DukeHealth

Institutional Review Board

Reliance on an External Institutional Review Board (IRB) Policy			
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1. Overview

1.1 Purpose

The purpose of this policy is to establish the criteria and procedures under which Duke University Health System (DUHS) may rely on an external Institutional Review Board (IRB), for the ethical review and approval of human subjects research. This policy ensures that reliance on an external IRB is conducted in a manner that protects research participants and complies with applicable federal regulations and guidance, and clearly defines roles, responsibilities, selection criteria for external IRBs, as well as the documentation and administrative processes required for reliance arrangements.

2. Definitions

Please note that definitions can be found throughout DUHS's IRB's policies and procedures, as applicable

IRB of Record means the IRB responsible for the regulatory review (e.g., OHRP, FDA, DOD) and oversight of a study.

Reliance Agreement means a formal agreement where an institution delegates review to an external IRB. This is often achieved by an IRB Authorization Agreement (IAA) or a SMART IRB Agreement.

Single IRB is often a reference to the federal mandate that one IRB provides review for multi-site studies as a requirement of the grant or funding agency.

3. Eligibility and Initial Review for Reliance on an External IRB

DUHS may rely on an external IRB for the review and approval of human subjects research when required by applicable single IRB mandates or when reliance is appropriate in consideration of institutional, investigator, or participant interests. Examples of circumstances in which reliance on an external IRB may be considered include but are not limited to: research in which DUHS has an institutional conflict of interest; multi-site research in which each participating site is performing the same study activities; industry-initiated or industry-sponsored research; and federally sponsored research for which a single IRB is required.

The DUHS Institutional Official (IO) or their designee retains final authority to determine whether DUHS will rely on an external IRB. Day-to-day reliance determinations are made by the IRB Executive Director, or their designee, acting under the authority of the IO. The Clinical Research Unit (CRU) responsible for oversight of a specific study may provide input and may request reliance on an external IRB on behalf of the study, provided the study meets the criteria outlined below; however, such requests do not confer decision-making authority.

3.1 Type of Research that May Utilize External IRB Review

DUHS may consider relying on a qualifying external IRB as defined in 3.3: Criteria for Selecting an External IRB for the review of non-exempt human subjects research when DUHS personnel are engaged and one or more of the following criteria are met:

- The research is industry-initiated or industry-funded,
- The research is conducted at multiple sites,
- An institutional or individual conflict of interest related to the research has been identified by the Duke University Conflict-of-Interest Committee, the Institutional Official, or the convened DUHS IRB, or
- The research is federally funded or conducted through a cooperative group and is subject to an applicable single IRB mandate.

3.2 Type of Research that May Not Utilize External IRB Review

Reliance on an external IRB may not be permitted when it would be inconsistent with institutional responsibilities, sponsor requirements, or the effectiveness of the human research protection program. External IRB review may not be permitted in circumstances including, but not limited to:

- Situations in which reliance on an external IRB is sought for the purpose of circumventing local IRB determinations, requirements, or suspensions (“IRB shopping”).
- Research involving a history of serious or continuing noncompliance, unresolved corrective actions, or other concerns that warrant direct local IRB oversight.

DUHS does not execute reliance agreements for research determined to be exempt under federal regulations. This policy reflects considerations of administrative efficiency, institutional responsibilities,

and DUHS's interpretation and application of the federally defined exempt categories. While reliance agreements are appropriate for non-exempt human subjects research subject to IRB review, exempt research remains under the oversight of DUHS IRB in accordance with institutional policies and federal requirements.

The decision to prohibit or limit the use of an external IRB is final and is intended to ensure participant protection, regulatory compliance, and consistency in institutional oversight. This policy does not preclude reliance on external IRBs when such reliance is appropriate and aligned with institutional standards.

3.3 Criteria for Selecting an External IRB

DUHS IRB will apply the following criteria when selecting an external IRB to rely on:

- The external IRB is currently registered with the Office for Human Research Protections (OHRP) as an Institutional Review Board Organization (IORG), registered to provide oversight of Food and Drug Administration (FDA) regulated research and, as applicable, maintains an active Federalwide Assurance (FWA).
- The external IRB is in good standing with OHRP and FDA, with no unresolved warning letters, enforcement actions, or open compliance investigations that would affect its ability to serve as the IRB of record.
- The IRB is AAHRPP-accredited or has been determined through administrative review to meet DUHS institutional standards and AAHRPP-aligned requirements for human subjects protection.
- The external IRB is located within the United States.

3.4 Ongoing Institutional Oversight

Reliance on an external IRB does not relieve DUHS of its responsibility to ensure that all institutional requirements, data protections, and local processes applicable to the conduct of research are met throughout the life of the study. As part of DUHS's Human Research Protection Program, the DUHS IRB and institutional offices (e.g., Duke Office of Scientific Integrity, Office of Audit, Risk, and Compliance) conducts ongoing oversight of research to fulfill these institutional responsibilities, including;

- Maintaining institutional oversight by confirming that IRB approval remains current and in good standing.
- Verifying that applicable institutional obligations, including ancillary committee reviews, training requirements, conflict of interest management, and other local compliance requirements, are met.
- Maintain records of continuing review determinations, approvals, and other relevant communications from the external IRB.
- Monitoring research to the same regulatory requirements and procedures.
- Implement institutional corrective actions or restrictions, to protect research participants and ensure ongoing compliance with federal regulations and DUHS policies.

Through these activities, DUHS ensures that institutional oversight is maintained, even when DUHS is not serving as the IRB of Record.

3.5 Initial iRIS Submission Requirements and Documentation of Reliance Agreements

The Duke Principal Investigator or designee is responsible for initiating the institutional process for reliance on an external IRB in accordance with DUHS requirements. Studies that will rely on an external IRB must be submitted through the DUHS IRB electronic system using the appropriate external IRB reliance application type. The investigator may not add any procedures to the sponsor's protocol (e.g., additional biopsies, storage of biological specimens for future research at DUHS, additional laboratory or imaging studies), as doing so could violate sponsor requirements, create additional regulatory obligations, or blur institutional and sponsor responsibilities, potentially increasing risk to participants. Any such procedures must be submitted as a separate study through the DUHS IRB, with all required institutional reviews completed.

Submissions will undergo applicable institutional and ancillary reviews in accordance with established DUHS procedures. These reviews include an assessment of institutional requirements and local context considerations relevant to the conduct of the research at DUHS.

Upon receipt of an application, DUHS study staff will initiate processes and coordinate with DUHS IRB staff to document the reliance relationship through execution of a reliance agreement (e.g., SMART IRB Agreement or IRB Authorization Agreement) with the designated IRB of record. The reliance agreement must be executed by the authorized signatory identified in Section 3.

The SMART IRB Agreement or IRB Authorization Agreement may be written to cover a single research project, multiple research projects on a case-by-case basis or under defined conditions. Each agreement includes a description of the regulatory responsibilities assumed by each party and documents the respective responsibilities of the relying organization and the organization operating the IRB to ensure compliance with applicable regulatory requirements (e.g., OHRP, FDA, DoD).

The outcomes of these reviews are documented in the DUHS IRB electronic system and made available to the study team. Upon completion of required institutional reviews, the study team is responsible for preparing and submitting all required materials in accordance with the reviewing IRB's procedures, which may include submission to the external IRB, a coordinating center, or the reviewing IRB's study team. The DUHS IRB does not submit applications on behalf of the study team.

Following approval by the external IRB, the study team must submit the external IRB's approval documentation, including the notice of approval, fully executed reliance agreement, and all externally approved study materials through the DUHS-designated system to enable completion of the DUHS administrative review and acknowledgement process. As part of the notice of administrative acknowledgement, the expiration date will align with those set by the external IRB.

Reliance agreements, notice of administrative acknowledgment by DUHS IRB, and institutional approval (i.e., OnCore or Clinical Research Management System) must be completed prior to the initiation of any research activities. If delaying human subjects research would, in the investigator's

judgment, result in increased risk of harm to subjects, research activities may proceed after the IRB of record has approved DUHS as a site. Such activities must be limited to those necessary to mitigate the immediate risk and must be reported to the IRB as a protocol deviation in accordance with DUHS reporting procedures.

4. Amendments and Subsequent Approval Notices

Once a study has been initiated, all externally approved amendments and their related approval notices must be submitted to DUHS via the DUHS IRB electronic system for administrative acknowledgment before implementation. Similar to initial reliance submissions, if urgent participant safety concerns or other compelling circumstances arise, the amendment may be implemented immediately and must be reported to the IRB as a protocol deviation, in accordance with DUHS procedures.

5. Personnel Changes

All DUHS personnel engaged in the conduct of human subject research must be listed on the DUHS IRB application, as the local IRB is responsible, under the standard terms of reliance agreements, for maintaining oversight of institutional requirements such as completion of required training and compliance with DUHS policies. In contrast, external IRB submissions typically require only those personnel necessary for the review by the IRB of record, while local oversight obligations remain the responsibility of DUHS for all listed personnel.

6. Adverse Event and Noncompliance Reporting

When a study is reviewed by an external IRB serving as the IRB of record, study teams must comply with the policies, procedures, and reporting requirements of the IRB of record, including requirements for reporting unanticipated problems involving risks to subjects or others (UPIRTSOs) and noncompliance. Even when not serving as the IRB of record, the DUHS IRB has an institutional obligation to review UPIRTSOs and instances of noncompliance to assess risks to local participants, apply institutional context, and implement measures to mitigate harm or require additional protections as needed. As such, investigators must report to the DUHS IRB:

- Any event or issue that has been determined to be a UPIRTSO by the IRB of record, regardless of whether the event occurs at DUHS.
- Any instance of noncompliance that impacted, or may impact, local participants, regardless of whether the noncompliance occurred at another site.

For additional details, timing, and information regarding event reporting and notifications, please refer to DUHS IRB's policies and procedures, specifically Prompt Reporting to the IRB.

7. Continuing Administrative Review and Oversight

When DUHS relies on an external IRB as the IRB of record, the IRB of record is responsible for conducting continuing review of the research in accordance with applicable federal regulations and its own policies and

procedures. The expiration date of the study remains the approval expiration date issued by the IRB of record.

As part of DUHS's ongoing institutional responsibilities, as described in Section 3.4, DUHS conducts an administrative continuing review to ensure that studies remain active, in good standing, and compliant with institutional requirements. This administrative continuing review is not intended to duplicate the continuing review conducted by the IRB of record but rather occurs in parallel and is limited to fulfilling distinct institutional responsibilities, sponsor requirements, and system integrations, including monitoring regulatory compliance, confirming local resources and safety requirements, and verifying adherence to institutional policies.

DUHS recognizes that IRB of record timelines and administrative processes may vary. Accordingly, DUHS allows an additional 30 calendar days following the expiration date in the DUHS IRB electronic system for the study team to submit documentation of continued approval to the DUHS IRB for completion of the required administrative continuing review and acknowledgment. The study does not expire for DUHS purposes unless it expires with the IRB of record. If a study expires with the IRB of record, all research activities must stop immediately. Failure to submit the required documentation to DUHS within the 30-day administrative window may constitute a reportable event and may result in the suspension of research activities at DUHS until the administrative continuing review and acknowledgment are completed.

8. Study Closure and Transfers of IRB Oversight

Once research is completed and the study has been closed with the IRB of record, the DUHS investigator must submit a final report in the DUHS IRB electronic system to close the study at the institution.

Study teams may not close a study with an external IRB or the IRB of record and subsequently seek review by the local IRB, or re-open the study as though it were a new study, for the purpose of avoiding or circumventing IRB determinations or requirements, or reducing IRB-related review costs. Such actions create additional burden for study personnel and the IRB, may disrupt ongoing oversight, and could increase the risk of harm to participants. Transition of IRB oversight from an external IRB to the local IRB may occur only in rare and justified circumstances and requires prior written approval from the Institutional Official, Executive Director, or designee.

9. Responsibilities

9.1 Investigator's Responsibilities

Investigators are responsible for following the policies and procedures of both the IRB of record and DUHS, and for submitting all required information into DUHS systems to ensure proper documentation and compliance. Investigators must ensure that study personnel conduct research in accordance with applicable regulations, institutional policies, and principles of Good Clinical Practice and Responsible Conduct of Research. They are responsible for reporting unanticipated problems, noncompliance, or safety concerns involving DUHS personnel or participants to both the external IRB and DUHS, and for implementing any additional corrective actions required by DUHS. Investigators must maintain

participant safety, uphold oversight responsibilities, and ensure all institutional obligations are met throughout the life of the study.

9.2 DUHS IRB's Responsibilities

As one of several stakeholders within the DUHS Human Research Protection Program, the DUHS IRB is responsible for maintaining institutional oversight of studies for which a reliance agreement has been executed with an external IRB. This includes ensuring compliance with regulatory and institutional requirements, as well as the terms of the reliance agreement. The DUHS IRB also ensures that policies, procedures, and related guidance are current, communicated, and consistently applied to align external IRB review with DUHS obligations, supporting participant safety and investigator compliance.

10. Revision

- **Version 2.0: Effective Date 02/01/2026-** Revised to updated DUHS IRB template, broadened research studies that may rely on external IRB, clarified administrative continuing review, removed work instructions and specific procedures, and added personnel section.
- **Previous Versions:** 11/20/2023, 08/05/2021, 03/03/2016, 01/09/2015, 05/02/2011, 04/21/2011, 10/14/2010, 06/04/2008