

Conducting Research at Miami Dade College
Standard Operating Procedures

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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 (whether professional or student) 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* (item 5). 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* (item l).

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, policies and procedures.

The IRB includes a group of research experts known as the IRB Determination Review Group, which supports the Chair in the initial review and classification of submitted applications by providing subject matter expertise and advisory input related to human subjects protection, ethical research practices, and regulatory compliance. This group serves in an advisory and screening capacity to promote consistency, timeliness, and regulatory alignment in the review process; however, final IRB determinations remain under the authority of the IRB Chair, Alternate Chair, or the convened IRB, as applicable.

The primary purpose of the IRB is to ensure that appropriate steps are taken to protect the rights and welfare of human subjects involved in research conducted at or under the auspices of Miami Dade College. The IRB is responsible for reviewing research activities in advance of their initiation and for conducting periodic reviews of ongoing research. The IRB evaluates research protocols and related materials to ensure that risks to participants are minimized, that participation is voluntary and informed, and that research is carried out in an ethical and responsible manner. To accomplish this purpose, the IRB uses a group process to review research protocols and related to ensure protection of the rights and welfare of human subjects of research.

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 Committee (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 Committee ensures whether the proposed research aligns with the College strategic priorities and institutional values. Additionally, the Committee 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 CASSC R&T Committee has a Collegewide mandate to ensure that research activities align with institutional mission, academic priorities, and operational feasibility. Its scope includes reviewing proposals for institutional impact, supporting faculty and student researchers, advising on research-related policies, maintaining consistency across campuses and divisions, and the review and dissemination of significant research findings.

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.

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.

Both the MDC IRB and CASSC R&T are authorized to review, approve, require modifications in, or not approve research activities conducted by or through the College involving human subjects.

The decision(s) of the MDC IRB and/or CASSC R&T Committee is final. Decisions cannot be appealed; however, investigators are encouraged to submit 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.

Scope

This policy applies to all research activities involving human subjects conducted by, through, or under the auspices of Miami Dade College (MDC)**,** regardless of the source of funding or the physical or digital location of the research.

For the purposes of this policy, *research* is defined as a systematic investigation, including research development, testing, or evaluation, designed to develop or contribute to generalizable knowledge, as set forth in 45 CFR § 46.102(l).

IRB oversight is required for any activity that meets this definition and involves human subjects or their identifiable data when the research:

1. Is conducted by or under the direction of an MDC employee, student, or agent acting in their MDC role;
2. Uses MDC property, facilities, classrooms, laboratories, digital platforms, systems, services, technology, or equipment;
3. Involves the recruitment, participation, or observation of MDC students, faculty, or staff as human subjects; or
4. Involves the collection, use, or analysis of MDC institutional, academic, administrative, or personnel data, including identifiable or potentially re-identifiable information.

This requirement applies regardless of whether the research is funded or unfunded, and regardless of whether it is conducted on MDC campuses, at external sites, online, or in community settings.

All research conducted at or through MDC requires documented approval from the relevant College leadership authority prior to IRB review.

Internal program evaluation, institutional research, assessment, and quality improvement activities conducted solely for MDC operational or decision-making purposes, where findings are not intended for external dissemination and where activities involve no more than minimal risk, generally do not require IRB review. However, if such an activity is intended to contribute to generalizable knowledge, is intended for publication or presentation, involves more than minimal risk, or requires identifiable institutional data beyond normal access, it is considered research and must be submitted to the IRB for review prior to initiation.
The IRB retains final authority to determine whether an activity constitutes research involving human subjects subject to IRB review.

INSTITUTIONAL AUTHORITY AND REGULATORY FRAMEWORK

The Miami Dade College Institutional Review Board (IRB) is established under the authority of College Procedure 1321, "Authorization to Conduct Research." The IRB operates in accordance with the ethical principles outlined in the Belmont Report and complies with the Federal Policy for the Protection of Human Subjects (45 CFR 46). Miami Dade College maintains a Federal Wide Assurance (FWA00020165) with the U.S. Department of Health and Human Services, Office for Human Research Protections (OHRP). Under this Assurance, the College applies the requirements of 45 CFR 46 to all non-exempt human subjects research conducted at or through MDC. The College maintains one IRB registered with OHRP as IRB00007621.

The IRB has the authority to review, approve, require modifications in, or not approve human subjects research; to suspend or terminate research not conducted in accordance with IRB requirements or associated with unexpected harm; and to require continuing review when appropriate. The Institutional Official (Signatory Official for the FWA) is responsible for ensuring institutional support for the IRB and for required reporting to OHRP or other oversight agencies. No administrator, department, sponsor, investigator, or other College authority may override an IRB determination.

COMPOSITION AND OPERATION OF THE IRB

Following the rules and regulations set forth in 45 CFR § 46.107, the membership of the Institutional Review Board (IRB) shall be as follows:

Institutional Oversight and Signatory Official

The Vice Provost for Strategy and Institutional Effectiveness serves as the Institutional Signatory Official for the Miami Dade College IRB.

The Signatory Official:

- Signs and maintains the College's Federal Wide Assurance (FWA) with the Office for Human Research Protections (OHRP);
- Appoints and reappoints the voting members of the IRB based on the recommendations from the Chair and Alternate Chair;
- Provides the IRB with the independence, administrative support, and resources necessary to fulfill its duties; and
- Receives annual activity reports, training updates, and compliance notifications from the IRB Chair.

The IRB operates under the delegated authority of the Signatory Official and reports administratively through the Division of Strategy and Institutional Effectiveness.

Chair and Alternate Chair

The Director of Institutional Research serves ex officio as Chair of the IRB.
The Director of Assessment, Evaluation, and Testing serves ex officio as Alternate Chair.

These IRB positions are included in their job description. They remain in effect as long as the individuals occupy the corresponding College leadership roles.

The Chair or designee is responsible for:

- Convening meetings and assigning primary reviewers;
- Ensuring that reviews adhere to ethical principles, federal regulations, and institutional policy;
- Communicating IRB determinations to investigators and institutional officials;
- Overseeing member training, certification, and procedural consistency; and
- Serving as the primary liaisons between the IRB, the Signatory Official, and OHRP.

Membership Composition

The IRB shall consist of no fewer than seven (7) voting members.

Members are selected to ensure the IRB has the professional expertise and diverse perspectives needed for effective ethical review.

Membership includes faculty, administrators, and staff from varied disciplines, such as behavioral sciences, education, health, social science, ethics, or information security as well as at least one unaffiliated community member.

All changes in membership are reported to the Office for Human Research Protections (OHRP) in accordance with the College's FWA.

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

1) The Director of Institutional Research serves as the chair of the IRB and the co-chair of the CASSC R&T Committee.
2) The Director of Assessment, Evaluation, and Testing serves as the alternate chair of the IRB and the co-chair of the CASSC R&T Committee.
3) The members of the IRB will be composed of at least five (5) members of the CASSC R&T Committee. IRB members, who are employees of MDC and subject matter experts, can serve on the CASSC R&T Committee as resource members.
4) Recommendations for IRB membership should be made directly to the IRB Chair and alternate chair and based on expertise, experience, knowledge of a specialized area, and interest in the involvement of research related studies. The aforementioned will select members based on recommendations and research experience. All changes are reported to OHRP.

Diversity and Expertise

In accordance with 45 CFR § 46.107(a), the IRB shall include members of diverse backgrounds, reflecting differences in race, gender, cultural experience, and sensitivity to community attitudes, to foster respect for its review process and recommendations.

Collectively, the IRB must possess the expertise necessary to evaluate the scientific, ethical, and legal aspects of proposed research.

When specific expertise is required, the IRB may invite ad hoc consultants to assist in its review. These individuals may not vote on IRB determinations.

Membership Categories

The IRB must include at least:

- One member whose primary concerns are in scientific areas;
- One member whose primary concerns are in nonscientific areas; and
- One member who is not affiliated with Miami Dade College and represents the community.

Terms of Appointment

Voting members are appointed to the board for a three-year term and may continue their membership for additional subsequent terms.

The term may be terminated prematurely by either written notice from the IRB member to the Chair or from the Chair to the member.

Members may be removed from the IRB before their term is completed if they are unable to perform their IRB duties. The IRB Chair and Alternate Chair will recommend a replacement.

Vacancies will be filled promptly to maintain compliance with federal membership requirements.

Training and Certification

IRB members must complete IRB Member Training through the Collaborative Institutional Training Initiative (CITI Program).

Human Subjects Research (HSR) training must be renewed every three (3) years.

Members must maintain current certification to participate in IRB duties.

DETERMINING WHEN IRB REVIEW IS REQUIRED

Requirement for IRB Determination

All projects that involve human participants, their data, or institutional data sources must be reviewed by the IRB to determine whether they qualify as human subjects research under 45 CFR § 46.102.

No investigator, department, or office may independently decide that a project is exempt from IRB oversight.

Only the **IRB Chair or Alternate Chair** has the authority to make an official determination regarding IRB applicability or exemption.

Submitting for Determination

Before any data collection, analysis, or access to identifiable information begins, investigators must submit a Miami Dade College Research Application to the IRB Office.

This requirement applies to:

- Any project involving interaction with individuals, use of surveys or interviews, or analysis of institutional data;
- Projects intended for publication, presentation, or external dissemination; and
- Any activity that could reasonably be interpreted as research within the meaning of federal regulations.

The submission must include a brief project description, research materials, objectives, intended outcomes, participant population, and data sources.

Investigators will receive written communication from IRB@mdc.edu within the applicable timeframe with one of the following outcomes: Approved or Not Approved.

The Research Application Review Schedule is followed based on date of completed application submission. Timelines may be extended when revisions are required, additional information is needed, or during periods

of high submission volume. Research request applications should be submitted well in advance of intended project start dates, particularly for projects requiring full board review.

Institutional Responsibility

All members of the College community share responsibility for ensuring that activities potentially involving human subjects are submitted for IRB review or determination prior to initiation.

All supervisors are expected to advise investigators of this requirement and ensure compliance.

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.

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.

The IRB Chair and Alternate Chair maintain 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.

MANAGEMENT OF THE IRB

A. The IRB Chair has authority to sign all IRB action items.

B. The IRB Alternate Chair can preside over convened IRB meetings from which the Chair is absent. The IRB Alternate Chair has 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) No member may participate in the initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB.

   b) Investigators shall not be involved in the selection of IRB members.

   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.

   d) Conflict of Interest Guidelines for IRB members are found in the Appendix C of this document.

LEVELS OF REVIEW AND OUTCOME

The IRB Chair or Alternate Chair with the support of the IRB Determination Review Group will issue one of the determinations below for each submitted and completed research request. The determination is based on whether the activity meets the definition of research involving human subjects, the nature of the procedures involved, the identifiability of information, and the level of risk to participants.

- **Not Research / Not Human Subjects Research** – no further IRB review required;
- **Exempt** – qualifies for exemption under 45 CFR § 46.104 categories;
- **Expedited Review** – eligible for review under 45 CFR § 46.110; or
- **Full Board Review** – requires review by the convened IRB.

A written determination will be provided from IRB@mdc.edu to the investigator and retained in the IRB's official records.

Not Research / Not Human Subjects Research

Activities that do not meet the regulatory definition of research and/or do not involve human subjects do not require IRB review or approval. An activity is considered Not Human Subjects Research when it does not involve interaction or intervention with living individuals and does not involve the collection, use, or analysis of identifiable private information or identifiable biospecimens.

In some cases, investigators may request a formal IRB determination to document that an activity does not constitute human subjects research. The IRB Chair or designee may issue a written determination confirming this status.

Exempt Research

Certain research activities involving human subjects may qualify for exemption from ongoing IRB review when they fall within one or more categories specified in 45 CFR § 46.104. Although exempt research is not subject to continuing IRB oversight, exemption determinations must be made by the IRB and may not be made by investigators.

Research that may qualify for exemption includes, but is not limited to, the following categories of activities:

- Research conducted in established or commonly accepted educational settings that involves normal educational practices.
- Research involving educational tests, survey procedures, interview procedures, or observation of public behavior, provided that the information is recorded in a manner that does not readily permit identification of participants, or that disclosure of identifiable information would not reasonably place participants at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation.
    - Research involving children may not be classified as exempt under this category when it involves survey or interview procedures, or observations of public behavior in which the investigator participates.

  - Research involving children may be classified as exempt under this category when it involves only educational tests and/or observation of public behavior in which the investigator does not participate, and all other criteria of the exemption category are met.

- Research involving benign behavioral interventions with adult participants, when participants prospectively agree to the intervention and information is collected in a manner consistent with regulatory requirements.
  - Benign behavioral interventions must be brief in duration, harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on participants, and the investigator must have no reason to believe the interventions will be offensive or embarrassing.
  - Research involving children may not be classified as exempt under this category.
- Research involving the collection or study of existing data, documents, records, or specimens, when such materials are publicly available or when the information is recorded by the investigator in a manner that renders participants not readily identifiable.
  - Secondary research for which consent is not required may qualify for exemption when:
    - The identifiable private information or identifiable biospecimens are publicly available; or
    - The information is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify the subjects.

Research involving prisoners does not qualify for exemption unless the research is aimed at a broader subject population that only incidentally includes prisoners.

In evaluating exemption eligibility, the IRB considers the nature of the research activities, the sensitivity and identifiability of the information involved, the characteristics of the study population, and whether investigator access could reasonably permit identification of individuals. Research activities determined to be exempt may not begin until an exemption determination has been formally issued by the IRB.

Expedited Review

Research involving human subjects that does not qualify for exemption under 45 CFR § 46.104 may be eligible for expedited review when the research involves no more than minimal risk to participants and falls within one or more of the expedited review categories authorized under 45 CFR § 46.110. Expedited review determinations must be made by the IRB and may not be made by investigators. Expedited review does not require review by the convened IRB.

Research that may qualify for expedited review includes, but is not limited to, the following categories of activities:

- Clinical studies of drugs or medical devices when an Investigational New Drug (IND) or Investigational Device Exemption (IDE) is not required and the research otherwise presents no more than minimal risk.

- Collection of blood samples through venipuncture or other minimally invasive methods, within regulatory limits and from eligible participant populations.
- Prospective collection of biological specimens for research purposes by noninvasive means.
- Collection of data through noninvasive procedures routinely employed in clinical or diagnostic practice, excluding procedures involving general anesthesia or sedation.
- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, for non-research purposes, when the research use presents no more than minimal risk.
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research involving individual or group characteristics or behavior, including studies using surveys, interviews, focus groups, program evaluation, quality improvement, or similar methodologies, when the research does not qualify for exemption and presents no more than minimal risk.

Research that does not meet the criteria for expedited review under 45 CFR § 46.110 must be reviewed by the convened IRB through the full board review process.

The expedited review process may be used for initial review, review of minor modifications to previously approved research, and continuing review, when applicable. Although conducted outside of a convened meeting, expedited review carries the same regulatory authority as full board review with respect to approval decisions.

Full Board Review

Research that involves greater than minimal risk such as vulnerable subjects does not qualify for exemption or expedited review, or presents complex ethical or regulatory considerations must undergo review by the convened IRB. 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.

Full board review is conducted at a scheduled IRB meeting with a quorum present, in accordance with federal requirements. In its review, the IRB evaluates potential risks and anticipated benefits, the adequacy of informed consent processes, protections for privacy and confidentiality, and safeguards for populations

requiring additional protections. Approval of research reviewed by the convened IRB requires a majority vote of members present.

Review Authority and Escalation

The IRB Chair or alternate chair may request additional information, assign or reassign the level of review, or escalate a project to a higher level of review when warranted by the nature of the activity, the level of risk, or regulatory considerations. A project initially submitted as exempt or eligible for expedited review may be referred for full board review if concerns arise during evaluation.

Please refer to the APPENDIX D for Adverse Event Reporting Guidance.

Timing and Review Timeline

An IRB determination must be obtained prior to initiating any project activities**,** including but not limited to recruitment, data collection, data analysis of identifiable private information, or access to existing datasets that are not fully de-identified.

Projects that begin without the appropriate IRB determination are considered noncompliant with institutional policy and federal regulations.

Retroactive IRB approval or exemption determinations will not be issued under any circumstances. Activities conducted prior to IRB determination may not be used for research purposes, publication, presentation, or external dissemination.

All research applications must be submitted through the Miami Dade College Research Application with all required materials completed at the time of submission. Applications that are incomplete or missing required components will be returned and will not enter the review process timeline until all required materials are received.

Submission of a research application does not constitute acceptance for IRB review. All applications undergo an administrative review to verify that required forms, supporting documents, training records, and approvals have been provided. Applications that are incomplete or require clarification will be returned to the investigator for revision. An application is considered accepted for review only after the IRB Office determines that all submission requirements have been met. Review timelines begin on the date the application is accepted as complete. This is consistent with the SOP's treatment of complete applications entering the review process.

Once a complete application is submitted, it proceeds through a series of reviews. During the first five business days, the IRB Office conducts an Administrative Review to verify application completeness and required documentation. The application is then forwarded for IRB Review by the IRB Chair or Alternate Chair, which is generally completed within the next ten business days. The application is subsequently reviewed by the Determination Review Group, which provides advisory input within the following five business days. The CASSC Research and Testing (R&T) Committee then conducts its review and electronic vote, typically within the next five business days. Following completion of all reviews, the IRB Office issues the Final Determination communication. Refer to the Research Application Review Schedule on the Conducting Research at MDC webpage. Additional details also available in Appendix F.



Review timeframes described within this SOP are intended as planning estimates and are not regulatory requirements or guaranteed approval periods. Consistent with 45 CFR 46 and applicable federal guidance, the IRB's primary obligation is to ensure the protection of human subjects through thorough ethical and regulatory review. Accordingly, review durations may vary based on application completeness, study complexity, required modifications, regulatory considerations, committee workload, and investigator responsiveness. Final review determinations remain the responsibility of the IRB Chair, Alternate Chair, designated reviewer, or convened IRB, as applicable.

Given specific projects timeline constraints, Exempt determinations are not contingent on a CASSC R&T Committee vote.

IRB MEETINGS

IRB meetings will be convened at MDC at least once each academic year and as necessary. A full review meeting of the IRB may suffice for the one required meeting.

The meeting format, time, agenda, and review materials are provided to IRB members at least 48 hours prior to the meeting.

Voting

a) Approval requires a majority vote of the members present at the meeting.

b) 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).

APPLICATION AND REVIEW PROCEDURES

Investigators must submit a complete MDC Research Application with all required supporting documentation. Applications that are incomplete, missing required elements, or do not meet submission requirements will be sent back for revision and will be moved to the next research review cycle according to when pending items are received.

Required Application Materials

Before beginning the application, investigators must ensure that all applicable documents are prepared, finalized, and compiled according to the MDC Research Application checklist and the requirements below.

1. Recruitment Materials

All materials and methods used to recruit participants must be submitted as part of the MDC Research Application and reviewed and approved by the IRB prior to use. Recruitment materials include any written, verbal, electronic, or visual communications intended to identify, inform, or invite individuals to participate in the research.

Recruitment materials must accurately describe the nature and purpose of the research, the eligibility criteria, and the voluntary nature of participation, and must not include language that is misleading, coercive, or unduly influential. The IRB will evaluate recruitment materials to ensure that they are appropriate for the target population and consistent with the approved consent process.

Any changes to recruitment materials or recruitment methods after IRB approval must be submitted for IRB review and approval prior to implementation.

2. Research Materials

Investigators must submit copies of all research materials to be administered to participants as part of the MDC Research Application. Research materials include, but are not limited to, surveys, questionnaires, assessments, tests, interview guides, focus group protocols, scripts, stimuli, and prompts.

The IRB will review all research materials to evaluate content, appropriateness for the study population, potential risks, and consistency with the approved consent process. Research materials must be presented in language appropriate to the intended participants and must not include content that is misleading, coercive, or inconsistent with the approved protocol.

Only IRB-approved research materials may be administered to participants. Any revisions to research materials following IRB approval must be submitted for change of research review and approval prior to use.

3. Informed Consent Documentation

General Requirement

Informed consent must be obtained from each prospective participant prior to participation in research involving human subjects, unless the IRB has approved a waiver or alteration of informed consent in accordance with applicable federal regulations. Informed consent documents and procedures must comply with the requirements set forth in this section. Use of the Miami Dade College IRB Consent template in Appendix E is strongly encouraged.

Investigators may not initiate any research activities involving human subjects until the IRB has reviewed and approved the informed consent process and all associated consent documents.

Required Elements of Informed Consent

Informed consent must be presented in language understandable to the participant and must include all applicable elements required under 45 CFR § 46.116, including:

- A statement that the activity involves research
- An explanation of the purposes of the research
- A description of the research procedures and the expected duration of participation
- A description of any reasonably foreseeable risks or discomforts
- A description of any anticipated benefits to the participant or others
- A disclosure of appropriate alternative procedures or courses of action, when applicable
- A statement describing the extent to which confidentiality of records identifying the participant will be maintained
- For research involving more than minimal risk, an explanation of any compensation or medical treatment available if injury occurs, or where further information may be obtained
- Contact information for the investigator(s) and for the Miami Dade College IRB (IRB@mdc.edu; 305-237-7445)
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and the participant may discontinue participation at any time without penalty

When applicable, informed consent must also include:

- Identification of any experimental procedures
- A statement that the particular treatment or procedure may involve risks that are currently unforeseeable
- Anticipated circumstances under which participation may be terminated by the investigator
- Any additional costs to the participant that may result from participation
- The consequences of a participant's decision to withdraw and procedures for orderly termination
- A statement that significant new findings that may affect willingness to continue participation will be provided
- Disclosure of audio, video, or digital recording, including optional consent for recording when applicable

Informed consent documents must include a statement that the participant will receive a copy of the signed consent form and must provide space for the participant's printed name, signature, and date of consent. Consent forms must also include confirmation that the participant is 18 years of age or older, unless parental permission and assent procedures apply.

Waiver of Alteration of Informed Consent

Investigators may request a waiver or alteration of informed consent as part of the MDC Research Application. Such requests will be reviewed by the IRB in accordance with applicable federal criteria and must be explicitly approved prior to the initiation of any research activities.

Consent Requirements for Research Involving Children

For research involving children (individuals under the age of 18), additional protections apply. Parental permission is required for all research involving children unless a waiver of parental permission has been approved by the IRB in accordance with 45 CFR § 46.408(c). A waiver may be approved only when the IRB determines that parental permission is not a reasonable requirement to protect the child participants and that appropriate alternative protections are in place.

When children are capable of providing assent, the IRB will require child assent in addition to parental permission. As a general guideline, children seven (7) years of age or older are expected to provide assent unless the IRB determines otherwise.

Documentation and Ongoing Compliance

All informed consent, parental permission, and assent documents must be submitted with the MDC Research Application and must reflect the IRB-approved consent process. Any proposed changes to consent materials or procedures require IRB review and approval prior to implementation.

4. Human Subjects Research Training

All investigators and any individuals who will interact with human subjects or have access to identifiable private information as part of the research must complete human subjects research training prior to submission of an MDC Research Application. Training must be current and completed within the past three (3) years.

For research involving protected health information (PHI) or activities subject to the Health Insurance Portability and Accountability Act (HIPAA), all investigators and research personnel with access to PHI must also complete IPS: Information Privacy and Security training prior to submission. IPS training is required in addition to human subjects research training.
Training requirements apply to Principal Investigators, Co-Investigators, research staff, collaborators, and any individuals with access to identifiable private information or identifiable data.

Acceptable training consists of completion of the CITI Human Subjects Research course and, when applicable, the CITI IPS: Information Privacy and Security course. Miami Dade College employees and students must complete training through CITI using their MDC email address. Training completed through another institution or organization may be accepted at the discretion of the IRB, provided the content and completion date meet institutional requirements.

Documentation of completed training must be submitted with the application. Applications submitted without required training documentation will be administratively declined.

5. Letter of Support

All research conducted at Miami Dade College or involving Miami Dade College students, faculty, staff, programs, courses, or institutional data requires a letter of support from an appropriate MDC academic administrator. The support letter must be submitted as part of the MDC Research Application.

The support letter should be issued by a faculty dean, school dean, student dean, director, chair, or other appropriate faculty, student services, school, or service-unit leader with oversight of the academic or service area, program, or course affected by the proposed research. If those reviewers are unavailable or have been exhausted, the letter may be issued by the Campus President, Associate Provost, or Vice Provost. The purpose of the support letter is to confirm institutional and campus awareness of the research and to verify that the proposed activities are feasible and appropriate within the academic/service unit.

The support letter must include:

- Identification of the department, program, course, or academic/service unit affected by the research
- A brief statement acknowledging the proposed research activities
- Confirmation that the research does not conflict with instructional responsibilities, academic operations, or institutional policies

A support letter is required for all research applications, regardless of the level of IRB review. Applications submitted without the required support letter will be administratively declined.

All research conducted at Miami Dade College will be sent to campus leadership. The purpose of informing Campus Leadership is to confirm campus or collegewide awareness of the proposed research, assess feasibility and potential operational or instructional impact, and identify institutional considerations relevant to conducting the research. Leadership review through this process does not constitute IRB approval and does not replace IRB review.

6. Prior Approval and External Authorizations

Investigators must submit documentation of all required external approvals and authorizations applicable to the proposed research as part of the MDC Research Application. Required approvals must be obtained prior to submission and must be current at the time of application.
For investigators whose primary institutional affiliation is not Miami Dade College, documentation of IRB approval, exemption, or determination from the investigator's home institution is required for all research involving human subjects, when such an IRB exists. Approval or determination by the investigator's home institution is required regardless of the level of review.

When an investigator does not have an affiliated institution with an IRB, the Miami Dade College IRB will serve as the primary reviewing IRB for the proposed research.
When proposed research is conducted in connection with an externally funded or sponsored project, investigators must disclose the funding source and submit relevant grant or sponsor documentation as part of the application. Documentation must be sufficient to allow the IRB to evaluate the scope, purpose, and requirements of the research.

Submission of external IRB approval or sponsor authorization does not replace the requirement for review and approval by the Miami Dade College IRB when the research involves MDC students, faculty, staff, programs, courses, or institutional data.

The IRB may request additional documentation or clarification related to external approvals or funding arrangements as part of its review. Applications submitted without required approvals or disclosures will be administratively declined.

7. Data Security Privacy and Safeguarding Measures (Data Collection)

Investigators must describe all data collection activities as part of the MDC Research Application. This includes the type of data to be collected, the methods and instruments used, the setting in which data collection will occur, and the roles of research personnel involved in collecting or handling data. Data collection procedures must be consistent with the approved research protocol and informed consent process and must be designed to minimize risks to participants.

The IRB will review proposed data collection methods to evaluate potential risks to participants, the sensitivity and identifiability of the information collected, and the adequacy of protections for participant privacy and confidentiality. Research activities involving data collection may not begin until IRB approval or determination has been issued.

Investigators are responsible for ensuring that research data are stored, accessed, and maintained in a secure manner that protects against unauthorized access, disclosure, or loss. The MDC Research Application must describe how data will be stored, including whether data will be maintained in electronic or physical form, where data will be stored, and who will have access to the data.

Access to identifiable research data must be limited to authorized members of the research team as listed in the MDC Research Application. Appropriate safeguards must be implemented to protect electronic data, such as password protection, encryption, and secure servers, as well as physical safeguards for hard-copy records when applicable. Storage of identifiable research data on personal devices or unapproved cloud-based platforms may be restricted or prohibited, depending on the nature of the data and institutional requirements.

Investigators must also specify the duration of data retention and the procedures for secure destruction or de-identification of data at the conclusion of the study or at the end of the required retention period. Any changes to data collection procedures, data storage locations, access controls, or security measures after IRB approval must be submitted for change of research IRB review and approval prior to implementation.

Change of Research

Pursuant to OHRP guidelines, change of research is categorized into minor changes and significant changes.

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:

- Addition or deletion of study team members, or

- Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study, or
- Removal of research procedures that would thereby reduce the risk to subjects, or
- Addition of non-sensitive questions to unvalidated survey or interview procedures, or
- Addition of or revisions to recruitment materials or strategies, or
- Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors).

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:

- Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.), or
- Addition of research procedures that involve greater than minimal risk to subjects, or
- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation, or
- Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

Level of Review for Change of Research

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 shared with the IRB and then included on the agenda of the next CASSC R&T Committee meeting as an information item.

Significant modifications will generally be reviewed at the same level as the original study, unless the change requires full board review.

USE OF INSTITUTIONAL DATA AND FERPA

Research involving Miami Dade College institutional data or education records is subject to the Family Educational Rights and Privacy Act (FERPA), Florida Statute §1002.22, and MDC Procedure 4085: Collection, Maintenance, Review, and Release of Student Education Records. Investigators are responsible for ensuring that the collection, use, disclosure, retention, and reporting of institutional data comply with all applicable laws, institutional policies, and IRB requirements. IRB approval or determination does not grant access to institutional data. ~~All requests for Miami Dade College data must be reviewed and approved through appropriate institutional data governance processes.~~

IRB approval or exemption does not obligate Miami Dade College's Office of Institutional Research, Information Technology, Academic Affairs, Student Affairs, or any other institutional office to release data

requested for a research study. Access to institutional data remains subject to FERPA, applicable federal and state laws, College policies and procedures, established data governance processes, data availability, disclosure risk assessment, security requirements, and operational feasibility. Institutional offices serving as data stewards retain the authority to approve, modify, limit, aggregate, de-identify, delay, or deny data requests independent of the IRB's determination. Researchers must obtain all required institutional approvals before receiving or accessing institutional data.

Access to institutional data or education records without student consent is permitted only when the individual requires the information to fulfill an assigned professional responsibility and the use of the data is consistent with that responsibility.

A legitimate educational interest exists only when access to the information is necessary to perform institutional duties that the individual cannot reasonably complete without such access. Possession of data access privileges or employment status alone does not establish legitimate educational interest. Research questions most commonly arise when individuals are employed as faculty or staff and research constitutes a component of their professional role. Under 34 CFR §99.31(a)(6), prior student consent is not required when studies are conducted *for or on behalf of the institution* for purposes such as improving instruction, administering student aid programs, or developing or validating institutional processes or predictive models.

This provision is intended to support institutional improvement and internal decision-making. It does not extend to research activities whose primary purpose is to produce generalizable knowledge for dissemination beyond the institution.

Use of personally identifiable information from education records for research that is not conducted for or on behalf of Miami Dade College, or that will result in external publication or presentation, requires either:

- Written student consent; or
- Use of data that have been fully aggregated or de-identified in accordance with FERPA standards.

Personally identifiable information may not be used for research purposes outside the scope of legitimate educational interest or institutional authorization, regardless of the individual’s role or access for other professional purposes.

De-Identification of Institutional Data

When research involves Miami Dade College institutional data and is conducted without written participant consent, data must be de-identified in accordance with institutional disclosure avoidance standards and/or FERPA prior to release or use.

De-identified data are data from which personally identifiable information has been removed or sufficiently masked such that a reasonable person in the school community could not identify an individual participant, either directly or indirectly.

At a minimum, de-identification requires:

- Removal of direct identifiers, including names, identification numbers, Social Security numbers, email addresses, and other unique personal identifiers.

- Review and mitigation of indirect identifiers, including combinations of demographic characteristics, program information, enrollment patterns, term data, modality, or other attributes that could reasonably permit re-identification.
- Aggregation or suppression of small cell sizes (data elements representing very small numbers of individuals) in tables, figures, or analytic outputs, consistent with institutional disclosure avoidance standards.
- Evaluation of the context of the dataset, including whether unique characteristics, small populations, or limited time frames increase the risk of re-identification.

Removal of names or identification numbers alone does not constitute de-identification. Data are not considered de-identified if an individual participant could be identified based on the remaining information or the context of the data.

De-identified datasets must be prepared or verified through Institutional Research or another authorized institutional office, as determined by institutional policy. Investigators may not independently de-identify institutional data unless explicitly authorized.

Institutional data that cannot be reasonably de-identified due to small sample sizes, unique characteristics, or elevated risk of re-identification may not be released without written participant consent, regardless of IRB approval.

POST APPROVAL REQUIREMENTS, CONTINUING REVIEW, MODIFICATIONS, AND STUDY CLOSURE

IRB approval at Miami Dade College is granted for a period of up-to two years. Approval remains in effect only while the research is conducted in accordance with the IRB-approved protocol, applicable regulatory requirements, and institutional policies.

Investigators cannot start data collection (including pilot data) until the following:

- Obtain a final letter of approval from the IRB,
- Obtain letters of approval required from any site, department, or division necessary when research involves their resources and/or subjects,
- Obtain legal, informed consent from human subjects or their representatives, when applicable.

Continuing review is required for all research approved by the IRB, including research determined to be exempt. Investigators must submit a continuing review application prior to the expiration of IRB approval. The submission must include sufficient information for the IRB to evaluate the ongoing conduct of the research, including study status, enrollment activity, protocol deviations, unanticipated problems, and any new information that may affect participant risk or willingness to continue participation. Refer to Change of Research section, page 20 for additional information.

IRB approval may be renewed or extended through the continuing review process. Approval of a renewal or extension is at the discretion of the IRB or designee and is not automatic. Research activities must cease

upon expiration of IRB approval if continuing review has not been completed and approval has not been renewed or extended.

Requests solely to extend the approval period, with no changes to the approved protocol, participant population, recruitment methods, consent process, data collection, data security measures, or level of risk, may be reviewed and approved by the IRB Chair or designee. Such requests do not require DRG or CASSC R&T review unless the Chair or designee determines that substantive changes, increased participant risk, or other factors warrant additional review. Administrative extensions approved by the IRB Chair or designee shall be documented in the IRB record and reported to the IRB at its next scheduled meeting.

Investigators must obtain IRB review and approval prior to implementing any modification to an approved research protocol, except when necessary to eliminate an immediate hazard to participants. Modifications include, but are not limited to, changes to the research purpose, design, methodology, study population, recruitment methods or materials, informed consent or assent documents, data collection procedures or instruments, data storage or security measures, research personnel, or the use of institutional data or education records.

Changes implemented to eliminate an apparent immediate hazard to participants may be made without prior IRB approval but must be reported to the IRB as soon as possible. The IRB will review such changes to determine whether additional review, modification, or corrective action is required.

The IRB may conduct monitoring activities for approved research as necessary to ensure ongoing compliance. Monitoring may include review of study records, consent documentation, recruitment materials, data security practices, and research procedures. Monitoring may be conducted on a routine, random, or for-cause basis at any time during the conduct of the research. Investigators are required to cooperate fully and provide requested documentation within the timeframe specified by the IRB.

At the conclusion of the research, investigators must notify the IRB that the study is complete. A study is considered complete when all data collection and analysis involving identifiable private information have concluded and no further interaction with participants or access to identifiable data will occur.

Investigators must promptly report unanticipated problems involving risks to participants or others, protocol deviations, and any unauthorized use or disclosure of identifiable data. Failure to comply with continuing review, modification, or reporting requirements may result in administrative suspension or termination of IRB approval.

INVESTIGATOR RESPONSIBILITIES AND MDC NAME IN RESEARCH DISSEMINATION

Investigators are responsible for ensuring that all research dissemination complies with institutional authorization requirements in addition to IRB approval.

The Miami Dade College name may not be used or referenced in any research dissemination materials, including posters, publications, reports, presentations, findings, or journal articles, without prior written permission from the College President or the College Provost.

Only the President or the College Provost may authorize use of the Miami Dade College name in disseminated research materials. IRB approval, funding approval, or departmental support does not confer such authorization and does not imply institutional endorsement of the research or its findings.
When authorization to reference Miami Dade College has been granted, documentation must be submitted to the IRB and retained as part of the official IRB record.

RECORDKEEPING, PUBLIC DISCLOSURE AND COMMUNICATION

The Institutional Review Board maintains records of its activities in accordance with 45 CFR §46.115, applicable state law, and institutional policy.

IRB records include sufficient documentation to demonstrate compliance with federal human subjects protection requirements and institutional oversight responsibilities. At a minimum, IRB records include:

- Records of all research applications, protocols, and supporting materials submitted for IRB review;
- Records of IRB determinations, including approvals, exemptions, disapprovals, suspensions, and terminations;
- Approved informed consent, parental permission, and assent documents, and any modifications thereto;
- Records of continuing review, renewals, extensions, and protocol modifications;
- Reports of adverse events, unanticipated problems involving risks to participants or others, and instances of noncompliance;
- Records of monitoring activities, findings, and required corrective actions;
- IRB membership rosters, including names, earned degrees, representative capacity, affiliations, and training documentation;
- Records of convened IRB meetings when required, including minutes sufficient to document attendance, actions taken, vote counts, and the basis for required changes or disapprovals.

IRB records are retained for at least three years after completion of the research, or longer when required by federal regulations, state law, sponsor requirements, or institutional policy. Records relating to research that is suspended or terminated are retained for the same minimum period.
Access to IRB records is limited to authorized IRB staff, IRB members, institutional officials, and regulatory authorities as permitted under federal and state law.

Public Disclosure

The IRB makes records available for inspection and copying as required under 45 CFR §46.115(b) and applicable public records laws.

Public disclosure of IRB records is limited to information required by law and does not include personally identifiable information about research participants, confidential institutional data, or information otherwise protected from disclosure under FERPA, HIPAA, or other applicable privacy laws.

Requests for IRB records are processed in coordination with appropriate institutional offices to ensure compliance with federal regulations, state public records requirements, and institutional confidentiality obligations.

Communication with Investigators

The IRB communicates all determinations, approvals, conditions, and requirements to investigators in writing. Written IRB determinations constitute the official record of IRB action.

Investigators are responsible for maintaining IRB approval documentation and for complying with all conditions of approval. Investigators must promptly respond to IRB requests for information and submit required reports, continuing reviews, modifications, and notifications in accordance with institutional timelines.

Failure to comply with IRB communication or documentation requirements may result in administrative action, including delay, suspension or termination of IRB approval.

Communication with Institutional Officials and External Agencies

The IRB reports findings of serious or continuing noncompliance, suspensions, or terminations of IRB approval to appropriate institutional officials in accordance with 45 CFR §46.113 and 45 CFR §46.115.

When required by federal regulations or sponsor requirements, the IRB also reports such actions to external oversight agencies, including the Office for Human Research Protections (OHRP), funding agencies, or other regulatory authorities.

All communications related to IRB oversight, reporting, and compliance are documented and retained as part of the official IRB record.

APPENDIX A
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 systematic and reflective inquiry conducted within an individual's own area of professional practice for the purpose of evaluating, improving, or informing instructional practices, student support services, programs, processes, or organizational effectiveness. Action research may involve faculty and students, administrators and employees, advisors and students, or other participant groups within an educational or organizational setting.

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 (FWA).

Belmont Report: A foundational statement of ethical principles for research involving human subjects, issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. The Belmont Report establishes three core ethical principles that guide the design, review, and conduct of human subjects research: Respect for Persons, Beneficence, and Justice. These principles form the foundation of modern human subjects protections and are reflected in federal regulations, IRB review criteria, and informed consent requirements. The Belmont Report may be accessed online through the U.S. Department of Health and Human Services. Find the Belmont Report online.

College Academic and Student Support Council (CASSC) Research & Testing Committee: At MDC, a standing subcommittee of the College Academic and Student Support Council responsible for supporting and overseeing institutional research activities. Following approval by the Miami Dade College Institutional Review Board (IRB), research applications are reviewed by the CASSC Research & Testing Committee to ensure alignment with institutional priorities and operational considerations. The Committee (i) advises on College research priorities, (ii) reviews and approves research studies conducted within the College, and (iii) reviews significant research findings and forwards them to appropriate College leaders and stakeholders.

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. Code of Federal Regulation website: https://www.archives.gov/federal-register/cfr

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 is 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 person, faculty member, department, course, etc. 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: Research that falls within one or more of the exemption categories under 45 CFR § 46.104 and generally involves no more than minimal risk to participants. Investigators may not self-determine that a study is exempt; exemption determinations must be made by the Miami Dade College IRB. Exempt research remains subject to applicable ethical principles, institutional policies, and regulatory requirements.

Expedited Review: A review process for research involving human subjects that does not qualify for exemption, involves no more than minimal risk to participants, and falls within one or more expedited review categories authorized under 45 CFR § 46.110. Expedited review does not require review by the convened IRB and may be used for certain initial reviews, continuing reviews, and minor modifications to previously approved research. Investigators may not determine for themselves that a study qualifies for expedited review.

FERPA: The Family Educational Rights and Privacy Act, a federal law that protects the privacy of student education records and governs the collection, use, disclosure, and release of personally identifiable information from those records. See full description here.

Full Board Review: A review process conducted by the convened IRB for research involving greater than minimal risk, vulnerable populations, or other studies requiring review by the full board. Approval requires review and vote by the IRB at a convened meeting with a quorum present.

HIPAA: The Health Insurance Portability and Accountability Act is a U.S. federal law that protects the privacy and security of certain health information, known as protected health information (PHI). In the research/IRB context, HIPAA is especially relevant when a study involves access to or use of identifiable health information. See rule description here.

Human Subjects: Under federal regulations, a human subject is a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction

with the individual, or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. See common rule description here.

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. See additional details here.

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 by the IRB that a research study has been reviewed and satisfies applicable ethical, regulatory, institutional, and legal requirements for the protection of human subjects.

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.).

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."

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.

APPENDIX B
COMMON RESEARCH PROJECT CLASSIFICATIONS AT MIAMI DADE COLLEGE

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.

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 may 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.

Grant-based Research Projects

Grant projects involving human subjects must be reviewed and approved through the MDC Research Approval process before starting the research. 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 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.

Special Projects

Special projects such as President's Innovation Fund, 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.

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.

APPENDIX C
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). 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/ , 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.

APPENDIX 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:

   a) Unanticipated problems involving risks to subjects or others, or

   b) Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB, or

   c) 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.

APPENDIX E
INFORMED CONSENT FORM TEMPLATE

Informed Consent Form Template
Miami Dade College Institutional Review Board
Based upon HHS.gov guidelines

Informed Consent
Title of Study

Purpose: Provide a statement that the study involves research and explain of the purpose of the research. Include a brief description about how the data will be used.

Procedure: Provide a description of the procedures to be followed and identify any procedures which are experimental. Provide an explanation of what participation in the study will entail and give the expected duration of the subject's participation. Provide a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

Risks: Provide a description of any reasonably foreseeable risks or discomforts to the subject. For research involving more than minimal risk, provide an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. See **Appendix 1** below for additional elements that are to be included in this section, if applicable.

Benefits: Provide a description of any benefits to the subject or to others which may reasonably be expected from the research.

Confidentiality: Provide a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

Rights: Provide a clause stating that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may withdraw from the study at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Contact information: Provide an explanation of whom to contact for answers to pertinent questions about the research and the subject's rights, and whom to contact in the event of a research-related injury to the subject. At minimum, this section must include the PI's contact information. If Miami Dade College is the PI's home institution, this section should also include the following statement: "Please contact Miami Dade College's IRB at IRB@mdc.edu if you have any questions, complaints, or concerns regarding your rights as a research participant."

Provide a statement of consent, such as "I have read and understood the information above, I voluntarily agree to participate in this study, and I certify that I am 18 years of age or older. All of my questions have been answered, and I have received a copy of this consent form."

_____ _____
Participant Name Date

_____
Participant Signature

_____
Participant Signature Authorizing Audio/Video Recording (if applicable)

Informed Consent Form Template
Miami Dade College Institutional Review Board
Based upon HHS.gov guidelines

Appendix 1

Additional Elements of Informed Consent

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

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) A statement that anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) A statement that any additional costs to the subject that may result from participation in the research;

(4) A statement that the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject

(6) A statement pf the approximate number of subjects involved in the study; and

(7) A statement that indicates the recording devices that will be used and a statement of consent to being recorded.

APPENDIX F
TIMELINE OF REVIEW PROCESS

The following visuals provide an overview of the review process for research applications submitted to the Miami Dade College Institutional Review Board. The process begins when an application is received and reviewed for completeness, followed by the applicable IRB and institutional review steps and issuance of the final determination. The timeframes shown are planning estimates that begin only after the IRB Office accepts the application as complete. Review durations may vary based on the completeness and complexity of the submission, the need for revisions or additional information, committee workload, and investigator responsiveness. Investigators should plan accordingly and may not begin recruitment, data collection, or other research activities until all required approvals have been issued in writing.

Institutional Review Board Process



Timeline of Review Process

OWNER / LANE	ACTIVITY / OUTPUT	1-5	6-10	11-15	16-20	21-25	26-30
Investigator	Research application submitted	●					
IRB Processor	Administrative Review; Prepare and route complete application	PREPARE + ROUTE					
IRB Chair / Alternate Chair	IRB Review; Chair assesses and makes the primary determination		INITIAL REVIEW				
Determination Review Group	DRG Review; Review application materials and provide advisory input			ADVISORY REVIEW			
CASSC R&T Committee	Committee Review; Conduct committee review and electronic vote				REVIEW + E-VOTE		
IRB Office	Final Determination; Issue and record the final determination communication						●