INTRODUCTION

I. INSTITUTIONAL AUTHORITY

II. PURPOSE

III. BASIC PRINCIPLES

IV. THE AUTHORITY OF THE IRB

V. THE IRB’S FUNCTIONAL RELATIONSHIPS

VI. THE MEMBERSHIP OF THE IRB

VII. MANAGEMENT OF THE IRB

VIII. PROCEDURES OF THE IRB

A. Initial Review

   Exempt

   Expedited Review

   Full Review

   Actions of the IRB

B. Continuing Review

C. Procedures Pertaining to Both Initial and Continuing Review

D. Adverse Event Reporting Guidance

IX. OPERATIONS OF THE IRB

X. RECORD REQUIREMENTS

XI. INFORMATION THE INVESTIGATOR PROVIDES TO THE IRB

XII. PRINCIPLES OF INFORMED CONSENT

XIII. CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS

APPENDIX 1: MIAMI DADE COLLEGE FWA# (pending)
INTRODUCTION

Miami Dade College encourages and supports the scholarly endeavors of students, faculty, and staff of the College. 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. 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 only volunteer to participate in research after being provided with legally effective informed consent; and 5) any research is conducted in an ethical manner and in compliance with established standards.

Once approved by MDC IRB, the research proposal is routed, for review, to the College-Wide Academic and Student Support Council Research and Testing (CASSC R&T) Committee; all research – regardless of whether human subjects are involved or not – must be reviewed for approval by CASSC R&T. CASSC R&T evaluates the proposed research to determine whether the pending research will be a good fit within MDC in addition to not creating undue burden on MDC resources. Those individuals seeking to conduct research may not solicit subject participation or begin data collection until they have obtained approval from CASSC R&T, with IRB clearance prior to CASSC R&T review if human subjects are involved.

Some research projects involving human subjects are exempt from IRB approval requirements. The types of research generally exempt from IRB approval requirements include normal educational practices such as work undertaken as a part of a course; educational tests when the subjects are not identified; and surveys or interviews in which the subjects volunteer and are not personally identified.

The Institutional Review Board (IRB) for Human Subjects Research at Miami Dade College has responsibility to oversee procedures for carrying out the College’s commitment to protect human subjects in research. The role of the IRB is to review proposed research projects that involve the use of human subjects; ensure that the individuals involved in the project are treated ethically; ensure that all subjects are provided with substantial information about the study and consent to be a subject in the study; and that all private information will be handled with confidentiality.

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

Both MDC IRB and CASSC R&T are authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College involving human subjects.

I. INSTITUTIONAL AUTHORITY.

College Procedure 1321 – “Authorization to Conduct Research” establishes and empowers the Miami Dade College (MDC) human subjects’ protection committee or Institutional Review Board (IRB). Currently MDC has one committee, registered with the federal Office for Human Research Protections (OHRP) as IRB00007621. This committee is hereinafter referred to as “the IRB.”

According to the terms of the Federal Wide Assurance, Miami Dade College adopts the following reporting requirements:

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

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

Upon receipt of such information, or if a research project is suspended or terminated by the IRB, the IRB Chair will make a written report to the Miami Dade College IRB committee, the College-Wide Academic and Student Support Committee Research and Testing (CASSC R&T) Committee, the President of Miami Dade College, the head of any department or agency conducting or supporting the research, any applicable regulatory body, and to OHRP.

II. PURPOSE.

The primary purpose of the IRB is to protect the welfare of human subjects used in research.

III. BASIC PRINCIPLES.


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

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

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

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

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

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

6. All research programs that involve human subjects must be reviewed by MDC IRB and CASSC R&T and must receive approval of a formally constituted review prior to their initiation or prior to initiating any changes to the protocol. Continuing research programs are subject to periodic review, to be carried out on an annual basis.

Guidelines for Granting IRB Review

In making its decision to approve submitted proposals, the first priority of CASSC R&T must be a focus on factors promoting MDC’s mission. Any submitted proposal must be in the best interests of MDC’s faculty, staff, and students. The first priority of MDC’s IRB when reviewing submitted proposals is the safety and well-being of human subject participants in the proposed research.

In reaching its conclusions concerning the granting of approval to a research proposal, MDC IRB will take into consideration the following factors:
a. Are the rights and welfare of the subjects involved in the research being adequately protected?

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

c. Has the researcher identified the potential benefits of the project? Have all possible benefits of the research proposal been maximized, including benefits to the participant, to the researcher, to MDC, and to the educational and scientific community at large?

d. Is the research proposed being conducted in an ethical manner? Are the procedures involved in the research study in compliance with all applicable and established standards and procedures?

In reaching its conclusions concerning the granting of approval to a research proposal, CASSC Research and Testing Committee will take into consideration the following factors:

a. Has the researcher made a strong and compelling case that the research will provide insight into learning and student success factors and is the research aligned with MDC’s mission?

b. Have all costs which will be incurred by the MDC community been fully considered; do the benefits outweigh the costs, and has provision been made to reimburse MDC for any unusual data collection expenses?

c. In the opinion of the CASSC, is the research design sufficiently rigorous to lead to meaningful insights?

d. If the researcher is not employed by MDC, has the researcher identified a MDC full-time faculty or staff member who is willing to serve as the internal sponsor for the research? Has the individual acknowledged acceptance of this role and has the individual identified the value of the research findings to his/her area of responsibility?

e. In the opinion of CASSC, have the individuals making up the research sample been overly burdened with requests to serve as research subjects?

IV. THE AUTHORITY OF THE IRB.

A. Miami Dade College has applied for a Federalwide Assurance (FWA) through OHRP (status pending). As part of this Assurance, MDC will agree to consider all research involving the use of humans as research participants as being subject to federal human subject protection regulations - regardless of the source of funding - if one or more of the following apply:

1. The research occurs at this institution, or
2. The research is sponsored by this institution, or
3. The research is conducted by or under the direction of any employee or agent of this institution, or
4. The research is conducted using any property or facility of this institution, or
5. The research involves the use of this institution’s non-public information to identify or contact human research subjects or prospective subjects, or
6. The research will directly involve any employees, students or agents of this institution.

In some instances, students may be involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals. The course instructor is responsible for determining whether such activity is classified as those kinds of activities that require MDC research approval, including review and approval by the IRB. If the instructor has any doubt concerning the classification of these activities, he/she is encouraged to visit the IRB website at www.mdc.edu/ir to gain further explanation and guidance on whether research approval may be needed. Alternately, the chair of the IRB can be contacted via email at oie@mdc.edu for additional guidance.
B. The IRB reviews all projects and programs involving human subjects in accordance with applicable federal regulations, and sponsor policies and guidelines.

C. The IRB provides continuing advice and counsel to personnel engaged in activities involving human subjects.

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

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

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

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

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

V. THE IRB’S FUNCTIONAL RELATIONSHIPS.

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

B. The IRB advises and makes recommendations to the President, 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.

VI. THE MEMBERSHIP OF THE IRB.

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

B. The IRB is composed of seven (7) voting members. Three of the members of the IRB will be composed of the three (3) members of the CASSC R&T research subcommittee. All appointments are made by Executive Memorandum and reported to OHRP.

C. The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of MDC regulations, relevant law, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed.

D. The IRB must include both men and women, at least one member whose primary concerns are in science areas, one whose primary concerns are nonscientific areas, and at least one member who is not otherwise affiliated (either directly or through immediate family) with the MDC.
E. No person shall be excluded from serving on the IRB based on sex, race, color or national origin.

VII. MANAGEMENT OF THE IRB.

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

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

C. Members of the IRB shall be appointed for a period of two (2) years. However, the term of appointment may be terminated by notice of the Committee member to the Chair or by notice from the Chair. If a member finds that he/she is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is no reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately. In either event, the Chair will appoint a replacement. Tenure on the IRB may be extended by mutual agreement between the member and the Chair.

D. All IRB members are required to undergo formal training at the time of their initial appointment. Training that satisfies this requirement is the online Responsible Conduct of Research Workshop offered by MDC’s College Training and Development [http://www.mdc.edu/ctd/catalog/workshops/ctd0768.htm]. The IRB Chair will maintain a record of all IRB members’ completed training.

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

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

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

H. Conflict of interest policy and procedure

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

2. Investigators and IRB members who are MDC employees and who apply for federal grants and contracts are subject to the MDC Conflict of Interest Policy [see https://www.mdc.edu/policy/Chapter2/02-II-23.pdf].

3. Other conflict of interest guidelines specifically for IRB members are found in section XIV of this document.

VIII. PROCEDURES OF THE IRB.

A. Initial Review.

Prospective investigators must submit one (1) original of the “Miami Dade College Research and Testing Committee Research Application” to the IRB Chair at least two (2) months prior to the start date of the anticipated research project in order to provide time for review and processing. Copies of the forms are available via https://www.mdc.edu/ir/rt/researchproposals.aspx.
Under the auspices of the IRB, the IRB Chair, or a designated member of the IRB, will review the Research Application to determine if the research proposal is eligible for "exempt" (see below) or expedited review or, if significant risk is inherent in the study, refer the petition to the IRB for full board review.

1. Exempt:

Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise [see 45 CFR 46 (Department of Health and Human Services): http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.110]. Exempt types of research include:

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

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

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

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

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

Research deemed exempt by the IRB Chair, or a designee of the IRB, will be forwarded to the CASSC Research and Testing Committee research subcommittee for review and approval, followed by presentation and review of the research proposal by the full CASSC Research and Testing Committee. Once the CASSC Research and Testing Committee have made its decision, the IRB Chair will inform the investigator via an Exempt Memo which will be signed and dated by the IRB Chair and a copy maintained in the IRB Files. The decision of the CASSC Research and Testing Committee is final; no appeal of disapproved research will be allowed.

2. Expedited

Under federal regulations certain types of research qualify for an ‘expedited’ review [see 45 CFR 46.110]. These are activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

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

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute
Research Approval Procedures, Standard Operating Procedures

citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electretorinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

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

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

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
Research deemed expedited by the IRB Chair or his/her designee will be reviewed by either the IRB Chair or a selected member from the IRB. The IRB Chair or selected IRB member may either: (1) approve the research; (2) approve with conditions; or (3) forward to the IRB for full review. Under the expedited process, the IRB Chair or selected IRB member can approve the research but may not disapprove the research proposal. If the research is approved, the proposal is forwarded to the CASSC Research and Testing Committee research subcommittee for review and approval, followed by presentation and review of the research proposal by the full CASSC Research and Testing Committee. Once the CASSC Research and Testing Committee have made its decision, the IRB Chair will inform the investigator via an Approval Memo which will be signed and dated by the IRB Chair and a copy maintained in the IRB Files. The decision of the CASSC Research and Testing Committee is final; no appeal of disapproved research will be allowed.

3. Full Review

All research requests that are not exempt and do not qualify for expedited review OR were not approved under expedited review must be reviewed by the full IRB. The IRB Chair will convene the full IRB after determining that full review is needed. Prior to the meeting, copies of the Research Application and all related documentation will be supplied to each member of the IRB. Full IRB review may lead to either: (1) approval of the research; (2) a request for modifications to the proposal in order to secure IRB approval; (3) table the discussion and approval of the proposal to a later meeting of the full IRB; or (4) disapproval.

If the research is approved under full IRB review, the proposal will be forwarded to the CASSC Research and Testing Committee research subcommittee for review and approval, followed by presentation and review of the research proposal by the full CASSC Research and Testing Committee. Once the CASSC Research and Testing Committee have made its decision, the IRB Chair will inform the investigator via an Approval Memo which will be signed and dated by the IRB Chair and a copy maintained in the IRB Files. The decision of the CASSC Research and Testing Committee is final; no appeal of disapproved research will be allowed.

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

The investigator should be available to discuss the protocol and/or consent forms at the discretion of the IRB.

4. Actions of the IRB:

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

Approved

When a protocol has been approved, the Chair completes the Approval Memo, signs and dates it, and distributes one copy of the memo to the investigator and place one copy in the IRB files. Approval of the protocol will be based on the following:

a. The extent to which the protocol makes explicit in design and procedures the protection of subjects’ rights.
b. Should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative, sufficient justification that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any such deception.

c. Assurances of acceptable debriefing, if appropriate.

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

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

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

e. Anticipated benefits, if any.

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

g. The adequacy of procedures for securing informed consent from the subject.

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

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

Approved Subject to Restrictions

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

Tabled

Tabled action means that the protocol was not sufficiently complete for the IRB to reach a final decision. In this case, the investigator is notified by the Chair of the IRB and the additional information necessary for completion of the IRB review is requested. In the case of a tabled protocol, the investigator may be invited to attend an IRB meeting to present/clarify the protocol for the Board.

Disapproved

If the protocol is disapproved, the investigator will be informed in writing of the reasons for disapproval. The decision to disapprove the research is final and may not be appealed.
B. Continuing Review.

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

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

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

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

C. Procedures pertaining to both Initial and Continuing Review.

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

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

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

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

D. Adverse Event Reporting Guidance.
Research Approval Procedures, Standard Operating Procedures

1. The Office of Human Research Protections (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 Institutional Review Boards 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).

2. Investigator(s) and any Miami Dade College employee will report to the Chair of the IRB Committee any of the following upon knowledge of such:
   a. Unanticipated problems involving risks to subjects or others; and
   b. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

IX. OPERATIONS OF THE IRB.

A. IRB meetings will be convened as necessary at MDC.

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

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

D. Voting requirements

1. Except when an expedited review procedure is used, a quorum of the IRB, duly convened through written notice, shall be a majority of voting members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas.

2. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. IRB meetings conducted via telephone conference call are permitted pursuant to OHRP guidelines.

3. Investigators, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).

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

E. Appeals

The decision of the MDC Institutional Review Board and/or CASSC Research and Testing Committee are final.

F. Amendments
1. Amendments are 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.

**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 **minor changes** to a research study include but are not limited to, the following:
- Addition or deletion of study team members;
- Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study;
- Removal of research procedures that would thereby reduce the risk to subjects;
- Addition of non-sensitive questions to unvalidated survey or interview procedures;
- Addition of or revisions to recruitment materials or strategies;
- Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors).

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.);
- Addition of research procedures that involve greater than minimal risk to subjects;
- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation;
- Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

2. Level of Review for Amendments

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

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

G. Grievances

The IRB shall be informed of all grievances (e.g., of a research subject against an investigator) and, if requested, the board will act in an advisory capacity.

X. RECORD REQUIREMENTS.

A. The IRB prepares and maintains adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by investigators.

2. Detailed minutes of IRB meetings, showing:
Research Approval Procedures, Standard Operating Procedures

a. Members present (any consultants/guests/others shown separately).

b. Results of discussions on debated issues and record of IRB decisions.

c. Record of voting (showing votes for, against and abstentions).

3. Records of continuing review activities, updated consent documents and summaries of ongoing project activities. Consent documents are stamped to show IRB approval and date of approval expiration.

4. Copies of all correspondence between IRB and the investigators.

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

6. Adverse reactions reports and documentation that the IRB reviews such reports.

7. Emergency use reports.

8. General project information provided to subjects (e.g., fact sheets, brochures).

These documents and records shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

In addition, the IRB maintains a permanent record of the list of current IRB members and written procedures for research approval at MDC (this document).

B. All forms submitted or retained as evidence of informed consent must be preserved by the investigator indefinitely. Should the investigator leave MDC, signed consent forms are to be transferred to the IRB Chair.

XI. INFORMATION THE INVESTIGATOR PROVIDES TO THE IRB.

A. Professional qualifications to do the research (including a description of necessary support services and facilities);

B. Appropriate MDC review form including protocol summary;

C. Complete study protocol which includes/addresses:

1. Title of the study and summary of the research to be conducted,

2. Purpose of the study (including the expected benefits obtained by doing the study and how risks are reasonable in relation to expected benefits),

3. Sponsor of the study, if applicable,

4. Subject inclusion/exclusion criteria (including scientific and ethical reasons for excluding subjects who might otherwise benefit from the research),

5. Justification for use of any special/vulnerable subject populations (such as children [under age 18], prisoners, or handicapped, economically/educationally disadvantaged, or mentally disabled persons),
6. Study design (including, as needed, a discussion of the appropriateness of research methods),

7. Description of procedures to be performed,

8. Provisions for managing adverse reactions,

9. Circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations,

10. Procedures for documentation of informed consent, including any procedures for obtaining assent from minors (‘minor’ is defined in Florida as an individual under the age of 18), using legally authorized representatives (see XII.B.&C.), witnesses, translators and document storage,

11. Remuneration to subjects for their participation,

12. Any compensation for injured research subjects,

13. Provisions for protection of subject’s privacy,

14. Extra costs to subjects for their participation in the study,

15. Any materials used to recruit subjects,

16. Survey instruments, questionnaires, or other materials provided to subjects;

D. Investigator’s brochure (when one exists);

E. The case report form (when one exists);

F. The proposed informed consent document, including translated consent documents, as necessary, considering likely subject population(s);

G. Copies of relevant grant applications (if any);

H. Requests for changes in study after initiation including changes to consent forms;

I. Reports of unexpected adverse events and unanticipated problems involving risks to subjects, including, if available, data safety monitoring reports;

J. Progress/interim reports that include reports of protocol violations and/or deviations and any other instances of investigator non-compliance.

XII. PRINCIPLES OF INFORMED CONSENT.

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

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

B. “Informed consent” means insuring that potential subjects and/or their legally authorized representatives are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. For more information regarding the necessary basic elements for consent: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116.

The IRB may approve a telephonic consent procedure under which the subject’s legally authorized representative (“LAR”) is sent a faxed or hand-carried version of the informed consent document, a consent interview is conducted by phone while the LAR has the document in hand, and the LAR signs and returns the signed document to the investigator by return fax (or courier) before the subject is enrolled in the study. In cases where this process is used, a witness who is not connected to the study (e.g., as an investigator, coordinator, etc.) should monitor the consent process.

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

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

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

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research (e.g., a cover letter). Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.

Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the investigator must include justifiable reasons in the protocol.
The IRB may also choose to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

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

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

XIII. CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS.

A. An IRB member is said to have a conflicting interest whenever that IRB member, or spouse, or dependent child of the member:

1. Is an investigator or sub-investigator on the protocol;
2. 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 Policy, https://www.mdc.edu/policy/Chapter2/02-II-23.pdf for the definition of “significant financial interest”);
3. 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
4. Has identified him or her self for any other reason as having a conflicting interest.

B. It is the responsibility of each IRB member to identify and avoid any situations in which he or she, 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 assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer. In order not to delay the review process, it is essential that potential reviewers peruse the matters for which they are assigned reviewers immediately upon receipt to determine whether they may have a conflict.

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, clarifications, etc. 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 a member (by name) when he or she leaves the meeting during deliberations and actions regarding matters for which they have, or may be perceived to have, a potential conflict of interest.