DUHS IRB Policy Catalog

Policy #*	Policy Title	Current Version Date	Category
	Advertisement of Research (Participant Recruitment Materials)	01/26/2024	Recruitment
	Amendments (Amendments to Previously Approved Research)	11/22/2023	Review by the IRB
	Appropriate Study Personnel to Conduct the Consent Process (Requirements of Study Personnel Conducting the Consent Process)	09/28/2021	Consent
	Assessing the Data and Safety Monitoring Plan	04/04/2021	Review by the IRB
	Autopsy Authorizations (Policy Statement Regarding Autopsy Authorizations)	11/22/2023	Conduct of Research
	Blood Drawing (Blood Drawing for Human Subject Research)	11/22/2023	Conduct of Research
	Case Reports (Case Reports: Single Case Reports-Limited Case Series)	08/03/2023	Review by the IRB
	Certificates of Confidentiality (Participant Enrollment in Studies Involving a Certificate of Confidentiality)	11/22/2023	Conduct of Research
	Children Who are Wards of the State (Research Involving Minors Who Are Wards of the State)	11/22/2023	Vulnerable Populations
	Children's Research (Research Involving Children)	11/20/2023	Vulnerable Populations
	Coded (De-Identified) or Anonymized Private Information or Biospecimens	06/18/2024	Database, Repository, & Retrospective Research
	Compensation for Injury (Compensation or Medical Treatment in the Event of Injury Due to Participation in a Research Study)	11/20/2023	Conduct of Research
	Conduct of an IRB Meeting (Conduct of a Convened Meeting of the DUHS IRB)	11/22/2023	Review by the IRB
	Conflict of Interest (COI Pertaining to DUHS IRB Members and Consultants)	11/22/2023	Conflict of Interest
	Consent and Its Documentation (Informed Consent and Its Documentation)	02/07/2025	Consent
IRB-1225	Compensation for Participation (Compensation and Payments to Research Participants and Research Personnel)	01/01/2026	Conduct of Research
	Consent Monitoring	04/18/2021	Consent
	Consultants in IRB Review (DUHS IRB Use of Consultants)	11/22/2023	Review by the IRB
	Continuing Review	11/22/2023	Review by the IRB
	Continuing Review Frequency (Determining Frequency of Continuing Review)	11/22/2023	Review by the IRB
	Contraceptive Use (Reproductive Risk Considerations in Research)	07/02/2019	Conduct of Research
	Corrective Actions for COI (Investigator COI Managed by the DUCOM COI Committee)	06/27/2026	Conflict of Interest
	De-Identification of Protected Health Information (De-identification of Health Information Subject to the Privacy Rule HIPAA)	09/28/2021	Database, Repository, & Retrospective Research
	Decision Making Capacity in Adults (Assessment of Decision Making Capacity in Adults Participating in A Research Study)	11/22/2023	Vulnerable Populations
	Department of Defense (DoD) Research (Research Supported by a DOD Component)	06/22/2026	Conduct of Research
	Department of Education Research (Research Subject to the US Department of Education Regulations-FERPA)	07/22/2021	Conduct of Research
	Engagement and Recruitment of Patients to a Research Protocol	06/18/2024	Recruitment

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	Expanded Access Including Emergency Use (Expanded Access for an Investigational Medical Product for an Individual Patient, Including for Emergency Use)	11/20/2023	Review by the IRB
	Expedited Review	12/19/2023	Review by the IRB
	Expiration of IRB Approval and Closing Reports (Expiration of IRB Approval and Subsequent Notice to Cease Study Activity)	11/20/2023	Reporting and Compliance
	External Research by Duke Faculty or Staff (Policy Statement for Duke Faculty or Staff Members Engaged in Research Involving Humans Solely at a Site Other than within DUHS)	12/19/2023	Conduct of Research
	External Research by Duke Trainees (Duke Trainees Engaged in Research Involving Human Subjects)	11/20/2023	Conduct of Research
	External Use of Duke Data by Former Students & Employees (Use of Research Data/Samples by Former Duke Students or Former Duke Faculty and Employees)	12/19/2023	Conduct of Research
	Finder Organizations & Subjects Lost to Follow-Up or Withdrawn	11/20/2023	Conduct of Research
	Gadolinium Contrast Agent (Policy Statement Regarding the Use of Gadolinium Based Contrast Agents in Research)	11/20/2023	Conduct of Research
	HIPAA as it Relates to Research (The Privacy Rule HIPAA in Research)	11/20/2023	Conduct of Research
	HIPAA Exemption (Deidentification of Health Information Subject to the Privacy Rule HIPAA)	03/01/2016	Conduct of Research
	Holds, Suspensions, and Terminations	11/20/2023	Reporting and Compliance
	HRPP Emergency Preparedness Plan (HRPP Emergency Preparedness Procedure & Guidance)	06/12/2026	Conduct of Research
	Humanitarian Use Devices	04/21/2021	Drugs, Devices, & Biologics
	In Vitro Diagnostic Devices (In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are not Individually Identifiable)	03/26/2021	Drugs, Devices, & Biologics
	Institutional Official (IO)	05/22/2025	Conduct of Research
	Institutional Oversight of Human Research	05/22/2025	Conduct of Research
	Interaction with Compliance Offices by the IRB (IRB Interaction with Compliance Offices)	11/20/2023	Review by the IRB
	International Research	03/24/2025	Conduct of Research
	Investigator Who is Also a Sponsor (Responsibilities of an Investigator Who is Also a Sponsor)	11/20/2023	Drugs, Devices, & Biologics
	Investigator/Study Team Concerns	04/18/2021	Conduct of Research
	IRB Approval Stamp on Consent Forms (Policy Statement Regarding The IRB Approval Stamp on Consent Forms)	11/20/2023	Consent
IRB-1450	IRB Review and Reporting of Promptly Reportable Information	09/01/2026	Reporting and Compliance
	Key Personnel	02/27/2025	Review by the IRB
	Legal Counsel Opinion (Requesting Legal Counsel Opinion)	04/09/2021	Review by the IRB
	Legally Authorized Representative (LAR) (Use of the LAR in Research Involving a Vulnerable Population of Adult Participants)	11/20/2023	Consent
	Local Physician Participation (Policy Statement on Administration of a Study Drug or Study Procedure by a Research Participant's Local Physician)	11/20/2023	Conduct of Research
	Mandatory State Reporting Requirements	02/08/2021	State Law Considerations
	Membership, Voting and Quorum for the IRB (IRB Membership, Voting, and Quorum)	11/20/2023	Review by the IRB

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	Minutes of the IRB Meetings (The Preparation, Recording and Finalization of IRB Meeting Minutes)	11/20/2023	Review by the IRB
	Modifications Processing Procedure	11/20/2023	Review by the IRB
	Multiple Site Research (Research Involving Multiple Sites)	11/20/2023	Conduct of Research
	Nomination and Evaluation of IRB Members (New IRB Member Identification, Training, and Member Evaluation)	11/20/2023	Review by the IRB
	On-going Training for IRB Office Staff, Chairs and IRB Members	06/24/2026	Conduct of Research
	Pathology Tissue/Specimen Exclusions	02/2013	Conduct of Research
	Permissible Interim Activities (Permissible Research-Related Activities Prior to IRB and Institutional Approvals)	04/25/2024	Activities Permitted Before IRB and Institutional Approvals
	Placement of a Research Consent Form in the Participant's Medical Record	11/22/2023	Consent
	Planned Research in an Emergency Setting	12/19/2023	Review by the IRB
	Pregnancy Testing (Pregnancy Testing for Exclusion of Pregnant Women from Clinical Studies)	07/02/2019	Conduct of Research
	Pregnant Partners of Research Subjects (Collecting Data from Pregnant Partners of Research Participants)	08/17/2023	Conduct of Research
	Pregnant Women, Fetuses, and Neonates (Research Involving Pregnant Women, Human Fetuses and Neonates Involved in Research)	04/18/2021	Vulnerable Populations
	Principal Investigator Qualifications (Who May Serve as Principal Investigator in the Duke Medicine Human Research Protection Program)	04/03/2021	Conduct of Research
	Prisoners (Research Involving Prisoners)	04/18/2021	Vulnerable Populations
	Processing Payments to Participants		Conduct of Research
IRB-1400	Promptly Reportable Information	09/03/2026	Reporting and Compliance
	Quality Improvement (QI) vs. Research (Policy and Checklist)	04/14/2021	Review by the IRB
	Re-opening a Closed Study	12/19/2023	Conduct of Research
	Recruiting Students, Employees (including study team members), Friends, & Family Members	04/04/2021	Recruitment
	Reliance by External Sites on the DUHS IRB	11/20/2023	Conduct of Research
IRB-0950	Reliance on an External IRB	06/30/2026	Conduct of Research
	Research Databases, Specimen Repositories, and Contact Lists	11/22/2023	Database, Repository, & Retrospective Research
	Research for Which Review by the DUHS HRPP is Required	06/10/2026	Review by the IRB
	Research Involving Devices	11/22/2023	Drugs, Devices, & Biologics
	Research Involving Drugs or Biologics	06/18/2026	Drugs, Devices, & Biologics
	Retention of Records (Retention of IRB Records and Other Documents)	11/20/2023	Review by the IRB
	Scientific Validity of a Research Protocol (Assessing the Scientific or Scholarly Validity of a Research Protocol)	11/20/2023	Review by the IRB
	Significant Risk vs. Non-Significant Risk Device Studies (Significant Risk or Non-Significant Risk Device Determinations by the DUHS IRB)	12/03/2024	Drugs, Devices, & Biologics
	Specialty Committee Review Forms (Review and Approval by Other (Specialty) Committees)	07/13/2021	Review by the IRB
	State Law for Research (State Law Terms and Principles Applicable to Human Subjects Research)	11/20/2023	State Law Considerations
	Translation Policy (Translation Requirements for Research)	05/31/2024	Consent
	Undue Influence Upon the IRB (Allegations of Undue Influence Upon the DUHS IRB)	04/18/2021	Review by the IRB

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IRB-1175	Undergraduates Conducting the Consent Process (Duke Undergraduates Engaged in the Consent Process on DUHS IRB Protocols Policy)	12/01/2025	Consent
	Verification of Studies (Determining Which Studies Need Verification From Sources Other than the Investigator)	07/15/2021	Review by the IRB
	Waiver for a Single Person (Review of an Investigator's Request for a Waiver of Selected Inclusion/Exclusion Criteria for a Single Person)	11/20/2023	Review by the IRB
	Waivers or Alteration of Consent & HIPAA Authorization	11/20/2023	Consent

*The DUHS IRB is currently transitioning policies to their revised template, as part of this process they are being assigned a policy number, if no policy number is listed, it remains on the previous template however the policy remains in effect.