

# **The Administrative Policies**

## **TAP NO. 41: THE USE OF HUMAN SUBJECTS IN RESEARCH**

Guidelines for the Protection of Living Individuals Involved in All Forms of Research Regardless of Scope

### **A. PREAMBLE**

This policy is applicable to any research activity conducted at or sponsored by Duquesne University which involves human subjects, i.e. living individuals about whom an investigator (professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual.
2. Identifiable private information. The policy is, therefore, applicable to research involving human beings whose physical, emotional, or behavioral condition, responses, tissues, or fluids are investigated for any purpose other than for the sole purpose of benefiting the subject as an individual. It is applicable to the use of interviews, tests, observations, and inquiries designed to elicit or obtain non-public information about individuals or groups. The policy is applicable whether the research is undertaken on a large or small scale. Pilot projects, student dissertations projects, independent study projects, and course projects must follow this policy if they involve human subjects in research.

### **B. SUMMARY OF STATEMENT OF THE POLICY**

1. Investigations conducted or sponsored by Duquesne University must:
  - a. Adhere to the Principles of Respect for Persons, Beneficence, and Justice.
  - b. Comply with the Nuremberg Code or one of the ethical codes developed by the various professional associations.
2. Participation of human beings as subjects in research governed by this policy must be voluntary, i.e. it must occur as the result of free choice, without compulsion or obligation.
3. Adequate standards for informed consent must be satisfied, including the essential elements of voluntariness as described above, disclosure, and comprehension. If children are involved as subjects and are capable of assent, normally their assent to participate must be solicited in addition to the permission of their parents.
4. Adequate provision must be made to protect the privacy of subjects and to maintain the confidentiality of identifiable information.
5. The selection of research subjects must be carefully considered and should include fair procedures and outcomes. Subjects should not be selected for potentially beneficial research on the basis of favoritism, nor should risky research be restricted to subjects who are powerless. Differences among groups in ability to bear burdens should be respected.
6. The methods used for approaching subjects and securing their participation should be designed carefully to protect the privacy of the subjects and should be reasonable in terms of their condition or circumstances. No coercion, explicit or implicit, should be used to obtain or maintain cooperation. Where access to subjects is gained through cooperating institutions or individuals, care should be

taken not to abridge prior commitments made to the subjects about the confidentiality or other terms of the primary relationship.

7. Any payment made to subjects should not be large enough to constitute excessive inducement for participation of the subjects.
8. Projects involving human subjects should be carefully designed to minimize risk to the subjects.

All research involving human subjects conducted at or sponsored by Duquesne University must be submitted for prior review, and when necessary timely periodic review after approval, in accordance with the policies and procedures of the Duquesne University Institutional Review Board.

Additional information and forms are available through the Chair of the Institutional Review Board.

This policy is subject to periodic review and update by the Office of the Provost and the Academic Vice President for research.

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