OMB No. 0990-0278
Approved for 01/31/2011

Federalwide Assurance (FWA) for the Protection of Human Subjects for International (Non-U.S.) Institutions

[ ] New Filing **[ ] Update or Renewal for FWA Number: _____**

1. Institution Filing Assurance

Legal Name:

City: State/Province: Country:

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) or the Independent Ethics Committee(s) (IEC), IRB/IEC 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.

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

Name of Component or Alternate Names Used	City	State or Country

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 Declaration of Helsinki***
	[ ] ***The Belmont Report***
	[ ] ***Other:*** *(Please submit copy to OHRP with this Assurance)*

4. Applicability

This Institution assures that whenever it engages in human subjects research conducted or supported by any U.S. department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Institution will comply with the following, unless the research is otherwise exempt from the requirements of the Common Rule or a U.S. department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance:

a) the Terms of the Federalwide Assurance for International (Non-U.S.) Institutions (contained in a separate document on the OHRP website); and

b) the following procedural standards (*please check one or more of the following)*:

[ ] ***The Common Rule (see section 3 of the Terms of the FWA for Institutions within the United States for a list of U.S. federal departments and agencies that have adopted the Common Rule and the applicable citations to the Code of Federal Regulations)***

[ ] ***The Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46***

[ ] ***The U.S. Food and Drug Administration regulations at 21 CFR parts 50 and 56***

[ ] ***The May 1, 1996, International Conference on Harmonization E-6 Guidelines for Good Clinical Practice (ICH-GCP-E6), Sections 1 through 4***

[ ] ***The 2002 Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects***

[ ] ***The 1998(with 2000, 2002, 2005 amendments) Medical Research Council of Canada Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans***

[ ] ***The 2006 Indian Council of Medical Research Ethical Guidelines for Biomedical Research on Human Subjects***

[ ] ***Other standard(s) for the protection of human subjects recognized by U.S. federal departments and agencies which have adopted the U.S. Federal Policy for the Protection of Human Subjects (please submit copy to OHRP with this Assurance)***

5. <u>Designation of Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs)</u>

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/IEC of another institution or organization or an independent IRB/IEC 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 IRB(s)/IEC(s) requires an update of the FWA.

HHS IRB Registration Number	**Name of IRB/IEC as Registered with HHS**

6. <u>Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)</u>

First Name: Middle Initial: Last Name:

Degrees or Suffix: Institutional Title:

Institution:

Telephone: FAX: E-Mail:

Address:

City: State/Province: Country:

7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution -- Cannot be IRB/IEC Chairperson or IRB/IEC Member)

I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB/IEC Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing research investigators, IRB/IEC 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)/IEC(s) designated above are to provide review for all research to which this Assurance applies. The designated IRB(s)/IEC(s) will comply with the **Terms of the Federalwide Assurance for International (Non-U.S.) Institutions** 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: Middle Initial: Last Name:

Degrees or Suffix: Institutional Title:

Institution:

Telephone: FAX: E-Mail:

Address:

City: State/Province: Country:

8. <u>FWA Approval</u>

The Federalwide Assurance for the Protection of Human Subjects for International (Non-U.S.) Institutions 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 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.*