RESEARCH POLICY 2 (RP-2) (FORMER TAP/RP-41)
THE USE OF HUMAN SUBJECTS IN RESEARCH

1. Policy Scope

This Research Policy provides guidelines for the protection of living individuals involved in all forms of research regardless of scope. It is applicable to all research activity conducted at or by Duquesne University faculty, students, or staff which involves human subjects. Failure to comply could lead to termination of the research as well as disciplinary action for the researchers, up to and including termination from the University.

2. Policy Statement

1. Duquesne University is guided by the ethical principles regarding research involving human subjects as set forth in the Belmont Report and all research involving human subjects must adhere to these ethical principles. Sponsoring entities may specify extra provisions in addition to these standards that must be followed.
2. Participation of human beings as subjects in research governed by this Research 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 procedures to protect the privacy of research subjects and to maintain the confidentiality of identifiable information must be established and followed.
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. Other than reimbursement for reasonable travel and lodging expenses, researchers should be sensitive to whether other aspects of proposed payment for participation could present an undue influence, thus interfering with the potential subject's ability to give voluntary informed consent.

8. Research involving human subjects should be carefully designed to minimize risk to the subjects.

3. Definitions of Terms

Certain terms are used in this document with specific meanings, as defined in this section. These definitions may not necessarily conform to customary usage.

Collaborative Institutional Training Initiative (CITI)	Represents the best practice in ethics compliance training. Used by Duquesne University, the CITI program is dedicated to serving the training needs of colleges and universities, healthcare institutions, technology and research organizations, and governmental agencies, as they foster integrity and professional advancement of their learners.
Belmont Report	Report written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Ethical Principles and Guidelines for the Protection of Human Subjects of Research). The Belmont Report identifies basic ethical principles and guidelines that address ethical issues arising from the conduct of research with human subjects.
Common Rule	Federal Policy for the Protection of Human Subjects. All IRBs must maintain policies that reflect guidance of the Common Rule. The minimum standard is set by the Department of Health and Human Services regulations at 45 CFR 46.
Institutional Review Board (IRB)	Committee that applies research ethics by reviewing and approving the methods proposed for research to ensure they are ethical and meet all federal regulations.
Mentor	The software system that facilitates the submission and review of IRB Protocols at Duquesne University.

4. Procedures

1. All research involving human subjects conducted at or by Duquesne University faculty, students, or staff must be submitted for prior review, and when necessary, for timely periodic review after approval, in accordance with the policies and procedures of the Duquesne University IRB. The submission must include the research Protocol, Consent Forms, and other supporting documents. Human subjects research policies, procedures and forms, including the Mentor web-based system, be accessed here: Human Subject Research Policies and Procedures | Duquesne University Information may also be obtained by contacting any IRB board member or the chair of the IRB.

2. Regardless of the sponsoring entity, all proposed research that meets the definition of research involving human subjects as specified in the Common Rule shall be reviewed according to the standards therein, as well as any other applicable laws or regulations, including the Family Educational Rights and Privacy Act (FERPA) and the Health Insurance Portability and Accountability Act (HIPAA).
3. Whether or not the Common Rule mandates review, proposed research involving human subjects must be submitted to the IRB for review and approval, or determination of exclusion or exemption.
4. Before engaging in any research involving human subjects, researchers must have completed training in various aspects of research conduct governing their work available at no cost to Duquesne University faculty, students, and staff through the Collaborative Institutional Training Initiative (CITI).

5. Exceptions

Exceptions to this Research policy and procedures require approval from the Vice Provost for Research and normally will be made with the agreement of the Chair of Duquesne University IRB.

6. Related Documents

This Research Policy works in conjunction with the following Research and University Policies, which are fully applicable. To the extent there is any conflict between this Research Policy and any of the Research or University Policies listed below, the University retains the sole discretion to determine which takes precedent.

Research Policy	Title	Web Address
RP-1	Procedure for Submitting External Sponsored Grants and Awards	https://www.duq.edu/research/research-conduct
RP-3	Effort Reporting on Sponsored Grants and Awards	https://www.duq.edu/research/research-conduct
RP-4	Governmental, Corporate, Foundation and Private Sources Sponsored Grants and Awards	https://www.duq.edu/research/research-conduct
RP-5	Intellectual Property	https://www.duq.edu/research/research-conduct
RP-6	Research Integrity	https://www.duq.edu/research/research-conduct

RP-7	Conflicts of Interest in Sponsored Grants and Awards	https://www.duq.edu/research/research-conduct
RP-8	Research Agreements and Private Business Use	https://www.duq.edu/research/research-conduct
TAP-33	Conflict of Interest	https://www.duq.edu/work-at-du/human-resources-home/the-administrative-policies-(taps)/33-conflict-of-interest
RP-9	Participation in Commercial Entities	https://www.duq.edu/work-at-du/human-resources-home/the-administrative-policies-(taps)/46-commercial-entities%E2%80%94faculty-staff-and-student-participation

6. Contacts

Office	Telephone Number	Email Address and/or URL
Office of Research and Innovation	(412) 396-6326	duq.edu/research ORI@duq.edu
Institutional Review Board	(412) 396-4032	duq.edu/irb irb@duq.edu

Web Address for this Research Policy: https://www.duq.edu/research/research-conduct

7. Effective Date and Revision History

This Research Policy is subject to periodic review and update by the Office of the Provost and the Vice Provost for Research.

9/12/22 (Previous revision not dated)