OMB No. 0990-0278
DRAFT REVISION – 9/9/2010

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 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.

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

Name of Component or Alternate Names Used	City	State/Province and/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 Belmont Report***
	[ ] ***The Declaration of Helsinki***
	[ ] ***Other:*** *(Please submit copy to OHRP with this Assurance)*

4. <u>Applicability</u>

(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 for U.S. institutions:* This Institution voluntarily elects to apply the following to all of its non-exempt human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

[ ] ***The Common Rule (see section 3 of the Terms of the FWA 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***

5. <u>Assurance of Compliance with the Terms of the Federalwide Assurance</u>

(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)**.

(b) **Non-U.S. institutions only**: This Institution assures that whenever it engages in research to which this Assurance applies it will comply with the following procedural standards (*please check one or more of the following)*:

[ ] ***The Common Rule***

[ ] ***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 Common Rule (please submit copy to OHRP with this Assurance)***

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 that the institution relies upon.

HHS IRB Registration Number	Name of IRB as Registered with HHS	Is the IRB Internal or External to the Institution?

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

First Name: Middle Initial: Last Name:

Degrees or Suffix: Institutional Title:

Institution:

Telephone: FAX: E-Mail:

Address:

City: State/Province: Country:

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: (Electronic signature - Exact procedure to be determined)

Date: _____

First Name: Middle Initial: Last Name:

Degrees or Suffix: Institutional Title:

Institution:

Telephone: FAX: E-Mail:

Address:

City: State/Province: Country:

9. <u>FWA Approval</u>

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: _____ Date:_____