

FWA #: FWA00005399  
Institution: U Wisconsin-Madison  
Expires: 02/25/2014

OMB No. 0990-0278  
Approved for use through May 31, 2011

## Federalwide Assurance (FWA) for the Protection of Human Subjects for Institutions Within the United States

### 1. Institution Filing Assurance

Name of Organization: U Wisconsin-Madison

City: Madison State: WI

HHS Institution Profile File (IPF) code, if known:

Federal Entity Identification Number (EIN), if known:

If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number:

### 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(s) (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.)	Status
Wisconsin Ste Lab Hygiene	MADISON	WI	A

### 3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the ethical principles in the following document(s): *(indicate below)*

*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:

#### **5. Designation of Institutional Review Boards (IRBs)**

This Institution designates the following IRB(s)/IEC(s) for review of research under this Assurance (*if the IRB(s)/IEC(s) 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.

<b>HHS IRB Registration Number</b>	<b>Name of IRB as Registered with HHS</b>	<b>Status</b>
IRB00000008	National Insts Hlth - NICHD - IRB #8	A
IRB00000020	Mayo Clinic IRB #1 - IRB - C	A
IRB00000026	Johns Hopkins U School of Medicine - JHM IRB #5	A
IRB00000038	U of Pennsylvania IRB #1	A
IRB00000078	Medical College of Wisconsin - Froedtert Mem L Hosp IRB #4	A
IRB00000104	U of Utah IRB #1	A
IRB00000105	U of Utah IRB #2	A
IRB00000106	U of Utah IRB #3	A

IRB00000107	U of Utah IRB #4	A
IRB00000125	Duke U Hlth System Inc. IRB #2 - DUMC	A
IRB00000126	Duke U Hlth System Inc. IRB #4 - DUMC	A
IRB00000161	U of Kansas Med Ctr IRB #1	A
IRB00000181	U Cincinnati Social & Behavioral Sci IRB #2XM	A
IRB00000246	U of Michigan IRB #3 - Behavioral Science	A
IRB00000263	U of Wisconsin Milwaukee IRB #1	A
IRB00000313	Georgetown U IRB #1 - Committee A	A
IRB00000366	U Wisconsin-Madison (Hlth Science) IRB #1	A
IRB00000367	U Wisconsin-Madison (Educ Rsch) IRB #2	A
IRB00000368	U Wisconsin-Madison (Social & Behavioral Sci) IRB #3	A
IRB00000405	Northwest Region IRB #5	A
IRB00000469	Oregon Hlth & Science U IRB #1	A
IRB00000470	Oregon Hlth & Science U IRB #2	A
IRB00000471	Oregon Hlth & Science U IRB #3	A
IRB00000533	Western IRB #1-8, #11-14, & #35	A
IRB00000648	Colorado- Panel A	A
IRB00000650	Colorado Multiple Inst Review Board (COMIRB) - Panel B (Adult)	A
IRB00000651	Colorado Multiple Inst Review Board (COMIRB) Panel C (Ped)	A
IRB00000673	Marshfield Clinical Rsch Foundation (MCRF) IRB #1(	A
IRB00000723	Duke U Hlth System Inc. IRB #3 - DUMC	A
IRB00000724	Duke U Hlth System Inc. IRB #5 - DUMC	A
IRB00000744	Duke U Hlth System Inc. IRB #6 - DUMC	A
IRB00000781	National Cancer Inst Central IRB #1 (Adult)	A
IRB00001023	Population Council IRB #1	A
IRB00001253	National Marrow Donor Program IRB #1	A
IRB00001266	Aurora Hlth Care IRB #1	A
IRB00001395	Medical College of Wisconsin - Froedtert Mem L Hosp IRB #1	A
IRB00001396	Medical College of Wisconsin - Froedtert Mem L Hosp IRB #2	A
IRB00001564	Medical College of Wisconsin - Froedtert Mem L Hosp IRB #3	A
IRB00001694	Gundersen Clinic, Ltd. IRB #1	A
IRB00002082	Children's Hosp of Wisconsin IRB #1	A
IRB00002117	Georgetown U IRB #2 - Committee B	A
IRB00002118	Georgetown U IRB #3 - Committee C	A
IRB00002160	Aspirus Wausau Hosp IRB #1	A
IRB00002754	Aurora Hlth Care IRB #3	A
IRB00002760	Colorado Multiple Inst Review Board (COMIRB) Panel D	A

IRB00002978	Meriter Hospital, Inc. IRB #1	A
IRB00003277	Oregon Hlth & Science U IRB #4	A
IRB00003294	Mayo Clinic IRB #2 - Blue Friday	A
IRB00003295	Mayo Clinic IRB #3 - Orange Thursday	A
IRB00003739	U Wisconsin-Madison (Minimal Risk) IRB #5	A
IRB00004122	Duke U Hlth System, Inc. IRB #1 - DUMC	A
IRB00004473	U of California Los Angeles-Neuroscience MIRB3 IRB #4	A
IRB00004989	Duke U Hlth System, Inc. IRB #7 - DUMC	A
IRB00004990	Duke U Hlth System, Inc. IRB #8 - DUMC	A
IRB00004992	Duke U Hlth System, Inc. IRB #10 - Rapid Response	A
IRB00005256	Mayo Clinic IRB #6 - Wednesday	A
IRB00006080	Children's Hosp of Wisconsin IRB #1 - IRB #2	A
IRB00006196	U of Kansas Med Ctr IRB #3	A
IRB00006380	Medical College of Wisconsin - Froedtert Mem L Hosp IRB #5	A
IRB00006846	Colorado Multiple Institutional Review Board (COMIRB) IRB #1 - Panel S	A

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

First Name: Lois Middle Initial: Last Name: Kallunki  
 Degrees or Suffix: J.D. Organizational Title: Senior Administrativ  
 Institution: University of Wisconsin-Madison  
 Telephone: 608 262-1224 FAX: 608 262-5134 E-Mail: lskallunki@grad.wisc.edu  
 Address: 201 Bascom Hall, 500 Lincoln Drive  
 City: Madison State: WI Zip Code: 53706

Submission#: 25137

Assurance#: FWA00005399

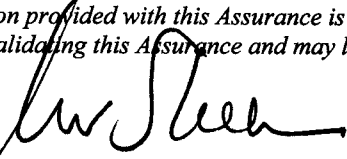
**7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)**

*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: 02-21-11

First Name: William

Middle Initial: S.

Last Name: Mellon

Degree or Suffix: Ph.D.

Organizational Title: Associate Dean for R

Institution:

U Wisconsin-Madison

Telephone: 608 262-1044

FAX: 608 262-5134

E-Mail: wsmellon@grad.wisc.edu

Address: 327 Bascom Hall, 500 Lincoln Drive

City: Madison

State: WI

Zip Code: 53706

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.

**8. FWA Approval**

The Federalwide Assurance for the Protection of Human Subjects for Institutions Within the United States submitted to HHS by the above Institution is hereby approved.

Assurance Number:

Expiration Date:

Signature of HHS Approving Official:

Date:

Public burden for this collection of information is estimated to average two hours for a new FWA filing and less than an hour for an FWA

FWA #: **FWA00005399**

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*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:

First Name: **William**

Middle Initial:

Last Name: **Mellon**

Degrees or Suffix: **Ph.D.**

Organizational Title: **Associate Dean for R**

Institution:

**U Wisconsin-Madison**

Telephone: **608 262-1044**

FAX: **608 262-5134**

E-Mail: **wsmellon@grad.wisc.edu**

Address: **327 Bascom Hall, 500 Lincoln Drive**

City: **Madison**

State: **WI**

Zip Code: **53706**

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Assurance Number: **FWA00005399**

Expiration Date: **02/25/2014**

Signature of HHS Approving Official: **Jean Makle**

Date: **02/25/2011**

Public burden for this collection of information is estimated to average two hours for a new FWA filing and less than an hour for an FWA renewal or update. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OS Reports Clearance Officer, Room 537H, 200 Independence Avenue, SW., Washington, DC 20201. *Do not return the completed form to this address.*

**Subject:** Electronic Update/Renewal of FWA Application for U Wisconsin-Madison Approved by OHRP as FWA00005399  
**From:** Jean.Makle@hhs.gov  
**Date:** 2/25/2011 11:41 AM  
**Attachments:**  FWA.pdf  
**To:** Iskallunki@grad.wisc.edu, wsmellon@grad.wisc.edu, Iskallunki@grad.wisc.edu  
**CC:** Jean.Makle@hhs.gov

This is an automated message from an unmonitored address. Please do not reply.

Your institution's electronic submission for the update/renewal of its Federalwide Assurance U Wisconsin-Madison has been approved by the Office for Human Research Protections (OHRP). The expiration date for your FWA renewal is 2/25/2014 12:41:43 PM. You will find this approval listed on our website at <http://ohrp.cit.nih.gov/search/search.aspx>. Funding agencies use this website to verify that an institution holds an active OHRP-approved FWA.

Whenever information provided to OHRP changes for your institution's FWA, you must submit an update/renewal. You may do this electronically by going to the OHRP Electronic Submission System at <http://ohrp.cit.nih.gov/efile/>. Your FWA must be renewed at least every 3 years.

When an electronic submission is processed, an automatically generated e-mail notifies the Human Protections Administrator and Signatory Official, as well as the person submitting the electronic record, that the FWA document has been approved. This, of course, is dependent upon the electronic file submitted to OHRP providing e-mail addresses as requested.

Sincerely,

Division of Policy and Assurances  
Office for Human Research Protections  
U.S. Department of Health and Human Services  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852(240) 453-6900  
Toll-Free within the U.S. (866) 447-4777