

Institution	Procedures and Policies for: (specimen acquisition, CTSA, tumor banking, IRB, etc.)	Brief Title	Current Version Date
Duke	Human Research Protection	Advertisement Guidelines	1/26/2024
Duke	Human Research Protection	Amendments	11/22/2023
Duke	Human Research Protection	Appropriate Study Personnel to Conduct the Consent Process	9/28/2021
Duke	Human Research Protection	Assessing the Data and Safety Monitoring Plan	4/4/2021
Duke	Human Research Protection	Autopsy Authorizations	11/22/2023
Duke	Human Research Protection	Blood Drawing	11/22/2023
Duke	Human Research Protection	Case Reports	8/3/2023
Duke	Human Research Protection	Certificate of Confidentiality	11/22/2023
Duke	Human Research Protection	Coded or Anonymized Private Information or Biospecimens	6/18/2024
Duke	Human Research Protection	Compensation for Study-Related Injury	11/20/2023
Duke	Human Research Protection	Compensation Payments to Research Participants	1/29/2024
Duke	Human Research Protection	Complaints, Concerns, Questions	11/22/2023
Duke	Human Research Protection	Conduct of an IRB Meeting	11/22/2023
Duke	Human Research Protection	Consent Form in Medical Records	11/22/2023
Duke	Human Research Protection	Consent Monitoring	4/18/2021
Duke	Human Research Protection	Continuing Review	11/22/2023
Duke	Human Research Protection	Contraceptive Use	7/2/2019
Duke	Human Research Protection	Corrective Actions for COI	11/22/2023
Duke	Human Research Protection	Databases & Repositories	11/22/2023
Duke	Human Research Protection	Decision Making Capacity in Adults	11/22/2023
Duke	Human Research Protection	De-Identification of Protected Health Information	9/28/2021
Duke	Human Research Protection	Department of Defense (DoD) Research	8/3/2021
Duke	Human Research Protection	Department of Education Research	7/22/2021
Duke	Human Research Protection	Determining Frequency of Continuing Review	11/22/2023
Duke	Human Research Protection	Determining Which Studies Need Verification From Sources Other Than the Investigator	7/15/2021
Duke	Human Research Protection	Emergency Setting Research	12/19/2023

Duke	Human Research Protection	Engagement and Recruitment of Patients to a Research Protocol	6/18/2024
Duke	Human Research Protection	Expanded Access Including Emergency Use	11/20/2023
Duke	Human Research Protection	Expedited Review	12/19/2023
Duke	Human Research Protection	Expiration of IRB Approval	11/20/2023
Duke	Human Research Protection	External Data Use by Former Students and Employees	12/19/2023
Duke	Human Research Protection	Faculty and Staff Away from Duke	12/19/2023
Duke	Human Research Protection	Finder Organizations & Participants Lost to Follow-Up	11/20/2023
Duke	Human Research Protection	Gadolinium Use in Research	11/20/2023
Duke	Human Research Protection	HIPAA Exemption	3/1/2016
Duke	Human Research Protection	HIPAA Privacy Rule	11/20/2023
Duke	Human Research Protection	Holds, Suspensions, and Terminations	11/20/2023
Duke	Human Research Protection	Humanitarian Use Devices	4/21/2021
Duke	Human Research Protection	In Vitro Diagnostic Devices	3/26/2021
Duke	Human Research Protection	Informed Consent and its Documentation	11/20/2023
Duke	Human Research Protection	Institutional Official (IO)	4/8/2021
Duke	Human Research Protection	Institutional Oversight of Human Research	4/8/2021
Duke	Human Research Protection	Interim Activities	1/8/2024
Duke	Human Research Protection	International Research	5/31/2024
Duke	Human Research Protection	Investigator as Sponsor	11/20/2023
Duke	Human Research Protection	Investigator/ Study Team Concerns	4/18/2021
Duke	Human Research Protection	IRB Approval Stamp on Consent Forms	11/20/2023
Duke	Human Research Protection	IRB Interactions with Compliance Offices	11/20/2023
Duke	Human Research Protection	IRB Meeting Minutes	11/20/2023
Duke	Human Research Protection	IRB Member Identification, Training and Evaluation	11/20/2023
Duke	Human Research Protection	IRB Members - Consultants COI	11/22/2023
Duke	Human Research Protection	IRB Membership, Voting & Quorum	11/20/2023
Duke	Human Research Protection	IRB Use of Consultants	11/22/2023
Duke	Human Research Protection	Key Personnel Qualifications	11/22/2023
Duke	Human Research Protection	Legal Counsel Opinion	4/9/2021
Duke	Human Research Protection	Legally Authorized Representative	11/20/2023

Duke	Human Research Protection	Local Physician Participation	11/20/2023
Duke	Human Research Protection	Mandatory State Reporting Requirements	2/8/2021
Duke	Human Research Protection	Modifications Processing Procedure	11/20/2023
Duke	Human Research Protection	Non-compliance	12/13/2022
Duke	Human Research Protection	Pathology Tissue/Specimen Exclusions	n/a
Duke	Human Research Protection	Pregnancy Testing	7/2/2019
Duke	Human Research Protection	Pregnant Partners of Research Subjects	8/17/2023
Duke	Human Research Protection	Pregnant Women, Fetuses, and Neonates	4/18/2021
Duke	Human Research Protection	Principal Investigator Qualifications	4/3/2021
Duke	Human Research Protection	Prisoners	4/18/2021
Duke	Human Research Protection	Processing Payments to Participants	n/a
Duke	Human Research Protection	Prompt Reporting to the IRB	11/20/2023
Duke	Human Research Protection	Quality Improvement (QI) vs. Research (Policy and Checklist)	4/14/2021
Duke	Human Research Protection	Recruiting Students, Employees (including study team members), Friends, & Family Members	4/4/2021
Duke	Human Research Protection	Reliance by External Sites on the DUHS IRB	11/20/2023
Duke	Human Research Protection	Reliance on External IRBs	11/20/2023
Duke	Human Research Protection	Re-opening a Closed Study	12/19/2023
Duke	Human Research Protection	Reporting to DUHS Officials and Federal Agencies	11/20/2023
Duke	Human Research Protection	Research Involving Children	11/20/2023
Duke	Human Research Protection	Research Involving Devices	11/22/2023
Duke	Human Research Protection	Research Involving Drugs or Biologics	3/26/2021
Duke	Human Research Protection	Research Involving Multiple Sites	11/20/2023
Duke	Human Research Protection	Research Subject to DUHS HRPP	11/20/2023
Duke	Human Research Protection	Retention of IRB Records	11/20/2023
Duke	Human Research Protection	Scientific Validity of a Protocol	11/20/2023
Duke	Human Research Protection	Significant Risk vs Non-Significant Risk Device Studies	3/25/2021
Duke	Human Research Protection	Specialty Committee Review	7/13/2021
Duke	Human Research Protection	State Law as It Relates to Research	11/20/2023
Duke	Human Research Protection	Trainees Away from Duke	11/20/2023
Duke	Human Research Protection	Translation Requirements for Research	5/31/2024

Duke	Human Research Protection	Undergraduate Consenting	11/20/2023
Duke	Human Research Protection	Undue Influence Upon the IRB	4/18/2021
Duke	Human Research Protection	Waiver for a Single Person	11/20/2023
Duke	Human Research Protection	Waivers or Alteration of Consent & HIPAA Authorization	11/20/2023
Duke	Human Research Protection	Wards of State	11/22/2023