DUHS IRB MEMORANDUM

To: DUHS Research Community
From: DUHS IRB
Date: August 28, 2026
Subject: Clarification of historical DUHS IRB Reporting Requirements and Transition to Revised Policies 1400 and 1450 Effective September 1, 2026

Purpose

The purpose of this memorandum is to clarify the application of DUHS IRB reporting requirements for events arising from studies for which the DUHS IRB is not the IRB of record and to document the transition to the revised **DUHS IRB Policies 1400 and 1450**, effective September 1, 2026.

This memorandum is intended solely to provide clarity and consistency in the application of the policies during this transition. The clarification is intended to ensure that events are handled consistently when the reporting determination involves a non-DUHS IRB and when events occurring before September 1, 2026, are reviewed by the DUHS IRB after the revised policies become effective.

Reporting of Events from Non-DUHS IRBs

DUHS IRB has had a longstanding approach for studies for which a non-DUHS IRB is the IRB of record: the applicable determination regarding an event, including whether an event constitutes a UPIRTSO, Serious Noncompliance (SNC), or Continuing Noncompliance (CNC), is made by the IRB of record in accordance with its applicable requirements.

Where the reviewing IRB (non-DUHS IRB) has not made a determination regarding whether an event constitutes a UPIRTSO, SNC, or CNC, or where such a determination is pending, the event does not need to be reported to the DUHS IRB unless the event is otherwise independently reportable under DUHS IRB requirements. As of September 1, 2026, such independently reportable information is referred to as “Other Reportable Information.”

Once the non-DUHS IRB has made its determination, the event can be evaluated for DUHS IRB reporting, as applicable. If the non-DUHS IRB determines that the event does not meet its criteria for a UPIRTSO, SNC, or CNC, and the event is not otherwise independently reportable to the DUHS IRB, no submission to the DUHS IRB is necessary on that basis.

Thus, the September 1, 2026 policy revision **does not represent a change to this longstanding approach**. Rather, the combined policy document formally **clarifies and solidifies** the approach that has been reflected in DUHS IRB policy and practice.

This approach ensures that the determination by the IRB of record occurs before any subsequent DUHS IRB reporting that is dependent upon that determination and avoids unnecessary or duplicative submissions.

Transition to Revised Policies 1400 and 1450

Effective September 1, 2026, the DUHS IRB will implement revised Policies 1400 and 1450. As part of this transition, it is important to distinguish between the date an event occurred and the date the DUHS IRB reviews the event.

For purposes of the transition, events reviewed by the DUHS IRB on or after September 1, 2026, will be evaluated under the revised Policies 1400 and 1450, regardless of when the underlying event occurred.

Thus, an event that occurred before September 1, 2026, but is reviewed by the DUHS IRB on or after September 1, 2026, will be evaluated using the revised policies applicable at the time of the DUHS IRB's review. This includes events that may have been submitted under the prior policies but remain pending DUHS IRB review or outcome completion as of September 1, 2026.

As a result of the transition, application of the revised Policies 1400 and 1450 may result in a different outcome for an event that occurred prior to the revised reporting requirements. Depending on the circumstances and the requirements of the revised policies, the DUHS IRB may determine that an event that occurred prior to the revised reporting requirements:

- Is not reportable under the revised reporting criteria;
- Should be withdrawn because a submission is no longer required;
- Does not require additional action under the revised policies;
- Requires only acknowledgment where acknowledgment is the appropriate action under the revised policy; or
- Requires additional information consistent with the revised Policies 1400 and 1450.

These potential outcomes should be understood as part of the normal implementation and transition to the revised policies and should not be interpreted as indicating that the original submission was inappropriate under the policy in effect at the time it was submitted.

The revised policy will simply govern the DUHS IRB's review and outcome of the event when that review occurs on or after September 1, 2026.

This memorandum is intended to provide clarification regarding the transition and promote consistent application of the revised DUHS IRB reporting requirements. The applicable version of DUHS IRB Policies 1400 and 1450 should be consulted for individual event determinations.

We want to thank the DUHS Research Community for their continued engagement and if they have any questions to please contact Cassandra Myers, DUHS IRB Director of Compliance and Operations at cjm171@duke.edu.