

FWA #: FWA00000414  
Institution: Aurora Hlth Care, Inc.  
Expires: 11/22/2026

OMB No. 0990-0278  
Approved for use through August 31, 2023

## Federalwide Assurance (FWA) for the Protection of Human Subjects

### 1. Institution Filing Assurance

Legal Name: Aurora Hlth Care, Inc.  
City: Milwaukee State/Province: WI Country: USA

### 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.

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

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)	
Aurora Medical Group, Inc. (Includes all AMG Clinics in Wisconsin)	Milwaukee	WI	A
Aurora Advanced Healthcare, Inc.	Milwaukee	WI	A
Aurora Health Care Central, Inc. (d/b/a Aurora Sheboygan Memorial Medical Center)	Sheboygan	WI	A
Aurora Health Care Metro (d/b/a Aurora St. Luke's Medical Center)	Milwaukee	WI	A
Aurora Health Care Metro (d/b/a Aurora St. Luke's South Shore)	Milwaukee	WI	A
Aurora Health Care Metro (d/b/a Aurora Sinai Medical Center)	Milwaukee	WI	A
Aurora Health Care Southern Lakes, Inc. (d/b/a Aurora Memorial Hospital of Burlington)	Burlington	WI	A
Aurora Health Care Southern Lakes, Inc. (d/b/a Aurora Lakeland Medical Center)	Elkhorn	WI	A
Aurora Health Care Southern Lakes, Inc. (d/b/a Aurora Medical Center Kenosha)	Kenosha	WI	A
Aurora Medical Center of Washington County, Inc. (d/b/a Aurora Medical Center Washington County)	Hartford	WI	A
Aurora Psychiatric Hospital, Inc. (d/b/a Aurora Psychiatric Hospital)	Wauwatosa	WI	A
Aurora Medical Center of Oshkosh, Inc. (d/b/a Aurora Medical Center Oshkosh)	Oshkosh	WI	A
Aurora Health Care North, Inc. (d/b/a Aurora Medical Center Manitowoc County)	Two Rivers	WI	A

West Allis Memorial Hospital, Inc. (d/b/a Aurora West Allis Medical Center)	West Allis	WI	A
Aurora Consolidated Laboratories, a Co-Tenancy	Milwaukee	WI	A
Aurora UW Academic Medical Group, Inc.	Milwaukee	WI	A
Visiting Nurse Association of Wisconsin, Inc.	Milwaukee	WI	A
Aurora Health Care Ventures, Inc.	Milwaukee	WI	A
Aurora Family Service, Inc.	Milwaukee	WI	A
All Vince Lombardi Cancer Clinics in Wisconsin	Milwaukee	WI	A
Aurora Health Care Southern Lakes, Inc. (d/b/a Aurora Medical Center Summit)	Summit	WI	A
Aurora Medical Center Grafton, LLC (d/b/a Aurora Medical Center Grafton)	Grafton	WI	A
Aurora Health Care Metro, Inc.	Milwaukee	WI	A
Aurora Health Care Metro (d/b/a Aurora Cancer Care)	Milwaukee	WI	A
Aurora Medical Center Bay Area, Inc.	Marinette	WI	A
Aurora Bay Area Medical Group, LLC (Includes all ABAMG clinics in Wisconsin)	Marinette	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 following statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. (indicate below)

#### ***The Belmont Report***

### 4. Applicability

(a) This Assurance applies whenever this Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under 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. Assurance of Compliance with the Terms of the Federalwide Assurance

(a) This Institution assures that whenever it engages in research to which this Assurance applies, it will comply with the Terms of the Federalwide Assurance (contained in a separate document on the Office for Human Research Protections (OHRP) website).

#### 6. Designation of Institutional Review Boards (IRBs)

This Institution assures that it will rely upon only IRBs registered with OHRP for review of research to which this FWA applies. This institution (a) designates the following internal IRB(s) for review of research under this Assurance; or (b) does not have an internal IRB and designates the following external IRB for review of all research to which this FWA applies or, if multiple external IRBs are relied upon, the following external IRB that reviews the largest percentage of research to which this FWA applies.

NOTE: Institutions designating internal IRBs do not need to designate any of the external IRBs upon which it relies.

HHS IRB Registration Number	Name of IRB as Registered with HHS	Is the IRB Internal or External to the Institution?
IRB0000078	Medical College of Wisconsin - Froedtert Mem L Hosp IRB #4	E
IRB0000180	U of Cincinnati Med Ctr IRB #1A	E
IRB0000263	U of Wisconsin Milwaukee IRB #1	E
IRB0000533	WCG IRB	E
IRB0000673	Marshfield Clinic Research Institute (MCRI) IRB#1	E
IRB0000781	National Cancer Inst Central IRB #1 (Adult)	E
IRB0000971	Advarra, Inc. IRB #1	E
IRB0001253	National Marrow Donor Program IRB #1	E
IRB0001266	Advocate Aurora Health IRB	I
IRB0001395	Medical College of Wisconsin - Froedtert Mem L Hosp IRB #1	E
IRB0001396	Medical College of Wisconsin - Froedtert Mem L Hosp IRB #2	E
IRB0001564	Medical College of Wisconsin - Froedtert Mem L Hosp IRB #3	E
IRB0001790	Sterling Institutional Review Board IRB #1 - IRBs 3-7	E
IRB0003226	Quorum Review Inc. IRBs 1-4	E
IRB0003869	U of Texas M.D. Anderson Cancer Ctr IRB #3 - Executive Session	E
IRB0005015	U of Texas M.D. Anderson Cancer Ctr IRB #4 - Psychosocial/Behavioral	E
IRB0006380	Medical College of Wisconsin - Froedtert Mem L Hosp IRB #5	E
IRB0007642	Schulman Associates Institutional Review Board, Inc. IRB #2	E

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

First Name: Michelle Middle Initial: Last Name: Maternowski  
 Degrees or Suffix: BS Institutional Title: Director, Research Subject Protection Program  
 Institution: Aurora Health Care, Inc.  
 Telephone: 414 219-7744 FAX: 414 219-7477 E-Mail: michelle.maternowski@aah.  
 org  
 Address: 1020 N 12th Street, PO Box 342  
 City: Milwaukee State/Province: WI Country: USA

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

I have read and agree to the Terms of the Federalwide Assurance.

I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education and training 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) that this institution relies upon will comply with the Terms of the Federalwide Assurance when reviewing research covered by this Assurance 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: Jacob Bidwell MD

Date: 11/19/2021

First Name: Jacob Middle Initial: Last Name: Bidwell

Degrees or Suffix: MD Institutional Title: DIO & VP, Academic Affairs, President, AUWMG

Institution: Aurora Health Care, Inc.

Telephone: 414 219-7713 FAX: 414 219-7044 E-Mail: jacob.bidwell@aah.org

Address: c/o Aurora Health Care Research Subject Protection Program  
1020 N 12th Street, P.O. Box 342

City: Milwaukee State/Province: WI Country: USA

9. 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: FWA00000414

Expiration Date: 11/22/2026

Signature of HHS Approving Official: Cecilia Chirinos

Date: 11/22/2021

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