Amendment to Washington University Institutional Review Board (WU IRB) Policies and Procedures

Effective March 13, 2020, the WU IRB policy on the timeframe for reporting changes to approved research initiated without IRB approval to eliminate an apparent immediate hazard has been changed.

The new reporting timeframe is 10 working days from the date the change was implemented. If the change was implemented as a result of the death of a research participant, the reporting timeframe is 1 working day. This change pertains to all research under the oversight of the WU IRB.

CURRENT:

Changes in approved research initiated without IRB approval to eliminate an immediate hazard:

The PI should report the change immediately after the occurrence as a reportable event. The event should be reported as either an unanticipated problem involving risks to participants or others or noncompliance depending on the circumstances. The review process for these events follow the review process for unanticipated problems involving risks to participants or others or noncompliance as further described in this section of the policy. In addition, the Executive Chair (or designee) or the IRB will determine whether the change was consistent with ensuring the participants’ continued welfare.

NEW:

Changes in approved research initiated without IRB approval to eliminate an immediate hazard:

The PI should report the change after the occurrence as a reportable event within 10 working days from the date the change was implemented. If the change was implemented as the result of the death of a research participant, the reporting timeframe is 1 working day. The event should be reported as either an unanticipated problem involving risks to participants or others or noncompliance depending on the circumstances. The review process for these events follow the review process for unanticipated problems involving risks to participants or others or noncompliance as further described in this section of the policy. In addition, the Executive Chair (or designee) or the IRB will determine whether the change was consistent with ensuring the participants’ continued welfare.