MORGAN STATE UNIVERSITY

POLICIES AND PROCEDURES
FOR PROTECTION OF HUMAN SUBJECTS IN RESEARCH
1.0 **Introduction**

This document prescribes the policies and procedures of Morgan State University for the protection of human subjects in research and related activities conducted under the auspices of the University. It also serves to implement the Department of Health and Human Services assurance of compliance, policies, regulations (45 CFR 46), and laws passed by the Maryland Legislature.

2.0 **Applicability**

2.1 The policies and procedures described herein apply to all research development and related activities involving human subjects for which Morgan State University is a responsible participant regardless of the source of funding or whether there is funding, except for research exempted/waived under DHHS regulations (45 CFR 46.101).

2.2 Safeguarding the rights and welfare of subjects in research and related activities is primarily the responsibility of this institution.

2.3 which receives or is accountable for the funds awarded for the support of the activity. In order to meet this institutional responsibility, it is the policy of this University that no research activity involving human subjects shall be undertaken unless the Institutional Review Board (IRB) has reviewed and approved such activity. This institution will submit a certification of such review and approval in accordance with any requirements of such action.

2.3 The IRB may refer questions regarding the applicability of policies and procedure to the University legal counsel.
3.0 **Statement of Policy on Human Subjects**

Morgan State University is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the Belmont Report). In addition, the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) are upheld. Morgan State University has chosen to require that research covered by its assurance be conducted in accordance with the requirements of 45 CFR 46, regardless of the source of funding, or whether there is funding.

Underlying the policy of Morgan State University are the following basic principles embodied in the policy statement contained in part 46 of Title 45. These principles will serve to assist the University in discharging its responsibilities, through its authorized representative, the Institutional Review Board, to protect the rights and welfare of human subjects, as well as to assist faculty engaged in relevant research from unknowingly committing unethical acts. Morgan State University bears full responsibility for the performance of all research involving human subjects covered by this set of policies and procedures.

3.1 Research involving human subjects is an important and necessary activity of the University and must be conducted in an ethical manner. Such research has the encouragement of the University when the following principles are fulfilled:

A. Risks are minimized by using the safest procedures consistent with sound research design.

B. The anticipated benefits to the subjects and others outweigh the risks

C. Important knowledge may be reasonably expected to result.

D. The privacy of the subject is protected and confidentiality of data is maintained.

E. Before any person is a subject of research, informed, voluntary, competent and understanding consent must be obtained from that person, or a legally authorized representative. This involves a full and careful explanation in language that is understandable by laypersons. The consent of the Subject must be obtained without duress, deception, or the withholding of
information. This means that the purpose of the research, the procedures to be followed, the possible risks involved, and the benefits to result from the activity, are explained to the subject and the subject is invited to ask questions. The subject should also be told that he/she is free to withdraw from the research at any time without bias or jeopardy.

Modification of the written informed consent requirement may be allowed when justified and documented. A policy of allowing a waiver or alteration of written informed consent will be considered as follows (Cf., 45 CFR 46.116):

The Institutional Review Board adheres to the consent procedure as set forth in 45 CFR 46.116(a) and (b), or waives the requirement to obtain informed consent provided the Institutional Review Board finds and documents under 46.116(c) that:

1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

   (a) Programs under the Social Security Act or other public benefit or service programs;

   (b) Procedures for obtaining benefits or services under those programs;

   (c) Possible changes in or alternatives to those programs or procedures;

   (d) Possible changes in method or levels of payment for benefits or services under those programs; and

2) The research could not practically be carried out without the waiver or alteration.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of the informed consent set forth in 45 CFR 46.116(a) & (b), 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 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.

The Institutional Review Board has the authority to observe or have a third party observe the consent process and the research.

F. Research involving populations such as children, prisoners, parolees, addicts, AIDS victims, the mentally or physically infirm, and others in conditions of dependency, helplessness, or deprivation, may require additional precautions and procedures to assure their protection.

G. Whenever medical or physical intervention is used, or whenever the subject's environment is likely to be changed beyond normal limits, the research must be performed in conformity with established standards of health care practice under proper health care supervision.

H. Subjects may be compensated for time and travel for their participation. Where subjects are drawn from particularly vulnerable groups, however, compensation may under certain circumstances cast doubt upon the voluntariness of their consent. In such circumstances the IRB may either limit or disapprove compensation. Vulnerable groups include, children, individuals with questionable capacity to consent, prisoners, fetuses and pregnant women, terminally ill, students/employees, and comatose patients.

I. If participation as a subject is part of the academic work of a subject, informed consent procedures must be sufficiently sensitive not to be coercive and clearly not be made a mandatory requirement of the course. Students not wishing to participate should be given a choice of a reasonable alternate academic activity.

J. Before any research project which uses human subjects can be started and conducted at Morgan State University, the project must be submitted for review to the Institutional Review Board. Classroom activity, laboratory courses or field assignments are normally not classified as research, and therefore are not reviewed. All proposals submitted to federal agencies must
have approval of the IRB prior to submission. All proposals must comply with the University's policies, DHHS Policies and Regulations on Protection of Human Subjects (45 CFR 46).

K. It shall be the responsibility of the principal investigator to make certain that all current policies and procedures governing the participation of humans as research subjects are adhered to in his/her research. In the event that the principal investigator is an undergraduate or graduate student, then the supervisory full-time faculty member is the responsible person. All proposals detailing the use of human subjects in research should contain the statement, "The Rules Governing the Participation of Human Beings in Research at Morgan State University have been reviewed. This proposal and the subsequent research will be conducted within the framework of these rules."

L. Constructive communication shall be encouraged and promoted among the principal investigator, human subjects, research administrators, institutional officials, and all other relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of subjects.

Supplemental to DHHS regulations or applicable law are ethical codes developed and adopted by various professional associations which will assist and guide investigators in various disciplines in protecting the rights of human subjects. They do not supplant or substitute for DHHS regulations or this document.

4.0 The Institutional Review Board

4.1 Membership Composition. The Institutional Review Board must be composed of sufficient members (no less than five) with varying background to assure complete and adequate review of research projects and activities conducted by Morgan State University. In addition to a balance of research expertise, the Committee shall also include persons able to determine the acceptability of a research proposal with respect to institutional commitments and regulations, applicable law, standards of professional conduct and practice and community attitudes.

The IRB will be sufficiently qualified through the experience and expertise of its members, as well the diversity of the members’ backgrounds, in order to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the Board shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable
law, and standards of professional conduct and practice. The Committee shall therefore include persons knowledgeable in these areas. If the Board regularly reviews research that involves a vulnerable category of subjects, including but not limited to subjects covered by other subparts of this part, the Board shall include one or more individual who are primarily concerned with the welfare of these subjects.

No Board may consist entirely of men or entirely of women, or entirely of members of one profession. The Committee shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy. The Board shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

The members shall be identified to DHHS by name, earned degrees (if any), position or occupation, representative capacity, and pertinent experience indicative of members’ anticipated contribution to Committee deliberations. In conforming with federal regulations, all permanent changes of membership, replacement or additions, are reported to DHHS (OHRP, National Institutes of Health, DHHS, Bethesda, Maryland 20892).

No Board may have a member participating in its initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the Board. These individuals may not vote with the Institutional Review Board.

4.2 Method of Appointment. The administrative authority for the protection of human subjects at Morgan State University has been delegated to the Assistant Vice President for Sponsored Programs.

The members of the Institutional Review Board are nominated by the IRB Administrator in consultation with the Assistant Vice President for Sponsored Programs. The IRB is administratively responsible to the Assistant Vice President for Sponsored Programs.

4.3 Meetings, Quorum, Voting and Minutes. The IRB will normally meet on the third Thursday of the month as necessary. If an emergency meeting is necessary in order that the Committee’s action conform to any aspect of DHHS policy (45 CFR 46), such a meeting will be called by the chair.
4.3.1 **Quorum and Voting.** A quorum of the Board is defined as a majority of the total membership, and in order for official Committee business to be conducted, a majority must be present. No member of the Institutional Review Board shall be involved in either the initial or continuing review of an activity in which he or she has a professional responsibility, except to provide information requested by the Board and will not vote on any activity in which he or she has a conflicting interest. When the Board is considering an activity that involves testing a new drug, the FDA regulations require that the quorum of the Committee include at least two members who are licensed to administer drugs and at least one member who is not licensed.

4.3.2 **Minutes.** Provision must be made for taking written minutes or recordings of the proceedings of all meetings. Such minutes or recordings must include at least the following information: date, time and place of meeting, members of the Committee present or excused, an accurate description of all actions proposed, discussed or taken, and the names of the members who proposed each motion. The minutes also shall include applications discussed, the names of persons making statements or presenting material to the Board, the action taken with respect to the statements and material presented, and a listing of Administrative Approvals (Expedited Reviews) by the Chair since the previous minutes. All minutes will be stored in a confidential and secured file cabinet and are available for a period of at least three years.

5.0 **Review Process**

5.1 **Applicant's Procedure.** All research proposals to external agencies are routed through (1) the departmental chair, (2) dean of the school/college, and (3) Office of Sponsored Programs and Research.

The review process begins with identification of those projects or activities which involve human subjects. The University Proposal Routing and Approval form (appended) which must be completed by each person submitting a proposal, contains a question which determines whether human subjects will be used in the research project.

If the research project involves human subjects, it is the responsibility of the PI to complete the Human Subjects Approval Form and submit along with the protocol, project summary and other relevant materials to the IRB Administrator in the Office of Sponsored Programs and Research. Copies of the application packet will be sent to each member of the Board for review prior to the IRB meeting. It is, therefore, to the advantage of the applicant to submit all materials to the Office of Sponsored Programs and Research.
Programs and Research for review by the Board well in advance of the published submission deadline.

Time should be allowed for the possibility of changes to be incorporated into the protocol, to avoid subsequent delays in the project start date.

After the Institutional Review Board has approved the proposal, any significant changes which are made in the proposal must be reported to the Board through the IRB Administrator and IRB Chairperson for the Board's approval. These approvals will be kept on file and are available for a period of at least three years.

5.2 Exempted Research Activities.

(A) DHHS published its revised regulations governing research involving human subjects in the Federal Register of June 18, 1991, altering the scope of previous DHHS regulations by exempting categories of research that present no more than minimal risk to human subjects. At Morgan State University, the Institutional Review Board accepted the exempted research categories. Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt:

(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 subject's 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) above if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or

(ii) federal statutes(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 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 of the Food Safety and Inspection Service of the U.S. Department of Agriculture.

5.3 Committee Review Procedures

5.3.1 Preliminary Review. The Chair of the IRB will conduct a preliminary review of each protocol, proposal, and related documents to determine whether the materials
submitted (particularly the protocol) are sufficiently informative and complete to constitute a basis for a fair review by the entire Board. The protocol, proposal and related documents are to be submitted to the Chair of the IRB through the Office of Sponsored Programs in typewritten form for initial screening. The IRB Administrator reviews all materials, at which time a determination is made whether they qualify for Exempt status, may be approved as Expedited Review, or must be forwarded to the IRB for Full Board review. An inadequate protocol is returned to the investigator (applicant) to bring it into conformity with specifications given in Section 7.0.

5.3.2 Committee Review. In evaluating a research project, the following are basic considerations:

(1) Are the risks so outweighed by the potential benefit to the subjects themselves or by the importance of the knowledge to be gained as to warrant a decision to allow them to accept these risks?

(2) Are the risks to subjects minimized (i) by using procedures which are consistent with sound research design, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes?

(3) Is the selection of subjects equitable?

(4) When appropriate, does the research plan make adequate provision for monitoring the data collected to ensure the safety of subjects?

(5) When appropriate, are there adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data?

(6) Are the rights and welfare of the subjects adequately protected? Have steps been taken to protect the subject's personal privacy and the confidentiality of information received from the subject?

(7) Has appropriate informed consent to participate in the study been obtained? Have all the elements of informed consent been included, except where a request for waive or alteration has been submitted?

There are eight basic elements of informed consent (45 CFR 46.116):

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

(b) additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;
3. any additional costs to the subject that may result from participation in the research;
4. the consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. a statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject; and
6. the approximate number of subjects involved in the study.
(c) An IRB may approve a consent procedure which does not include, or which alter, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is 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; and
2. the research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the 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.

(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

The following IRB Procedures will be followed:

5.3.2.1 Review Board receives protocol.

A. The IRB Chair shall receive all research protocols from the IRB Administrator in the Office of Sponsored Programs and Research.

5.3.2.2 Determination of Review Procedure

A. The IRB Chair shall determine whether the research protocol meets the criteria necessary for an Expedited Review process.
B. The IRB Chair refers all research protocols to either Full Board Review, Expedited Review, or approves Exemption status.

5.3.2.3 Expedited Review

(A) DHHS published its revised regulations governing research involving human subjects in the Federal Register of November 9, 1998, altering the scope of previous DHHS regulations by exempting categories of research that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. These activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of the subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review -- expedited or convened-- utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.
Research Categories Activities For Expedited Review

(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:

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

(d) 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.

Children are defined in DHHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted” 45 CFR 46.402 (a).

(3) Prospective collection of biological specimens for research purposes by non-invasive means.

Examples: (a) hair and nail clippings in a non-disfiguring 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 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 sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through non-invasive 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 evaluated 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 involved input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility resting 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 the HHS regulation for the protection of human subjects. 45 CFR 46.101 (b)(4). 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 the HHS regulations for the protection of human subjects.

(8) Continuing review of research previously approved by the convened IRB as follows:
   (e) 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
   (f) where no subjects have been enrolled and no additional risks have been identified; or
   (g) 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.

G. Expedited review shall be conducted by the IRB Chair or by one or more of the experienced Institutional Review Board members designated by the chairperson to conduct the review.

H. The IRB member(s) conducting the expedited review may exercise all of the authorities of the Board except that the reviewer(s) may not disapprove the research. The reviewer(s) shall refer any research protocol which the reviewer(s) would have disapproved to the full Board for review. The reviewer(s) may also refer other research protocols to the full Board whenever the reviewer(s) believe(s) that full Board review is warranted.
5.3.2.4 Full IRB Review.

A. Research protocols scheduled for review shall be distributed to all members of the Institutional Review Board prior to the meeting.

B. When it is determined that consultants or experts will be required to advise the Board in its review of a protocol, the research protocol shall also be distributed to the consultants or experts prior to the meeting.

C. All IRB initial review and continuing review shall be conducted at convened meetings and at timely intervals.

D. A majority of the membership of the IRB constitutes a quorum and is required in order to convene a meeting for the review of research protocols.

E. An IRB member whose concerns are primarily in non-scientific areas must be present at the convened meeting before the Board can conduct its review of research.

F. For a research protocol to be approved, it must receive the approval of a majority of those members present at the convened meeting.

G. The Institutional Review Board may not have a member participating in the Board's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the Board.

H. In cases where research activities were initially approved under expedited procedures and subsequently reviewed by non-expedited procedures, the decisions reached at the convened meeting shall supersede any decisions made through the expedited review.

5.3.2.5 Criteria for IRB Approval of Research.

In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

A. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using
procedures already being performed on the subjects for diagnostic or treatment purposes.

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

C. Selection of subjects is equitable. In making this assessment the Committee should take into account the purposes of the research and the setting in which the research will be conducted.

D. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

E. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

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

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

5.3.2.6 IRB notification to research investigators and the Office of Sponsored Programs.

A. The IRB shall notify the research investigators and the IRB Administrator in the Office of Sponsored Programs and Research in writing of the Board's decisions, conditions and requirements.

B. The IRB shall also provide to the research investigator reasons for any decision to disapprove a research protocol and an opportunity for
the research investigator to respond. Reasons for disapproval shall also be transmitted to the Office of Sponsored Programs and Research by the IRB.

5.3.3 Continuing Review.

Projects extending beyond a period of one year require at least annual review and approval by the IRB. The Board may request more frequent reviews when the element of risk and the nature of the project warrant them. The Board uses written procedures for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no substantive changes have occurred since last IRB review. For this purpose, the Board will inform the investigator in writing about its decision whether or not project review more often than the investigators are required. The Committee Chair will keep track of these special requirements on their respective calendars to ensure that the requirements will be enacted.

If the research protocol remains substantively unchanged, the responsible investigator need only write the Board a brief memo, assuring the Board that the actual use of human subjects has been conducted in accordance with the approved protocol and conditions and that no changes are intended. Continuing studies with no substantive changes must be resubmitted for review and approval after three years of operation (in the 4th and 7th years).

If, in the conduct of research, problems involving risks to human subjects arise which were not foreseen in the approved protocol, the problem must be reported to the Board through the IRB Administrator in Office of Sponsored Programs and Research on extension 3447. In the case of DHHS projects, the Committee will report such problems to the DHHS (OHPR, The National Institutes of Health, DHHS, Bethesda, Maryland 20892) through the Office of Sponsored Programs.
6.0  **Protocols**

A protocol is a statement by the investigator which conforms to provisions 6.1 through 6.10 below. A protocol must be submitted to the Board for all research, development, or related activities in which human subjects are involved or in which there is a question of involvement. Protocols will be maintained for a period of at least three years following, completion of the data collection. A protocol must, contain the following information:

6.1  A brief summary of the nature and purpose of the research, development, or related activity.

6.2  A description of the subjects and the selection process, indicating explicitly whether any are minors or otherwise members of vulnerable populations (mentally or physically infirm, prisoners, or other individuals whose ability to give voluntary informed consent may be in question). The protocol must also indicate if any subjects are Morgan State University students.

6.3  A description of how the subjects are involved in the research.

6.4  A description of the benefits, if any, to the human subjects and of the contributions to knowledge.

6.5  A description of the risks, if any, to the subjects. Such risks may be physical, psychological, and/or social.

6.6  A description of the means to be taken to minimize such risks, including the means by which the subject's personal privacy is to be protected and the confidentiality of the information obtained from him or her maintained. Occasionally some human subjects do not want confidentiality of information maintained; if that circumstance pertains, it should be specified clearly in the protocol.

6.7  A description of the procedures to be used in obtaining and documenting the informed consent of the subjects. If written consent forms are to be used, a copy of the consent form and a verbatim copy of any accompanying oral instructions should be attached to the protocol.

6.8  If a waiver from the requirement of written informed consent is sought, the justifications for the waiver should be specified.

6.9  If questionnaires or interview schedules are to be used in the project, a copy of each should be attached. If they are not available at the time of submission an informative
description of their content and manner of administration should be included in the protocol, along with an assurance that when completed they will be filed with the Committee.

6.10 The protocol must be signed by the investigator. If the investigator is a student, the signature of the faculty advisor is also required. If the investigation is a part of a larger project, the title and identifying number should be provided.

6.11 A copy of the principal investigator's curriculum vitae (faculty only) is to be attached to the protocol.

7.0 **Administrative Functions and Responsibilities**

The Office of Sponsored Programs is responsible for obtaining an Application for the Conduct of Research Involving Human Subjects along with other materials necessary for the review by the IRB.

It is the responsibility of the IRB Administrator in the Office of Sponsored Programs and Research, who is responsible to the Assistant Vice President Vice President for Academic Affairs, to assure that the policies and procedures concerned with projects involving human subjects are carried out in accordance with the institutional assurance.

The IRB Administrator through the above office will also disseminate current policies and procedures to the faculty and departmental offices of the University. Copies of the University Policies and Procedures and the DHHS materials will be available upon request to faculty, administrators, subjects and any other interested person. Each time a revision occurs, the revised version of the University Policies and Procedures will be mailed to all deans, chairs, and directors of academic units.

In addition, this office has the authority and is responsible for promptly reporting to the NIH-OHRP on a variety of issues. In conjunction with this requirement, the IRB must be prepared to receive and act on information received from a variety of sources, such as human subjects, research investigators, the Office of Sponsored Programs or other institutional staff. For reporting purposes, the IRB will follow the procedures described below:

A. Noncompliance: Any noncompliance by research investigators with the requirements of the IRB shall be reported promptly to the Assistant Vice President for Sponsored Programs for appropriate follow-up.
B. Injuries to human subjects: Information received by the IRB concerning injuries to subjects shall be reported promptly to the Assistant Vice President for Sponsored Programs.

C. Unanticipated problems: Information received by the IRB concerning unanticipated problems involving risks to subjects or others shall be reported promptly to the Assistant Vice President for Sponsored Programs, who is responsible for reporting to the OHRP.

D. Suspension or termination of IRB approval: Whenever the Institutional Review Board suspends or terminates approval of research protocols, it shall include a statement of the reasons for the Board's action and shall report the action promptly to the research investigator, the Office of Sponsored Programs, and the OHRP.

The IRB shall prepare and maintain adequate documentation of its activities, including the following:

A. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent document, progress reports submitted by research investigators and reports of injuries to subjects.

B. Minutes of Board meetings which shall be in sufficient detail to show the names of attendees at the meetings; actions taken by the Board; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution; and dissenting reports and opinions. If a member in attendance has a conflicting interest regarding any project, minutes shall show that this member did not participate in the review, except to provide information requested by the University Committee.

C. Records of continuing review activities.

D. Copies of all correspondence between the Board and the research investigators.

E. A list of IRB members as required by 45 CFR 46.103(b)(3).

F. Written procedures for the IRB as required by 45 CFR 46.103 (b) (4).
G. Statements of significant new findings provided to subjects, as required by 45 CFR 46.116 (b) (5).

The Institutional Review Board and the Office of Sponsored Programs and Research shall provide for the maintenance of records relating to a specific research activity for at least 3 years after termination of the last IRB approval period for the activity.

IRB records shall be accessible for inspection and copying by authorized representatives of DHHS at reasonable times and in a reasonable manner, or shall be copied and forwarded to DHHS when requested by authorized DHHS representatives.

The Office of Sponsored Programs and Research will maintain records for each project which will be available for audit at any time. Minutes of each meeting of the IRB will be kept by this office which acts as a liaison office processing the proposals, applications, notices of approval, and review requests. Project directors/principal investigators will be responsible for maintaining files of signed informed consent statements obtained from individual subjects. These files will be subject to audit. An annual report will be developed by the office in conjunction with the Chair of the Institutional Review Board.

7.1 Certification Requirements

The Office of Sponsored Programs is responsible for submitting a certification to DHHS, and when otherwise required by DHHS, a supplement to an original protocol, when:

A. It is proposed to involve human subjects, and the activity previously had only indefinite plans for the involvement of human subjects, or

B. It is proposed to involve human subjects, and, the activity previously had no plans for the involvement of human subjects, or

C. It is proposed to change the involvement of human subject that involvement is significantly different from that which was initially approved by the IRB.

In addition, the Office of Sponsored Programs shall ensure that no human subjects are involved in research projects for which the filing
of a supplement is required by DHHS, prior to review of the submitted supplement and approval by appropriate DHHS officials.

7.2 Reporting Requirements

The Office of Sponsored Programs and Research shall be responsible for promptly reporting information, as appropriate, to the Institutional Review Board, the OHRP, and research investigators and department heads on a variety of issues. Information may flow from sources such as human subjects, research investigators, IRB or other institutional staff. Specifically, the Office of Sponsored Programs and Research shall:

A. Report promptly to the OHPR any instances of injuries to subjects and unanticipated problems involving risks to subjects or others;

B. Report to the IRB information received concerning noncompliance by research investigators, injuries to subjects, unanticipated problems involving risks, changes proposed in research activities and the progress of the research;

C. Maintain information concerning the IRB's reasons for the termination or suspension of the Board's Approval; and

D. Report promptly any changes in the IRB membership to the OHRP.

7.3 Retention of signed consent documents.

Principal investigators are responsible for placing the consent documents signed by human research subjects in repository approved by the Office of Sponsored Programs. These documents shall be retained for at least three years after termination of the last IRB approval period.

7.4 Submission of progress reports on the research.

Principal investigators are responsible for reporting the progress of the research to the Office of Sponsored Programs, as often as and in the manner prescribed by the IRB, but no less than once per year.
7.5 Submission of report of injury and/or unanticipated problems involving risks.

A. Principal investigators are responsible for promptly reporting (in writing) to the Office of Sponsored Programs, through their department heads, of any injuries to human subjects.

B. Principal investigators are responsible for promptly reporting (in writing) to the Office of Sponsored Programs, through their department heads, any unanticipated problems that involve risks to the human research subjects or others.

7.6 Reporting changes in the research.

A. Principal investigators are responsible for reporting in writing promptly to the IRB Chair through the IRB Administrator in Office of Sponsored Programs any proposed changes in a research activity.

Changes in research during the period for which IRB approval has already been given shall not be initiated by research investigators without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject. In such occurrence the IRB is to be notified as soon as possible through the IRB Administrator in Office of Sponsored Programs and Research.

7.7 Reporting of noncompliance.

Research investigators and department heads are responsible for reporting promptly to the IRB Administrator in Office of Sponsored Programs and the IRB any serious or continuing non-compliance with the requirements of this assurance or the determinations of the IRB.

7.8 Attending IRB meetings.

To facilitate the review of research and the protection of the rights and welfare of human subjects, research investigators may be invited to attend IRB meetings.
8.0 Procedures for Special Circumstances

8.1 In research projects involving audio or video taping of subjects, the following guidelines apply:

A. A release must be obtained from the subjects or guardian (following same guidelines as informed consent 3.1.1) before taping of the interview takes place; this release statement may be included on the tape.

B. In studies which do not include written informed consent (i.e., taped interviews in person or over the telephone), the elements of informed consent as they are explained to the subjects should be included as a preamble to the taped procedures;

C. Before consenting to being taped, subjects should be informed of the current and planned use of the taped materials including storage and access by persons other than the researcher. Normally, this information will be contained in the release form;

D. The researcher must make proper arrangements for secure storage of all audio and video tapes and assure that their use compiles with the guidelines outlined in the release form. Plans may include storage, erasing, or destroying after a given time period.

8.2 Any research that uses electrical, electronic or mechanical equipment with which the subject will be in contact must supply the IRB with:

A. Trade name
B. Manufacturer
C. Model number
D. Schematic diagram, picture or other representation of the equipment including a demonstration or other means of showing the Committee the machine's normal operation;
E. Verification of safety including UL certification or other certification;
F. For old equipment, equipment that has been out of usage, equipment that has been moved, or equipment of local fabrication and/or not available from commercial vendors, the researchers must provide evidence of recent inspection and certification for safety.

8.3 In cases where subjects are recruited from other institutions (hospitals, community agencies), the first contact with potential subjects should be made by institutional
staff who, after outlining the researcher's interest and ascertaining the potential subject's interest, will refer the person to the researcher.

8.4 All research that includes the study of subject use or abuse of controlled substances will be required to state their intent to acquire a Certificate of Confidentiality from NIDA or other appropriate agency before the research can begin. Certificate must be shared with the IRB before research begins.

8.5 Research with Acquired Immune Deficiency Syndrome (AIDS) patients is subject to additional precautions prescribed by the federal guidelines. This information will be shared with all interested researchers. Researchers should allow extra time for review of protocols for studies involving this population.

8.6 Research with retarded persons or bedridden elderly: Whenever potential subjects are capable of giving assent, the researcher must obtain their assent in addition to obtaining informed consent of their guardian before involving the individual in a study.

9.0 Amendments to Policies and Procedures

This document constitutes the policies and procedures under which the Human Subjects Research Institutional Review Board shall operate. Any amended policies and procedures must be approved by OHRP, NIH before addition to this document.