I. PURPOSE: This Human Subjects Research Review Committee (HSRRC) serves as the Institutional Review Board (IRB) to approve the use of human subjects in proposed research at Daemen College and to ensure such use is consistent with the standards and practices set forth herein. The Committee’s responsibilities and procedures follow those outlined in the Regulations of the Department of Health and Human Services on the Protection of Human Subjects (45 CFR Part 46). No research involving the use of human subjects is to be conducted by faculty or students unless approved by the HSRRC. Faculty and students who receive the Committee’s approval for human subjects research projects are responsible for conducting the research as approved, without material changes pertaining to the treatment of subjects, and for maintaining ethical standards while conducting research.

II. DEFINITIONS:

A. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

B. Human subject means a living individual about whom a researcher (whether faculty member or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

"Intervention" includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between researcher and subject. "Private Information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the researcher or associated with the information) in order for obtaining the information to constitute research involving human subjects.

C. HSRRC approval means the determination of the HSRRC that the research has been reviewed and may be conducted at the College within the constraints set forth by the HSRRC and by other institutional requirements.

D. Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

III. COMMITTEE MEMBERSHIP: The HSRRC shall consist of at least six (6) members. Four (4) of the Committee members shall be full-time or part-time Daemen faculty who are knowledgeable about and have experience in working with human subjects. These members should be primarily concerned with the social/behavioral sciences and the biological/health sciences. The faculty members will be appointed annually at the beginning of the academic year by the Faculty Senate. Two (2) members of the HSRRC shall be designated annually by the Administration, at least one (1) of whom shall be a person who is not affiliated with Daemen College and who is not part of the immediate family or a person affiliated with Daemen College.
At least one member shall be a person whose primary concerns are in a non-scientific area. One or more non-voting student observers may also be appointed by the Faculty Senate.

The HSRRC shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. Every nondiscriminatory effort shall be made to ensure that the committee does not consist entirely of men or entirely of women. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice."

The HSRRC may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the HSRRC, including the avoidance of conflict of interest in proposal review. These individuals may not vote on any research proposal.

IV. MEETINGS AND RECORDS: The HSRRC shall elect a Chairperson at the first meeting each academic year. The Chairperson of the HSRRC shall receive a one course (3 credit hours) reduction in teaching load per semester.

No action may be taken by the HSRRC at a meeting unless a quorum is present. A quorum shall be four (4) members provided at least one of the members constituting the quorum is the member appointed by the Administration who is affiliated with the College. The HSRRC may approve research requests by a majority vote of the members at a meeting at which a quorum is present. The HSRRC shall prepare and/or maintain:

A. Copies of all research proposals and accompanying materials.
B. Minutes of HSRRC meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the Committee; the vote on those actions; the basis for disapproving research or requiring changes; and a summary of controverted material issues and their resolutions.
C. Records of continuing review activities.
D. Copies of all correspondence involving the HSRRC.

V. AUTHORITY: The HSRRC shall have the authority to approve, modify or disapprove all human subjects research requests subject to review by the President of Daemen College. The President shall not approve any research that has been disapproved by the HSRRC, but may return the request to the Committee for reconsideration. The Committee may require that informed consent be obtained and that such consent be in accordance with paragraph IX.

The HSRRC shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the Committee’s requirements or that has been associated with unexpected harm to subjects. The College President also has the authority to suspend or terminate approval of research in his/her discretion.

VI. CRITERIA FOR APPROVAL: A faculty member or student who intends to conduct research involving the use of human subjects must have the approval of HSRRC or a Certification of Exemption prior to commencing the research. While this Committee must review and approve research involving human subjects by both students and faculty, it is not intended as a substitute for courses in research design and ethics. Before a student submits a proposal to the Committee, the faculty member who teaches the course for which the research is required is responsible for communicating the principles of research design and ethics and for previewing the student’s proposal for ethical acceptability.

Faculty are particularly responsible for communicating to their students the safety standards particular to their fields of study, such as the use of specialized equipment and the protection of subjects in risk categories (i.e., children, disabled persons, etc.). Students should consult with their faculty concerning the proper review category; Exempt, Expedited or Full. Departments that generate a substantial quantity of student research projects are encouraged to initiate departmental review committees to screen proposals and to approve the choice of review categories before they are submitted to the HSRRC. Students who are planning to conduct research involving human subjects that is not part of course work must have the approval of faculty sponsors in their fields of study.

In order to approve research covered by this policy, the HSRRC shall determine that all of the following requirements are satisfied:
1. Risks to subjects are minimized by (i) using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the HSRRC should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The HSRRC should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the HSRRC should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by paragraph IX.

5. Informed consent will be appropriately documented.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the Committee shall ensure that additional safeguards have been included in the proposal to protect the rights and welfare of these subjects.

VII. PROCEDURE: Prior to commencing research involving the use of human subjects, a student or faculty member must either (1) apply for review and approval of the research from the HSRRC (Expedited or Full) or (2) submit a Certification of Exemption to the HSRRC. The application for review or Certification for Exemption should be submitted as early as possible to allow the Committee sufficient opportunity to consider it. Faculty and students who are planning research with human subjects must prepare a statement describing the proposed research and determine which of the three (3) review processes is applicable (Exempt, Expedited, or Full Review as defined below). The relevant forms and other required documents should then be submitted to the HSRRC Chairperson.

FULL REVIEW: This applies to any proposal that does not qualify for a Certification for Exemption or Expedited Review. If any of the questions on the Application for Investigation Involving Human Subjects are answered affirmatively, a Full Review is required. Proposals requiring a Full Review will be submitted in an original hard copy, using the Application for Investigation Involving Human Subjects, to the Committee Chair. The researcher shall also submit an electronic copy of the proposal to the Chair. The Committee will meet at least once per semester to review these proposals and will announce its meeting date to enable researchers an opportunity to submit their proposals in time for review prior to the scheduled meeting. Approval of Full Review proposals requires an affirmative vote from a majority of members at a meeting at which a quorum is present. If proposals for Full Review are submitted after a scheduled meeting, each Committee member may review the proposal individually, and if all members unanimously approve, the research may begin. If any Committee member disapproves of the proposal or demands a meeting, a meeting must be held to review the proposal.

EXPEDITED REVIEW: An application for Expedited Review may be approved when the research would only involve Minimal Risk. Minimal Risk applies to research which does not use deception, which does not study populations defined as "at risk" and which does not involve risks beyond those encountered in normal daily affairs. If any of the questions on the Application for Investigation Involving Human Subjects are answered affirmatively, a Full Review is required. An original copy of the Investigation Involving Human Subjects must be submitted to the Committee Chair, but the proposal may be reviewed and approved by a member of the Committee designated by the Chairperson without a meeting. The
proposal is to be submitted in both hard copy and electronically to the Chairperson. Expedited Reviews will be conducted only by Committee members who have a professional background in human subjects research. The research may proceed with the project when approval of the Expedited Review is obtained. The designated reviewer shall not have authority to disapprove the research. If the reviewer cannot approve the application for Expedited Review, it shall be placed on the agenda for the next meeting of the full Committee. All Expedited Review approvals will be reviewed by the HSRRC at its meeting following the approval. If two (2) members of the Committee disagree with the approval of the Expedited Review, the research will be suspended and the research will be subject to Full Review procedures.

CERTIFICATION OF EXEMPTION: If a researcher is able to check “no” to all items on the Application for Investigation Involving Human Subjects and meet at least one (1) of the five (5) criteria on the Certification of Exemption form, the research is eligible for an exemption. The Checklist and the Certification of Exemption form signed by the appropriate faculty member for student research will be submitted to the Chairperson of HSRRC along with a brief description of the research. If the Chairperson determines that there is a question about whether the research is Exempt, he/she will direct that the researcher seek Full or Expedited Review.

VIII. DISAPPROVAL: If the HSRRC decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the researcher the opportunity to respond in writing or in person.

IX. INFORMED CONSENT: Except as provided elsewhere in this policy, no researcher may involve a human being as a subject in research covered by this policy unless the researcher has obtained the informed consent of the subject or the subject’s legally authorized representative. A researcher shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the researcher, the faculty member, the institution or its agents from liability for negligence.

A. Basic elements of informed consent. Except as provided in paragraph C of this section in seeking informed consent the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than Minimal Risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact (faculty supervisor for student work) for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
9. A statement that a copy of the consent will be provided to the participant.

B. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject’s participation may be terminated by the researcher without regard to the subject’s consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may related to the subject’s willingness to continue participation will be provided to the subject; and,
6. The approximate number of subjects involved in the study.
7. If the project involves more than minimal risk, the following disclaimer should appear in the consent document:

**REIMBURSEMENT FOR MEDICAL TREATMENT**  Routinely, Daemen College, its agents, or its employees do not compensate for or provide free medical care or other compensation for human subjects participants in the event that any injury results from participation in a human research project. In the unlikely event that you become ill or injured as a direct result of participating in this study, you may receive medical care, but it will not be free of charge even if the injury and/or any related expenses are a direct result of your participation.

C. The HSRRC may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the HSRRC finds and documents that:

1. The research involves no more than Minimal Risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

X. DOCUMENTATION OF INFORMED CONSENT.

A. Except as provided in paragraph B of this section, informed consent shall be documented by the use of the written consent form signed by the subject or the subject’s legally authorized representative. A copy shall be given to the person signing the form.

B. The HSRRC may waive the requirement for the researcher to obtain a signed consent form for some or all subjects if it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or
2. That the research presents no more than Minimal Risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the HSRRC may require the researcher to provide subjects with a written statement regarding the research.

XI. RESEARCH PARTICIPATION REQUIREMENTS: If participation in research as subjects is required for students enrolled in a course, the instructor must (1) include this requirement in the course outline (2) provide students with a reasonable number of research projects to choose from (3) provide students who do not want to participate as subjects with an appropriate alternative requirement that is no more time consuming than research participation.

XII. CLASS DEMONSTRATIONS: Brief demonstrations of research techniques with Minimal Risk in relevant courses do not require review by the HSRRC. Faculty should follow the standards of professional ethics in carrying out such demonstrations.

XIII. ONGOING RESEARCH: The committee shall continue to review ongoing research at intervals appropriate to the degree of risk, but not less than once per year. Investigators conducting ongoing research shall provide the committee with a status report at the designated interval. Any aspects of the research involving changes in the degree of anticipated risk, outcome, or similar effects on human subjects, are to be reported.
XIV. RESEARCH QUALITY: Faculty who supervise student research are responsible for evaluating the quality of student’s finished work. A faculty member’s approval of a student’s proposal to the HSRRC is not necessarily an endorsement of the scientific quality of the proposed work, but only its acceptability with regard to planned treatment of human subjects. Similarly, faculty who conduct research ultimately answer to their peers when submitting research for publication. The HSRRC will only make judgments about the scientific merit of a proposal when research involving risk is proposed, in which case, the Committee must consider whether the potential benefits of the research to the participants and to society, outweigh the risks.