



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 commits 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 FWAs and registration may be obtained from the OHRP database, http://ohrp.cit.nih.gov/search/, under 'IRBs & Assurances' by selecting 'Status of IRBs & FWAs', and searching the *FWA* tab for the assurance 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.

2013-2014 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 20+ membership each, and a 4th eleven member board which convenes to review urgent issues. The overall IRB membership includes the following expertise, and consultants provide additional expertise, if needed.

Medical and Science Representatives

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

Behavioral / Social Scientists

Neurology	- MA (1)
Psychiatry	- PhD (1)

Public Health Sciences - PhD (2), MS (1), MA (1)

Criminal Justice - PhD (1)

Other Scientists

Biostatistics & Public Health Sciences - PhD (1)

Medicine – Cancer Institute - PhD (1)

Nursing and/or Research Coordination - RN (3), MSN (1)

Pharmacology - PhD (1)

Pharmacy - PharmD (2) and RPh (1), PharmD (1) alternate, RPh (1) alternate

Student Representatives - Student members (4)

Participant Representatives

Non-scientists - Affiliated staff (5), Non-affiliated community representatives (6)

Other scientists - Retired staff members (1)

Human Subjects Protection Office Staff - IRB Coordinators (4) and alternates (8)