1: Principles and Purpose 1.2 Regulatory Requirements for Human Research	Effective Date: 1/21/2019 Revised: 12/8/2017

North Dakota State University complies with applicable requirements mandated by various federal agencies and sponsors in the conduct, review and oversight of human subjects research in which the institution is engaged.

1.0 FederalWide Assurance of Compliance.

NDSU maintains an approved FederalWide Assurance (#FWA00002439) of Compliance from the Office of Human Research Protections (OHRP) that describes procedures for protecting the rights and welfare of research participants. NDSU applies these standards to all Federally-funded human research projects. One internal IRB (#IRB00001365) is designated for review of human research, unless arrangements are made to rely on the review of a collaborator or external IRB.

2.0 Department of Health and Human Services.

NDSU human research projects funded by Common Rule agencies comply with Department of Health and Human Services (DHHS) regulations for protection of research participants.

2.1 Common Rule.

Code of Federal Regulations (CFR) Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR Part 46), including:

- Subpart A – Basic Policy for Protection of Research Subjects
- Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
- Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
- Subpart D – Additional Protections for Children Involved as Subjects in Research
- Subpart E – Registration of Institutional Review Boards

2.2 Clinical investigations.

Additional regulations at CFR Title 21 – Food & Drugs apply to human research projects that constitute clinical investigations involving articles regulated by the Food and Drug Administration (FDA) (e.g., drugs, biologicals, medical devices, etc.):

- Part 50 - Protection of Human Subjects
- Part 56 – Institutional Review Boards
- Part 312 – Investigational New Drug Application
- Part 314 – New Drug Applications
- Part 812 – Investigational Device Exemptions
- Additional parts as applicable

3.0 Other federal agencies.
NDSU complies with any additional requirements in the review and conduct of a human subjects research project supported by any non-DHHS federal sponsor, which may include.

- Department of Agriculture, 7 CFR Part 1c
- Department of Energy, 10 CFR Part 745
- National Aeronautics and Space Administration, 14 CFR Part 1230
- Department of Commerce, National Institute of Standards and Technology, 15 CFR Part 27
- Consumer Product Safety Commission, 16 CFR Part 1028
- Agency for International Development (USAID), 22 CFR Part 225
- Department of Housing and Urban Development, 24 CFR Part 60
- Department of Justice, National Institute of Justice, 28 CFR Part 46
- Department of Defense, 32 CFR Part 219
- Department of Education, 34 CFR Part 97
- Department of Veterans Affairs, 39 CFR Part 16
- Environmental Protection Agency, 40 CFR Part 26
- National Science Foundation, 45 CFR Part 690
- Department of Transportation, 49 CFR Part 11

Consult applicable terms and conditions of the funding sponsor for any additional requirements for a human research project.

DEFINITIONS:
Human subject: (HHS) a living individual about whom an investigator (whether professional or student) conducting research obtains: information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human subject (FDA): an individual who is or becomes a participant in research, either as a recipient of a test article, or as a control; also includes someone on whom, or on whose specimen, an investigational device is used, or who participates as a control.

REFERENCES:
Office of Human Research Protections (OHRP), Dept. of Health and Human Services (DHHS)
45 CFR Part 46 Protection of Human Subjects – DHHS
FederalWide Assurance of Compliance - OHRP
21 CFR Part 50 Protection of Human Subjects – Food and Drug Administration (FDA)
21 CFR Part 56 Institutional Review Boards – FDA
North Dakota Century Code

RELATED HRPP SECTIONS AND STANDARD OPERATING PROCEDURES:

1.1 Ethical Principles for Human Research
2.2 NDSU Engagement in Human Subjects Research
2.3 Collaborative, Multi-site and Off-site Research
3.2 Roles and Responsibilities – Institutional Official and Institutional Review Board