

NCI Pediatric Central IRB Authorization Agreement

Institution Name: Johns Hopkins University School of Medicine

OHRP Federalwide Assurance Number: 00005752

Other Institutions that may rely on this Institution's IRB reviews (list all below):

- IRB00000025 - Johns Hopkins University School of Medicine- JHM IRB #1*
- IRB00001555 - Johns Hopkins University School of Medicine- JHM IRB #2*
- IRB00001656 - Johns Hopkins University School of Medicine- JHM IRB #3*
- IRB00000026 - Johns Hopkins University School of Medicine- JHM IRB #5*

And

The National Cancer Institute Pediatric Central Institutional Review Board (PedCIRB)

Federalwide Assurance Number FWA00002195 Pediatric CIRB IRB Registration Number IRB00004296
Institution Organization Number IORG0000460

The Officials signing below agree that Johns Hopkins University School of Medicine may rely on PedCIRB reviews, approvals and continuing oversight, as provided under the accompanying document, "Division of Responsibilities between NCI's Central IRB (CIRB) and Local Institutions."

The reviews, approvals, and continuing oversight performed by the PedCIRB satisfy the requirements of the DHHS regulations for the protection of human subjects at 45 CFR 46, as well as the requirements of Johns Hopkins Medicine IRB 1,2,3 & 5 and Johns Hopkins University School of Medicine's OHRP-approved Assurance.

As described in the accompanying document ("Division..."), relevant minutes of PedCIRB meetings shall be made readily available to Johns Hopkins University School of and Johns Hopkins Medicine IRB 1,2,3 & 5 IRB, and Johns Hopkins University School of Medicine and Johns Hopkins Medicine IRB 1,2,3 & 5 IRB remain responsible for ensuring compliance with the PedCIRB's determinations and with the terms of its OHRP-approved Assurance.

This document should be kept on file at both institutions and must be provided to OHRP upon request.

Institutional Official for Participating Site: Michael J. Klag, M.D., M.P.H.
(print name)

Signature: Michael J. Klag Date: 9/20/04
Title: Vice Dean for Clinical Investigation

Institutional Official for NCI: James H. Doroshow, M.D. Date: 9/20/2004
James H. Doroshow, M.D.
Director, Division of Cancer Treatment and Diagnosis