The following policies were recently revised (see list below within each policy type/category). We also have checklists that have been revised as well that are listed at the end. Furthermore, we have attached this list as a word document so you can print out as needed.

Here is a quick link to the policy page: <https://irb.duhs.duke.edu/policies-and-regulations/policies>

**Policy Type: Compliance (the below policies were revised)**

* Expiration of IRB Approval and Closing Reports
* Holds, Suspensions and Terminations
* Non-Compliance
* Reporting to DUHS Officials and Federal Agencies

**Policy Type: Conduct of Research (the below policies were revised)**

* Compensation for Participation
* Department of Defense (DoD) Research
* Department of Education Research
* External IRBs
* External Research by Duke Trainees
* External Use of Duke Data by Former Students & Employees
* HIPAA as It Relates to Research
* HIPAA Exemption
* International Research
* Investigator/Study Team Concerns
* Local Physician Participation
* Multiple Site Research
* Principal Investigator Qualifications
* Re-Opening a Closed Study
* Reliance by External Sites on the DUHS IRB

**Policy Type: Conflict of Interest (the below policies were revised)**

* Conflict of Interest
* Corrective Actions for COI

**Policy Type: Consent (the below policies were revised)**

* Appropriate Study Personnel to Conduct the Consent Process
* Consent and Its Documentation
* Consent Monitoring
* Legally Authorized Representative (LAR)
* Short Form Consent
* Undergraduates Conducting the Consent Process
* Waiver of Documentation of Consent

**Policy Type: Database, Repository, & Retrospective Research (the below policies were revised)**

* Research Databases, Specimen Repositories, and Contact Lists
* Research Using Coded Private Information or Biospecimens

**Policy Type: Drugs, Devices & Biologics (the below policies were revised)**

* Humanitarian Use Devices
* In Vitro Diagnostic Devices
* Investigator Who Is Also a Sponsor
* Research Involving Devices
* Research Involving Drugs or Biologics
* Significant Risk vs Non-Significant Risk Device Studies

**Policy Type: Recruitment (the below policies were revised)**

* Advertisement
* Recruiting Students and Employees
* Recruitment of Other Providers' Patients (No Cold Calling Policy)

**Policy Type: Reporting to the IRB (the below policies were revised)**

* Protocol Deviations/Violations
* Unanticipated Problems

**Policy Type: Review by the IRB (the below policies were revised)**

* Amendments
* Case Reports
* Conduct of an IRB Meeting
* Consultants in IRB Review
* Continuing Review
* Continuing Review Frequency
* Data and Safety Monitoring
* Emergency Use
* Expedited Review
* Interaction with Compliance Offices by the IRB
* Key Personnel Qualifications
* Legal Counsel Opinion
* Membership, Voting and Quorum for the IRB
* Minutes of the IRB Meetings
* Modifications Processing Procedure
* Nomination and Evaluation of IRB Members
* Planned Research in an Emergency Setting
* Quality Improvement (QI) vs. Research (Policy and Checklist)
* Research for Which Review by the DUHS HRPP Is Required
* Retention of Records
* Scientific Validity of a Research Protocol
* Specialty Committee Review
* Subject Problems, Complaints, Concerns and Questions
* Undue Influence Upon the IRB
* Verification of Studies
* Waiver for a Single Person

**Policy Type: State Law Considerations (the below policies were revised)**

* Mandatory State Reporting Requirements
* State Law for Research

**Policy Type: Vulnerable Populations (the below policies were revised)**

* Children Who Are Wards of the State
* Children’s Research
* Decision Making Capacity in Adults
* Pregnant Women, Fetuses, and Neonates
* Prisoners

**Checklists**

Here is a quick link to the forms page where the checklists reside (please filter under “form type”): <https://irb.duhs.duke.edu/forms>

**Form Type: Principal Investigator Checklists (the below checklists were revised)**

* Humanitarian Use Device Checklist
* IDE Checklist
* IND Checklist

**Form Type: IRB Reviewer Checklists (the below checklists were revised)**

* Checklist on Adequate Provisions for Soliciting the Permission of Parents or Guardians and Checklist on Adequate Provisions for Soliciting the Assent of Children
* Children: Checklist for Review of Research Involving Children
* DOD Supported Research Checklist
* Humanitarian Use Device Checklist
* IDE Checklist
* IND Checklist
* Pregnant Women: Checklist for Research Involving Pregnant Women or Fetuses
* Prisoners: Checklist for Research Involving Prisoners