FWA #: **FWA00001809**

Institution: **Children's Hosp of Wisconsin, Inc.**

Expires: **06/24/2013**

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: **Children's Hosp of Wisconsin, Inc.**

City: **Milwaukee** State: **WI**

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

Federal Entity Identification Number (EIN), if known: **39-0812532N**

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
Children's Research Institute, Inc.	**MILWAUKEE**	WI	**A**
Children's Hosp Wisconsin - Fox Valley	**NEENAH**	WI	**A**
Surgicenter of Greater Milwaukee LLC	**Milwaukee**	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.

HHS IRB Registration Number	Name of IRB as Registered with HHS	Status
IRB00002082	Children's Hosp of Wisconsin IRB #1	A
IRB00004296	National Cancer Inst Central IRB #2 (Pediatric)	A
IRB00006080	Children's Hosp of Wisconsin IRB #1 - IRB #2	A

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

First Name: **Lori** Middle Initial: Last Name: **Mroczek**
Degrees or Suffix: **CIP** Organizational Title: **IRB Coordinator**
Institution: **Children's Hosp Wisconsin**
Telephone: **414 266-2986** FAX: **414 337-7105** E-Mail: **lmroczek@chw.org**
Address: **999 North 92nd Street, Suite 730**
City: **Milwaukee** State: **WI** Zip Code: **53226**

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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:

First Name: **Peggy** Middle Initial: Last Name: **Troy**

Degrees or Suffix: Organizational Title: **President**

Institution: **Children's Hosp of Wisconsin, Inc.**

Telephone: **414 266-6400** FAX: **414 266-6409** E-Mail: **ptroy@chw.org**

Address: **999 North 92nd Street, Suite 760**

City: **Milwaukee** State: **WI** Zip Code: **53226**

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: **FWA00001809** Expiration Date: **06/24/2013**

Signature of HHS Approving Official: **Hal Blatt** Date: **06/24/2010**

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.*