PD learns of event or information that requires reporting to IRB and Initiates Report

If UP is a STANFORD death or life-threatening experience
[one of the "serious AEs" (per OHRP)]

Within 5 working days

If report is NOT a STANFORD death or life-threatening experience
[one of the "serious AEs" (per OHRP)]

Within 10 working days

Report Received by Research Compliance Office

If report indicates immediate action needed to prevent unacceptable risk to participants,
RCO Director: Instigates necessary action(s)

“ASAP” Immediate Action

If potentially serious or continuing noncompliance
RCO Director:
- Oral report to Dean of Research
- Subsequent updates on fact-finding and IRB review process

Within 5 working days

Report goes to IRB Convened Meeting, results in a “Reportable Decision” - either UP, Serious or Continuing Noncompliance, or Suspension or Termination

RCO Director: Oral report to Dean of Research
Also "in some cases" (see OHRP guidance):
Oral or preliminary report to external regulatory agencies, sponsors, as required; also give estimated time for final report.
See OHRP guidance
http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm

Within 5 working days

IRB Chair: Written report to Dean of Research

Within 30 days after meeting

Dean of Research: Written report to external regulatory agencies, sponsors, as required
OR after receiving Chair’s report
(If longer than 1 month after IRB meeting, request extension from OHRP if necessary)

Within 30 days after meeting (one month - OHRP)

Date Completed