IRB Assurance and Compliance Statement

The Penn State Milton S. Hershey Medical Center and Penn State College of Medicine hold Federalwide Assurances (FWA) from the Office of Human Research Protection (OHRP), under the U.S. Department of Health and Human Services (DHHS), as follows:

- **Penn State College of Medicine (IORG#0000031), Federalwide Assurance (FWA) #4251**
  (Expires: 06/15/2020); includes Penn State College of Medicine IRB 1 (IRB #046); IRB 2 (IRB #047); IRB 3 (IRB #048); and IRB 4 (IRB #2337)

- **Milton S. Hershey Medical Center - Federalwide Assurance (FWA) #4252**
  (Expires: 09/26/2021); relies on the COM IRBs


The IRBs follow institutional written policies and procedures for operation, and maintain IRB review documentation in a closed electronic system (CATS IRB) that conforms to 21 CFR Part 11 (Electronic Records: Electronic Signatures) for research subject to FDA regulation, as outlined in the IRB Statement of 21 CFR Part 11 Compliance document.

The IRBs comply with regulatory membership requirements (45CFR46 and 21CF56), register membership rosters with the Department of Health and Human Services, and provide membership rosters to regulatory authorities as required. Patricia Gordon, MD, Associate Professor of Pediatrics/Human Genetics serves as the IRB executive chair. Penn State College of Medicine maintains three boards with a chair, vice chair and 20+ members each, and a 4th board that reviews urgent issues. The IRB Roster Representation statement provides information about the IRB membership categories and expertise represented.