

Series 602 Notifications and Reporting | Institutional Review Board

Notifications & Reporting from Series 602 of the Standard Operating Procedures

I. Communication with Participants or Others

In processing each reportable event, the IRB shall consider whether notification to participants (or others, such as family or community members) is appropriate, regardless of the language in the informed consent documentation. If notifications to participants or others is appropriate, the PI shall work with the IRB Chair or HRP Director to design such notifications and propose a process, via Quali Protocols, for delivery of those notifications to appropriate parties. Notifications to participants should include:

- A summary of the study's original terms (such as by providing a copy of the informed consent document);
- Any unexpected risks they may have been exposed to;
- Whether any follow up is being provided or suggested;
- Whether the study will continue or be terminated (if known); and
- A reminder that any adverse events or other research-related problems can be reported to the IRB for further resolution

II. Internal Reporting of Reportable Events

When a Reportable Event results in the suspension or termination of a previously-approved research project per SOP 601.VI, the Institutional Official shall be notified once the IRB has ratified or lifted the suspension or termination. The Institutional Official shall, in consultation with the IRB Chair and HRP Director, determine whether further internal notifications are appropriate (such as to a Department Head, Dean, Office of General Counsel, Information Security Officer, Clinic Director, etc.). The IO or their designee shall expeditiously make such a report, except in the case of noncompliance, in which case the report is made by the IRB and sent by the IRB Chair or their designee.

III. External Reporting of Unanticipated Problems

Reports of unanticipated problems involving risks to participants or others, terminations, suspensions and serious or continuing non-compliance shall be submitted to federal agencies or other relevant parties (such as a covered entity in the event of a HIPAA violation) in compliance with applicable regulations. The IO shall ensure delivery within an appropriate timeframe – usually, 15 days following the resolution of the issue by the IRB.

The HRP Director shall have responsibility for coordinating with the principal investigator, gathering any additional required information and writing the initial report, which shall include:

- The nature of the event or problem
- The findings of USU
- The action taken by the IRB and USU
- Facts which support the underlying actions taken by the IRB and USU
- Any plans or recommendations for a continuing inquiry or investigation

The HRP Director shall submit the draft report in a timely manner to the IRB Chair and IO. The IO shall have responsibility for final approval of the report, and for its submission to the appropriate agency or entity. Copies of the reports shall be

distributed to the IRB and to other federal agencies when research is overseen by those agencies and such agencies require reporting separate from reports to OHRP.