PENNSTATE HERSHEY
Milton S. Hershey Medical Center

PENNSTATE HERSHEY
College of Medicine

IRB Assurance & Membership Representation Statement

The Institutional Review Boards (IRB) of Penn State Milton S. Hershey Medical Center and Penn State College of Medicine are organized and operate in compliance with the U.S. Department of Health & Human Services (DHHS) and Food & Drug Administration regulations for the protection of human subjects, Commonwealth of Pennsylvania law, and Pennsylvania State University policies for the conduct of human subject research. For clinical trials, the Organizations commit to apply the "International Conference on Harmonisation – Good Clinical Practice E6" (ICH-GCP).

The organizations hold Federalwide Assurances (FWA) from the Office of Human Research Protection (OHRP), under DHHS, as follows:

Penn State College of Medicine (IORG#0000031), Federalwide Assurance (FWA) #4251 (Expires: 07/08/2016), which 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: 04/05/2017); relies on the COM IRBs

Information on the IRB registrations may be obtained from the OHRP database, http://ohrp.cit.nih.gov/search/, under 'IRBs' by searching for the Penn State College of Medicine, or by the IRB or FWA numbers listed above.

The IRBs comply with membership requirements of the Code of Federal Regulations (45 CFR 46 and 21 CFR 56), follow written policies and procedures for operation, and maintain detailed documentation for the review of all research projects. IRB policy excludes individuals with a conflict of interest from participating in the review of a project.

2014-2015 IRB Representation

Patricia Gordon, M.D., Associate Professor of Pediatrics/Clinical Genetics, serves as the IRB executive chair. The IRB membership includes separate chairs and vice chairs for 3 boards with 22+ membership each and a 4th eleven member board that convenes to review urgent issues. The overall IRB membership includes the following expertise, and consultants provide additional expertise if needed.

Medical and Science Representatives

Physician / Scientists:

Anesthesiology	- MD (3)
Cardiology	- MD (3)
General Surgery	- MD (1)
Hematology/Oncology	- MD (2), MD/PhD (4)
Obstetrics/Gynecology	- MD (1)
Pathology	- MD/PhD (1)
Pediatric Cardiology	- MD (1)
Pediatric Critical Care	- MD (1)
Pediatric Genetics	- MD (1)
Pediatric Oncology	- MD (1)
Pediatric Pulmonary	- MD (1)
Pulmonary, Allergy, Critical Care	- DO (1)
Radiation Oncology	- MD (1)

Behavioral/Social Scientists:

Humanities	- MEd, MA (1)
Psychiatry	- PhD (1)
Public Health Sciences	- PhD (2), MS (1), MA (1)
Criminal Justice	- PhD, JD (1)

Other Scientists:

Biostatistics & Public Health Sciences	- PhD (1)
Medicine - Cancer Institute & Personalized Med.	- PhD(1) & BS(1)
Nursing and/or Research Coordination	- RN (4), MSN (1)
Pharmacy	- PharmD (3), alternates: PharmD (1), RPh (2)
Students Representatives	- MS, BSN (1); BA, MPH(1); BS(5)

Other Representatives

Non-scientists:	-Affiliated staff (6); Non-affiliated community reps.(6)
Other scientists:	-HMC retired community rep. (1)

Human Subjects Protection Office Staff: -IRB Analysts staff (4) and alternates (7)