Reporting of Adverse Events & Unanticipated Problems

The IRB approves a monitoring plan, which designates who is responsible for determining when an AE is also considered a UP. Depending on the risk, this can be the PI, the research team, an Independent Safety Monitor or a Central Monitoring group (i.e., DSMB, DMC, Sponsor, etc.)

PI duty to report begins when PI becomes aware of AE either directly from a subject, co-investigator or central monitoring group. PI follows monitoring plan to identify AEs. PI follows protocol reporting requirements and OHSU policy to determine which AEs are reported to Central Monitor, FDA, IRB and any other regulators.