

Submission Number: 13906

9/29/2006 11:47:46 AM

FWA Number: FWA00004696

Institution Name: BATTELLE MEM INST

OMB No. 0990-0278

Approved for use through 1/31/2008

U.S. Department of Health and Human Services (DHHS)
Federalwide Assurance (FWA) for the Protection of Human Subjects
For Domestic (U.S.) Institutions

1. Institution Filing Assurance

Legal Name: BATTELLE MEM INST
City: COLUMBUS

State: OH

DHHS Institutional Profile Code:

Federal Entity Identification Number (EIN): 34-4379427

This Assurance replaces:

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates. The Institution should have available for review by the Office for Human Research Protections (OHRP) upon request a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the Institutional Review Board (IRB), IRB support staff, and investigators in these various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below. Entities that the Signatory Official

is not legally authorized to represent may not be listed here without the prior approval of OHRP.

Name of Component or Alternate Names Used	City, State (or Country if Outside U.S.)
BATTELLE COLUMBUS OPERATIONS	COLUMBUS, OH
BATTELLE CENTERS FOR PUBLIC HEALTH RESEARCH AND EVALUATION	DURHAM, NC
<u>BATTELLE PACIFIC NORTHWEST DIVISION</u>	<u>RICHLAND, WA</u>
BATTELLE EASTERN SCIENCE & TECHNOLOGY CENTER (BEST)	ABERDEEN, MD
BATTELLE DUXBURY OPERATIONS	DUXBURY, MA
BATTELLE WASHINGTON OPERATIONS	WASHINGTON, DC
BATTELLE WEST JEFFERSON OPERATIONS	WEST JEFFERSON, OH
BATTELLE ARLINGTON OPERATIONS	ARLINGTON, VA
BATTELLE ATLANTA OPERATIONS (BCO & CPHRE)	ATLANTA, GA
BATTELLE BALTIMORE OPERATIONS (CPHRE)	BALTIMORE, MD
BATTELLE CRYSTAL CITY OPERATIONS	ARLINGTON, VA
BATTELLE DURHAM OPERATIONS	DURHAM, NC
BATTELLE MOUNTAIN VIEW OPERATIONS	MOUNTAIN VIEW, CA
BATTELLE SEATTLE OPERATIONS	SEATTLE, WA
BATTELLE SEQUIM OPERATIONS	SEQUIM, WA
BATTELLE ST. LOUIS OPERATIONS	ST. LOUIS, MO

FWA Number: FWA00004696

Institution Name: BATTELLE MEM INST

OMB No. 0990-0278

Approved for use through 1/31/2008

BATTELLE ST. ROBERT OPERATIONS

ST. ROBERT, MO

BATTELLE STAFFORD OPERATIONS

STAFFORD, VA

BATTELLE TOOEELE OPERATIONS

TOOELE, UT

BATTELLE ATLANTIC CITY OPERATIONS

ATLANTIC CITY, NJ

BATTELLE NATICK OPERATIONS

NATICK, MA

3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of funding source, will be guided by the ethical principles in the following documents:

THE BELMONT REPORT

4. Applicability:

(a) This Institution assures that whenever it engages in human subjects research conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Institution will comply with the Terms of the Federalwide Assurance for Institutions Within the United States (contained in a separate document on the OHRP website), unless the research is otherwise exempt from the requirements of the Common Rule or a department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.

(b) Optional: This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

The Common Rule (see section 3 of the Terms of the FWA for Institutions Within the United States for a list of departments and agencies that have adopted the Common Rule and the applicable citations to the Code of Federal Regulations)

Submission Number: 13906

9/29/2006 11:47:46 AM

FWA Number: FWA00004696

Institution Name: BATTELLE MEM INST

OMB No. 0990-0278

Approved for use through 1/31/2008

5. Designation of Institutional Review Boards (IRBs)

This Institution designates the following IRB(s) for review of research under this Assurance (if the IRB has not previously registered with HHS or has not provided a membership roster to HHS, please submit to OHRP the appropriate IRB registration materials which are available on the OHRP website).

NOTE: Reliance on the IRB of another institution or organization or an independent IRB must be documented by a written agreement that is available for review by OHRP upon request. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the parties involved may develop their own agreement. Future designation of other IRBs requires an update of the FWA.

HHS IRB Registration Number	Name of IRB As Registered with HHS
IRB00000184	CENTERS FOR DISEASE CONTROL & PREVENTION IRB #2 - B
IRB00000241	U OF WASHINGTON IRB #1 - A
IRB00000242	U OF WASHINGTON IRB #2 - B
IRB00000243	U OF WASHINGTON IRB #3 - C
IRB00000283	BATTELLE MEMORIAL INST, BSTI IRB #1
IRB00000284	BATTELLE MEMORIAL INST, CPHRE IRB #2
IRB00000285	BATTELLE MEMORIAL INST, PNNL IRB #3
IRB00000469	OREGON HLTH & SCIENCE U IRB #1
IRB00000470	OREGON HLTH & SCIENCE U IRB #2
IRB00000471	OREGON HLTH & SCIENCE U IRB #3
IRB00000533	WESTERN IRB #1-8 & #11-12
IRB00000653	RESEARCH TRIANGLE INST IRB #1
IRB00000654	RESEARCH TRIANGLE INST IRB #2
IRB00000655	RESEARCH TRIANGLE INST IRB #3
IRB00000737	U OF MISSISSIPPI
IRB00000755	NEW ENGLAND INSTITUTIONAL REVIEW BOARD (NEIRB) IRB #1
IRB00000911	BIOANALYTICAL SYSTEMS, INC. IRB #1
IRB00001313	COPERNICUS GROUP IRB #1
IRB00003277	OREGON HLTH & SCIENCE U IRB #4
IRB00003591	CENTRAL BERYLLIUM (CBEIRB) IRB #2
IRB00005670	BATTELLE MEMORIAL INST (PNNL) IRB #4

Submission Number: 13906

9/29/2006 11:47:46 AM

FWA Number: FWA00004696

Institution Name: BATTELLE MEM INST

OMB No. 0990-0278

Approved for use through 1/31/2008

6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: JAN

Middle Initial: B

Last Name: JAEGER

Degrees or Suffix (e.g., MD, PhD): MS

Institutional Title: DIRECTOR INDEPENDENT OVERSIGHT/CHAIR OFF RES ADMIN

Institution: BATTELLE MEMORIAL INSTITUTE

Telephone: (614) 424-6387

FAX: (614) 458-6387

E-mail: JAEGERJ@BATTELLE.ORG

Address: 505 KING AVENUE, A-1-73A

City: COLUMBUS

State: OH

Zip Code: 43201

NOTE: Institutions operated by the U.S. Government may need to obtain department or agency clearance prior to submission of the FWA to OHRP. Please contact the relevant department or agency Human Subject Protections Officer before forwarding this Assurance to OHRP.

Submission Number: 13906

9/29/2006 11:47:46 AM

FWA Number: FWA00004696

Institution Name: BATTELLE MEM INST

OMB No. 0990-0278

Approved for use through 1/31/2008

7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution
-- cannot be IRB Chairperson or IRB member)

I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) designated above are to provide review for all research to which this Assurance applies. The designated IRB(s) will comply with the Terms of the Federalwide Assurance for Institutions Within the United States and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.

Signature:  Date: 10/03/06
Russell P Austin

First Name: RUSSELL

Middle Initial: P

Last Name: AUSTIN

Degrees or Suffix (e.g., MD, PhD):

Institutional Title: SENIOR VICE PRESIDENT AND GENERAL COUNSEL

Institution: BATTELLE MEMORIAL INSTITUTE

Telephone: (614) 424-5456

FAX: (614) 424-3260

E-mail: AUSTINR@BATTELLE.ORG

Address: 505 KING AVENUE, 11-8-061

City: COLUMBUS

State: OH

Zip Code: 43201