ANA G. MENDEZ UNIVERSITY SYSTEM (AGMUS)
Office of Regulatory Compliance

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The purpose of the Office of Regulatory Compliance is to address issues in compliance with local and federal laws, rules and regulations that govern scientific procedures in research and academic activities. The office monitors and regulate the use of humans, animals, chemicals, biohazards, radiation and DNA in research and teaching activities at all Ana G. Méndez University System (AGMUS) Institutions.

Regulatory Committees:
The Office of Regulatory Compliance develops, implements and oversees university policies related to the following areas, through three Standard Committees and related programs and activities:

- Research involving humans, Institutional Review Board (IRB)
- Research for the use of biohazard materials, Institutional Biosafety Committee (IBC)
- Research involving laboratory animals, Animal Care and Use Comitte (ACUC)

Message from the Compliance Director

As time passes and we project ourselves towards the future, we are able to see that research has become one of the most competitive and challenging areas in history. The complexity is greater as time goes by; however, we may feel proud that the Ana G. Méndez University System has maintained itself at the cutting edge in the majority of the changes and requirements of the state and federal agencies.

Much has been achieved thanks to the collaboration and interest of all the University Institutions that comprise AGMUS, its Chancellors, Deans and faculty in general. I will give you an advance on the future; we will continue with our work of facilitating the processes through different mechanisms in favor of our students. I invite you to continue looking forward to new and innovative ideas to reach our goals in compliance with the core values of our organization's conduct.

Evelyn Rivera Sobrado, RN, MPH
Ana G. Mendez University System
Office of Regulatory Compliance Director

I-CARE NEWS

OFFICE OF REGULATORY COMPLIANCE — November 2009, Special Edition

In this Issue:

Responsible Conduct of Research (RCR)

The Ana G. Mendez University System (AGMUS) has included in its Strategic Plan for 2015 a core of values that will direct all of its operations, actions and initiatives. This includes, and is not limited to, respect for diversity and human dignity; integrity in all of its activities as an academic entity, and social responsibility to the needs of the community, Puerto Rico and humanity. To ensure adherence to its core values, AGMUS has three Standing Regulatory Committees to review research involving the use of human and animal subjects, as well as, the use and handling of biological and chemical substances. Each Committee had developed policies and procedures to ensure the responsible conduct of research and compliance with applicable federal and local laws. The Office of Regulatory Compliance has also implemented a Quality Assurance Program (QAP) to assist in the responsible conduct of research by monitoring, at least once a year, the processes and articulation between the Academic Institutions and the Committees.

Responsible research is built on a commitment to important values such as honesty, accuracy, efficiency and objectivity that define what is meant by integrity in research. These are defined in Nicholas H. Steneck's book as:

Honesty - the quality or fact of being honest; uprightness and fairness; truthfulness, sincerity, or frankness; freedom from deceit or fraud.

Objectivity - not influenced by personal feelings, interpretations, or prejudice; based on facts; unbiased

Accuracy- the condition or quality of being true, correct, or exact; freedom from error or defect; precision or exactness; correctness.

Efficiency- the state or quality of being efficient; competency in performance; accomplishment of or ability to accomplish a job with a minimum expenditure of time and effort.

AGMUS is committed to the Responsible Conduct of Research in all of its scenarios. It is committed to the effective use of time and money in the search for answers required to improve the health and well being of all living individuals.

NSF Update: Effective January 4, 2010, grant applications submitted to the National Science Foundation will require that the Institution's Authorized Representative certify that it has implemented a plan to provide appropriate training and oversight in the responsible and ethical conduct of research for undergraduates, graduate students, and postdoctoral researchers that will be supported by NSF. It is recommended that each University review its plan to ensure that it meets NSF's minimum requirements.

For more information, please visit the Office of Regulatory Compliance website: **compliance.suagm.edu** or contact your Institutional Compliance Coordinator.

Source: [1]Introduction to the Responsible Conduct of Research by Nicholas H. Steneck, National Institutes of Health (NIH), Office of Research Integrity (ORI). Federal Register: August 20, 2009 (Volume 74, Number 160) and NIH website.

60 Años Sistema Universitario Ana G. Méndez

COMPLIANCE: The key for responsible research.

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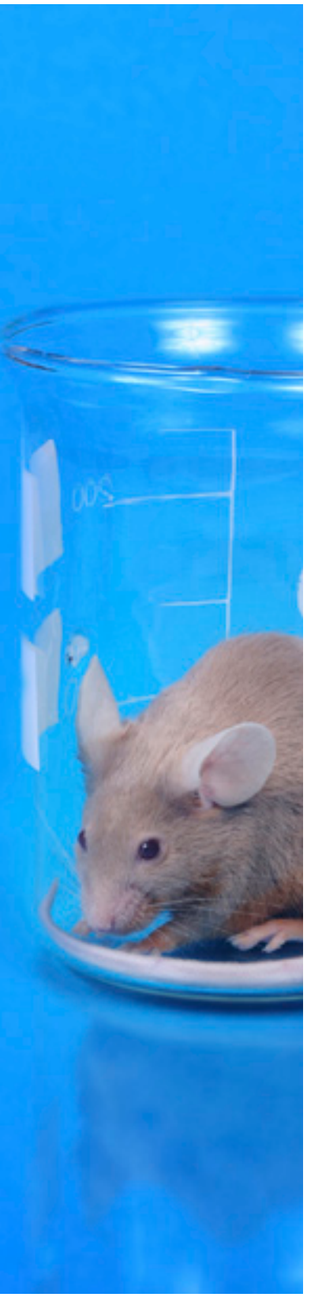
Vice Presidency for Planning and Academic Affairs
Associate Vice Presidency for Sponsored Programs



AGMUS Ad Hoc Committees

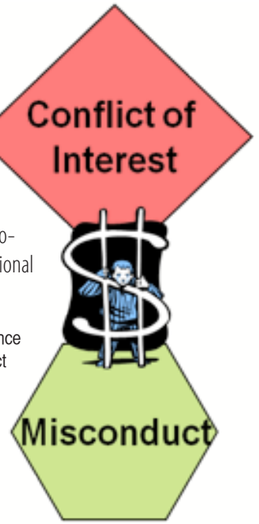
Ad Hoc Committees are convened by the Office of Regulatory Compliance to respond to allegations of Research Misconduct or Potential Conflict of Interest.

Research Misconduct - It is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- **Fabrication** - is making up data or results and recording or reporting them.
- **Falsification** - is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- **Plagiarism** - is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Conflict of Interest- a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.

Source: University of Texas Health Science Center at Houston, Research Misconduct Training and the Office of Research Integrity at, http://ori.dhhs.gov/education/products/rcr_misconduct.shtml



NIH Requirements for Animal Care and Use Grants

The National Institutes of Health (NIH) Office of Extramural Research, published some guidelines for the grant processes that include an element of animal care and use. Here you will find some of the most important tips when applying for a grant involving the care and use of animals:

The Proposal

Proposals involving the use of vertebrates must include a discussion of 5 points regarding the use and treatment of animals in the Research Design and Methods section: 1) the proposed use of the animals; 2) a justification for the use of animals; the choice of species, and the numbers to be used; 3) description of the veterinary care; 4) a description of procedures for minimizing pain and distress; and, 5) a description of and rationale for the method of euthanasia. NIH requirements are included in the AGMUS Animal Care and Use Committee Study Proposal Form.

Animal Welfare Assurance

NIH will not make an award for research involving live vertebrate animals unless the applicant organization and all performance sites are operating in accordance with an approved Animal Welfare Assurance (which AGMUS already has) and provide verification that the Animal Care and Use Committee (ACUC) has reviewed and approved those sections of the application that involve use of vertebrate animals, in accordance with the requirements of the Policy.

ACUC Review

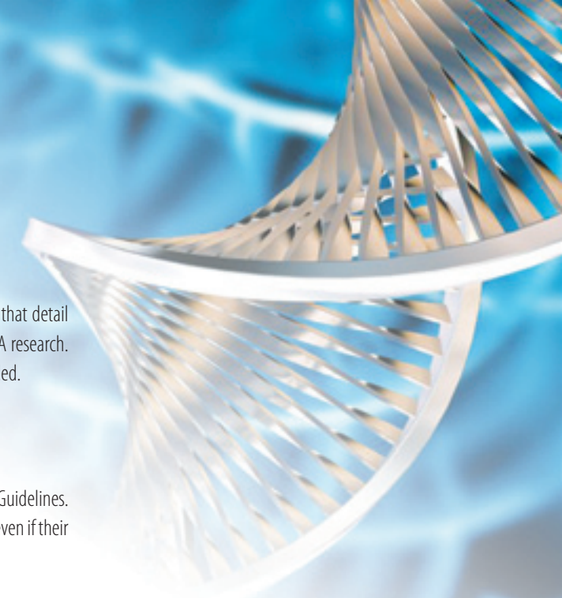
Researchers who proposes to use animals as part of their projects must submit a detailed description of the experiments and a scientific justification of the need for the use of animals not only to the NIH, as discussed above, but also to their local Animal Care and Use Committee (AGMUS-ACUC). The ACUC is charged with confirming that the research will be conducted with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. NIH will not fund the research until the ACUC has approved the grant application.

For more information, access the NIH website or contact your Institution Office of Regulatory Compliance or Sponsored Research Office.

The AGMUS Policies state that all use of animals, vertebrate and invertebrate, should be submitted to the ACUC for review and approval. AGMUS does not provide double standards in the care and use of animals.

Source: National Science Foundation (NIH) Office of Extramural Research, http://grants.nih.gov/grants/policy/air/NIH_Funded_Resources.htm.

The What and Who of The NIH Guidelines



WHAT are the NIH Guidelines for research involving recombinant DNA molecules?

The NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) are those that detail procedures and practices for the containment and safe conduct of various forms of recombinant DNA research. Research involving genetically modified plants and animals, and human gene transfer are also included.

WHO must comply with the NIH Guidelines?

All institutions that receive NIH funding for recombinant DNA research must comply with the NIH Guidelines. Researchers at institutions that are subject to the NIH Guidelines must comply with the requirements even if their individual projects are not funded by NIH.

For more information on the NIH Guidelines access the NIH website at http://oba.od.nih.gov/oba/index.html.

Source: Office of Biotechnology Activities Training and Educational Materials, June 22, 2009 brochure, http://oba.od.nih.gov/oba/ibc/InvestigatorEducationalBrochureRecombinant%20DNA.pdf

Informed consent is an active ongoing process, not just a form.

Obtaining Informed Consent

The 45 Code of Federal Register part 46 section 116 (§45 CFR 46.116) describes the general requirements in order to obtain informed consent.

- No investigator may involve a human being as a subject in research, unless the investigator has obtained legally effective informed consent of the subject or the subject's legally authorized representative.
- The investigator shall provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate.
- Minimize the possibility of coercion or undue influence.
- The information that is given to the subject shall be in language understandable to the subject or the representative.
- No informed consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Basic elements of an informed consent are:

- Statement that the study involves research, explaining the purpose and expected duration. Also a description of the procedures and which are experimental.
- Reasonable foreseeable risks or discomforts to the subjects.
- Description of benefits.
- A disclosure of alternative procedures or treatments.
- Description of confidentiality of records.
- Explanation of whether compensation or medical treatments are available if injury occurs (greater than minimal risk research).
- Contact information for questions about the research, subject rights, or injuries.
- Statement that participation is voluntary; refusal to participate or withdraw will involve no penalty or loss of benefits otherwise entitled.

Source: 45 CFR 46.116 (a).