

FWA Number: FWA00000376

Institution Name: U NORTH DAKOTA

OMB No. 0990-0278

Approved for use through 1/31/2008

**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: U NORTH DAKOTA

City: GRAND FORKS

State: ND

DHHS Institutional Profile Code: 6093301

Federal Entity Identification Number (EIN): 46-6002491

This Assurance replaces:

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.

None Selected

3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of funding source, will be guided by the ethical principles in the following documents:

THE BELMONT REPORT

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4. Applicability:

(a) This Institution assures that whenever it engages in human subjects research conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Institution will comply with the Terms of the Federalwide Assurance for Institutions Within the United States (contained in a separate document on the OHRP website), unless the research is otherwise exempt from the requirements of the Common Rule or a department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.

(b) Optional: This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

No Selection Made

5. Designation of Institutional Review Boards (IRBs)

This Institution designates the following IRB(s) for review of research under this Assurance (if the IRB 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 of another institution or organization 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 parties involved may develop their own agreement. Future designation of other IRBs requires an update of the FWA.

HHS IRB Registration Number	Name of IRB As Registered with HHS
IRB00000268	U OF SOUTH DAKOTA IRB #2
IRB00000533	WESTERN IRB #1-8, #11-14, & #35
IRB00000794	WALTER REED ARMY INST OF RSCH IRB #1
IRB00000971	SCHULMAN ASSOCIATES INSTITUTIONAL REVIEW BOARD, INC. IRB #1
IRB00001040	U OF NORTH DAKOTA IRB #1
IRB00001313	COPERNICUS GROUP IRB #1
IRB00002563	ALTRU HLTH SYSTEM IRB #1
IRB00003226	QUORUM REVIEW INC. IRB #1
IRB00004058	ST. ALEXIUS MED CTR IRB#1

Submission Number: 18035

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

First Name: RENEE

Middle Initial: M

Last Name: CARLSON

Degrees or Suffix (e.g., MD, PhD): B.S.

Institutional Title: IRB COORDINATOR

Institution: UNIVERSITY OF NORTH DAKOTA

Telephone: (701) 777-4079

FAX: (701) 777-6708

E-mail: RENEECARLSON@MAIL.UND.NODAK.EDU

Address: RESEARCH DEVELOPMENT AND COMPLIANCE

TWAMLEY HALL ROOM 106

City: GRAND FORKS

State: ND

Zip Code: 58202-7134

NOTE: Institutions operated by the U.S. Government may need to obtain department or agency clearance prior to submission of the FWA to OHRP. Please contact the relevant department or agency Human Subject Protections Officer before forwarding this Assurance to OHRP.

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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 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 review for all research to which this Assurance applies. The designated IRB(s) will comply with the Terms of the Federalwide Assurance for Institutions Within the United States 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: _____

Barry I Milavetz

First Name: BARRY

Middle Initial: I

Last Name: MILAVETZ

Degrees or Suffix (e.g., MD, PhD): PH.D.

Institutional Title: ASSOCIATE VICE PRESIDENT FOR RESEARCH

Institution: UNIVERSITY OF NORTH DAKOTA

Telephone: (701) 777-4280

FAX: (701) 777-6708

E-mail: BARRYMILAVETZ@MAIL.UND.NODAK.EDU

Address: RESEARCH DEVELOPMENT AND COMPLIANCE

ROOM 105 TWAMLEY HALL, BOX 7134

City: GRAND FORKS

State: ND

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8. FWA Approval

The Federalwide Assurance for the Protection of Human Subjects for Institutions Within the United States 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 503, 200 Independence Avenue, SW., Washington, DC 20201.

Do not return the completed form to this address.