

IRB Authorization Agreement Form A

JHUSOM is IRB of Record

(Designated IRB Agreement between Collaborating FWA Holding Institutions*)

Name of Designated IRB Providing IRB Review (Institution A):

The Johns Hopkins University School of Medicine (JHUSOM)

IRB Registration #: 00000025, 00001555, 00001656, 00000026, 00003794, 00000533

OHRP Federalwide Assurance (FWA) #: 00005752

Name of Institution Relying on the Designated IRB (Institution B):

THE BALTIMORE CITY HEALTH DEPARTMENT (a department of the MAYOR AND CITY COUNCIL OF BALTIMORE)

OHRP Federalwide Assurance (FWA) #: 00002106

The Officials signing below agree that THE BALTIMORE CITY HEALTH DEPARTMENT may rely on Johns Hopkins University School of Medicine for review and continuing oversight of its human subjects research described below involving all human subjects research with the participation of researchers of Institution A at locations covered by Institution B's FWA:

The review and continuing oversight performed by the designated IRB will meet the human subjects protection requirements of Institution B's OHRP-approved FWA. Both institutions agree to the following conditions:

1. The designated IRB will notify *Institution B* if the study is suspended or terminated and will provide a summary of the reasons for the suspension or termination.
2. The designated IRB will notify *Institution B* of any unanticipated problems involving risks to human participants or others.
3. The designated IRB will notify *Institution B* of audits/investigations by oversight agencies, the sponsor or funding agencies and will provide a summary of the findings.
4. If the designated IRB fails to notify *Institution B* as stated above, *Institution B* shall have the right to terminate this agreement immediately, and request that the designated IRB return to *Institution B* any study requested by *Institution B* within 10 business days.
5. Each Institution will cooperate with the other Institution in response to any reasonable request for information or the conduct of any review or investigation by either Institution, whether the Institution is carrying out its own internal processes or is acting in response to third party requests or governmental reviews and investigations.

Signature of Signatory Official (Institution A):
The Johns Hopkins University School of Medicine

Attest/Witness:
Judith A. Carrothers
Judith A. Carrothers

By: *[Signature]* Date: 1-30-2006
Print Full Name: DANIEL FORD, MD
Institutional Title: VICE DEAN CLINICAL INVESTIGATION
JOHNS HOPKINS SCHOOL OF MEDICINE

Signature of Signatory Official (Institution B):
MAYOR AND CITY COUNCIL OF BALTIMORE, acting by and
through THE BALTIMORE CITY HEALTH DEPARTMENT

Attest:

Carly Low
Custodian of the City Seal

By: *[Signature]* Date: 2/6/06
Print Full Name: Joshua M. Sharfstein, M.D.
Institutional Title: Commissioner of Health

Approved as to Form and Legal Sufficiency:

Michael D. Schrack
Assistant City Solicitor

Approved by the Board of Estimates:

[Signature] *[Signature]*
Clerk Date

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

***In order for this agreement to be valid, both Institutions must have a Federal Wide Assurance (FWA). An Institution can have an FWA but not have an IRB.**