☐ **New Filing** ☐ **Update for Assurance Identifier:**

Department of Health and Human Services
Federalwide Assurance of Protection for Human Subjects

(1) Institution Name:

City: State: (if USA) Country: (if outside USA):

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

Federal Entity Identity Identification Number (EIN), if known:

assures that all of its activities related to human subject research, regardless of funding source, will be guided by the ethical principles in the following document. (*indicate below*)

☐ **Domestic Institutions:** ☐ ***The Belmont Report***
(*choose one*) ☐ ***Other*** *(please submit copy to OHRP with this Assurance)*

☐ **International Institutions:** ☐ ***The Declaration of Helsinki*** ☐ ***The Belmont Report***
(*choose one*) ☐ ***Other*** *(please submit copy to OHRP with this Assurance)*

(2) This institution assures that all of its activities related to Federally-supported human subject research will comply with the following procedural standards. (*indicate below*)

☐ **Domestic Institutions**: ☐ **45 CFR 46 as Stipulated in the Terms of Assurance for Protection of Human Subjects Within the United States,** provided on this date at the OHRP website.

☐ ***Other*** *(please submit copy to OHRP with this Assurance)*

(please check one of the following)

☐ This institution elects to assure compliance with the Terms of Assurance for all of its human subject research, regardless of funding source.

☐ This institution assures compliance with the Terms of Assurance only for Federally-supported research.

☐ **International Institutions:** **Terms of Assurance for Protection of Human Subjects Outside the United States** as provided on this date at the OHRP website and in the standards indicated below.

(please check one of the following)

☐ 45 CFR 46, 21 CFR 50, and 21 CFR 56 ☐ ICH-GCP-E6 Sections 1 through 4

☐ Canadian Tri-Council Policy ☐ Indian Council of Medical Research

☐ CIOMS International Ethical Guidelines

☐ Other *(please submit copy to OHRP with this Assurance)*

(3) Institutional Components

List below all components of the institution that may operate under a different name [e.g., All Saints Medical Center is comprised of All Saints Hospital, St. Mary's Children's Hospital, St. Mathias Psychiatric Hospital, and St. Paul's Rehabilitation Center]. Also list any alternate names under which the institution may operate. The institution should have available, for review upon OHRP request, a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the IRB, IRB support staff, and investigators in the various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the named institution and all components listed here. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of OHRP.

G Please check here if there are no such components or alternate names.

Name of Component	City	State (or Country if Outside US)

(4) Operations, Procedures, and Oversight Mechanisms (a, b, c, e = optional)

(a) Institutional procedures for protecting human subjects were last updated on: *(date)*

(b) These procedures include formal mechanisms for monitoring compliance with human subject protection requirements. ☐**Yes** ☐**No**

(c) The institution has established continuing programs to educate IRB members, IRB staff, and research investigators about human subject protection requirements. ☐**Yes** ☐**No**

(d) For Domestic Institutions, the Signatory Official, Human Protections Administrator, and IRB Chairpersons of all designated IRBs have completed the relevant OHRP modules(s), and other staff are appropriately trained. For International Institutions, relevant personnel are required to complete appropriate comparable training. ☐**Yes** ☐**No**

(e) Number of full time positions devoted solely to human subject education activities:

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

(5) Designation of Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs)

This institution designates the following IRB(s) for review of research on a regular basis* under this Assurance *(if the IRB is not previously registered with HHS or has not provided a membership roster to HHS, please attach the necessary materials available elsewhere on this website).*

* Institutions may, on an occasional or ad hoc basis, choose to rely on an IRB operating under another Institution's Assurance. Such occasional reliance must be documented in writing and provided to OHRP upon request, but need not be listed below. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the institutions may develop their own agreement.

HHS IRB Registration Identifier	Name of IRB As Registered with HHS	Name and Signature of IRB Chairperson or IRB Organization Head Authorizing Designation of the IRB Under This Assurance

(6) Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person -- cannot be IRB Chairperson):

First Name: Middle Initial: Last Name:

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

Human subject protection training last taken on *(date)*

Telephone: FAX: E-Mail:

Address:

City: State (if USA): Zip Code (if USA):

Country (if outside USA):

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

Acting officially and in an authorized capacity on behalf of this institution, I assure protections for human subjects as specified above. The IRBs above are designated to provide oversight for research under this Assurance. These IRBs will comply with the terms of the 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 have personally satisfied the education requirements referenced in the Terms of Assurance and will require that all other relevant personnel also do so. I will further require that all such personnel receive appropriate additional initial and

continuing education about human subject protection requirements. *(Note: False statements could be cause for invalidating this Assurance and may lead to administrative or legal action.)*

I understand that all collaborating institutions engaged in Federally-supported human subject research must submit their own Assurance.

Signature _____ Date: _____

First Name Middle Initial: Last Name:

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

Human subject protection training last taken on: (date)

Telephone: FAX: E-Mail:

Address:

City: State (if USA): Zip Code (if USA):

Country (if outside USA):

NOTE: Facilities operated by the US Government may require Department or Agency clearance. Please contact the relevant Department or Agency Human Protections Officer before forwarding to OHRP.

(8) HHS Approval

The Federalwide Assurance of Protection for Human Subjects submitted to HHS by the above institution is hereby approved for the conduct of Federally-supported research.

Signature of HHS Approving Official: Date:

Assurance Identifier: