DAEMEN COLLEGE HUMAN SUBJECTS RESEARCH REVIEW COMMITTEE
RESEARCH POLICY

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 HSRRC'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). All research involving the use of human subjects must be approved by the HSRRC before the research is initiated. Once approved, investigators (including faculty mentors sponsoring student research) are responsible for maintaining ethical standards and to conduct the research exactly as described in the approved proposal, without any changes in the study design, the methodology, recruitment of participants, surveys or other materials used within the research and the treatment of human subjects.

II. DEFINITIONS:

A. *Research* is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
B. *A human subject* is a living individual about whom an investigator (whether professional or student) conducting research:
    1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
    2) obtains, uses, studies, analyzes, or generates *identifiable* private information or identifiable biospecimens.
C. "Intervention" includes both physical procedures by which information or biospecimens are gathered and manipulations of the participant or the participant's environment that are performed for research purposes.
D. "Interaction" includes communication or interpersonal contact between researcher and participant.
E. "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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
F. "Identifiable Private Information" is private information for which the identity of the participant is or may readily be ascertained by the researcher or associated with the information.
G. *HSRRC approva*l means the HSRRC has reviewed the proposed research protocol and determined that the proposed research protocol may be conducted within the constraints set forth by the HSRRC and by other institutional and federal requirements. Specifically, the research has been deemed appropriate in terms of the risk-to-benefit for human subjects, the research includes an appropriate participant informed consent process, the research details how the privacy and confidentiality of participants will be maintained, the research and includes a plan for mitigating risks associated with participating in the research. Once approval has been granted, the investigator may proceed with conducting the research exactly as indicated in the approved protocol. The HSRRC is responsible for assessing the proposed research in terms of institutional policy, federal

government regulations, applicable law, and standards of ethical treatment of human subjects and applicable professional conduct and practice standards.

H. *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. HSRRC MEMBERSHIP:

The HSRRC shall consist of at least five primary members. Four of these members must be full-time Daemen College employees who have appropriate education and training in human subjects research and have had direct experience in conducting research involving human subjects. At least one of these members shall be designated whose primary concerns are in scientific areas and at least one whose primary concerns are in nonscientific areas. Additionally, at least one primary member will be designated who is not otherwise affiliated with Daemen College (past or present) and who is not part of the immediate family of a person who is affiliated with Daemen College.

The HSRRC members should have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The HSRRC shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including scientific discipline (including but not limited to: the social/behavioral/psychological sciences, biomedical science, education, business, and economics), 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.

The primary HSRRC members who are full-time Daemen College employees, will be appointed annually at the beginning of the academic year by the Faculty Senate, with recommendations made by the HSRRC members from the previous year. Alternate members of the HSRRC or additional non-voting observers may also be appointed at this time. Alternate members are non-voting, unless specifically replacing a primary member at a given HSRRC meeting. The non-affiliated member will be appointed annually by the college administration or the HSRRC chair.

The HSRRC may invite individuals with competence in special areas to assist in the discussion and review of proposed research, which may require expertise beyond or in addition to that available on the HSRRC; however, these individuals may not vote with the HSRRC. Additionally, a committee member may not participate in the HSRRC's initial or continuing review of any project in which the member has a conflicting interest, except to provide any information requested by the HSRRC (i.e., an investigator, faculty research supervisor on a student's research protocol, a consultant on a research protocol, or a project in-kind collaborator must leave the room during the discussion and voting process as a safeguard to prevent potential conflict of interest).

All investigators are welcome to attend the portion of the HSRRC meeting when their proposed research is discussed; however they may not be present during the voting process or during discussions of other investigator's research proposals as to maintain the confidentiality of the proposed research and privacy of the submitting investigators.

IV. MEETINGS AND RECORDS:

The HSRRC or the college administration shall elect a chairperson at the first meeting of each academic year. The chairperson of the HSRRC shall receive a one-course (3-credit hour) reduction in teaching load per semester or an agreed upon stipend. The HSRRC Chair must have extensive knowledge in research design and methodology and protections of human

subjects in research. The HSRRC Chair must have direct experience in conducting human subjects research. The HSRRC Chair must be well versed in the federal regulations on research with human subjects to ensure institutional compliance and to ascertain that the HSRRC functions in accordance with federal law.

No formal discussion or action may occur at an HSRRC meeting unless a quorum is present. A quorum shall occur when a majority of the primary HSRRC members are present, including least one member whose primary concerns are in nonscientific areas. Alternate members do not count towards a quorum unless specifically replacing a primary member at a given HSRRC meeting. A majority vote of the members at a meeting during which a quorum is present is required to grant approval (e.g., meeting minutes, research proposals, etc.), or to take action (e.g., make a substantive change to practice or institutional policy).

The HSRRC is responsible for:

A. Maintaining records of all active and approved research proposals and accompanying materials in hard copy or electronically.
B. Maintaining minutes of all HSRRC meetings with sufficient detail to indicate: attendance, actions taken by the HSRRC and the vote of those actions, the basis for disapproving research or the specific changes requested, and a summary of any substantial issues and their resolutions.
C. Records of continuing review activities.
D. Records and appropriate reporting of any adverse events, records and investigation of any concerns/complaints from research participants, records and resolution related to investigator issues (violation of protocol, conducting non-approved human subjects research, failure to submit research closure documentation, maintenance of research activities after expiration of project approval).

V. AUTHORITY:

The HSRRC shall review and have the authority to approve, require modification (to secure approval), or disapprove all human subjects research activities 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 disapprove or request that the HSRRC reconsider and/or require modification of a proposed research protocol.

The HSRRC shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the HSRRC'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 at his/her discretion.

VI. CRITERIA FOR APPROVAL:

An investigator (Daemen College employee, affiliate, faculty member, or student) who intends to conduct research involving the use of human subjects must request the approval of the Daemen College HSRRC, supply documentation of approval from another IRB registered under the United States Department of Health and Human Services (USDHHS) for review, or request a Certification of Exemption, and then subsequently obtain HSRRC approval prior to the start of any research activities. Student investigators must have a Daemen College faculty member who will directly oversee the research activities. The faculty sponsor must be listed on the research protocol as an investigator and is required to thoroughly review and sign the protocol prior to submission. The faculty sponsor is responsible for communicating the principles of research design and methodology to the student and should ensure the research proposal is scientifically sound. Additionally, the faculty sponsor is responsible for the ethical treatment of human subjects during the duration of the research as well as ensuring the research is conducted

according to the approved protocol, exactly. Any changes are required to be reported immediately to the HSRRC Chair or Administrator and must gain approval before the project can resume.

In order to approve research covered by this policy, the HSRRC shall determine that all of the following requirements are satisfied:

1. Risks to human subjects are minimized by (a) using procedures which are consistent with sound research design and that do not unnecessarily expose human subjects to undue risk, and (b) whenever appropriate, using procedures already being performed on human subjects for diagnostic or treatment purposes.
2. Risks to human subjects are reasonable in relation to anticipated benefits, if any, to participants 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 or treatments human 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 (e.g., 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 human 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. The HSRRC should be particularly cognizant of the special problems of research that involves subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capability, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each participant or the participant's legally authorized representative, in accordance with, and to the extent required by Section IX - Informed Consent, below.
5. Informed consent will be appropriately documented unless or appropriately waived in accordance to Section - IX Informed Consent, below.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of human subjects.
7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
8. When a study has the potential for some or all of the participants to be vulnerable to coercion or undue influence, the HSRRC shall ensure that additional safeguards have been included in the protocol to protect the rights and welfare of these participants, such as including procedures to reduce or eliminate the potential for undue influence.

VII. PROCEDURE:

Prior to beginning any research involving the use of human subjects, an investigator must submit either:

1. a proposal to the HSRRC to review (for Expedited or Full review)
2. a proposal for Certification of Exemption to the HSRRC
3. documentation of approval, along with the original proposal submitted, from another IRB registered under the USDHHS.

The appropriate application form and supporting documents should be completed and submitted to the HSRRC Administrator as early as possible to allow the HSRRC sufficient opportunity for review and discussion.

A. Types of Review:

1) Exempt Review:

   Under Federal regulations 45 CFR 46.104 (b), certain categories of activity may be considered research but are declared exempt from the requirements in the Federal regulations concerning IRB review and approval. If a study falls into one of the exempt categories, researchers still have ethical responsibilities to protect participants' rights. The researcher should not make the determination of exemption, rather he/she should submit the proposed research to the HSRRC Administrator under the exempt review category or contact the Administrator or Chair to discuss. If a researcher is able to check "no" to all items on the *Application for Investigation Involving Human Subjects* and meet at least one of the criteria (and corresponding sub-criteria where relevant) on the *Application for Certification of Exemption form*, the research may be eligible for an exemption. An application for certification of exemption must be electronically submitted to the HSRRC Administrator along with a thorough description of the proposed research and all supporting documentation. The HSRRC Chairperson will review the material and determine if the study is exempt or if the study does not meet the criteria for exemption and requires revisions or resubmission under the expedited or full review category. The research may proceed only when official approval of exemption is obtained.

2) Expedited Review:

   For HSRRC purposes, the term 'expedited' refers to a process, not necessarily a timeline, whereby the review is conducted by, typically, only one or two committee members and not the full HSRRC. Expedited review is appropriate for research that does not qualify for exemption, but presents minimal risk to human subjects, and the researcher is able to check "no" to all items on the *Application for Investigation Involving Human Subjects.* If any are checked "yes", Full Review is required. Applications for Exempt Review must be electronically submitted to the HSRRC Administrator along with a thorough description of the proposed research and all supporting documentation.

   The expedited protocol may be reviewed and approved by the HSRRC Chair and/or a primary HSRRC member designated by the Chair or Administrator without having to convene a meeting. A designated reviewer shall not have authority to disapprove the research; however the reviewer may suggest revisions for the investigator to may make in order to resubmit the research for approval. If the reviewer cannot approve the application under Expedited Review, it can be placed on the agenda for the next HSRRC meeting to be evaluated under Full Review. The research may proceed only when official approval is obtained.

   Any HSRRC member has the opportunity to review all research approved under Expedited Review and will be given the chance to disagree with the approval at the next HSRRC meeting following the previous approval. If at least two members of the HSRRC disagree with an approval granted under Expedited Review, the research will be subjected to Full Review procedures and may be suspended until approval is granted under Full Review.

3) Full Review:

   Research involving greater than minimal risk to human subjects is required by federal regulations to be reviewed by all HSRRC members and discussed among

the committee at a convened HSRRC meeting. This applies to any proposal that does not qualify for a Certification of Exemption or Expedited Review. If a researcher can check "yes" to *any* of the items on the *Application for Investigation Involving Human Subjects*, a Full Review is required. Protocols requiring a Full Review will be submitted electronically to the HSRRC Administrator along with a thorough description of the proposed research and all supporting documentation. Approval of a Full Review protocol requires an affirmative vote from a majority of HSRRC members at a meeting during which a quorum is present. If a majority is not reached, the committee may suggest revisions for the investigator to make in order to resubmit for approval. If the revisions are substantial, the protocol will be reviewed again at the next convened HSRRC meeting. If the HSRRC agrees that the revisions are minor (with a majority vote), the revised protocol may be reviewed again using Expedited Review procedures. The research may proceed only when official approval is obtained.

The HSRRC will convene at least once per semester to review and discuss the any submitted protocols for Full Review. The HSRRC meeting dates will be publically available to the college community to provide investigators ample opportunity to submit proposals in time for review prior to the scheduled meeting. If protocols for Full Review are submitted after an HSRRC meeting, and there are no upcoming scheduled meetings in the relatively near future (e.g., during the summer months), each primary HSRRC member may review the protocol individually, and if all members unanimously approve, the research may proceed. If any primary HSRRC member does not approve the protocol or requests further discussion, the HSRRC must convene to discuss and review the research at the next scheduled meeting or earlier at the discretion of the committee members.

A maximum of four Full Review protocols can be discussed at a convened HSRRC meeting. In the event more than four protocols are submitted for Full Review, they will be added to the meeting agenda on a first come basis, whereby those submitted first will be discussed, and the remaining will be assigned to the next scheduled HSRRC meeting (or a future meeting if the committee is able to convene prior to the next scheduled meeting, at the discretion of the members).

B. Modifications to Previously Approved Research Protocols

Once a proposal has been reviewed and approved by the HSRRC, *no changes* can be made to the approved protocol (including, but not limited to the study methodology, survey/interview questions, tests or instruments, recruitment methods/materials, or participant inclusion/exclusion criteria). The investigator is responsible for conducting the research exactly as described in the approved protocol. If a change is required, the investigator must electronically submit a *Research Protocol Modification Form* to the HSRRC Administrator and receive official approval prior to implementing any change.

Modifications are categorized into minor changes and significant changes.

1) Minor modifications/changes

Minor modifications refer to proposed changes in research related activities that do not significantly affect an assessment of the risks and benefits of the study and do not substantially change the specific aims or design of the study.

Examples of minor changes to a research study include but are not limited to, the following:

a) Change of protocol title
b) Change in principal or co-investigators
c) Change of research site
d) Addition/removal of procedures that do not significantly increase risk to participants, considering the original purpose and study design of the approved study
e) Removal of research procedures that would thereby reduce the risk to participants
f) Addition of non-sensitive questions to survey or interview procedures
g) Addition of or revisions to recruitment materials or strategies
h) Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors)

2) Significant Modifications/Changes

Significant modifications refer to proposed changes in research related activities that *do* significantly affect an assessment of the risks and benefits of the study or *do* substantially change the specific aims or design of the study. Significant modifications may be required to undergo Full Review procedures.

Approved research protocols expire within one year of official HSRRC approval. Research related activities associated with expired protocols must cease immediately upon expiration unless the study has progressed to the point that it involves only one or both of the following: (1) data analysis (including analysis of identifiable private information or identifiable biospecimens), or (2) accessing follow-up clinical data from procedures that participants would undergo as part of clinical care. A *Research Protocol Modification Form* can be used to request that a closed or expired (previously approved) protocol be re-opened or to request that a study's approval duration be extended. However, if the re-open or extension request is related to a protocol that was approved using Full Review procedures, the study protocol must undergo Continuing Review at a convened HSRRC meeting, during which Full Review procedures will be followed. The Modification Form and most recent version of the approved protocol should be electronically submitted to the HSRRC Administer to be reviewed at the next convened meeting. Official approval must be granted before the research can resume.

VIII. DISAPPROVAL:

If the HSRRC decides to disapprove a research protocol, written notification and a statement of the reasons for the decision will be provided to the investigator(s) along with an opportunity to respond in writing or in-person at the next scheduled HSRRC meeting or to make changes to the protocol and resubmit for a new review.

IX. INFORMED CONSENT PROCESS:

A. Except as provided elsewhere in this policy, all research involving human subjects must provide information to prospective participants about their rights as a human subject in research and obtain the informed consent, whether provided written or orally, of each participant/legally authorized representative according to the following requirements:

1) A researcher shall seek such consent only under circumstances that provide the prospective participant/legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
2) The information given to prospective participants/legally authorized representatives shall be in language that is understandable to the

participants/legally authorized representatives.

3) The information given to prospective participants/legally authorized representatives must contain that which a reasonable person would want to have in order to make an informed decision about whether or not to participate, and an opportunity to discuss that information
4) The information given to prospective participants/legally authorized representatives must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant/legally authorized representative in understanding the reasons why one may or may not want to participate, in sufficient detail relating to the research and organized/presented in a way that facilitates the understanding of the reasons why one may or may night want to participate.
5) No informed consent may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the researcher, the sponsor, the faculty supervisor, the institution, or its agents from liability for negligence.

B. Basic Elements of Informed Consent - Except as provided (in rare circumstances) in Paragraph D of this section, the following information shall be provided to each participant during the consent process:

1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of 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 participant
3) A description of any benefits to the participant or to others that may reasonably be expected from the research (e.g., therapy, treatment, diagnostic screening, education, use of a device, etc.).
4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be of benefit to the participant
5) A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
6) For research involving more than minimal risk, an explanation as to whether any compensation will be provided 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 or referrals may be obtained – Daemen's statement is as follows: *'Daemen College, its agents, or its employees do not compensate for or provide free medical care for human subjects/participants in the event that any injury or harm 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 or treatment, but it will not be free of charge even if the illness or injury is a direct result of your participation.'*
7) An explanation of whom to contact about specific questions about the research (investigator and/or faculty supervisor) and whom to contact for questions related to human subjects' rights or to report concerns related to participation in a research study (HSRRC Chair)
8) A statement that participation is voluntary and that not wanting to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time or skip any part

of the research process without penalty or loss of benefits otherwise entitled

9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (a) that identifiers might be removed from the identifiable private information or biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant/legally authorized representative, or (b) that the participant's information or biospecimens collected as part of the research, even if identifiers removed, will not be used or distributed for future research

C. When appropriate, one or more of the following elements of information shall also be provided to each participant:

1) A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable
2) Anticipated circumstances under which the participant may be terminated by the researcher without regard to the participant's/legally authorized representative's consent
3) Any additional costs to the participant that may result from involvement in the research (e.g., travel, equipment, etc.)
4) The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation
5) A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided
6) The approximate number of participants involved in the study
7) A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit
8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions
9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

D. Waiver or Alteration of The Informed Consent Process – The HSRRC may waive the requirements to obtain consent under the information set forth in Paragraphs A through C of this section or approve an alteration of a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in Paragraphs B and C of this section, provided that the following instances below can be demonstrated and documented:

1) The research involves no more than minimal risk to the participants.
2) The research could not practicably be carried out without the waiver or alteration.
3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practically be carried out without using such information or biospecimens in an identifiable format.

4) The waiver or alteration will not adversely affect the rights and welfare of the participants.
5) Whenever appropriate, the participants/legally authorized representatives will be provided with additional pertinent information after their participation in the study.

X. DOCUMENTATION OF INFORMED CONSENT:

A. Informed consent shall be documented by the use of an approved, written informed consent form (including electronic format) and signed by the participant/legally authorized representative. A written copy shall be given to (or able to be printed or downloaded by) the person signing the consent form. The Informed Consent may be Either of the Following - Except as provided in Paragraph X of this section:

1) A written informed consent form that meets the requirements described in Paragraphs A through C of Section IX – Informed Consent, in which the investigator gives the prospective participant/legally authorized representative adequate opportunity to read the informed consent before it is signed or in which the investigator reads the form to the prospective participant/legally authorized representative before it is signed

2) A shortened written informed consent form, in which all the elements of informed consent required by Paragraphs A through C of Section IX – Informed Consent, are read to the prospective participant/legally authorized representative from an approved consent script, and a witness is present for the oral presentation of the consent. The short form must be signed by the participant/legally authorized representative and the witness, the consent script must be signed by the witness, and a copy of both the short form and the consent script must be given to the participant/legally authorized representative.

B. The HSRRC may waive the requirement for the investigator to document the informed consent of a participants/legally authorized representative with a signature, if any of the instances below have been demonstrated. Even so, informed consent should still be documented by other means or actions whenever possible, which if enacted, indicates the consent of the participant/legally authorized representative (e.g., the participant begins to respond to survey items, the participant/legally authorized representative clicks a box that reads, 'I agree', or verbally states, 'I agree', which is then confirmed and noted by the investigator, etc.)

1) The only record linking the participant and the research would be the informed consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant/legally authorized representative will be asked if he/she wants documentation linking the participant with the research, and their wishes will govern.

2) The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

3) The participant/legally authorized representative is a member of a distinct cultural group or community in which signing forms in not the norm, that the research presents no more than minimal risk of harm to participants, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

XI. CLASS DEMONSTRATIONS:

Courses that include instruction and development of research techniques including survey development and interviewing with a purpose to teach research design and methodology do not constitute research as defined by federal regulations and do not require review by the HSRRC. Faculty should follow the standards of professional ethics in carrying out such demonstrations and be mindful with assignments and classroom exercises.

XII. ONGOING RESEARCH:

The HSRRC 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 complete a *Research Protocol Modification Form* to extend the approval date and provide the HSRRC 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. Unless the HSRRC determines otherwise, continuing review for ongoing research is not required in any of the following circumstances:

1. The research has been given an approved Certification of Exemption.
2. The research has been approved using Expedited Review procedures.
3. The research has progressed to the point that it involves only one or both of the following: (a) data analysis (including analysis of identifiable private information or identifiable biospecimens), or (b) accessing follow-up clinical data from procedures that participants would undergo as part of clinical care.

XIII. RESEARCH QUALITY:

Faculty who supervise student research are responsible for the quality of the research, which includes the proposal submitted to the HSRRC, the conduct during participant recruitment, the informed consent process and the collection of data, the treatment of participants, the handling and storage of human subjects data, the accurate analysis of the data, and the outcome of the student's finished work. Research that is not is not fully conceived (protocols lacking a research objective/unclear purpose, undefined independent and dependent variables, study materials not provided, missing participant inclusion/exclusion criteria, no attempt to recruit a representative sample/a sample too small to yield valid conclusions (without justification or rationale provided), inconsistencies throughout the protocol, failure to appropriately describe protections for participant privacy and confidentiality of data, or simply, protocols so flawed that generalizable data is unlikely to result) exposes human subjects and the institution to unnecessary risk and will not be approved by the HSRRC. The guidance provided by the USDHHS states that "if it is not good science, it is not ethical".