Communication from Sponsors Affecting IRB Oversight

216.1 General

The University has included in their standard sponsored research contract templates, provisions that the sponsor will notify the site-PI or the IRB of:

- Non-compliance with the protocol or applicable laws, particularly those laws related to participants, that could impact the safety or welfare of the participants;
- Serious adverse events that have been reported to the FDA or other governmental agency in relation to the protocol at UH or any other site;
- Unanticipated problems in the protocol at UH or any other site that could relate to risks to participating participants; and
- Circumstances that could affect participants’ willingness to continue to participate in the protocol or the IRB’s continuing approval of the protocol.

When non-standard contract templates are used, the sponsor is asked to include equivalent language.

See ORS’ CTA Guide SOPP 301.1

216.2 Data and Safety Monitoring (DSM) in Sponsor Agreements

For sponsored research, UH agreements specify that, as appropriate:

- Provisions are made for monitoring study data which could affect participants’ safety;
- The results of this monitoring are reported to the researcher (PI) so that:
  - Routine monitoring reports will be submitted as part of Continuing Review applications to the IRB, and
  - Urgent reports are submitted according to the guidelines specified in GUIDE 614: Events and Information which Require Prompt Reporting to the IRB.

See:
- ORS’ CTA Guide SOPP 301.1
- ORS’ CTA Training Start Clauses