PennState
College of Medicine

Human Subjects Protection Office
Institutional Review Board
Mail Code A115, Room 1140
90 Hope Drive
P.O. Box 855
Hershey, PA 17033-0855
717-531-5687
med.psu.edu/irb

IRB Roster Information for Research Study Binders

Date: November 17, 2016

From: Kathleen A. Hay, Ph.D., C.I.P, Director
Human Subjects Protection Office

Subject: IRB roster information for research study binders

The Institutional Review Board (IRB) membership rosters are registered with and approved by the Department of Health and Human Services and are made available to regulatory authorities as required.

The IRB Roster Representation statement is available to provide roster information for inclusion in research records and for sponsors outside the institution. This statement includes the name of the IRB executive chair, the number of boards and members, the membership categories and specific expertise and representation available on the IRB. For confidentiality reasons it is the policy of the Human Subjects Protection Office and the IRB that the roster information provided for inclusion in the research records and to sponsors does not include the name of each board member.

Also, a separate IRB Assurances and Compliance statement provides details about the Institution's regulatory compliance, Federal Wide Assurance (FWA) and IRB registrations, and affirmation of compliance with IRB membership requirements of the Code of Federal Regulations (45 CFR 46, 21 CFR 56), and commitment to apply Good Clinical Practice guidelines to clinical trials.

These two documents are provided to address research documentation and sponsor requirements for assessing IRB membership and compliance.

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