O2
- 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
- UMG – University Medical Group see the University Medical Group page on O2

Review charges with the PI. Contact CRBO to request transfer of SI related charges to study account

Invoice sponsor, if SI’s reimbursable per contract

Sponsor unwilling to pay?
- Yes
  - Notify CTO Contracting

Was subject billed for SI charges?
- Yes
  - Notify CRBO