Conducting Research at Miami Dade College
Standard Operating Procedures

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Miami Dade College
Standard Operating Procedures for Research Approval
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CONDUCTING RESEARCH AT MDC

Miami Dade College (MDC) supports research initiatives within the institution and the scholarly endeavors of students, faculty, administrators, and staff of the College, as well as external investigators. Pursuit of scholarly work and research may often involve the use of human subjects for data collection and analysis, and these procedures will focus largely on human subject research.

Review and approval are required for projects that meet the definition of "research" involving "human subjects". Per 45 CFR § 46.102, for the purpose of conducting research at Miami Dade College, "human subjects" are herein referred to as defined by the U.S. Department of Health and Human Services (HHS) as *any living individual about whom an investigator conducting research (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.* MDC will further consider human subjects as defined by the U.S. Food and Drug Administration (FDA) as individuals who are or become participants in research, either as recipients of a test article or as a control. A subject may be either a healthy human or a patient. Federal regulations define "research" as *a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge*.

MDC Research Approval Process

Research approval at MDC is a two-step process:

First, MDC's Institutional Review Board (IRB) reviews human subjects research proposals to ensure all of the following: 1) the rights and welfare of human subjects used in research studies at the College are protected; 2) risks have been considered and minimized; 3) the potential for benefit has been identified; 4) all human subjects volunteer to participate in research only after being provided with legally effective informed consent; and 5) any research is conducted in an ethical manner and in compliance with established MDC standards, policy and procedures.

Second, once approved by the MDC IRB, the research proposal is routed, for review, to the College Academic and Student Support Council Research and Testing Subcommittee (CASSC R&T). All research that falls under federal regulation – regardless of whether human subjects are involved or not – **must** be reviewed for approval by CASSC R&T. The Subcommittee determines whether the research aligns with strategic priorities of the College and institutional values. Additionally, the Subcommittee determines if the research will not create undue burden on MDC resources. Those individuals seeking to conduct research may not solicit subject participation or begin data collection until their proposal has been approved by the MDC IRB and CASSC R&T. This additional step of the review process complies with 45 CFR § 46.112 as subject to further review by institution officials.

The IRB approval process might differ based on the purpose of the research study, the type of study, and where the study occurs. However, it is important to note, that most research studies involving human subjects are required to be submitted to the IRB for their review and determination. Some examples of research project classifications are as follows:

A. Classroom-based Research Projects

Classroom-based research projects may not fall under the jurisdiction of the IRB and do not require IRB application and approval. As a general rule, classroom-based student course / research projects and related activities are not systematic data collection efforts intended to develop or contribute to generalizable knowledge and, thus, do not meet the federal regulatory definition of research. However, even if a class project is non-research and, thus, not under the jurisdiction of the IRB, faculty members have a responsibility to ensure that students understand their ethical obligations in carrying out their assignments.

45 CFR § 46.102 defines "research" as *a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.* As such, research conducted in the classroom does not automatically require IRB review so long as the research does not align with the prescribed definition. Rather, classroom-based student course / research projects and related activities *mimic* research study projects. However, should classroom-based student course / research projects and related activities meet the definition of "research" as aforementioned or involve human subjects, investigators will be required to follow the MDC Research Approval Process.

B. Student Research Projects

Student projects, such as independent research projects (e.g., theses, honors projects, independent studies) and co-curricular research activities through student involvement in various student organizations (e.g., Honor societies, student clubs, student organizations) conducted by students that involve the collection of data through interactions with human subjects or access to private information fall under the jurisdiction of the IRB. Application to the IRB for these student research projects must include an acceptance of overall responsibility by a faculty member and the faculty member should be listed as the Principal Investigator (PI). Research projects intended to be shared outside of the College for publication or conference/presentation purposes require MDC Research Approval Process BEFORE starting any data collection.

C. Grant-based Research Projects

Grant projects involving human subjects must be reviewed and approved through the MDC Research Approval process before starting the research. Despite the Revised Common Rule 45 CFR § 46.103 that went into effect on January 19, 2019, which removed the requirement for IRB to review the entire grant/funding application for consistency with the IRB application. The Principal Investigator is responsible for ensuring that the IRB initial application submission and potential change of research requests are consistent with the grant or research proposal submitted to a federal agency.

Federal regulations found in 45 CFR § 46.103 indicate that ultimately any grant or proposal involving research on human subjects that are considered to be federally-supported require IRB review and approval. This means that any federally-funded study, or use of human subjects and/or programs in a study that are in receipt of federal funding, require IRB approval. Some exemptions may waive this requirement should conditions be met under 45

CFR § 46.101 and 45 CFR § 46.104. As Miami Dade College is largely a recipient of federal funding, investigators in pursuit of grant funding should anticipate the requirement of IRB review and approval. This requirement may be waived if the conditions are met under 45 CFR § 46.101 and 45 CFR § 46.104. As Miami Dade College is largely in receipt of federal funding, investigators in pursuit of grant funding should anticipate the requirement of IRB review and approval. Any involvement with outside parties should also be noted in the application. No federal funds may be utilized for research on human subjects unless federal regulations have been met, under 45 CFR§ 46.122.

If a grant is received during the course of research (either to expand the scope of the project or to advance measures) that was not initially part of the research study design or protocols, a study change of research form must be submitted to the IRB. The PI will also need to determine if any changes to consent or protocol are required in response to the grant award and further notify all participants or such changes.

All grants must follow MDC Research Approval Process and Post-Approval Responsibilities.

D. **Special Projects**

Special projects such as Presidential Innovation Funds, Program for the Exception to the Doctorate (PED) must follow the MDC Research Approval Process if the research project meets the definition of "research" as aforementioned or involve "human subjects" under 45 CFR § 46.102.

E. **Faculty-led Action Research Projects**

Action research projects at MDC are defined as a form of inquiry conducted by faculty with current term students in the classroom. Information gathered is not personally identifiable or connected to any one individual. The information gathered will be used for decision-making within the course and term and will not be used for publication/presentation outside of the College. This type of project is used to explore topics of teaching, curriculum development, and student behavior in the classroom. If there is any likelihood that the results of the project might later be used for research that does lend to generalizable knowledge (for example, a presentation to a group other than the class or at the College), the MDC Research Approval Process must be sought prior to conducting the research. Research approval cannot be granted retroactively.

F. **Other Projects**

Some research projects involving human subjects are exempt from IRB approval requirements. Research can qualify for an exemption if it is no more than minimal risk and all research procedures fit within one or more of the exemption categories in the federal IRB regulations. Studies that qualify for exemption must be submitted to the IRB for review before starting the research. The IRB must conduct the initial review and approve the exemption but is then exempt from further review.

The MDC IRB has responsibility to oversee procedures for carrying out the College's commitment to protect human subjects in research. The role of the MDC IRB is to review proposed research projects

that involve the use of human subjects; to ensure that the individuals involved in the project are treated ethically; to ensure that all subjects are provided with substantial information about the study and consent to be a subject in the study; and to ensure that all private information shall be handled with confidentiality.

The CASSC R&T Subcommittee has the responsibility of determining the research priorities at MDC, determining approval for research on any MDC campus or research that will involve the College data files, and the review and dissemination of significant research findings.

Both the MDC IRB and CASSC R&T are authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College involving human subjects. The disapproval of research decision is final and cannot be appealed; however, investigators may resubmit a new research request.

Members of the IRB and CASSC R&T act as advocates of the MDC Research Approval Process, as resource members at their campuses, and as facilitators of consistent communication regarding MDC's research processes among all members of the College community.

I. INSTITUTIONAL AUTHORITY

As per 45 CFR § 46.103, the Institutional Review Board is authorized by Miami Dade College to execute the review of human subject research conducted or supported by federal departments or agencies to assure compliance.

A. College Procedure 1321 – "Authorization to Conduct Research" establishes and empowers the Miami Dade College Institutional Review Board (MDC IRB). MDC has one committee, registered with the federal Office for Human Research Protections (OHRP) as **IRB00007621**. This committee is hereinafter referred to as "the IRB."

B. According to the terms of the Federal Wide Assurance (FWA), Miami Dade College adopts the following reporting requirements:

   a) All investigator(s) and all Miami Dade College employees are required to report to the Chair of the IRB any of the following upon knowledge of:

      1. Unanticipated problems involving risks to subjects or others.
      2. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

   b) Upon receipt of such information, or if a research project is suspended or terminated by the IRB, the IRB Chair will make a written report to the Miami Dade College IRB, the CASSC R&T, the Signatory Official of Miami Dade College, the head of any department or agency conducting or supporting the research, any applicable regulatory body, and to OHRP.

   c) Miami Dade College is registered under Federal Wide Assurance number **FWA00020165**.

   d) Information regarding registration of IRBs and the FWA status of an institution is available online using OHRP database.

II. PURPOSE

The primary purpose of the IRB is to ensure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of human subjects involved in research activities being conducted at Miami Dade College. To accomplish this purpose, the IRB uses a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

III. BASIC PRINCIPLES

A. The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained in ***Ethical Principles and Guidelines for the Protection of Human Subjects of Research*** ("The Belmont Report"), and The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, May 25, 1979.

B. Therefore, the following principles apply to all research activities, including student projects, involving human subjects at Miami Dade College to ensure that adequate safeguards are provided:

a) Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.

b) Risks to subjects must be reasonable in relation to anticipated benefits (if any), subjects, and the importance of the knowledge that may reasonably be expected to result.

c) Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.

d) Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified.

e) Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.

f) All research programs that involve human subjects must be reviewed by MDC IRB and CASSC R&T and must receive approval from a formally constituted review prior to their initiation or prior to initiating any changes to the protocol.

C. Approval Considerations for IRB Review

Any submitted proposal must be in the best interests of MDC's faculty, administrators, staff, and students. The first priority of the MDC IRB when reviewing submitted proposals is the safety and well-being of human subject participants in the proposed research. In reaching its conclusions concerning the granting of approval to a research proposal, the MDC IRB will take into consideration the following factors:

a) The rights and welfare of the subjects involved in the research are adequately protected.

b) Any potential risks associated with the proposed research project are considered and identified by the researcher. If there are more than minimal risks involved with the proposed research, the risks to the participants are adequately minimized in the research design.

c) The researcher identified potential benefits of the project. All possible benefits of the research proposal are maximized, including benefits to the participant, to the researcher, to MDC, and to the educational and scientific community at large.

d) The research proposed will be conducted in an ethical manner. The procedures involved in the research study follow all applicable and established standards and procedures.

D. Approval Considerations for CASSC R&T

In reaching its conclusions concerning the granting of approval to a research proposal, the CASSC R&T will take into consideration the following factors:

a) The researcher made a strong and compelling case that the research will provide insight into learning and success factors and the research aligns with MDC's mission.

b) All costs incurred by the MDC community are fully considered; the benefits outweigh the costs, and provision is made to reimburse MDC for any unusual data collection expenses.

c) The research design is sufficiently rigorous to lead to meaningful insights.

d) If the researcher is not employed by MDC, the researcher identified an MDC full-time faculty, administrator, or staff member who is willing to serve as the internal sponsor/gatekeeper/internal contact for the research. The identified individual has acknowledged acceptance of this role and has identified the value of the research findings to their area of responsibility.

e) The participant pool is not overly burdened with requests to serve as research subjects.

f) The research is in the best interest of the College.

IV. THE AUTHORITY OF THE IRB

A. Miami Dade College is registered under Federal Wide Assurance number **FWA00020165**. As part of this Assurance, MDC agrees to consider all research involving human subjects as research participants are subject to federal protection regulations - regardless of the source of funding - if one or more of the following apply:
   a) The research occurs at this institution, or
   b) The research is sponsored by this institution, or
   c) The research is conducted by or under the direction of any employee, student, or agent of this institution, or
   d) The research is conducted using any property or facility of this institution, or

e) The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects, or
f) The research will directly involve any employees, students, or agents of this institution.

B. In some instances, students may be involved in course activities such as participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals. The course instructor is responsible for determining whether such activity requires MDC research approval, including review and approval by the IRB. If the faculty has any doubt concerning the classification of these activities, they are encouraged to visit the website on Conducting Research at MDC to gain further explanation and guidance on whether research approval may be needed. Alternately, the chair of the IRB can be contacted via email at irb@mdc.edu for additional guidance.

C. The IRB reviews all projects and programs involving human subjects in accordance with applicable federal regulations.

D. The IRB has approval authority of human subject protocols, and can disapprove, modify, or approve studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB will be subject to further appropriate review and approval or disapproval by the CASSC R&T.

E. The IRB has authority to require progress reports from the investigators and oversee the conduct of the study.

F. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, if it is deemed for this action to be in the best interests of the subjects in that study.

G. The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved protocol, especially in cases where the consentee is from a vulnerable population.

H. The IRB has the authority to access, and to obtain copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement), regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of on-going research.

V. THE IRB'S FUNCTIONAL RELATIONSHIPS

A. The IRB functions administratively through the Division of Strategy and Institutional Effectiveness. This structure provides for administrative coordination of the IRB with the various academic and administrative units at MDC.

B. The IRB advises and makes recommendations to the Signatory Official of Miami Dade College, to policy and administrative bodies, and to any member of the MDC community on all matters related to the use of human subjects in research.

C. The IRB Chair maintains records as described in the federal policy and maintains and renews the registration of MDC's IRB with the Department of Health and Human Services OHRP renewing it every three years. The registration information for the IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson.

VI. THE MEMBERSHIP OF THE IRB

Following the rules and regulations set forth in 45 CFR § 46.107, membership of the IRB is set forth as follows:

A. The Director of Research and Data Analytics will serve as both the co-chair of the CASSC R&T as well as the chair of the IRB.

B. The IRB is composed of at least seven (7) voting members. The members of the IRB will be composed of at least three (3) members of the CASSC R&T Subcommittee. IRB members, who are employees of MDC and subject matter experts, but are not part of the CASSC R&T can receive the invitation to join the CASSC R&T Subcommittee meetings as resource members when needed. Recommendations for IRB appointment should be made directly to the IRB Chair or designee. The aforementioned will appoint members based on recommendations and research experience. All appointments are reported to OHRP.

   The IRB chair may request faculty recommendations for IRB appointment from IRB members, the CASSC R&T Subcommittee, or Campus Presidents when a vacancy occurs. Recommendations should be based on expertise, experience, knowledge of a specialized area, and interest in the involvement of research related studies.

C. The IRB is composed of diverse members (including but not limited to 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), expertise, and experience in special areas to provide complete and adequate review of the research. Board members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of MDC regulations, relevant law, ethical standards, and standards of professional practice. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals will not have voting powers within the IRB.

D. The IRB must include at least one member whose primary concerns are in science areas, one whose primary concerns are nonscientific areas, and at least one member who is not otherwise affiliated (either directly or through immediate family/community member) with MDC. No members may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

E. IRB members will be appointed to the board for a minimum term of three (3) years and may then renew their membership for additional subsequent terms. The term of

appointment may be terminated prematurely by either notice of the IRB member to the Chair or by notice from the Chair to the member. If a member is unable to attend meetings for an extended period, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed if they are unable to perform the IRB duties. The Chair will appoint a replacement.

F. IRB members are expected to have completed the nationally recognized trainings that are required of researchers (principal and co-investigators) (such as PHRP or CITI) and member certification must have been acquired/renewed before assuming the position. Administrative support staff are trained individually through annual training/workshop/information sessions offered by IRB. IRB Training Certification must be renewed every five (5) years.

VII. MANAGEMENT OF THE IRB

A. The IRB Chair is the Director of Research and Data Analytics. The Chair has authority to sign all IRB action items.

B. The IRB Chair can designate a voting member of the IRB to preside over convened IRB meetings from which the Chair is absent. The IRB designee will have the authority to sign all IRB actions, in the absence of the Chair.

C. IRB members do not receive compensation for their service.

D. Liability coverage for IRB members is provided through MDC's liability insurance coverage, whether or not the IRB member is an employee of MDC.

E. Consultants with competence in special areas may be used when deemed appropriate.

F. Conflict of interest:

a) Investigators shall not be involved in the selection of IRB members.
b) The IRB may not have a member participating in the initial or continuing review of any project in which the member has a conflicting interest (except to provide information requested by the IRB).
c) Investigators and IRB members who are MDC employees and who apply for federal grants and contracts are subject to the MDC Conflict of Interest and Code of Ethics Policy [see https://www.mdc.edu/policy/Chapter2/02-II-23.pdf].
d) Other conflict of interest guidelines specifically for IRB members are found in section XIII of this document.

VIII. PROCEDURES OF THE IRB

The IRB follows review procedures outlined in 45 CFR § 46

A. **Initial Review**

a) Prospective investigators must submit one (1) original of the "Miami Dade College Research and Testing Subcommittee Research Application" to the IRB in accordance

with the research application review schedule prior to the start date of the anticipated research project in order to provide time for review and processing. Information regarding MDC's research review process is available via https://www.mdc.edu/ir/datapages/researchproposal.aspx

b) Under the auspices of the IRB, the IRB Chair, or a designated member of the IRB, will review the Research Application to determine if the research proposal is eligible for "exempt" (see below) or expedited review or, if significant risk is inherent in the study, refer the petition to the IRB for full board review.

c) Under federal regulations, research that involves vulnerable subjects will be referred to the IRB for full board review. Vulnerable subjects include children, prisoners, pregnant women, mentally-disabled persons, or economically or educationally-disadvantaged persons. The IRB must further determine which of four categories of research apply to the study pursuit to 45 CFR § 46 when minors are involved. HHS regulations permit IRBs to approve (i) research not involving greater than minimal risk to children, 45 CFR § 46.404; (ii) research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research, 45 CFR § 46.405; or (iii) research involving greater than minimal risk and no prospect of direct benefit of the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition. A special level of HHS review beyond the IRB is required when research that the IRB believes does not meet the condition of 45 CFR § 46.404, § 46.405, or § 46.406, but find the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children 45 CFR § 46.407.

Specific regulations as they pertain to vulnerable subjects should be addressed as applicable. Additional protections for pregnant women, human fetuses and neonates involved in research can be found in 45 CFR 46 Subpart B; protections for biomedical and behavioral research involving prisoners can be found in 45 CFR 46 Subpart C; and protections for children can be found in 45 CFR 46 Subpart D.

Exempt Review

a) Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise (45 CFR § 46.104)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the

subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR § 46.111(a)(8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained; (ii) documentation of informed consent or waiver of documentation of consent was obtained; (iii) an IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent; and (iv) the investigator does not include returning individual research results to subjects as

part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

b) The IRB Chair or designee, not the investigator, shall make the determination as to whether a project is or is not exempt. To obtain an exemption, an investigator must submit a completed Research Application, along with all required documentation, and the IRB Chair or designee will review to determine whether the research proposal meets the exempt criteria.

c) Research deemed exempt by the IRB Chair, or a designee of the IRB, will be forwarded to the CASSC R&T Research Subcommittee for review and approval. Once the CASSC R&T has made its decision, the IRB Chair will inform the investigator if approved via an Exempt Memo which will be signed and dated by the IRB Chair and a copy maintained in the IRB Files. If the research is not approved, the IRB chair will notify the investigator via a Disapproval Memo of the decision and provide the investigator an opportunity to respond in person or in writing. The disapproval of research decision is final and cannot be appealed; however, investigators may resubmit a new research request.

Expedited Review

a) Under federal regulations certain types of research qualify for an expedited review (45 CFR § 46.110). These are activities that (i) present no more than minimal risk to human subjects, and (ii) involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

b) The list of categories of research that may be reviewed by the IRB through an expedited review is as follows:

1. Clinical studies of drugs and medical devices only when either of the following two conditions is met.
    i. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    ii. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    i. From healthy, non-pregnant adults who weigh at least 110 lbs. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week, or
    ii. From other adults and children (persons who have not attained the legal age for consent to treatments or procedures involved in the research) considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (i) hair and nail clippings in a no disfiguring manner; (ii) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (iii) permanent teeth if routine patient care indicates a need for extraction; (iv) excreta and external secretions (including sweat); (v) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (vi) placenta removed at delivery; (vii) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (viii) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (ix) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; or (x) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (i) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (ii) weighing or testing sensory acuity; (iii) magnetic resonance imaging; (iv) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; or (v) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be

exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
    i. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (ii) the research remains active only for long-term follow-up of subjects, or
    ii. Where no subjects have been enrolled and no additional risks have been identified, or
    iii. Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

    i. Research deemed expedited by the IRB Chair or designee will be reviewed by either the IRB Chair or a selected member from the IRB. The IRB Chair or selected IRB member may either: (i) approve the research; (ii) approve with conditions; or (iii) forward to the IRB for full review. Under the expedited process, the IRB Chair or selected IRB member can approve the research but may not disapprove the research proposal. If the research is approved, the proposal is forwarded to the CASSC R&T Research Subcommittee for review and approval. Once the CASSC R&T has made its decision, the IRB Chair will inform the investigator if approved via an Exempt Memo which will be signed and dated by the IRB Chair and a copy maintained in the IRB Files. If the research is not approved, the IRB chair will notify the investigator via a Disapproval Memo of the decision and provide the investigator an opportunity to respond in person or in writing. The disapproval of research decision is final and cannot be appealed; however, investigators may resubmit a new research request.

Full Review

a) All research requests that are not "Exempt" or do not qualify for "Expedited" review must be reviewed by the full IRB. The IRB Chair will convene the full IRB after determining that "Full Review" is needed. Prior to the meeting, copies of the Research Application and all related documentation will be supplied to each member of the IRB. Full IRB review may lead to either: (i) approval of the research; (ii) a request for modifications to the proposal in order to secure IRB approval; (iii) table the discussion and approval of the proposal to a later meeting of the full IRB; or (iv) disapproval.

b) If the research is approved under full IRB review, the proposal will be forwarded to the CASSC R&T Subcommittee for review and approval. Once the CASSC R&T has made its decision, the IRB Chair will inform the investigator if approved via an Exempt Memo which will be signed and dated by the IRB Chair and a copy maintained in the IRB Files. If the research is not approved, the IRB chair will notify the investigator via a Disapproval Memo of the decision and provide the investigator an opportunity to respond in person or in writing. The disapproval of research decision is final and cannot be appealed; however, investigators may resubmit a new research request.

c) In the application, the investigator assures the IRB that they will follow the principles, procedures and guidelines established in the present document and agrees to allow the IRB access to pertinent records or research. In addition, the investigator should present any information that will aid in evaluating the proposal for compliance with this policy.

d) The investigator should make themselves available to discuss the protocol and/or consent forms at the discretion of the IRB.

Actions of the IRB

a) The IRB may take one of the following four actions in regard to the proposed protocol and consent form after full-board review: Approved, Approved Subject to Restrictions, Tabled, or Disapproved.

Approved

When a protocol has been approved, the Chair completes the Approval Memo, signs, dates, and distributes one copy of the memo to the investigator and places one copy in the IRB files.

Approval of the protocol will be based on the following:

1. The extent to which the protocol makes explicit in design and procedures the protection of subjects' rights.

2. Should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical

alternative, satisfactory justification that the potential benefits to subjects or the importance of the knowledge to be gained outweighs any potential risks that may be present because of any such deception.

3. Assurances of acceptable debriefing, if appropriate. It is the responsibility of the investigator to give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject, but if, in the judgment of the IRB, such information could adversely affect subsequent data collection in the same study, the full explanation may be delayed for a reasonable period.

   There is an exception to this delay: In those cases in which it is unavoidable to mislead subjects and/or in which it is possible that the experimental treatment may result in emotional stress for the subjects, it is mandatory that they receive a full debriefing immediately following participation.

4. The adequacy of facilities and other resources necessary for completion of the study and protection of subjects' rights.

5. Anticipated benefits, if any.

6. The personal risk to the subject in relation to expected benefits.

7. The adequacy of procedures for securing informed consent from subjects.

8. The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of subjects.

9. The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

Approved Subject to Restrictions

If the protocol is approved subject to restrictions, then the Chair completes the appropriate form, signs, and dates, and sends the form with a memo to the investigator outlining the restrictions. The investigator must then respond to the restrictions as indicated by the IRB. Upon receipt and approval of the responses by IRB, the restrictions are removed, and the protocol is then processed as an approved protocol and distributed as described above.

Tabled

Tabled action means that the protocol was not sufficiently complete for the IRB to reach a final decision. In this case, the investigator is notified by the Chair of the IRB, and the additional information necessary for completion of the IRB review is requested. In the

case of a tabled protocol, the investigator may be invited to attend an IRB meeting to present/clarify the protocol for the Board.

Disapproved

If the protocol is disapproved, the investigator will be informed in writing of the reasons for disapproval and an opportunity to respond in person or in writing will be offered to the investigator. The disapproval of research decision is final and cannot be appealed; however, investigators may resubmit a new research request.

B. **Continuing Review**

a) Initial IRB approval will be provided for the period of no longer than one (1) year from the date of the completed review. Investigators wishing to extend the project approval beyond the initial period should submit a Change of Research Application no later than thirty (30) days prior to the expiration of the current IRB approval. The Change of Research Application must be completed and returned to the Chair of the IRB along with the informed consent document currently in use with the project being reviewed. The investigator will be notified of the action taken (e.g., Approved, Approved Subject to Restrictions, etc.). Additionally, the IRB reserves the right to conduct continuing review of research at intervals appropriate to the degree of risk.

b) When a Change of Research request is submitted, the IRB Chair shall consider the following: changes to the research, protocol deviations and violations since the last scheduled review; adverse event reports; reports of unanticipated problems involving risks to subjects and, if available, data safety monitoring reports; and investigator compliance.

c) If the protocol and/or other documents used in the project have been amended since the prior review without approval by the IRB, the investigator will be requested to submit a new protocol incorporating these amendments if such have not previously been submitted.

d) Pursuant to OHRP guidelines, the IRB approval period may be held constant from year to year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within thirty (30) days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. However, if an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB Chair finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions, and this finding is ratified at the next convened IRB meeting. After the expiration of IRB approval, the protocol will be considered closed, and enrollment of new subjects cannot occur, nor can any data collected be used for research purposes.

C. Procedures Pertaining to Both Initial and Continuing Review

a) The IRB shall have authority to determine which studies need verification from sources other than the investigators that no material changes have occurred since previous IRB review, particularly: (i) complex projects involving unusual levels or types of risk to subjects; (ii) projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and (iii) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

b) Investigators shall be informed at the time of protocol approval (both initial and continuing) that changes in approved research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects.

c) Investigators shall be informed at the time of protocol approval (both initial and continuing) that any serious or on-going problems are to be reported promptly to the IRB.

d) Serious or continuing noncompliance by an investigator, or any suspension or termination of activities by any individual, is to be reported promptly to the IRB Chair so that appropriate remedial action can be taken, including, but not limited to, appropriate reporting to the granting agency.

D. Adverse Event Reporting Guidance

a) The OHRP recognizes that any adverse event in a trial is a potentially important occurrence because it may reflect additional risks to subjects. In accordance with their requirements, these regulatory bodies have charged IRB with the responsibility of conducting continuing review of research. Included in this review is the monitoring of adverse reactions and unexpected events (21 CFR § 56.108 and 45 CFR § 46.103).

b) Investigator(s) and any Miami Dade College employee will report to the Chair of the IRB any of the following upon knowledge of such:

1. Unanticipated problems involving risks to subjects or others, or
2. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB, or
3. All unanticipated problems and adverse events regardless if the investigator consider the event as being unrelated to the subject's participation in the study. The IRB will review the event and determine if there is a direct relation to the study and will also determine if changes need to be made to the study as a result of the event.

IX. OPERATIONS OF THE IRB

A. IRB meetings will be convened as necessary at MDC. If an application is in a need of full review, a meeting of the IRB would be convened at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas.

B. The place and time of meeting, agenda, and study material to be reviewed are made available to IRB members prior to the meeting.

C. The IRB Chair assigns one primary reviewer and possibly one or more secondary reviewers for each new research request that has the complete study documentation for review. The primary reviewer is assigned consistent with protocol content within the research request and reviewer expertise. Secondary reviewer(s) may be assigned using additional factors such as their ability to provide a valuable perspective on salient non-scientific aspects of the research. If external reviewers are also assigned, they must be subject to the same conflict of interest policies as IRB members.

D. Voting Requirements

a) Except when an expedited review procedure is used (as described in CFR 45 §46.110), an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. Investigators, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting, but must not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).

b) Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside of the meeting context. If, during an IRB meeting, the Chair moves the meeting to members only session, any visitors will be asked to leave the room until the members only session has ended.

E. Appeals

The decision(s) of the MDC Institutional Review Board and/or CASSC R&T is final. Decisions may not be appealed; however, investigators are encouraged to submit a new application and repeat the IRB approval process.

F. Amendments

a) Pursuant to OHRP guidelines, amendments are categorized into minor changes and significant changes.

1. Minor modification/change - A proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the study and does 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:
    i. Addition or deletion of study team members, or
    ii. Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study, or
    iii. Removal of research procedures that would thereby reduce the risk to subjects, or
    iv. Addition of non-sensitive questions to unvalidated survey or interview procedures, or
    v. Addition of or revisions to recruitment materials or strategies, or
    vi. Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors).

2. Significant modification/change - A proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Examples of significant changes to a study may include, but are not limited to, the following:
    i. Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.), or
    ii. Addition of research procedures that involve greater than minimal risk to subjects, or
    iii. Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation, or
    iv. Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

b) Level of Review for Amendments

1. Minor modifications/changes may be reviewed and approved using an "administrative approval" process. Administrative approval may be given by the IRB Chair or IRB Alternate Chair. Such approvals are then put on the agenda of the next IRB or screening committee, as appropriate, for concurrence.

2. Significant modifications/changes will generally be reviewed at the same level of review in which the study was first reviewed, either by the screening individual or by the full IRB. However, if an amendment by the screening individual is determined to increase the level of risk beyond minimal risk, the screening individual will refer the amendment for full IRB review.

X. RECORD REQUIREMENTS

A. The IRB prepares and maintains adequate documentation of IRB activities as described in the federal policy (45 CFR §46.115), including the following:

a) A permanent record of the list of current IRB members and written procedures for research approval at MDC (Titled: Standard Operating Procedures for Research Approval.

b) Detailed minutes of IRB meetings, showing:
   1. Members present (any consultants/ guests/others shown separately).
   2. Results of discussions on debated issues and record of IRB decisions.
   3. Record of voting (showing votes for, against and abstentions).

c) Copies of all research proposals reviewed, approved sample consent documents, continuing reports submitted by investigators, and reports of injuries to subjects.

d) Records of continuing review activities, updated consent documents and summaries of on-going project activities. Consent documents are stamped to show IRB approval and date of approval expiration.

e) Copies of all correspondence between IRB and the investigators.

f) Any statements of significant new findings (unanticipated risks or adverse reactions) provided to subjects.

g) Adverse reactions reports and documentation that the IRB reviews such reports.

h) The rationale for an expedited reviewer's determination under 45 CFR §46.110(b)(1)(i) that research appearing on the expedited review list described in 45 CFR §46.110(a) is more than minimal risk.

i) Documentation regarding the responsibilities of the institution and organization operating an IRB to ensure compliance with federal regulations as indicated in 45 CFR § 46.103(e).

B. The documents and records shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner. The IRB shall maintain the records in printed form, or electronically.

XI. INFORMATION PROVIDED BY THE INVESTIGATOR

A. The research investigator provides the following information in the research request:
   a) Professional qualifications to do the research (including a description of necessary support services and facilities).
   b) Research applications must include documentation that the Principal and Co-Investigators have successfully completed training (such as PHRP or CITI) in the responsible conduct of research.
   c) A letter of support from an MDC administrator (e.g., a chairperson, dean, or higher that is impacted by data collection and research). This letter is required for all research conducted at Miami Dade College.
   d) Prior approvals and/or signed agreements (e.g., data sharing/service agreement) from a principal/home institution.
   e) Letters of support and/or authorization from participating departments, divisions, or research sites when applicable.
   f) Approved Reliance Agreement Form must be submitted to MDC, if applicable.
   g) Appropriate MDC review form including protocol summary.
   h) Complete study protocol which includes/addresses:
      1. Title of the study and summary of the research to be conducted,
      2. Purpose of the study (including the expected benefits obtained by doing the study and how risks are reasonable in relation to expected benefits),
      3. Sponsor of the study, if applicable,
      4. Subject inclusion/exclusion criteria (including scientific and ethical reasons for excluding subjects who might otherwise benefit from the research),
      5. Justification for inclusion of any special/vulnerable subject populations (such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons),
      6. Study design (including, as needed, a discussion of the appropriateness of research methods),
      7. Description of procedures to be performed,
      8. Provisions for managing adverse reactions.
   i) Circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations.
   j) Procedures for documentation of informed consent, including any procedures for obtaining assent from minors ("minor" is defined in Florida as an individual under the age of 18), using legally authorized representatives (see XII.B.&C.), witnesses, translators, and document storage.
   k) Remuneration to subjects for their participation.
   l) Any compensation for injured research subjects.
   m) Provisions for protection of subject's privacy.
   n) Extra costs to subjects for their participation in the study.
   o) Any materials used to recruit subjects.
   p) Survey instruments (including permission letters, letters of support, or other authorizations as required), questionnaires, or other materials provided to subjects,
   q) Investigator's brochure (when one exists).
   r) The case report form (when one exists).

s) The proposed informed consent document, including translated consent documents, as necessary, considering likely subject population(s).
t) Copies of relevant grant applications (if any).
u) Requests for changes in study after initiation including changes to consent forms.
v) Reports of unexpected adverse events and unanticipated problems involving risks to subjects, including, if available, data safety monitoring reports.
w) Progress/interim reports that include reports of protocol violations and/or deviations and any other instances of investigator non-compliance.

XII. PRINCIPLES OF INFORMED CONSENT

A. When an activity does not involve therapy, diagnosis, or management, and a professional/subject relationship exists, e.g., participation in a research project, the subject is entitled to certain information. This information includes a full and frank disclosure of all the facts, probabilities, options, and opinions which a reasonable person might be expected to consider before giving the consent. A copy of the signed (including in an electronic format) consent form must be given to the person signing the form and a copy must be kept on file with the investigator or MDC as indicated below.

B. The informed consent of subjects will be obtained by methods that are adequate and appropriate. Consent must be obtained from the subjects themselves except when the subjects are not legally capable of giving informed consent because of age, mental incapacity, or inability to communicate. In the case of a minor, the IRB may accept the permission of the minor's parents (or parent) or legal guardian, along with the assent of the minor, in accordance with applicable federal regulations. In the case of other subjects not legally capable of giving informed consent, the IRB may accept the consent from a legally authorized representative ("LAR"). The LAR must be authorized either by a power of attorney or a court order.

C. "Informed Consent" means ensuring that potential subjects and/or their legally authorized representatives are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion (45 CFR § 46.116).

D. The IRB shall determine whether the consent is adequate considering the risks to the subject and the circumstances of the research. The IRB shall also determine whether the information to be given to the subject or to qualified third parties, verbally or in writing, is a fair explanation of the procedure, its possible benefits, and its attendant hazards. Where debriefing procedures are considered as a necessary part of the research plan, the IRB will ascertain that any such debriefings will be complete and prompt. In addition, the language used should be clear and unambiguous with every attempt to eliminate technical terms and jargon (i.e., use lay language appropriate to the subject population).

E. For research involving more than minimal risk to subjects or if determined by the IRB during the ordinary review process to involve more than minimal risk, a compensation for injury statement will be required in the consent form. This statement should clarify who is responsible for any costs associated with any medical treatments required or any personal compensation for injuries received as a result of participation in the research.

F. Some research may not impose on the rights and welfare of human subjects so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:

   a) 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
   b) 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 where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research (e.g., a cover letter). Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.

G. Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the investigator must include justifiable reasons in the protocol.

H. The IRB may also choose to approve a consent procedure which does not include, or which alters, some or all elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

   a) The research involves no more than minimal risk to the subjects,
   b) The waiver or alteration will not adversely affect the rights and welfare of the subjects,
   c) The research could not practicably be carried out without the waiver or alteration, and
   d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

I. Informed consent need not be based on full pre-study information. However, it is the responsibility of the IRB to set limits on the incompleteness of such information. In addition, in those studies in which it is proposed to mislead the subjects during data collection, the IRB has the responsibility of assessing the degree to which this violates the rights of the subjects and then setting the limits for such procedures.

XIII. CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS

A. An IRB member is said to have a conflicting interest whenever that IRB member, or spouse, domestic partner, children, or dependents of the member:

   a) Is an investigator or sub-investigator on the protocol,
   b) Has a "significant financial interest" in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest (see the MDC Conflict of Interest and Code of Ethics Policy, https://www.mdc.edu/policy/Chapter2/02-II-23.pdf). Standards in the consideration of what constitutes a "significant financial interest" have been established in collaboration with the MDC instruction on Conflict of Interested Reporting for Grants, which states that "significant financial interest in anything of monetary value, including salary, equity interest, or intellectual property rights, that could affect the employee's ability to

objectively execute the grant or contract." More information about this standard can be at the MDC website for grant development: https://www.mdc.edu/grant-development/documents/3117201435323PM.pdf.F115, or

c) Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB, or
d) Has identified themselves for any other reason as having a conflicting interest.

B. It is the responsibility of IRB members to identify and avoid any situations, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. If the IRB member feels there might be a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer.

C. Typically, there are three distinct phases of an IRB's consideration of a matter: discussion, deliberation, and actions (including vote). In general, IRB member(s) who have a real, or perceived conflict of interest may remain in the meeting room, at the discretion of the IRB Chair, during the discussion of the matter, in order to provide answers to questions or clarifications (21 CFR §56.107(e)), (45 CFR §46.107(e)). However, said member must leave the meeting room for deliberations and actions/votes regarding the matter.

D. Minutes of IRB meetings will reflect the absence of members during deliberations and actions regarding matters for which they have, or may be perceived to have, a potential conflict of interest.

XIV. RELIANCE AGREEMENTS

The IRB follows Cooperative Research procedures outlined in 45 CFR § 46.114
When multiple agencies or institutions are involved in the same human subject research project, a reliance agreement may be necessary for approval. Particularly when an outside party, such as a non-MDC agent, is involved in the study, and the study requires IRB review, the Principal Investigator will be required to utilize a reliance agreement as part of the IRB approval. A reliance agreement is a formal, written document that provides authorization and guidelines for all agencies and institutions involved in the research study.

The Reliance Agreement must outline clear and specific terms and regulations that all agents involved in the human subject research relying upon one another must adhere to. The reliance agreement, which may also be an IRB Authorization Agreement (or IAA), ultimately serves as the agreement shared between two institutions sharing a single research project for the establishment of accountability and authorization. The IAA allows institutions with a Federalwide Assurance (FWA) to extend its FWA to cover another institution as well. For more guidelines on producing an IAA, please visit https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html

Starting January 20, 2020, most federally-funded collaborative research projects located in the U.S. are required to use a single IRB (commercial, academic, or hospital-based) to streamline the review process for human participant protections and to avoid duplicate review by an institutional review board at each site. The IRB overseeing the research must be approved by the funding agency. For

single IRB guidelines please visit The Revised Common Rule's Cooperative Research Provision. Alternately, the chair of the IRB can be contacted via email at irb@mdc.edu for additional guidance.

Reliance agreements requests will be reviewed on a case-by-case basis. These requests **must** be reviewed for approval by CASSC R&T. The Subcommittee determines whether research will be an acceptable fit within MDC in addition to not creating undue burden on MDC resources.

XV. POST-APPROVAL RESPONSIBILITIES

Following MDC Research Approval investigators assume the responsibility of adhering to the policies and regulations set forth within the research approval procedures and executing their study within the guidelines as approved by MDC. The Principal Investigator must remain cognizant and adhere to the following:

A. Researcher cannot start data collection (including pilot data) until the following:
   a) Obtain a final letter of approval from the IRB,
   b) Obtain letters of approval required from any site, department, or division necessary when research involves their resources and/or subjects,
   c) Obtain legal, informed consent from human subjects or their representatives.

B. Researcher must submit the Change of Research Request for any changes to research applications that have been previously approved. All changes must be reviewed and approved by IRB prior to implementation of changes.

C. Researcher must conduct human research with the protocols as approved by the IRB and in compliance with all federal regulations and local laws when applicable.

D. Researcher must ensure that research is conducted within one-year time frame for which the study is approved or apply for extensions as required within the Standard Operating Procedures for Research Approval Manual in a timely manner prior to approval expiration.

E. Researcher should notify the IRB when their study is complete.

APPENDIX I – Glossary of Research and IRB-Related Terms

The glossary is designed to assist investigators with terms related to the conduct of research with human subjects and language associated with the research-review process of the Institutional Review Board (IRB) for the Protection of Human Subjects. The definitions included in the glossary are taken directly from, or informed by the federal regulations, and are meant to provide investigators with guidance during the IRB submission and review process.

Action Research: A form of inquiry conducted by faculty with current term students in the classroom. Information gathered is not personally identifiable or connected to any one individual. The information gathered will be used for decision making within the course and term and will not be used for publication/presentation outside of the College.

Anonymous: Subjects' identities are unknown to the investigator, not requested, and not given. Data collected do not contain any information that would permit identification of the individual subjects. Subjects cannot be described as anonymous if the research involves audio/video recordings or in-person interviews.

Assent: Agreement by an individual not competent to give legally valid informed consent (e.g., a child or adult who is cognitively impaired) to participate in research.

Assurance: A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved. Also referred to as a federalwide assurance or FWA.

Belmont Report: A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978. The Belmont Report attempts to summarize the basic ethical principles identified by the commission in the course of its deliberations. It has become a seminal document in establishing principles for research with human subjects. Find the Belmont Report online.

College Academic and Student Support Council (CASSC): The College committee charged with the following responsibilities; (i) Review and recommend for approval all proposed curriculum changes, including new courses, new degree and certificate programs, and revisions to existing programs; and courses; (ii) Function as a communication vehicle for discussion and dissemination of topics related to academic and student affairs such as student success initiatives and legislative updates and changes to College policies and procedures; (iii) Provide a forum for open dialogue for student success initiatives and innovations; (iv) Undertake other responsibilities as assigned by the Executive Vice President & Provost.

College Academic and Student Support Council (CASSC) Research & Testing Subcommittee: At MDC, approval of research applications is a two-step process: First, MDC's IRB reviews research applications involving human subjects. Once approved by MDC's IRB, research applications are reviewed by the CASSC Research & Testing Subcommittee. The Subcommittee is charged to (i) advise and help determine College research priorities for the year,

(ii) approve research studies at the College, and (iii) review and forward significant research findings to Deans, and others, as appropriate.

Code of Federal Regulations (CFR): Rules published in the Federal Register by the executive departments and agencies of the Federal Government. The CFR is divided into 50 titles that represent broad areas subject to Federal regulation. Each volume of the CFR is updated once each calendar year and is issued on a quarterly basis.

Confidentiality: Subjects' identities are known to the researchers and/or data contain information that would permit identification of the individual(s) about whom the data were collected. The data are transmitted and stored in a manner that protects the information from release to unauthorized individuals.

De-Identified Data: Data that has been stripped of all identifiers so that the information cannot be traced back to an individual. De-identified data may also pertain to information that has been assigned and retains a code provided that:

- The code is not derived from or related to the information about the individual;
- The code could not be translated to identify the individual; and
- No link to identifiers exists, or the holder of the link record does not use or disclose the code for other purposes or disclose the mechanism for re-identification.

Engagement in Research: An institution becomes "engaged" in human subjects research when its employees or agents1 (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes. The institution is automatically considered to be "engaged" in human subjects research whenever it receives a direct Health and Human Services (HHS) award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award.

Exempt Review: Eight categories of minimal risk research that are exempt from federal oversight. However, these categories of research are not exempt from review by the MDC IRB or the ethical guidelines of the Belmont Report. It is the responsibility of the institution, not the investigator, to determine whether human research is exempt from IRB review.

Expedited Review: Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

Full Board Review: Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

Human Subjects: Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (i) data through intervention or interaction with the individual; or (ii) identifiable private information.

Individually identifiable information: The identity of the participant is or may readily be ascertained by the investigator or associated with the information.

Informed Consent: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

Institutional Review Board (IRB): A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

Intervention: Physical procedures or manipulations of those individuals or their environment for research purposes.

IRB Approval: The determination of the IRB that the research study has been reviewed and meets the criteria set forth by the IRB, the institution, and other federal, state, and local requirements.

Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.

Modification: Any change to an IRB-approved study protocol regardless of the level of review it receives initially. Also referred to as an amendment.

Risk: The discomforts, hazards, or inconveniences to the subjects related to the subjects' participation in the research. The probability, magnitude, duration, and reversibility of the risks should be described in the application. Consider physical, psychological, social, legal, and economic risks.

OHRP: The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).

Principal Investigator (PI): The PI is the person who is ultimately responsible for the conduct of the study. For student-initiated research, the student's faculty advisor serves as the PI and is ultimately responsible for the conduct of the study.

Privacy: Privacy is about people and means respecting an individual's right to be free from unauthorized or unreasonable intrusion, including control over the extent, timing and circumstances of obtaining personal information from or about them. For example, individuals may

not want to conduct the consent process in an open area or may not want to be seen entering a study site that might stigmatize them.

Protocol: The written description of a research study. It includes the study's objectives, design, and methods. It may also include relevant scientific background and statistical information. For IRB review, a protocol should include detailed information about the study population and components of human subjects protection (risks, benefits, recruitment, consent, etc.).

Reliance Agreement: A formal, written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to an independent IRB or an IRB of another institution. Institutions that are engaged in human subjects research, where one institution will rely on the other institution's IRB, must agree to the terms of the Reliance Agreement before research can begin.

Research: Federal regulation defines "research" as a systematic investigation, including research development, testing, and evaluation, that is designed to develop or contribute to generalizable knowledge.

- Systematic Investigation: A "systematic investigation" is a detailed or careful examination that has or involves a prospectively identified approach to studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing theory based on a system, method, or plan. Systematic investigations include observational studies, interview or survey studies, group comparison studies, test development, and interventional research.
- Generalizable knowledge: Developing or contributing to "generalizable knowledge" means that the intent or purpose of the systematic investigation is to produce knowledge from which conclusions will be drawn that can be applied to populations outside of the specific study population. This usually includes one or more of the following concepts:
    - knowledge that contributes to a theoretical framework of an established body of knowledge;
    - the primary beneficiaries of the research are other researchers, scholars, and practitioners in the field of study;
    - dissemination of the results is intended to inform the field of study (this alone does not make an activity constitute research "designed to contribute to generalizable knowledge");
    - the results are expected to be generalized to a larger population beyond the site of data collection;
    - the results are intended to be replicated in other settings.

Research Involving Animals: The IRB reviews research that involves human participants. For questions regarding research involving animals, you may contact the Dean of the School of Science. Contact/additional information regarding research opportunities within the School of Science is available at https://www.mdc.edu/science/research-opportunities/.

Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

Single IRB (sIRB): An Institutional Review Board that oversees all sites participating in a multisite study.

Voluntary: Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

Withdrawal: A subject who enrolled (i.e., consented to participate) but later withdrew from (i.e., discontinued his or her participation in) a study, either before, during, or after completing research procedures. For a variety of reasons, a subject enrolled in a research study may decide to withdraw from the research, or an investigator may decide to terminate a subject's participation in research regardless of whether the subject wishes to continue participating (e.g., for non-compliance with research procedures). Withdrawals do not include individuals who failed initial eligibility screening.