1: Principles and Purpose 1.1 Ethical Principles of Human Research	Effective Date: 7/08/11 Revised: 1/19/2015

The mission and purpose of the Human Research Protection Program at North Dakota State University is to protect the rights, safety and welfare of those individuals participating in NDSU human research projects. All human subject activities, regardless of funding source, are guided by ethical principles described in ***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.*

1.0 Respect for persons.

The first ethical principle of 'respect for persons' requires individuals be treated as autonomous agents allowed to make their own decision whether or not to take part in a research project. Those with diminished autonomy are entitled to additional protection when enrolled in research. The application of this principle involves the process of informed consent, as well as the protection of vulnerable populations.

1.1 Information.

In order to make a reasoned choice regarding research participation, individuals must be provided with sufficient information about the study. This includes: the purpose and goals of the research, interventions or procedures, personal information obtained, privacy and/or confidentiality concerns, and risks, discomforts and/or benefits.

1.2 Comprehension.

Information presented to potential participants must utilize appropriate language, terms and reading level to contribute to comprehension by the majority of individuals recruited for the research. In addition, allowing sufficient time for consideration, discussion and questions ensures that participants fully understand the nature of the research, and their role as a participant.

1.3 Voluntariness.

Individuals invited to take part in research are respected when allowed a voluntary choice, free of coercion and undue influence. Considerations in ensuring the voluntary nature of a study include: the setting and timing of invitations to participate, minimizing the influence of those in authority or with dual relationships with the participants, threats of loss of benefits or harm, or an improper reward.

1.4 Vulnerable groups.

Those with diminished autonomy require extra protections to ensure their exercise of a free choice regarding research participation. Individuals who fall within this category may include individuals with cognitive impairments (due to illness or mental disability), or immaturity.

Other individuals may be vulnerable because they are institutionalized or in another setting that reduces their autonomy to make free, informed choices for themselves.

2.0 Beneficence.
The second ethical principle of 'beneficence' entails an obligation to secure the wellbeing of participants by protecting them from harm, while maximizing potential benefits of the research.

2.1 Risk assessment.
The application of this principle involves identification of possible harms to subjects, which may include physical, psychological, social, dignitary, economic or legal harms. Risk is the possibility that harm may occur, with a certain probability and magnitude. The investigator is responsible for incorporating safeguards into the study design to appropriately minimize any reasonably foreseeable risks.

2.2 Risk/benefit ratio.
In addition, the probability and magnitude of possible harms in the research must be outweighed by any anticipated benefits (societal or individual). Projects involving greater risks require careful consideration to ensure that the level of risk is justified based on the potential for significant benefits.

3.0 Justice.
The third ethical principle of 'justice' is applied through the fair distribution of burdens and benefits of research.

3.1 Subject selection.
Individuals or groups should be selected for reasons directly related to the research goals, rather than their easy availability or compromised position.

3.2 Vulnerable groups.
Historically, the most vulnerable and disadvantaged groups have been subject to research risks in order to benefit the broader population. Groups such as children, prisoners, the educationally or economically disadvantaged or institutionalized individuals may lack the ability for free consent, and should be protected against being involved in research simply for convenience or easy manipulability.

DEFINITIONS:
Human Subject (HHS): a living individual, about whom, an investigator (whether professional or student) conducting research obtains: data through intervention or interaction with the individual, or identifiable private information.

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:

The Belmont Report
NDSU Policy 345: Research involving Human Participants

RELATED HRPP SECTIONS AND STANDARD OPERATING PROCEDURES:

2.1 Human Subjects Research
2.2 NDSU Engagement in Human Subjects Research
8.1 Risks and Benefits
9.1 Consent Process
Section 10 Vulnerable Groups