

In this issue:

Thank you
IRB Protocol Monitoring
Federal Agency FAQ's
Meet the Committees
HARPO Presentations
HARPO Blog

[Thank you to outgoing IRB committee members](#)

The Institutional Review Board wishes to thank two outgoing members of the committee, Matthew Page and Lisa Toole. Both are student members who have contributed significantly to the protocol review process and committee discussions. Their replacements will be announced the next issue of the *Compliance Console*.

[IRB Protocol audits \(this is not the IRS\)](#)

Many faculty and students have received notices over the past several weeks regarding the post approval protocol monitoring (PAPM), or as it may be better known as a "protocol audit".

Because an investigator is chosen for an "audit" or PAPM, it doesn't mean he/she has done anything wrong. UMBC required by federal regulation to exercise "appropriate oversight mechanisms" to make sure the policies and procedures designed for protecting the rights and welfare of human participants are being followed and that participant's well being is safeguarded.

So, in addition to complying with procedures, the PAPM is used to educate researchers about human subject protection issues and improve the quality of research by finding potential errors or omissions as research is performed.

Errors found in this review cycle include using consent forms without the IRB approval stamp and not fully deleting or excising participant names from study measures. Kudos to all researchers for doing a great job.

Read more about [Protocol Audits](#).

[Federal Agency FAQ's](#)

The Office of Laboratory Animal Welfare (OLAW) developed the new Frequently Asked Questions (FAQs) in response to requests for guidance on these topics. The new FAQs have been added to previously posted FAQs and are marked as "New" to enable readers to quickly locate and review this new guidance. The FAQs are posted at: <http://grants.nih.gov/grants/olaw/faqs.htm>.

[Meet the Committees](#)

What are the specific functions of the animal care and use and human research use committees?

UMBC has an [Institutional Animal Care and Use Committee \(IACUC\)](#), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The purpose of the IACUC is to ensure that all such research meets federal regulatory criteria as outlined in the Animal Welfare Act, Health Research Extension Act and PHS Policy on Humane Care and Use of Laboratory Animals. The functions of the IACUC are:

- o Review at least once every six months the institution's program for humane care and use of animals;

Location and contact information:

bwtech@UMBC
5523 Research Park Drive
Suite 310
Baltimore, MD 21228

HARPO@umbc.edu
410-455-3868 (FAX)
www.umbc.edu/HARPO
Tim Sparklin: 410-455-2737 Mary Lilly: 410-455-3958

- Inspect at least every six months all of the institution's animal facilities;
- Review concerns involving the care and use of animals at the institution;
- Make recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training;
- Review and approve, require modification in (to secure approval) or withhold approval of new animal use proposals;
- Review and approve, require modification in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing study; and
- Be authorized to suspend a study involving animals.

The **Institutional Review Board (IRB)** the committee that has been formally designated at UMBC to approve, monitor, and review research involving humans. The members of the IRB are responsible for performing ethical review of research involving human participants in order to help ensure rights are protected and that they are safeguarded from risk and harm. There are three areas for protecting human research participants (1) freedom from harm,(2) privacy, and (3) voluntary participation. The IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. All human research is reviewed to assess the scientific merit of the research, to ensure fully informed and voluntary participation and to maximize the safety of participants once they are enrolled in the project.

HARPO Staff Presentations

Staff from the office is available to meet with faculty at departmental meetings or speak to students in informal or formal (research methodology classes) to better educate and inform about research compliance issues. The current schedule may be found at <http://www.umbc.edu/HARPO/presentHARPO.html>. Contact the HARPO office at HARPO@umbc.edu or 410-455-2737 for more information or to schedule a time for your group or class.

HARPO Blog

Additional news, updates and information from the Human and Animal Research Protections Office can also be found on the **HARPO blog** at <http://harponotes.blogspot.com/>

See the list of current publications and multi-media resources in the HARPO Reading Library (<http://www.umbc.edu/irb/harporeadingviewing.htm>)

Location and contact information:

bwtech@UMBC
5523 Research Park Drive
Suite 310
Baltimore, MD 21228

HARPO@umbc.edu
410-455-3868 (FAX)
www.umbc.edu/HARPO
Tim Sparklin: 410-455-2737 Mary Lilly: 410-455-3958