

Summary of updates to Policy IRB-01 (Revised 02/03/2021)

- Changed references from Downstate Medical Center (DMC) to Downstate or Downstate Health Sciences University
- Updated regulatory requirements based on certification to NYS DOH that we follow federal regulations (Common Rule, FDA, or HIPAA) for research, but no longer voluntarily apply the Common Rule to all research. This reflects a change in the NYS Article 24A and 'unchecking the box' on our FWA. The Common Rule applies to federally funded, supported, or conducted research. We apply the Common Rule (Part A) to all research that is not regulated by FDA or HIPAA. This policy also clarifies we may apply the federal requirements of the categorical vulnerable populations (Children, Pregnant Women, Neonates, and Prisoners) regardless of funding or support or where the research is conducted.
- Clarifies we apply foreign regulations, when applicable.
- Clarifies we now have an IRB Application for Acknowledgments.
- Clarifies the need to submit an IRB Decision Aid to request formal determinations from the IRB for non-human research activities.
- Added the Honest Broker application to the policy, which is currently posted on the IRB website.
- Removed many details which have been updated on the Downstate IRB website, including the following:
 - Details for exempt and expedited review
 - Process for using an external IRB (including sIRB)
 - Process for establishing an IRB Reliance Agreement or Individual Investigator Agreement for external investigators.
 - Specific information on requirements for informed consent (revised guidance document also attached).
 - Specific information on ancillary reviews
- Removed the requirements for a Downstate faculty member to be "seasoned" and have a "field-specific terminal degree" to be eligible to have PI Status. Revised the requirements for a Downstate Faculty member to have PI Status to read: "Be Downstate Faculty Member, who is approved to be a PI by a Department Chair or Dean."
- Add the requirement of a new or inexperienced PI to list a mentor on the IRB application.
- Updated the policy for when a copy of the consent must be placed in the medical record (clinical trials with IND/IDE or when CoC language is included for Downstate patients).

- Clarified that an experienced IRB Administrator who is not also an IRB member may make IRB Determinations/Exemptions, but not issue determinations which require limited IRB review or those that include HIPAA requirements.
- Removed the recommendation to make studies expire on the 15th of the month as we do not practice this.
- Updated the information on IRB Letters as we have updated our templates in IRBNet.
- Updated the requirements for when amendments for Exempt research are required.
- Clarified that a PI should submit notices from external IRBs to the Downstate IRB for acknowledgment.
- Clarified that annual continuing review is not required for IRB Determinations.
- Made minor changes to grammar, spelling, and language throughout the document where necessary to improve clarity.