

Federalwide Assurance (FWA) for the Protection of Human Subjects

☐ New Filing ☐ Update or Renewal for FWA Number: _____

1. Institution Filing Assurance

Legal Name:

City:

State/Province:

Country:

2. Institutional Components

List below component organizations 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 component organizations listed below.

☐ Please check here if there are no such component organizations or alternate names.

Name of Component Organization or Alternate Names Used	City	State/Province and/or Country

3. Applicability

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.

4. Assurance of Compliance with the Terms of the Federalwide Assurance

This institution assures that whenever it engages in research to which this Assurance applies, it will comply with the Terms of the Federalwide Assurance, which are contained in a separate document on the Office for Human Research Protections (OHRP) website here: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwafwas/fwafwa-protection-of-human-subject/index.html>

5. 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.

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

First Name: Middle Initial: Last Name:

Degrees or Suffix: Institutional (i.e., Job) Title:

Institution:

Telephone: E-Mail:

Address:

City: State/Province: Country:

7. 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 research 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.

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: (Electronic signature)

Date: _____

First Name: Middle Initial: Last Name:

Degrees or Suffix: Institutional (i.e., Job) Title:

Institution:

Telephone: E-Mail:

Address:

City: State/Province: Country:

8. FWA Approval

The Federalwide Assurance for the Protection of Human Subjects submitted to HHS by the above institution is hereby approved.

Assurance Number: Expiration Date:

Approving HHS Official: _____ Approval Date: _____

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0278. The time required to complete this information collection is estimated to average 20 minutes per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer.