Event

Is there a risk to participants or is prompt reporting required?

No

Yes

Is the Event Non-Compliance as determined by the EC?

Yes

No

Report to OHRP within 5 days
EC determines if the Event is Serious Non-Compliance

PI creates a log and reports at next progress report, modification, or study closure

EC determines if the Event is Continuing Non-Compliance

No

Yes

Event is reviewed by IRB

Adverse Event – report to OHRP within 72 hours if related to research and ↑ risk to participants

Is the Adverse Event serious?

No

Yes

Is the Adverse Event UPIRSO

No

Yes

EC determines next step

Or

Report to OHRP within 24 hours and EC reviews

Is the Adverse Event UPIRSO?

No

Yes

HRPP Staff generate a CAPA with PI