AGMUS
Policy and Procedures
For Human Subject Research Protection

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AGMUS Vision

The primary aim of “Vision 2015” has been and remains the establishment of AGMUS as a people-centered learning community with an international orientation, with the highest quality in education, based on the application of the most advanced technology available.

This objective is being met through innovative academic programs and services that are particularly relevant to local and global needs in the 21st century. The commitment to develop undergraduate research in science, technology, engineering and environmental science has significantly extended the reach of AGMUS beyond its traditional constituency. Likewise, the expanding application of distance learning technologies is projecting AGMUS to a broader market for higher education locally, regionally and globally.

Such innovations have fostered important international initiatives through strategic alliances with major institutions of knowledge in the Caribbean, Latin America and the major Hispanic communities of the United States and the world.

“Vision 2015” has proved to be ahead of its time and has catapulted AGMUS into the future of higher education. Constant review and improvement of these plans and strategies will keep the universities and schools within the system at the leading edge in terms of institutional quality and educational excellence.
INSTITUTIONAL MISSIONS

Universidad Metropolitana (UMET)

Universidad Metropolitana’s mission is to provide its students with an atmosphere of academic freedom and intellectual challenge, the necessary resources to help them develop high cultural and ethical values, critical thinking, intellectual curiosity, linguistic and technological skills as well as personal and professional skills required for success in their professions and their daily lives. The academic experience is supported by modern technologies applied to teaching, learning, and process assessment. UMET’s distinctive institutional features are marked by: the commitment to the quality of learning, undergraduate and graduate scientific research, local and international internship opportunities, student and faculty exchange with prestigious institutions, and community service. UMET is highly committed to environmental resources preservation and their sustainable development.

Universidad del Este (UNE)

Universidad del Este’s mission is to promote the integral development of a diverse student population through research, critical-creative thinking, the construction of knowledge and its application in a real world environment.

The principles that guide our institution are wisdom, justice, honor and freedom. Our commitment is to promote and demonstrate leadership in services provided to Puerto Rico and abroad.

Universidad del Turabo (UT)

The mission of Universidad del Turabo is to enhance knowledge through excellence in teaching, and to foster research, innovation, and the internationalization of its programs. The University is committed to graduate well-educated, professionally competent students, who can think critically and are technologically literate. The Institution also promotes the development of ethical principles and values that will allow them to contribute to the wellbeing of the community through their knowledge of social systems and their role as responsible citizens.
I. ETHICAL PRINCIPLES GOVERNING HUMAN SUBJECTS RESEARCH

The Ana G. Méndez University System (AGMUS) comprises three main institutions: Universidad Metropolitana, Universidad del Este and Universidad del Turabo and 12 university centers across the island and one in Orlando, Florida. AGMUS is guided by the ethical principles of research set forth in the Belmont Report (1979) of the National Commission for the Protection of Human Subjects.

AGMUS’ Policy and Procedures involving human subject research have been formed to comply with the Common Rule to protect individuals from harm, provide equitable selection of subjects, maximize the benefits, and minimize the risks of research participation.

These ethical principles will apply to all research:

1. Sponsored by the Ana G. Méndez University System; or
2. Conducted by or under the directions of any employee or agent of the Ana G. Méndez University System in connection with their responsibilities; or
3. Conducted by or under the direction of any employee or agent of the Ana G. Méndez University System using any property or facility of this System; or
4. Involving the use of the System’s non-public information to identify or contact human research subjects; or prospective subjects; or
5. Involving collaboration of the Ana G. Méndez University System under the sponsorship of another institution or organization, conducted in the other institution’s or a third-party facility, within or outside the U.S. territory.

AGMUS recognizes the principles of respect for persons (acknowledgment of autonomy and protection of those with diminished autonomy), beneficence (including minimization of harms and maximization of benefits), and justice (fair distribution of burdens and benefits) as stated in the Belmont Report and will apply these principles to all research involving human subjects. AGMUS also recognizes and accepts its responsibilities for protecting the rights and welfare of human research subjects.

II. Definitions

**Adverse Research Event**: Adverse research events include a wide spectrum of events. Adverse events include, but are not limited to, physical or psychological harm or injuries, threats to privacy or safety, and unusual attrition of human subjects. They also include breaches of confidentiality or emotional harms such as the emotional distress that could be triggered by questions about traumatic life events or a subject's complaints about the experimental procedures or the conduct of the investigators.

**Coercion**: To bring about participation in research by force or overt threat of harm.

**Human Subject Research**: This includes research obtained by an investigator through interaction or intervention with a human subject or any research on human subjects that includes identifiable private information.

**Interaction**: A communication or interpersonal contact between investigator and subject for research purposes.

**Intervention**: Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

**Key Personnel**: Participants on an award who contribute in a substantive way to the scientific development or execution of a project, including the principal investigator.
Major Protocol Violation: A protocol violation occurs when there is a variance in a research study between the protocol that has been reviewed and approved by the Institutional Review Board and the actual activities being performed. Major protocol violations include violations that have or pose 1) a significant risk of substantive harm to research participants, 2) damage the scientific integrity of the data collected, or there is evidence of willful or knowing misconduct on the part of the investigator, or the investigator(s) demonstrate other serious or continued noncompliance with federal, state or local research policy, laws or regulations.

Minimal Risk: Risk that is not greater than that encountered in every day life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102(i)].

Minor: An individual under the age of 21 years.

Minor Protocol Violation: A protocol violation occurs when there is a variance in a research study between the protocol that has been reviewed and approved by the Institutional Review Board and the actual activities being performed. Minor protocol violations 1) have no substantive effect on the risks to research participants or 2) the value of the data collected (meaning the violation does not confound the scientific analysis of the result); and 3) did not result from willful or knowing misconduct on the part of the investigator(s).

Prisoner: A prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Private information: Includes information about behavior that occurs in a context that an individual can reasonably expect no observation or recording is taking place, as well as information that has been provided for specific purposes by an individual that the individual can reasonably expect will not be made public.

Quorum: The attendance of 50% + 1 of the members at a regular IRB meeting. This quorum is also necessary at the full review meetings.

Research: A systematic investigation, including research development, testing and evaluation, designed to contribute or develop "generalizable" knowledge (intended to be shared with the general public). [45 CFR 46.102(d)]

Sensitive Information: Includes information that, if disclosed, may reasonably pose a risk to the subject's psychological, social, medical, legal, or economic well being or quality of life.

Signatory/Institutional Official: The signatory/institutional official (IO) is a high institutional official who has the legal authority to represent AGMUS' Assurance filed with the Office of Human Research Protection, and is responsible for the provisions of this policy. The President of the Ana G. Méndez University System has delegated the Assistant Vice President for Science and Research the authority and responsibility to appoint committee members and to ensure compliance of AGMUS and all of its components with the Federal Regulations for the Protection of Human Subjects in Research. He has the authority over the entire human subjects protection program and will be ultimately responsible for the review and conduct of human subjects research at each component of the Ana G. Méndez University System. A formal agreement between each separate legal entity will outline the relationship between the institutions and document the authority granted to the Signatory Official with regard to the oversight of human subjects research at each institution. A copy of this agreement will be kept on file at each institution.

Specimen: Specimen is used to refer to biological specimens (e.g., blood or tissue samples), as well as to other types of data "specimens" that could be stored for use in future research (e.g. audio tapes, video tapes, etc.).
**Undue Influence:** Excessive, unwarranted inappropriate or improper reward or other overture offered to an individual that may unfairly compel that individual to participate as a human research subject.

**III. POLICY**

AGMUS assures that it will comply with the requests set forth in this Policy and acknowledges that it and its investigators bear full responsibility for the performance of all research involving human subjects.[45 CFR 46.103(a)] Accordingly, AGMUS must assure that before human subjects are involved in research, proper consideration will be given to:

1. The risks to the subjects;
2. The anticipated benefits to the subjects and others;
3. Sound research design;
4. The importance of the knowledge that may be reasonably expected as a result;
5. The prospective informed consent process to be employed;
6. The provisions to protect the privacy of subjects;
7. The additional safeguards for vulnerable populations; and
8. Equitable selection of subjects.

AGMUS will exercise administrative oversight of all research activity involving human subjects by its Agents consistent with Federal Policy (Common Rule 45 CFR Part 46) for the Protection of Human Subjects and any additional policies pertaining to human subjects.

All Federally supported human subjects' research will comply with any human subject regulations and policies of any relevant regulatory Department or Agency. In reviewing research that is both Federally-supported and FDA-regulated, the AGMUS IRB will satisfy all of the responsibilities applicable to each of the following titles and regulations:

- 7 CFR 1c
- 10 CFR 745
- 14 CFR 1230
- 15 CFR 27
- 16 CFR 1028
- 22 CFR 225
- 24 CFR 60
- 28 CFR 46
- 32 CFR 219
- 34 CFR 97
- 38 CFR 16
- 40 CFR 26
- 45 CFR 46
- 45 CFR 690
- 49 CFR 11
- By Executive Order
- By Statute

Department of Agriculture
Department of Energy
National Aeronautics and Space Administration
Department of Commerce
Consumer Product Safety Commission
Agency for International Development
Department of Housing and Urban Development
Department of Justice
Department of Defense
Department of Education
Department of Veterans Affairs
Environmental Protection Agency
Department of Health and Human Services
National Science Foundation
Department of Transportation
Central Intelligence Agency
Department of Agriculture

AGMUS retains final judgment as to whether a particular activity is covered by this Policy, (Common Rule 45 CFR Part 46).
IV. INSTITUTIONAL REVIEW BOARD

The Institutional Review Board (IRB) of the Ana G. Méndez University System (AGMUS) serves as the primary institutional body to protect the rights and welfare of individuals recruited to participate in research conducted at AGMUS or affiliates of AGMUS. The Institutional Review Board at the Ana G. Méndez University System is vested with the responsibility to determine whether and how research with human subjects may be conducted and to review, regulate and monitor such research.

Each research study that proposes interaction or intervention with human subjects must be prospectively reviewed and approved by the Institutional Review Board (IRB) or exempted from IRB review by the IRB, the IRB’s designee or administrator prior to the onset of data collection. All human subject research, even if found exempt from IRB review, must follow the AGMUS Policy for the protection of human research subjects and the principles of the Belmont Report.

A. Institutional Review Board Responsibilities

1. Act on applications submitted to it by the AGMUS Community or Agents of AGMUS;
2. Monitor the research it has approved;
3. Report to the Office of Research Compliance (ORC), Institutional Official (IO) and the research funding source (for federally funded research) via the ORC or IO any action to suspend or terminate approved research;
4. Assist campus officials, as requested, in interpreting research with human subjects for any of Ana G. Méndez University System constituencies or the general public;
5. Assist peer review committees, as requested and where applicable;
6. Report its activities to the Assistant Vice President for Science and Research Development (IO) at least annually or more frequently as requested; and to
7. Ensure that legally effective informed consent of human research subjects will be obtained in a manner and method that meets the requirements of the Common Rule and AGMUS Policy.

B. Authorized IRB Powers

1. Approve the research as submitted
2. Approve the research contingent upon specific revisions
3. Table the protocol for substantive changes
4. Disapprove the research
5. Monitor the research for compliance with IRB recommendations by any means it deems appropriate, including observation of the consent process and the research, and appointment of a third party to undertake such observation; and to
6. Suspend or terminate research, whenever the research is not conducted in accordance with the IRB’s requirements of minor or major protocol violations or whenever it has been associated with an unexpected harm to human subjects if deemed appropriate by the IRB or Institutional Official.

C. IRB Membership

The President of the Ana G. Méndez University System has delegated appointment of members and alternate members to the IRB to the Assistant Vice President for Science and Research. All appointments are for 3-year terms. Each member must attend 50% or more of scheduled meetings per semester in order to maintain membership status. A Chairperson for the IRB will be appointed for a 2-year term. During the remaining year of their appointment, the former Chairperson will become a regular member of the IRB. A new Chairperson will be selected amongst the remaining regular members. There are no limits to the number of terms that a member may form part of the IRB. The IRB shall have at least 5 members with varying backgrounds to promote complete and adequate review of research activities commonly conducted at AGMUS.
The IRB shall be sufficiently qualified through the experience and expertise of its members, and the
diversity of the members, including consideration of race, gender, and cultural backgrounds and
sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in
safeguarding the rights and welfare of human subjects. In addition to possessing the professional
competence necessary to review specific research activities, the IRB 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 IRB shall therefore include persons
knowledgeable in these areas.

The IRB shall not consist entirely of men or entirely of women, including the institution's consideration
of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender.
The IRB neither may consist entirely of members of one profession. The IRB shall include at least
one member whose primary concerns are in scientific areas and at least one member whose primary
concerns are in nonscientific areas. At least one member of the IRB shall not be otherwise affiliated
with the institution and who is not part of the immediate family of a person affiliated with the
institution.

While carrying out responsibilities regarding research involving prisoners as subjects, the IRB shall
meet the following:

(a) A majority of the Board (exclusive of prisoner members) shall have no
association with the prison(s) involved, apart from their membership on the
Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner
representative with appropriate background and experience to serve in that
capacity, except that when a particular research project is renewed by
more than one Board, only one Board need satisfy this requirement.

The IRB meets at least once per month or more frequently as needed. The established quorum is
50% + 1. No member of the IRB may vote on or be present for the IRB review and discussion of a
proposal in which the member has a financial, institutional, or any other, kind of conflicting interest. In
such instances, the IRB member will excuse herself/himself from the IRB meeting until the IRB takes
action on the protocol.

D. IRB Member Education
All IRB members are required to complete the NIH educational requirements of Principal
Investigators. This education must be updated every 2 years. New IRB members must submit
documentation of completion of these training modules to the Office of Research Compliance prior to
voting on any submitted research projects. All IRB members will also be expected to attend a yearly
IRB educational training provided by the Office of Research Compliance or the equivalent, for
continuing education.

E. Annual Report
The IRB will report at least annually to the Institutional Official regarding the activities of the IRB. This
annual report will include the volume and status of protocols reviewed by the IRB, any adverse
research events and a synopsis of continuing education materials provided to the IRB members. At
the discretion of the IRB Chair, the IRB may make recommendations for procedural changes to
facilitate or improve the IRB process.

F. Health and Human Services IRB Registration
All voting IRB member names and qualifications are registered with the Department of Health and
Human Services, Office of Human Subject Protection. The ORC will notify OHRP within 15 working
days of any changes to membership.
G. Termination of Membership
An IRB member may be terminated for serious misconduct or breach of membership duties if recommended by a gross majority of voting IRB members at a convened IRB meeting, and approved by the IO.

H. IRB Procedure for Protocol Violations
A protocol violation occurs when there is a variance in a research study between the protocol that has been reviewed and approved by the Institutional Review Board and the actual activities being performed. Violation may be minor or major in nature. All incidents of alleged or known protocol violations may be investigated using the following procedures:

1. Minor Protocol Violation:
Minor protocol violations 1) have no substantive effect on the risks to research participants or 2) the value of the data collected (meaning the violation does not confound the scientific analysis of the results); and 3) did not result from willful or knowing misconduct on the part of the investigator(s). The following steps will be taken to investigate minor protocol violations:

   a. A fact finding inquiry process may be initiated by the IRB Chair in cooperation with the Office of Research Compliance (ORC)

   b. The IRB Chair and the ORC will analyze all information gathered regarding the protocol violation and compare it to the approved protocol. When necessary, the Chair and the ORC will consult with experts in the particular area of research in order to make definitive, unbiased and educated decisions regarding the violation. A conclusion will then be made regarding the seriousness of the violation.

   c. If the findings support all three criteria noted above (Section IV. H. 1) for a minor protocol violation, the IRB Chair will notify the principle investigator in writing that indicates what must be done (if anything) to correct the conditions that lead to the violation and what (if anything) must be communicated to the research participants.

   d. The IRB Chair will present a summary of the violation, process, facts, and conclusions at the next scheduled convened IRB meeting.

   e. If the findings support that the violation 1) has a substantive effect on the risks of the research subject, 2) has a substantive effect on the value of the data collected, and 3) resulted from a willful or knowing misconduct on the part of the investigator, the matter will be treated as a major protocol violation.

   f. If the findings from steps a or b above do not support that a violation has occurred, the matter will be dropped.

2. Major Protocol Violation:
Major protocol violations include violations that 1) have or pose a significant risk of substantive harm to research participants, 2) damage the scientific integrity of the data collected; or 3) there is evidence of willful or knowing misconduct on the part of the investigator; or 4) the investigator(s) demonstrate other serious or continued noncompliance with AGMUS research policy and/or the Common Rule. In such cases, the following steps will be taken to investigate major protocol violations:

   a. A fact finding inquiry process will be initiated by the IRB Chair in cooperation with the Office of Research Compliance (ORC)
b. The Chair will convene a hearing committee to consider all the facts of the case and to meet the investigator(s). The hearing committee will consist of:

1. IRB Chair
2. Office of Research Compliance Director
3. Assistant Vice President for Science and Research
4. Two or more representatives from the PI's department or discipline
5. One or more community members
6. A representative from AGMUS Legal Counsel

c. If the hearing committee finds any of the four criteria noted above for major protocol violations, the IRB Chair will immediately suspend the protocol. (Note: this does not preclude the IRB Chair from suspending the protocol in advance of the hearing if, in the Chair's assessment, the conditions in 45 CFR 46.113 have been met and warrant an emergency protocol suspension).

d. If suspension of the protocol or study procedures would result in harm to the enrolled research participants, the Chair will request that the PI's Department Chair assign PI duties to another qualified person and submit a Protocol Revision and Amendment Form explaining this substitution and indicating temporary closure of the study. In this situation, the official action will be the suspension of the investigator (45 CFR 46.109 (d)).

e. Any protocol or investigator suspension will be reported directly to the Director of the Office of Research Compliance, who will determine the appropriate federal agencies or sponsors to notify, and will prompt the IO to make such notification in writing.

f. Depending on the nature or the seriousness of the violation, the hearing committee may elect to direct the IRB to audit all protocols that involve the investigator in question. The IRB Chair may delegate this duty to a designee or appropriate third party.

g. If the findings of the hearing committee support research misconduct, the Director of Research Compliance will be notified and an AGMUS Misconduct Investigation will ensue.

h. A summary of the issue, process, facts, conclusions and actions will be presented at the next scheduled IRB meeting. A written summary will be forwarded to the PI, the PI's department chair, and the appropriate dean or director. A copy will be retained in the IRB study file.

If an investigator disagrees with the findings or requirements of the Committee, he/she will have the right to appeal the Hearing Committee's decision to the IO. The Chair will forward all information gathered by the inquiry or hearing process to the IO who will consider it along with any additional information provided by the investigator. The IO's decision will be final.

I. Procedure for Adverse Research Events

The Chair of the IRB and the ORC Director will review all reports of adverse events (See Section II Definitions). All adverse events will be communicated to the IRB at the next IRB meeting at which time the IRB may require additional protocol safeguards to protect human research subjects.

In the event of a death or life-threatening research event, a full IRB meeting will be convened to discuss the adverse event. In such cases, the following procedure will be followed:

a. The adverse event report form, the original IRB review forms, the original approval letter, continuing approvals, and any IRB or ORC protocol monitoring notes will be reviewed by the IRB for possible links of the event with the research procedure. As necessary, an advisor or expert in the field will be consulted if such expertise is not available from among the IRB board members or a perceived or actual conflict of interest exists for IRB members with such expertise.
b. The IRB will discuss the protocol in light of the adverse event(s) using the Criteria for Protocol Approval (See Section V.A. of this Policy) to assure that the protocol adequately protects research participants. The IRB may require additional safeguards and/or changes in the informed consent procedure to prevent additional adverse events or inform participants of the adverse events associated with the study to date. If the IRB finds the risks of the protocol are unacceptable, the board may vote to suspend or terminate the protocol or terminate the protocol with a majority IRB vote.

c. For adverse events related to minor or major protocol violations, the procedures for protocol violation(s) will be followed. For adverse events related to misconduct or alleged misconduct (see AGMUS Administrative Policy for Handling Allegations of Misconduct), the procedures for Alleged Misconduct will be followed.

d. The Investigator will be notified in writing of the scheduled IRB review of adverse events and any changes or actions taken by the IRB as a result of the adverse event. Unforeseen adverse research events will be reported to the DHHS/Office of Human Research Protections and all funding sources. Adverse research events that involve Alleged Misconduct or Misconduct will be reported to DHHS/Office of Research Integrity.

f. The Investigator must submit a follow-up adverse event report 30 days following IRB review of the adverse event. This report will be reviewed by the IRB at the next convened IRB meeting to assess the adequacy and effectiveness of the protocol protections. If necessary, the IRB may require additional changes. The investigator will be notified in writing if any additional changes are required.

V. RULES FOR IRB REVIEW

In forwarding proposals to the IRB, investigators acknowledge and accept their responsibility for protecting the rights and welfare of human subjects participating in their research studies and will comply with applicable federal, state and local rules and laws and AGMUS policies. To begin the review process, researchers must submit a complete Protocol Submission Form (IRB 06.A), original and two copies of the research proposal, and a biosketch.

A. Criteria for IRB Approval

The IRB approves research only when it has determined that all of the following criteria are satisfied:

1. Risks to subjects are minimized. Procedures used are consistent with sound research design and do not unnecessarily expose subjects to risk. Whenever appropriate, the research uses procedures already performed on the subjects for other purposes, such as diagnosis or treatment;
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably result from the study;
3. The selection of the subjects is equitable, taking into account the purposes of the research and the setting in which the research will be conducted;
4. Informed consent is sought from each prospective subject or the subject’s legal representative;
5. Informed consent is appropriately documented from each prospective subject in accordance with, and to the extent required by state and federal regulations;
6. Where appropriate, the research protocol makes adequate provisions for monitoring the data collected to ensure the safety of participating subjects;
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
8. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the protocol to protect the rights and welfare of those subjects.

B. Research Eligible for IRB Exemption

Some research may be eligible for an exemption from IRB review according to the rules stated in CFR 45 Part 46.101 (b) and for FDA governed research in 21CFR 50 and 56. Research involving children, pregnant women, fetuses, prisoners, mentally disabled, or subjects with a diminished capacity to give consent, is subject to special restrictions.

Research, that does not include any of the above mentioned subject populations, and is eligible for exemption may only be exempted by the IRB Chair, or designee, not the investigator. The IRB will attempt to process and review the application within 7 working days after the due date to submit protocols. The official assessment of exempt will be conveyed to the investigator in writing. Only research that poses no more than minimal risk may be exempted from IRB review. Research that is officially exempted from IRB review requires no further interaction with the IRB or the Office of Research Compliance unless adverse events occur (see section VIII.E of this Policy).

Exempt Categories as stated in 45 CFR 46.101(b):

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 (b)(2) of this section, if:

   (ii) 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 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.

C. Expedited Review Criteria

Some categories of research may be reviewed by the IRB using an expedited IRB review procedure 45 CFR 46.110 in accordance with designated expedited categories set forth in the DHHS/OHRP Guidance on the Use of Expedited Review Procedures, August 11, 2003, but only if the procedures or activities appear on the list and involve no more than minimal risk to the research subjects, and/or involve minor changes in previously approved research during the period of one year or less for which the approval is authorized.

The expedited review procedure may not be used where identification of the subjects or their responses would reasonably place them at risk of criminal or civil liability or a diminished quality of life. This includes any information that may be damaging to the subjects financial standing, employability, insurability, or reputation, or be stigmatizing. The expedited review procedure may not be used for classified research involving human subjects. The standard requirements for informed consent (or its waiver, alteration, or exception) apply to all research performed at AGMUS regardless of the type of review—expedited or full—utilized by the IRB.

1. Expedited Review Procedure

Investigators may request an IRB review of their protocol by submitting a Protocol Submission Form, original and two copies of the protocol, and an outline of investigator qualifications. All protocols that the IRB review will be analyzed for eligibility to use an expedited review procedure in accordance with the above Expedited Review Criteria. The ORC and the IRB will attempt to act on a request for IRB review that qualifies for an expedited review procedure within 20 days after the due date to submit protocols. Approved protocols must have the official approval stamp from the IRB. Expedited reviews are conducted by the IRB chairperson or by one or more experienced IRB member reviewer designated by the chairperson. In an expedited review, a reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. If the reviewer does not find that the proposal meets the criteria for expedited review, the proposal will be reviewed using a full review procedure at the next convened IRB meeting. All protocols that are reviewed using an expedited review procedure must meet all the criteria for IRB approval as outlined in Section V. A. of this Policy. The IRB shall adopt a method for keeping all members advised of research proposals approved under the expedited review procedure.

D. IRB Full Review

In full board review of research, all members read the research proposal (including all research instruments such as surveys, questionnaires or rating scales, advertisements for subject recruitment and the consent form), the grant or contract proposal, and the credentials of the researcher. One primary reviewer will present the proposal to the board members at a convened IRB meeting. After a substantial discussion and consideration of criteria for IRB approval (see section V. A Criteria for IRB
Approval) a vote will be cast, with a majority of members present and eligible for voting, the IRB may act according to the IRB authorized powers (see Section IV. B. Authorized Powers). Protocols that require full review at the time of initial review generally require full board review for continuing review purposes.

1. Full Review Procedure

Investigators may request IRB review of their protocol by submitting a Protocol Submission Form, original and two copies of the protocol, and an outline of the investigator’s qualifications. All protocols that require IRB review that are not eligible for an expedited review procedure (see Section IV C above) will be reviewed by the IRB at a convened IRB meeting in accordance with the criteria in Section IV B of this policy and the rules outlined in 45 CFR 46. The investigator must submit his/her proposal no later than the submission date posted on the IRB calendar for the particular month prior to the scheduled IRB meeting. Proposals that arrive after this date will be reviewed at the next month IRB meeting. The investigator will receive the results of the Full Board Review within 10 working days from the meeting date with the official stamp indicating the protocol approval number, the approval date, the expiration date, and an official signature. These deadlines only apply to research projects submitted to the IRB as complete applications and if no revisions are required.

E. Educational Requirements for Protocol Submission

All researchers must receive educational training on Human Subjects Research in order to receive exemption or approval of their protocols from the IRB.

If the protocols are NIH funded (whether these projects are exempted, or fully reviewed by the IRB), researchers are required to complete the National Institutes of Health (NIH) on-line training module on Human Subject’s Protection (http://cme.nci.nih.gov/).

All other researchers must either attend the AGMUS educational session regarding the AGMUS Human Subject Research Protection Educational Session or complete the NIH on-line training module. The AGMUS educational sessions will be held on a periodic basis by the Office of Research Compliance. This education must be updated at least every 2 years in order for investigators to continue research activities.

Upon completion, a copy of the certificate must be included with the protocol when submitted to the IRB. Protocols may only be exempted or approved if the Primary Investigator and key personnel have fulfilled and documented the completion of the above educational requirements.

F. Continuing Review Procedures

Review of research must occur not less than once per year. Some high-risk protocols may require more frequent review as deemed necessary by the IRB review process and federal regulations. Research protocols that extend five (5) years from the initial IRB review date must be reviewed de novo (as new) every five (5) years from the initial IRB review.

Sixty (60) days prior to the initial or continuing IRB approval expiration date, investigators must submit an IRB Continuing Review Form and a summary of the study that includes the following information:

1. Number of subjects enrolled in the study to date;
2. Withdrawal of subjects from the research;
3. Any unexpected events or complaints about the research and a method for monitoring the safety of research participants;
4. Information regarding any amendments or modifications to the research since the last review;
5. Any findings of the research;
6. Reports on multi-center trials or cooperative research;
7. An update of the initial literature review;
8. Any other relevant information, especially information about risks associated with the research;
9. A copy of the current informed consent document (both the Spanish and English versions).

Under no circumstances may an investigator continue data collection beyond the IRB expiration date, nor may any researcher use an expired research instrument (such as surveys, questionnaires, or tests). Upon continuing approval, the researcher must update all forms used in the research project to reflect the new IRB approval date. The IRB may require unannounced observation of research activities either by the IRB members, a designee or a third party observer. Researchers found to be collecting data without IRB approval may be required to expunge the data upon IRB request, and all research activities will be suspended by the IRB pending continuing IRB review and approval of research activities.

1. Data Safety and Monitoring of Research
   Each investigator must make provisions for monitoring the safety of participants involved in research. All research studies performed at AGMUS are subject to basic monitoring by the IRB or its designee to assure that the procedures comply with the original research protocol approved by the IRB. If the monitoring procedure shows minor deviations from the approved protocol, the Procedure for Minor Protocol Violations may be followed (see section IV. H.1).

   If the monitoring procedures find major deviations from approved protocol procedures, the procedure for Major Protocol Violations will be followed (See Section IV.H. 2). The IRB may, at its discretion appoint a third party to monitor AGMUS research activities if the IRB finds that third party monitoring best protects the research subjects’ confidentiality and the expertise for such monitoring does not exist within AGMUS or is inappropriate due to conflicts of interest with the AGMUS community.

G. Withdrawal or Termination of Research

When a study is withdrawn or completed, the investigator must notify the IRB in writing and indicate provisions to protect confidential information or indicate plans for destroying it. All records of IRB communications must be kept on file for five (5) years following termination or completion of research studies. Protocols are considered to be active as long as identifiable private information exists and will require at least yearly IRB continuing approval. Consequently, all information that links identities of subjects to data gathered should be destroyed as soon as possible in accordance with the specific aims of the study. In the case of Oral Histories, once data is permanently archived a study may be closed and considered completed for IRB purposes.

H. Foreign Research and/or Research Performed on the US Mainland

All of the AGMUS human subject research activities will be guided by statements of ethical principles of the Belmont Report including research performed in foreign countries and/or on the US Mainland by AGMUS Employees or Agents. The investigator will abide by that country’s or state’s laws or regulations or 45 CFR 46 whichever provides the greatest degree of protection to human research subjects.

I. Collaborative Research

The activities of individual research investigators who are not employees or agents of the institution may be covered under an AGMUS Federal Wide Assurance only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. OHRP’s sample Unaffiliated Investigator Agreement may be used for this purpose.
http://ohrp.osophs.dhhs.gov/humansubjects/assurance/unaflsup.rtf). AGMUS, through the Office of Research Compliance, will maintain such commitment agreements on file and provide copies of them to OHRP upon request.

All collaborative research projects must receive IRB approval and appropriate continuing review at each participating institution. The AGMUS IRB requires documentation of such approval and must be obtained prior to the initiation of research activities that are governed by the collaborating institution's IRB.

VI. APPLICATION REQUIREMENTS FOR RESEARCH INVOLVING HUMAN SUBJECTS

It is essential that all questions on the Protocol Submission Form be answered fully and in sufficient detail to allow IRB reviewers to discuss the criteria for Approval (see Section V. A. Criteria for IRB Approval).

A. Contents of the Research Proposal:

1. Introduction
2. Specific aims
3. Methods of data collection and analysis
4. Subject population, research setting, subject recruitment procedures
5. Informed consent procedure
6. Provisions for subject and data confidentiality
7. Statement of potential research risks to subjects
8. Statement of potential research benefits to subjects
9. Investigator’s biosketch

B. Informed Consent: General Requirements

Unless specifically authorized by the IRB, all research requires written informed consent in non-exculpatory language understandable to the subject unless these requirements are waived according to the policies set forth in Section VI. E. of this Policy (Alteration or Waiver of the Signed Informed Consent Requirements). Please submit Consent Forms in both Spanish and English.

Informed Consent is a process, not a single event. Since subjects always retain the right to withdraw from a research project, it is imperative that the investigator maintain subject's continuing, voluntary informed consent at all times. The application for IRB Review must describe the procedures for gaining and documenting the informed consent of the subjects.

The investigator shall seek informed consent only under circumstances that provide the prospective subject and or subject’s legal representative sufficient opportunity to consider whether or not to participate without undue influence or coercion. The information given to the subject or the subject’s legal representative will be in a format understandable to that subject or representative and it shall not be misrepresentative of the research or methods. No informed consent may include any exculpatory language that waives the subject’s legal rights or appears to release the investigator, the University or its agents from liability or negligence. The informed consent must include the Office of Research Compliance’s hotline number (787-751-3120) for any concerns the subject may have.

Informed consent must include the following elements:

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 how confidentiality of records that identify the subjects will be maintained;

6. For research involving more than minimal risk, an explanation of any compensation and an explanation of any medical treatments that are available if injury occurs and, what they consist of, or where further information may be obtained;

7. An explanation of who to contact for answers to pertinent questions about the research and research subjects’ rights, and who to contact in the event of a research-related injury to the subject; and

8. A statement that participation is voluntary and that the subject may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements of informed consent:

When appropriate, the following 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. Special Classes of Subjects (Vulnerable Populations)

There are special classes of people for whom extra precautions must be taken to be in compliance with federal regulations. These vulnerable populations require special protection, and include children, wards, prisoners, pregnant women, fetuses, human In Vitro Fertilization, Economically or Educationally Disadvantaged Persons, mentally disabled patients, the terminally ill and the comatose.

1. Research Involving Minors (subjects under 21 years of age)

In all human subject research, the agreement of the subject to participate is an essential protection of the subject’s rights and welfare. Minors, by definition, cannot give legal "consent".
Therefore, a combination of "assent" (affirmative agreement to participate in research) of the minor and "permission" (agreement to the participation of their child or ward in research) of the parent(s) or legal guardian(s) (authorized under applicable state or local law to consent on behalf of a child to general medical care) is generally deemed an adequate substitute. If either parent refuses permission or the minor subject refuses assent, the minor should not be enrolled in the research project.

a) **Parental Consent**: The AGMUS IRB requires the permission of both parents, unless one parent cannot reasonably be found, for research that involves minors. There may be exceptions to this general policy that the IRB will determine following the provisions of 45 CFR 46.408 et. seq.

b) **Legal Guardians vs. Caregivers**: The permission of caregivers and/or service providers is not sufficient to conduct research with minors. Only parents and legal guardians have that authority and responsibility. School principals, teachers, clinic personnel, etc., do not have the authority to give "blanket" permission for their students/patients/clients to participate in research. They do have the authority to permit the research to be conducted in the facility under their auspices. (This permission should be made part of the study submission.) In classroom research, it must be made clear that the research is not part of the regular educational program and that the student's grades or standing will not be affected by not participating.

c) **Child (minors) Assent**: Adequate provision must be made for soliciting the assent of those children capable of providing a meaningful statement. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived under 45 CFR 46.116, Subpart A. The process must be appropriate to the study as well as the age, maturity and psychological state of the child. Information must be presented in language and format that is understandable to the child. The children should have an understanding of the research procedures and it should be clear that their participation is voluntary. An investigator may not include a minor as a research subject without his or her assent unless the minor is not capable of giving assent and the assent is waived by the IRB because the research holds out a prospect of benefit for the child or provides important research information.

d) **Wards** (§46.409): Children who are wards of the state or any other agency, institution, or entity:

   (a) Children who are of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.497 only if such research is:
      (1) related to their status as wards; or
      (2) Conducted in schools, camps, hospitals, institutions, or similar settings
          in which the majority of children involved as subjects are not wards.

   (b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be a person who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's
participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Exempt categories for observation of public behavior of children must abide to additional protections except when the researcher is not directly involved in the observed activity.

2. Research Involving Subjects with a Diminished Capacity to Consent

Individuals in a wide variety of circumstances may have an impaired ability to make an informed decision. An impaired decision making capacity may not be limited to neurological, psychiatric, or substance abuse populations, nor should it be assumed that these populations automatically have diminished decision capabilities. Limited decision making capacity covers a broad spectrum, including a healthy person in shock or experiencing high stress, a severely mentally retarded individual since birth, or an individual in an acute psychotic state. Researchers must be sensitive to the fluctuating capacities of individuals and design the consent procedures accordingly.

It is recognized that some research questions may only be answered in populations with an impaired decision making capacity. In these matters, principle investigators and members of the research team are responsible for protecting research participants.

Consent procedures must be proportional to the research risk, as impairment increases, so does risk and discomfort associated with the study and the safeguards should increase on a sliding scale. When a researcher is determining a participant's capacity for decision-making, a key factor is the participant's appreciation of how the risks, benefits and alternatives to participation apply to them personally. It is advisable that the consent processes actually include the researcher asking the participant: "Do you understand the risks and benefits of participation?" or "Do you have any questions about the study or process?" Please follow the same guidelines under 45 CFR 46.401 Subpart D.

Options for additional safeguards include the use of an independent monitor, use of a legally authorized representative, use of assent and a legally authorized individual, use of an advance directive as local laws permit, or use of a waiting period.

3. Research Involving Experimental Biological or Behavioral Interventions

If the study is delivering an experimental intervention (biological or behavioral), the consent form must provide additional information. The consent must include a statement of the particular treatment or procedure that may be involved as well as any potential risks including the circumstances in which the subject's participation will be discontinued by the investigator. The subject must be informed of any costs for which she (he) is responsible as a result of the research participation or any consequences of early withdrawal from the study. The subject must also be informed of any recent significant findings discovered during the course of the research study.

4. Research Involving Pregnant Women, Fetuses, Neonates of Uncertain Viability or Nonviable Neonates, and Products of Labor and Delivery

Participation of pregnant women in research that may compromise maternal health requires the consent of both the mother and the father of the fetus unless the purpose of the research is to meet the health needs of the mother, or the identity or whereabouts of the father cannot be ascertained. Research activities involving products of labor and delivery or embryos including the dead fetus or placenta may only be conducted in accordance with federal, state and local laws and regulations. Upon request, a researcher (with IRB approval) may request a waiver for these
requirements with the approval of the Ethical Advisory Board of the Department of Health and Human Services after a public comment period published in the Federal Register (§ 46.207 (b)). In addition to the regulations noted in Title 45 CFR Part 46, clinical studies with pregnant women as research participants must also abide by FDA regulations (21 CFR50, 21 CFR 56). However, pregnant women can also participate in categories of waived research specified in 21 CFR Sect. 56.104 and all exemptions listed in 45 CFR 46.101(b).

5. Research Involving Non-Spanish Speaking Populations

Informed consent information must be presented in language understandable and readable to the subject and its representatives, and be documented in writing. Subjects who do not speak Spanish should be presented with a consent document written in a language understandable to them. Alternatively, an oral presentation of informed consent information in conjunction with a short written consent document (stating that the elements of consent have been presented orally) may be used (see Section VI. C of this Policy, Documentation of Informed Consent). A witness to the oral presentation is required and must sign a statement on the consent form. For additional guidance on oral witnessed consent, please see the AGMUS Investigator Guidelines for Research Involving Human Subjects.

When the short form written procedure is used, the subject or the subject's legally authorized representative must sign the short form document. If the person does not read or write, a witness may sign the consent form. If a translator assists the person obtaining consent, the translator should also sign the consent form.

All foreign language versions of the short form document must be submitted to the IRB with the Request for IRB Review Form. Expedited review of these versions is acceptable if the protocol, the full Spanish language informed consent document, and the Spanish version of the short form document have already been approved by the convened IRB. At AGMUS, researchers must always use English, Spanish, and the native language versions of their consent forms and permit the subject to choose which version to use. (45CFR46.116)

6. Research Involving Prisoner Populations

For the purpose of this Policy and Procedures (45CFR46.305/46.306), "prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial or sentencing.

Additional safeguards are applied to prisoner populations because prisoners may be under constraints imposed by their incarceration that could affect their ability to make a truly voluntary and uncoerced decision about participation as a subject in research. These protections apply whether the research involves prisoners or a person who at a later date becomes a prisoner. In the latter situation, it is unlikely that review of the research and the consent document contemplated the constraints imposed by incarceration. Researchers must contact the Office of Regulatory Compliance for guidance should this situation arise.

The following criteria must be used when including prisoners as research subjects:

a. The research must fall into one of the following categories:

i. Study of the possible causes, effects, processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk (the probability and magnitude of physical or psychological harm that is normally encountered in the daily
lives, or in the routine medical, dental, or psychological examination of healthy persons) and no more than inconvenience to the subjects;

ii. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

The following categories (iii and iv) of research may only be conducted if the Secretary of DHHS has consulted appropriate experts and published notice in the Federal Register of his/her intent to approve such research:

iii. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults);

iv. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well being of the subject.

b. Any possible advantages accruing to the prisoner through his or her participation in the research when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

c. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner subjects.

d. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for the particular research study, unless the principal investigator provides to the IRB justification in writing, for following some other procedure.

e. The information is presented in language that is understandable to the subject population.

f. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.

g. If there is a need for follow-up examination or care of participants after participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoner's sentences, and for informing participants of this fact.

7. Research Involving Ana G. Mendez University System Students

Use of AGMUS students presents a special set of concerns that are applicable in any study that could potentially recruit AGMUS students. This includes not only pools that specifically recruit students, but also studies that are advertised on campus. Undergraduates at AGMUS may be below the age of consent in Puerto Rico (under 21 years of age). As such, the special requirements for studies involving minors (See Section VI. C. 1) apply to studies using these students (Title 45 CFR Part 46, Subpart D).

An additional concern in studies that involve AGMUS students is the possibility of undue influence. Recruitment of a subject by his or her advisor holds the potential for undue influence.
This also holds true whenever a student's participation will be made known to someone who
holds power over that student's academic status or extra credit for course grading purposes.

Since participation in a research study is completely voluntary, there may not be any loss of
academic status if a student chooses not to participate. If academic benefits are offered as
compensation for participation in a study, an equivalent alternative activity must be offered (with
the same academic benefit offered) to students who choose not to participate.

The above issues must be addressed in all research studies involving AGMUS students.

8. Use of Specimens for Future Research

If specimens are to be stored for use in future research, this information must be included in the
informed consent process and the informed consent documentation. Further, it is the policy of
the AGMUS IRB to require that a specific consent statement be included in consent forms that
ask subjects to grant permission to store specimens for future research use. The purpose of the
extra consent statement is to clearly indicate that the subject can participate in the current
research study without agreeing to have specimens stored for future research. The only case
where the separate consent line is not required is when the purpose of the current research study
is to collect specimens for the purpose of storing them for future research or use.

D. Documentation of Informed Consent

Consent documents serve as documentation of the process of obtaining informed consent for
research participation. Consent forms are not a substitute for the consent process. Consent
documents must be clearly written and understandable to subjects and their representatives.
Researchers need to consider their audience in relation to the comprehension of the information
presented. This may require translation into the preferred language of the participants. The language
of the consent document must be non-technical (comparable to the language in a newspaper or
general circulation magazine). Scientific, technical or medical terms must be plainly defined. The
consent form or process may not include language that appears to waive subjects' legal rights or
appears to release the investigator from liability or negligence.

1. Written Consent Forms:

Informed consent shall be documented (unless the IRB has given approval for a waiver,
alteration, or exception, as provided herein) by the use of a written consent form approved by the
IRB and signed by the subject or the subject's legally authorized representative. A copy of the
consent form shall be given to the person signing the form (both English and Spanish versions
must be presented to the subject). The consent form may be either a full form written or a short
form written.

The IRB may waive the request for the investigator to obtain a signed consent form for some or
all subjects, under the provisions of 45 CFR §46.117 (c) when the only record linking the subject
and the research would be the consent document and the principal risk would be the potential
harm resulting from a breach of confidentiality. The subject and/or its representative will be
asked if he wants documentation linking him/her with the research; and, the subject's wishes will
govern; or when the research presents no more than minimal risk of harm to subjects and
involves no procedures for which written consent is normally required outside the research
context. If documentation requirement is waived, the IRB may require the investigator to provide
subjects with a written statement regarding the research.
2. Full Form Written Consent:

A full form written consent document embodies all the required documents of informed consent, under 45 CFR § 46.116. This form may be read to the subject or the subject's legally authorized representative, but the investigator must still give the subject or the representative adequate opportunity to read the document before it is signed. When the full form is used the following procedures must be implemented:

The subject or the representative signs the full form.
The subject or the representative receives a copy of the form.

3. Short Form – Written Consent (Oral Summary):

A short form written consent document is a statement indicating that the required elements of informed consent (Section VI.B of this Policy) have been presented orally to the subject or the subject's legally authorized representative.

When the short form is used the following procedure must be implemented:

   a) There must be a witness to the oral presentation.
   b) The researcher must provide the IRB a written summary of what will be said to the subject or the representative and the researcher must obtain IRB approval of the summary before it is implemented.
   c) The subject or the representative signs only the short form.
   d) The witness must sign both the short form and a copy of the IRB approved summary.
   e) The person actually obtaining consent (the researcher) must sign a copy of the summary.
   f) The subject or the representative receives a copy of the summary and a copy of the signed form.

E. Alteration or Waiver of Informed Consent Requirements

There are only two circumstances in which the IRB may waive the required consent. The first waiver authority is applicable only to research activities designed to study certain aspects of public benefit or service programs; the conditions under which this waiver may be authorized by an IRB are detailed at 45 CFR 46.116(c)(1-2). 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 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.

The second waiver authority is described at 45 CFR 46.116(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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

VII. GRIEVANCE PROCESSES

A. Subjects

Individuals who have participated in research who have concerns about their rights as human research subjects may contact the Office of Research Compliance to begin investigation. The Office of Research Compliance and the IRB are only responsible for monitoring Research with Human Subjects as defined in Section III of this Policy. Concerns over tests, evaluations, or surveys that do not fall under the definition of research as defined in Section II, that are conducted as part of course instruction must be brought to the academic department’s director or dean. Subjects or students who are not satisfied with corrective actions taken by the IRB or the academic department may confidentially bring their concerns to the Assistant Vice President for Science and Research Development (IO) for further investigation.

B. Investigators

If an investigator disagrees with the IRB required revisions or specifications, the investigator will have 10 working days to bring his or her concerns to the Chair of the IRB or the Director of Research Compliance which in turn will bring these concerns to the attention of the Assistant Vice President for Science and Research Development (IO) for a due process investigation and final decision.

VIII. INVESTIGATOR RESPONSIBILITIES

A. Responsible Conduct of Research

The Ana G. Méndez University System is committed to the highest ethical standards of all research including research that involves human subjects. It is the primary responsibility of the researcher to uphold the ethical standards of research as defined in the Belmont Report and the ethical guidelines that govern each researcher’s academic discipline(s). The individual researcher is responsible for adhering to all pertinent human subject protection laws and rules, and AGMUS Policy regarding Human Subject Research.

B. Research Misconduct

Research misconduct is defined as a willful disregard of AGMUS’ Policy on the responsible conduct of research as noted in Section VIII. A of this Policy. Anyone found guilty of willful research misconduct, is subject to disciplinary action by AGMUS. Faculty, staff, and students may confidentially disclose what they believe to be misconduct to the Office of Research Compliance to begin investigation as defined in AGMUS Policy on AGMUS Administrative Policy for Handling Allegations of Misconduct in Research and Other Professional Activities, which forms part of this Policy (Exhibit A). Individuals who have in good faith made an allegation of misconduct ("whistle-blower") will not be the object of retaliation. Retaliation against a "whistle-blower" will be construed as an act of misconduct.
C. Conflict of Interest

In as much as research is concerned, the AGMUS Conflict of Interest Policy in Sponsored Programs, which forms part of this Policy (Exhibit B) promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research will be biased by any conflicting financial interest of an Investigator.

To ensure the continued confidence of the people of Puerto Rico in AGMUS and its personnel, individuals serving AGMUS shall at all times act in a manner consistent with their responsibilities to AGMUS and shall exercise particular care that no real or perceived detriment to AGMUS results from conflicts between personal interests and those of AGMUS. Conflict of interest situations, or the appearance of conflicts of interest, either financial, personal or organizational, have the potential to result in serious harm and direct losses to AGMUS. The losses are often difficult to detect and include not only direct monetary losses and loss of confidence in AGMUS, but also negative publicity and erosion of employee morale.

It is the policy of the Ana G. Méndez University System that its officers, faculty, staff and others acting on its behalf have the obligation to avoid ethical, legal, financial or other conflicts of interest and to ensure that their activities and interests do not conflict with their obligation to the University or to its welfare. All researchers are expected to uphold the AGMUS Policy on Conflict of Interest in Sponsored Programs.

D. Changes in Approved Research

Any change in the approved protocol must be informed to the IRB prior to its implementation. The IRB Committee will decide the effects of these changes (minor or major). A minor protocol revision has no substantive effect on 1) the risks to research participants or 2) the value of the data collected (meaning the change does not affect the scientific analysis of the results). A copy of the changes will be added to the approved protocol file.

A major protocol change 1) has or poses a significant change in risk to research participants, or 2) changes the scientific value of the data collected. Investigators who wish to make major revisions to their protocols must seek IRB review and approval prior to the initiation of a major change to the protocol. To initiate this process the investigator may submit a Protocol Revision Amendment Form and any altered tools or forms for IRB review.

The IRB will periodically audit the procedures in approved protocols either by discussion with or by direct observation of the Investigator by an IRB member, ORC official or appointed third party to verify that only approved procedures are performed. Researchers who fail to notify the IRB of minor changes or investigate major protocol changes without IRB approval will be subject to the IRB Procedures for Protocol Violations (see Section IV. H). Performing research without IRB approval will be considered as research misconduct and will be handled according to the AGMUS Administrative Policy for Handling Allegations of Misconduct. Please contact the Office of Research Compliance for additional information.

E. Report of Unforeseen and Adverse Events

All adverse research events involving human subjects in AGMUS research must be communicated to the Office of Research Compliance. Reports of all fatal or life-threatening events, as well as non-life threatening events, must be submitted to the ORC within 24 hours of the event if at AGMUS, or within 24 hours of receiving notification of events at other sites. Adverse Research Events will be reviewed according to the rules stated in Section IV. I of this Policy.
All unanticipated adverse events that include human research subjects in federally sponsored research will be reported to the Department of Health and Human Services Office of Human Subjects Protections as well as any Federal Agency or sponsor that provides funding for the research study. Adverse research events that include misconduct as defined in the AGMUS Administrative Policy for Handling Allegations of Misconduct will be reported to the DHHS Office of Research Integrity.

1. Procedure for Reporting Adverse Events:

To report an adverse research event, investigators may submit an IRB Adverse Research Event Report Form available from the Office of Research Compliance (ORC). In many situations, an adverse event may prompt a change in the consent process and documentation (e.g., listing an additional risk or attrition of subjects). In such cases, revised documentation of the informed consent procedure, accompanied by a Protocol Revision and Amendment Form, must be included in the report. All Adverse Event reports must include a copy of the current consent form. For expected events, please highlight the section of the consent form that lists the event. If you wish to change the consent form, please submit it with a Protocol Revision and Amendment Form, with the changes highlighted. Federal regulations (45 CFR 46.117(a)) require IRB approval for consent form alteration.

IX. RESPONSIBILITIES OF THE AGMUS OFFICE OF RESEARCH COMPLIANCE

A. Administrative Support of IRB

The Office of Research Compliance (ORC) will provide administrative support to the IRB including general staffing services and application screening, and an administrative coordinator who oversees the operations of the IRB. As part of its general staffing duties, the ORC will prepare and maintain records of IRB activities for at least five (5) years and records related to protocols for at least five (5) years after the completion/termination of the research. The ORC will keep written IRB records of the following items;

1. Copies of all research protocols and research instruments that are reviewed;
2. Minutes of the IRB meetings in sufficient detail to show attendance, actions taken at the meeting and votes on actions, the basis for requiring changes in research, and a summary of the IRB discussion of controverting issues and their resolution;
3. Records of protocol review and continuing review activities
4. Copies of all correspondence between the IRB and investigators
5. A list of IRB members and their qualifications for serving on the board
6. Written IRB procedures
7. Statement of significant new findings provided to subjects

B. Human Protection’s IRB Administrator

The human protection’s IRB administrator will be the AGMUS official who exercises operational responsibility, on a day-to-day basis, for the institution’s program for protection of human subjects. Within his/her responsibilities are advising, managing protocol review, providing/overseeing education, recordkeeping, reporting, developing policies and procedures, handling allegations and complaints, coordinating “off-site” administrative agreements, conducting quality improvement of assurance reviews, managing staff and infrastructure, and serving liaison function. He/she should be contacted for comprehensive information regarding all aspects of AGMUS’ protection of human research subjects.

C. Communicating Adverse Events

The Office of Research Compliance must be contacted if any adverse research events or concerns occur. The Office’s hotline is (787) 751-3120. Unexpected adverse events in federally sponsored
research will be communicated to the Department of Health and Human Services (DHHS) via the AGMUS Signatory/Institutional Official (IO).

D. Policy Updates
The Assistant Vice-presidency for Science and Research and Development (IO) is responsible for updating Systemic Policy and Procedures regarding human subjects as new laws and regulations are promulgated, or in accordance with DHHS requests or guidelines, or as needed to execute the AGMUS Assurance.