U.S. Department of Health and Human Services (DHHS)
Federalwide Assurance (FWA) for the Protection of Human Subjects
For Domestic (U.S.) Institutions

1. **Institution Filing Assurance**

Legal Name: University at Buffalo - State University of New York
City: Buffalo
State: New York
DHHS Institution Profile File (IPF) code, if known: IORG0000206
Federal Entity Identification Number (EIN), if known: 114603200F6
If this Assurance replaces an MPA or CPA, please provide the “M” or “T” number: M-1270

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 (IRB), IRB 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 additional components or alternate names.

<table>
<thead>
<tr>
<th>Name of Component or Alternate Names Used</th>
<th>City</th>
<th>State (or Country if Outside U.S.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Institute on Addictions</td>
<td>Buffalo</td>
<td>New York</td>
</tr>
<tr>
<td>SUNY Buffalo*</td>
<td>Buffalo</td>
<td>New York</td>
</tr>
</tbody>
</table>

3. **Statement of Principles**

This Institution 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(s). *(indicate below)*

- *The Belmont Report*
- Other *(please submit copy to OHRP with this Assurance)*
4. Applicability

(a) This Institution assures that all of its activities related to federally-conducted or -supported human subject research will comply with the Terms of Assurance for Protection of Human Subjects for Institutions Within the United States. NOTE: The Terms of Assurance are contained in a separate document on the OHRP website.

(b) Optional: This Institution elects to apply the following to all of its human subject research regardless of source of support:

- 45 CFR 46 and all of its subparts (A,B,C,D)
- Common Rule (e.g., 45 CFR 46, subpart A)

5. Designation of Institutional Review Boards (IRBs)

This Institution designates the following IRB(s) for review of research under this Assurance (if the IRB is not previously registered with DHHS or has not provided a membership roster to DHHS, please attach the appropriate IRB registration materials available on the OHRP website).

NOTE: Reliance on another institution’s IRB or an independent IRB 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 institutions involved may develop their own agreement. Future designation of other IRBs requires update of the FWA.

<table>
<thead>
<tr>
<th>DHHS IRB Registration Number</th>
<th>Name of IRB As Registered with DHHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB 00003126</td>
<td>SUNY Buffalo IRB #13 - Health Sciences Com. A</td>
</tr>
<tr>
<td>IRB 00003127</td>
<td>SUNY Buffalo IRB #14 - Health Sciences Com. B</td>
</tr>
<tr>
<td>IRB 00003128</td>
<td>SUNY Buffalo IRB #15 - Soc. &amp; Behav. Sciences</td>
</tr>
<tr>
<td>IRB 00004088</td>
<td>SUNY Buffalo IRB #16 - Children &amp; Youth</td>
</tr>
</tbody>
</table>

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

First Name: Edward Middle Initial: M Last Name: Zabcoki

Degrees or Suffix (e.g., MD, PhD): BA, MS Institutional Title: Research Subjects Protection Administrator

Institution: University at Buffalo (SUNY Buffalo)

Telephone: 716-645-3321 FAX: 716-645-6792 E-Mail: zabcoki@research.buffalo.edu

Address: Office of VP for Research, 516 Cepen Hall

City: Buffalo State: NY Zip Code: 14260
7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution -- cannot be IRB Chairperson or IRB member)

I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing all research investigators, IRB 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) designated above are to provide oversight for all research conducted under this Assurance. These IRB(s) will comply with the Terms of Assurance and possess appropriate knowledge of the local context in which this Institution’s research will be conducted. I understand that all collaborating institutions engaged in federally-conducted or -supported human subject research must submit their own Assurance.

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: [Signature]
Date: 8-4-05

First Name: Jorge
Middle Initial: V.
Last Name: Jose

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

Telephone: 716-645-3321
FAX: 716-645-6792
E-Mail: vpr@research.buffalo.edu

Address: Office of the Vice President for Research, 516 Capen Hall
City: Buffalo
State: New York
Zip Code: 14260

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

8. DHHS Approval

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

Assurance Number:
Expiration Date:

Signature of DHHS Approving Official: ____________________________ Date: ____________________________

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Version Date 03/20/2002
FEDERALWIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS

U. S. Department of Health and Human Services (HHS)
Office for Human Research Protections (OHRP)

A. TERMS OF THE FEDERALWIDE ASSURANCE (FWA) FOR INSTITUTIONS WITHIN THE UNITED STATES

1. Human Subjects Research Must be Guided by Ethical Principles

All of the Institution’s human subjects research activities, regardless of whether the research is subject to federal regulations, will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or (b) other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule.

2. Applicability

These terms apply whenever the Institution becomes engaged in human subjects research conducted or supported* by any federal department or agency that has adopted the Common Rule, unless the research is otherwise exempt from the requirements of the Common Rule or a department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance. In general, the Institution becomes so engaged whenever (a) the Institution’s employees or agents intervene or interact with human subjects for purposes of federally-conducted or -supported research; (b) the Institution’s employees or agents obtain individually identifiable private information about human subjects for purposes of federally-conducted or -supported research; or (c) the Institution receives a direct federal award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

[*Federally-supported is defined throughout the FWA and the Terms of Assurance as the U.S. Government providing any funding or other support.]


When the Institution becomes engaged in federally-conducted or -supported human subjects research to which the FWA applies, the Institution and the institutional review boards (IRBs) designated under the Institution’s Assurance will comply with the Federal Policy for the Protection of Human Subjects.
The reference in the Code of Federal Regulations is shown below for each department and agency which has adopted the Common Rule:

7 CFR part 1c Department of Agriculture
10 CFR part 745 Department of Energy
14 CFR part 1230 National Aeronautics and Space Administration
15 CFR part 27 Department of Commerce
   16 CFR part 1028 Consumer Product Safety Commission
22 CFR part 225 Agency for International Development
24 CFR part 60 Department of Housing and Urban Development
28 CFR part 46 Department of Justice
   32 CFR part 219 Department of Defense
34 CFR part 97 Department of Education
38 CFR part 16 Department of Veterans Affairs
40 CFR part 26 Environmental Protection Agency
45 CFR part 46 Department of Health and Human Services
45 CFR part 46 Central Intelligence Agency
   (by Executive Order 12333)
45 CFR part 690 National Science Foundation
49 CFR part 11 Department of Transportation

For any federally-conducted or -supported human subjects research to which the FWA applies, the Institution also will comply with any additional human subjects regulations and policies of the department or agency which conducts or supports the research and any other applicable federal, state, local, or institutional laws, regulations, and policies. When the Institution is engaged in human subjects research conducted or supported by the Department of Health and Human Services (HHS), the Institution will comply with all subparts of the HHS regulations at Title 45 Code of Federal Regulations part 46 (45 CFR part 46, subparts A, B, C, and D).
Human subjects research conducted or supported by each federal department or agency listed above will be governed by the regulations as implemented by the respective department or agency. The head of the department or agency retains final judgment as to whether a particular activity conducted or supported by the respective department or agency is covered by the Common Rule. If the Institution needs guidance regarding implementation of the Common Rule and other applicable federal regulations, the Institution should contact appropriate officials at the department or agency conducting or supporting the research. For federally-conducted or –supported research covered by the FWA, the department or agency that conducts or supports the research retains final authority for determining whether the Institution complies with the Terms of Assurance. If HHS receives an allegation or indication of noncompliance related to human subjects research that is covered by the FWA and is conducted or supported solely by a Common Rule department or agency other than HHS, HHS will refer the matter to the other department or agency for review and action as appropriate.

Please note that if the Institution voluntarily extends the Common Rule or the Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46 to all research regardless of support, OHRP will have the authority to ensure that the Institution complies with this commitment for all research to which the FWA applies that is not federally-conducted or –supported.

4. Written Procedures*

a) The Institution submitting the FWA has written procedures* for ensuring prompt reporting to the IRB, appropriate institutional officials, the head of any department or agency conducting or supporting the research (or designee), any applicable regulatory body, and OHRP of any:

1. unanticipated problems involving risks to subjects or others;
2. serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB(s); and
3. suspension or termination of IRB approval.

Upon request, the Institution will provide a copy of these written procedures to OHRP and any department or agency conducting or supporting research covered by the FWA.

b) The Institution must ensure that the IRB(s) designated under the FWA has established written procedures* for:

4. conducting IRB initial and continuing review (not less than once per year) of research, and reporting IRB findings to the investigator and the Institution;
5. determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and
6. ensuring prompt reporting to the IRB of proposed changes in a research activity and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.

Upon request, the Institution will provide a copy of these written procedures to OHRP and any department or agency conducting or supporting research covered by the FWA.

[*For HHS-conducted or -supported human subjects research, see OHRP guidance on written IRB procedures on the OHRP website at http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd702.htm.]

5. Scope of IRB(s)'s Responsibilities

All human subjects research to which the FWA applies, except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, will be reviewed, prospectively approved, and subject to continuing review at least annually by the designated IRB(s). The IRB(s) will have authority to approve, require modifications in, or disapprove the covered human subjects research. For research approved by the IRB(s), further appropriate review and approval by any department or agency conducting or supporting the research or by officials of the institution holding the FWA may be required.

6. Informed Consent Requirements

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, informed consent for research to which the FWA applies will be:

a) sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, Section 116 of the Common Rule; and

b) appropriately documented, in accordance with, and to the extent required by, Section 117 of the Common Rule.

7. Requirement for Assurances for Collaborating Institutions

When the Institution holding the FWA is either a) the primary awardee under a federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for federally-conducted or –supported research to which the FWA applies, the Institution is responsible for ensuring that all collaborating institutions engaged in such research operate under an appropriate OHRP-approved or other federally-approved assurance for the protection of human subjects.
An institution holding an FWA may collaborate with another institution that does not have an FWA. In such circumstances, a collaborating institution may operate under the FWA with the approval of the department or agency conducting or supporting the research and the institution holding the FWA.

For federally-conducted or –supported research covered by the FWA, the department or agency that conducts or supports the research retains final authority for determining which institutions are engaged in the research and need to hold an assurance for the protection of human subjects.

8. Written Agreements with Independent Investigators Who are not Otherwise Affiliated with the Institution

When the Institution holding the FWA is either a) the primary awardee under a federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for federally-conducted or –supported research to which the FWA applies, the Institution is responsible for ensuring that all collaborating independent investigators engaged in such research operate under an appropriate OHRP-approved or other federally-approved assurance for the protection of human subjects.

The engagement in federally-conducted or –supported human subjects research activities to which the FWA applies by each independent investigator who is not otherwise an employee or agent of the Institution may be covered under the FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB review. OHRP’s sample Individual Investigator Agreement (see http://www.hhs.gov/ohrp/humansubjects/assurance/unaflsup.rtf) may be used or adapted for this purpose, or the Institution may develop its own commitment agreement in coordination with the department or agency conducting or supporting the research. Institutions must maintain commitment agreements on file and provide copies upon request to OHRP and any department or agency conducting or supporting the research.

For federally-conducted or –supported research covered by the FWA, the department or agency that conducts or supports the research retains final authority for determining which independent investigators are engaged in the research and need to be covered by a written commitment agreement with the institution holding the FWA.

9. Institutional Support for the IRB(s)

The Institution will ensure that each IRB designated under the FWA has meeting space and sufficient staff to support the IRB’s review and recordkeeping duties.

10. Compliance with the Terms of Assurance

The Institution accepts and will follow items 1-9 above and is responsible for ensuring that (a) the IRB(s) designated under the FWA agree to comply with these terms; and (b) the IRB(s) possess appropriate knowledge of the local research context for all research to
which the FWA applies (please refer to the OHRP Guidance on IRB Knowledge of Local Research Context on the OHRP website at http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm).

Any designation under the FWA of the IRB of another institution or organization must be documented by a written agreement between the Institution holding the FWA and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of the FWA. OHRP’s sample IRB Authorization Agreement may be used for such purpose, or the parties involved may develop their own agreement. This agreement should be kept on file at both institutions/organizations and made available upon request to OHRP and any department or agency conducting or supporting research covered by the FWA.

11. Assurance Training

The OHRP Assurance Training Modules (see http://137.187.172.153/CBTs/Assurance/login.asp) describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB Chair(s) that must be fulfilled under the FWA. OHRP strongly recommends that the Institutional Signatory Official, the Human Protections Administrator, and the IRB Chair(s) personally complete the relevant OHRP Assurance Training Modules, or comparable training that includes the content of these modules, prior to submitting the FWA.

12. Educational Training

OHRP strongly recommends that the Institution and the designated IRB(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, the following: relevant ethical principles; relevant federal regulations; written IRB procedures; OHRP guidance; other applicable guidance, state and local laws; and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB members and staff complete relevant educational training before reviewing human subjects research; and b) research investigators complete appropriate institutional educational training before conducting human subjects research.

13. Renewal of Assurance

All information provided under the FWA must be renewed or updated at least every 36 months (3 years), even if no changes have occurred, in order to maintain an active FWA. Failure to update this information may result in restriction, suspension, or termination of the Institution’s FWA for the protection of human subjects.