Is this a safety report (including DSMB reports) or suspension/termination of the research by the sponsor?

No

Is this report a required report under FDA regulations for an IDE, treatment IDE, or HDE?

No

Is this report a publication in the literature, interim results or other finding that indicates an unexpected change to the risks and benefits of the research?

No

Is this an adverse event/incident?

No

Is this deviation a breach of confidentiality or failure to obtain authorization (or waiver) before accessing records at UCLA?

Yes

Is the UCLA IRB acting as the Privacy Board for Research (per the reliance agreement)?

Yes*

Submit to reviewing IRB (per the reviewing IRB’s reporting requirements)

Yes

Did the reviewing IRB make any of the following determinations (about the portion of the research conducted at UCLA)?

- Unanticipated problem
- Serious non-compliance
- Continuing non-compliance
- Suspension
- Termination

No

Submit a PAR within 10 business days (of the determination made by the reviewing IRB or of becoming aware of the privacy/confidentiality related deviation)

No PAR submission
Maintain in study files

No

Yes

Is this some other post approval report required by the reviewing IRB?

No or Yes*