A Message from the Institutional Official

As you well know, the Ana G. Méndez University System (AGMUS) has engaged in a new world where there is no turning back. That is the road leading to a complex, competing and challenging enterprise known as research. Our researchers have taken gigantic steps in obtaining funding from competitive governmental sources such as: NASA, NIH, NSF, EPA, NOAA, just to mention some. AGMUS, in response to these initiatives, has made great accomplishments in developing the infrastructure for the compliance of federal and local regulations, as well as, the ethical conduct in research. A major accomplishment is the creation of an Office of Regulatory Compliance in each of the Academic Institutions that serve the main campuses as well as the University Centers throughout Puerto Rico.

As part of our commitment, a web based program will be implemented during the upcoming months to facilitate the management and handling of research related protocols submitted to the Internal Review Board. In a second and third phase of implementation, protocols to the Animal Care and Use Committee and the Biosafety Committees will be included. The program is IRBNet and is widely used in the United States and is very effective in meeting its purposes. I am confident that it will be an added value to the development of an efficient and compliant infrastructure for research.

I would like to add that AGMUS has a Federal Wide Assurance from the Office of Human Research Protection and an Assurance from the Office of Laboratory Research. This means that the AGMUS will ensure that researchers involved in research with human subjects and non-human subjects will be trained and certified in the ethical and responsible conduct of research prior to intervening with subjects. However, the care and use of animals goes beyond research. AGMUS is responsible for the transporting, handling, care and use of animals in teaching as well. AGMUS is committed to the humane treatment of animals in any activity inside the laboratory, in a classroom and in the field. All activities involving animals must be approved by the Animal Care and Use Committee.

I have seen talented and dedicated professionals fall into noncompliance, mostly by non-intentional wrong doing. I always say that there are no dumb questions, but many dumb mistakes. Therefore, I urge you, when in doubt to contact the Office of Regulatory Compliance in your institution.

Research is challenging and interesting, and needed to respond to the many questions imposed by the demanding and growing society in which we live.

Miriam Rivera Cano, CRA
Institutional Official for Research Compliance

In this new I-Care edition you will have the opportunity to learn more of the resources available for animal welfare (AWIC) and human subjects protection, AGMUS Animal Care and Use Certification, AGMUS laboratories registration, among other interesting topics.
IRBNet is Here!

IRBNet provides the research community with an unmatched set of secure solution, web-based collaboration tools to support the design, management, review and oversight of research involving human subjects. IRBNet supports the creation and sharing of study materials, coordination across multiple studies sites and research teams, and electronic IRB submission and review, all with unprecedented transparency and extensive set of communication and collaboration features for research, IRB’s and sponsors. IRBNet has the capability and oversight tools to support other boards like IACUC, IBC and others, with an unified solution.

The Office of Regulatory Compliance will be offering training and support to faculty, mentors and students during the months of March through June 2009.

IRBNet helps:

- Streamline your submission and review processes.
- Reduce paper, packets and mailings.
- Cut time wasted on redundant and clerical work.
- Reduce administrative tasks to allow staff to focus on complex issues and support your research community.
- Facilitate clear, coordinated communications and track correspondence.
- Enable Members, Researchers and Administrators to access data anytime, anywhere.
- Manage your meetings and committees.
- Increase process transparency.
- Increase data security.
- Maintain a clear audit trail with appropriate documentation.
- Increase control and reinforce guidance and consistency throughout the process.
- Share information seamlessly and securely in real time, wherever your research community may be.
- Improve the quality of documentation and study design.

AGMUS

Animal Care and Use Certification

AGMUS established the animal care and use certification as a requirement for any research activity with animals. This certification can be obtained via the Collaborative Institutional Training Initiative (CITI) program. CITI is a web based training program which includes: basic courses in the protection of human research subjects, biomedical focus, social and behavioral focus, laboratory animal welfare courses for investigators and ACUC Members, Responsible Conduct of Research (RCR), among many others.

The instructions for the Animal Care and Use Certification can be accessed in our website http://compliance.suagm.edu. For more information on required certifications please contact your Institution’s Office of Regulatory Compliance.
Animal Welfare Information Center (AWIC)

The Animal Welfare Information Center (AWIC) was established in 1986 as part of the U.S. Department of Agriculture (USDA) National Agricultural Library (NAL) in Beltsville, Maryland. In the 1985 amendments to the Animal Welfare Act (AWA) the Congress’ mission was clearly announced:

“The Secretary [of Agriculture] shall establish an information service at the National Agricultural Library. Such service shall, in cooperation with the National Library of Medicine, provide information:

- Pertinent to employee training;
- That can prevent unintended duplication of animal experimentation as determined by the needs of the research facility; and
- On improved methods of animal experimentation, including methods that can:
  (A) Reduce or replace animal use; and
  (B) Minimize pain and distress to animals, such as anesthetic and analgesic procedures.”

The main purpose of the Center is to promote the humane care and use of animals by providing information on alternatives improved methods of animal experimentation that can reduce or replace animal use or minimize pain and distress to animals. Also, you can find information on products, services, and activities to help the regulated community with employee training.


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AGMUS Laboratories Registration

The Ana G. Mendez University System (AGMUS) Biosafety Committee (IBC) will register all AGMUS laboratories in accordance with the requirements established by the Office of Biotechnology Activities (OBA) for IBC registration.

“…Section IV-B-2 of the NIH Guidelines requires institutions to establish an IBC to review research subject to the NIH Guidelines and to oversee investigators compliance with the biosafety and reporting requirements set forth in the NIH Guidelines. Institutions must ensure that their IBC’s are properly constituted and functioning in full compliance with the NIH Guidelines.”

Compliance includes:

- Registering the IBC with the NIH Office of Biotechnology Activities; the registration must include (1) a roster of IBC members indicating their principal role on the committee (e.g., chair, contact person) (2) biosketches of committee members. Biosketches should reflect the professional background and perspective of the individual.
- Filing a report at least annually that updates the committee roster and biosketches; and
- Ensuring the IBC fulfills all the administrative, oversight, review and reporting functions described in Sections IV-B-2-a and IV-B-2-b of the NIH Guidelines…”

The registration will take place in summer 2009 in order to identify all of AGMUS Institutions laboratories. Remember that all AGMUS Laboratories MUST be registered with the IBC in order to comply with the policies established by the Ana G. Mendez University System. The IBC created an IBC Laboratory Registration Form (IBC Form_5) which is available in the Office of Regulatory Compliance.

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**COMPLIANCE: The key for responsible research**
ANA G. MENDEZ UNIVERSITY SYSTEM (AGMUS)
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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 regulates the use of humans, animals, chemicals, biohazards, radiation and DNA in research and teaching activities at all Ana G. Mendez University System (AGMUS) Institutions.

Regulatory Committees:
Through three key committees and related programs and activities, the Office of Regulatory Compliance develops implements and oversees university policies related to the following areas:

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 Committee (ACUC)

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compliance.suagm.edu

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