Use of Human Subjects in Research Policy- Plymouth State University

1. Preamble

1.1 Plymouth State University (PSU) recognizes its responsibility to produce and disseminate knowledge in accordance with its mission of research, teaching, and public service. When non-human models are insufficient, use of human subjects in research is an integral aspect of scholarly activity at PSU. PSU recognizes its ethical and legal responsibilities to provide a mechanism to protect individuals involved as subjects in research conducted under the auspices of PSU. Accordingly, to protect the rights and welfare of every human subject involved in research activities, PSU maintains a policy on the use of human subjects in research. PSU strives to ensure that all members of its community understand and adhere to this policy.

2. Definitions

2.1 Assurance: Federalwide Assurance of Protection for Human Subjects.

2.2 Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

2.3 Institutional Official: The individual designated by PSU to ensure that research involving human subjects conducted under the auspices of PSU is in compliance with all applicable laws and regulations. This individual is the Provost.

2.4 Institutional Review Board for the Protection of Human Subjects in Research (IRB): The committee established by PSU to oversee the use of human subjects in research conducted under the auspices of PSU.

2.5 Research: A systematic investigation (including research development, testing, or evaluation), designed to develop or contribute to generalizable knowledge.

2.6 The Belmont Report: The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report titled Ethical Principles and Guidelines for the Protection of Human Subjects of Research.

3. Statement of the Policy

3.1 All PSU research activities proposing to involve human subjects must be reviewed and receive written, unconditional approval from the IRB before commencing. This applies to all research activities conducted under the auspices of PSU involving human subjects regardless of discipline or whether or not the activities are funded. In addition, all research activities involving human subjects must be conducted in accordance with:

3.1.1 Federal, state, and local laws and regulations applicable to use of human subjects in research. These include, but are not limited to, Federal Policy for the Protection of Human

Subjects, Title 45 Code of Federal Regulations Part 46; Food and Drug Administration (FDA) Regulations for Human Subjects Protections, Title 21 Code of Federal Regulations Parts 50 and 56; and, the principles set forth in "The Belmont Report"; and

3.1.2 PSU policy as set forth in the Assurance.

4. Applicability. This policy is applicable to any research activity:

4.1 Sponsored by PSU, or

4.2 Conducted by or under the direction of any employee, student, or agent of PSU in connection with his or her PSU responsibilities, or

4.3 Conducted by or under the direction of any employee, student, or agent of PSU involving the use of any PSU property or facility, or

4.4 Conducted by or involving any individual or institution working with PSU as part of a collaboration, subgrant, or subcontract.

5. Examples. Examples of activities involving the use of human subjects covered by this policy include, but are not limited to:

5.1 Research involving surveys or questionnaires, administered in person, by mail, or via the telephone or electronically, designed to elicit information about individuals, including behaviors, experiences, attitudes, or beliefs.

5.2 Research involving interviews or focus groups designed to elicit information about individuals, including behaviors, experiences, attitudes, or beliefs.

5.3 Educational practices or tests conducted for research purposes.

5.4 Research involving program evaluation.

5.5 Research involving observation of public behavior.

5.6 Research involving the collection and/or study of data, documents, records, or biological, pathological, or diagnostic specimens, including voice or image recordings, medical, academic, or court records, and, invasive and noninvasive clinical procedures.

5.7 Clinical studies of drugs and medical devices.

6. Administration of Policy

6.1 The Institutional Official is responsible for the administration of this policy and its procedures as set forth in the Assurance.

7. Enforcement

7.1 The Institutional Official is responsible for enforcing this policy. Violations of this policy fall under the purview of the Assurance.