

HSC Reportable Event Requirements

Significant Adverse Events

Any unfavorable occurrence associated with research participation, and substantively impacting the participant(s)

Unanticipated Problems

- 1) Unexpected
- 2) Possibly Related to the research
- 3) Likely to increase risk to subjects or others

Complaints about the Research

Regardless of whether from participants or bystanders, and whether it was resolved

Noncompliance

Ex. protocol deviations, failure to report, conducting Human Subjects Research without approvals

Report to the HARC Office

immediately upon learning of the event

Call: 510-486-6005

Email: HARC@lbl.gov

Data Breaches and/or Loss of PII

DOE Order 206.1 - **Immediate** Reporting to DOE-Cyber Incident Response Capability

DOE Order 443.1C - **Immediate** Reporting to HARC/DOE HSPP

APPLICABILITY

All Study Team Members Share Responsibility for Reporting, not only the PI or LBNL employees

Failure to meet these requirements will result in noncompliance

If you're unsure,
****REPORT ANYWAY****
HARC can help