As described on the Office for Human Research Protection’s website, the U.S. Department of Health and Human Services (HHS) has announced that “the federal government is contemplating various ways of enhancing the regulations overseeing research on human subjects. Before making changes to the regulations—which have been in place since 1991 and are often referred to as the Common Rule—the government is seeking the public’s input on an array of issues related to the ethics, safety, and oversight of human research. The changes under consideration can be found in an Advance Notice of Proposed Rulemaking (ANPRM), Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, published in the July 25 Federal Register. The proposed changes are designed to strengthen protections for human research subjects.”

This represents a major revision of the Common Rule. The federal government is considering changes to the Common Rule (45 CFR 46) for two reasons: (1) the human subject research landscape has changed dramatically since the early 1980s when the current regulations were first being formulated and (2) in light of that, there is a need to address effectiveness and the efficiency of the regulations for human subject protections in the current research environment.

The comment period ended on October 26, 2011. HHS is current reviewing the comments. Currently, no timeline has been announced for enactment of the rule changes. The Office for Research Compliance will provide updates when there is news to report.

Highlights of the proposed changes include the following:
1. Revising the existing risk-based framework to more accurately calibrate the level of review to the level of risk.

2. Updating the forms and processes used for informed consent. The regulations would be revised to provide greater specificity about how consent forms should be written and what information they should contain. The goal would be consent forms that are shorter, more readily understood, less confusing, that contain all of the key information, and that can serve as an excellent aid to help someone make a good decision about whether to participate in a study.

3. There are no specific data security protections for IRB-reviewed research: regulations require IRBs to determine, for each study, “when appropriate [that] there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.” Specified data security protections would apply to such research, calibrated to the level of identifiability of the information being collected. Establishing mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable data. In particular, studies approved under the exempt criteria would be subject to the new data security protections described above; and for some studies (e.g., those using biospecimens) new consent requirements would apply.

4. Implementing a systematic approach to the collection and analysis of data on unanticipated problems and adverse events across all studies to harmonize the complicated array of definitions and reporting requirements, and to make the collection of data more efficient.

5. Regulations would apply to all studies, regardless of funding source, that are conducted by a U.S. institution that receives some federal funding for human subjects research from a Common Rule agency. Note: UConn and many Universities already apply the regulations to all studies, regardless whether the study is funded.

6. Continuing review would not be required of studies that are eligible for expedited review unless the reviewer, at the time of initial review, determines that continuing review is required, and documents why.
7. The criteria for determining whether a study is exempt would be more clear-cut and less open to interpretation.

8. One of the six exempt categories applies to research using educational tests, survey procedures, or observation of public behavior, but not if both (i) information is recorded in a way that allows subjects to be identified, and (ii) disclosure of the subjects’ responses outside of the research could reasonably place subjects at risk of criminal or civil liability or cause damage to financial standing, reputation, or employability. This exempt category would be broadened by eliminating criteria (i) and (ii) for studies that involve competent adults, i.e., such research would be exempt even if the information was recorded in an identifiable way and the disclosure could pose such risks to the subject.

For anyone interested in learning more about the proposed Rule changes and to read a table comparing the existing regulations with the proposed change, visit the Office for Human Research Protection’s website - http://tinyurl.com/c7pcn3e.

Department of Defense (DoD)-Navy Addendum to the FWA held by UConn

In order for the University to conduct human subjects research supported by the Department of Navy (DoN) through contracts, grants, cooperative agreements, or through other arrangements such as collaborations with DoN personnel, the UConn IRB obtained a Department of Defense (DoD)-Navy Addendum to the Federalwide Assurance (FWA) held by UConn. The FWA is the University’s contract with the Office for Human Research Protections whereby the University agrees to conduct all human subjects research in compliance with the Department of Health and Human Services regulations. As noted on the Office of Naval Research website, the DoD-Navy Addendum “identifies and covers the unique DoD and DoN requirements that are not specifically included in the institution’s “FWA”. Additional key requirements include:

- Navy specific human subjects training for all personnel who conduct, review, approve, oversee, support or manage human subjects research.
- New research protocols and substantive amendments to approved research must undergo scientific approval prior to IRB review.
- Appointment of independent medical monitor. Depending on the nature of the study, the medical monitor may be assigned to assess one or more of the following phases of a research project: subject recruitment, subject enrollment, data collection, or data storage and analysis.
- Additional protections for military research participants to minimize undue influence.
- Limitations on compensation for U.S. military personnel.
Institutional Review Board (IRB)

Investigators who plan to apply to the Department of Navy for funding are strongly encouraged to plan accordingly and to contact the Office of Research Compliance before the research proposal is submitted to discuss these and other requirements. For more information, see the following websites:

Department of Navy, Human Research Protection Program - http://tinyurl.com/bml7lwe
Office of Naval Research, Research Protections - http://tinyurl.com/6plapub

FERPA and School Nutrition Programs

A researcher in the NEAG School of Education recently made the IRB aware that school nutrition programs and issues related to income eligibility applications for school nutrition programs are not among the educational records governed under The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99). FERPA is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education. FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level.

School nutrition programs and the eligibility information for these programs are governed by the U.S. Department of Agriculture (USDA) and Child Nutrition Program laws – not FERPA. Schools may provide researchers with aggregate data without obtaining parental permission; however, identifiable data regarding free/reduced price eligibility, for example, requires parental permission.

As a reminder, researchers who wish to obtain student education records for research purposes are required to obtain parental permission to do so. There are exceptions to this requirement, particularly for investigators who are conducting research requested and/or supported by the school. For more information, see the following websites:

Office of Research Compliance, Normal Educational Practice Guidance - http://tinyurl.com/6pmuekb
USDA/Food and Nutrition Service, Eligibility Manual for School Meals - http://tinyurl.com/7pr6b9b
EXTRACTION CONTROL REGULATIONS

The University of Connecticut is currently in the process of assessing our Export Control policy and procedures to determine areas in need of further development. This process is being overseen by the Office of Research Compliance and the Office for Sponsored Programs, along with a Committee comprised of representatives from related offices. On November 4, 2011, Mark Stomski, the Director of Export Control at Duke University, visited the UConn campus to meet with stakeholder groups to assist with the assessment of our Export Control program. A comprehensive website on export control issues is being developed as a resource for the University community.

As you may be aware, export control laws are federal regulations that govern how certain information, technologies, and commodities can be transmitted overseas or to a foreign national on U.S. soil. The scope of the regulations is broad: they cover exports in virtually all fields of science, engineering, and technology and apply to research activities regardless of the source of funding. These regulations also cover activities such as traveling abroad with a laptop computer, shipping research equipment overseas, and hiring foreign national students to work in UConn laboratories. Failure to comply with these laws can have serious consequences, both for the institution and for the individual researcher. Potential penalties include fines and possibly imprisonment. Thus, it is critical for UConn researchers to understand their obligations under these regulations and to work with the Office of Research Compliance and the Office for Sponsored Programs to ensure that the University is in compliance.

Pursuant to ITAR (International Trade in Arms Regulations) and EAR (Export Administration Regulations), restricted items/technology may not be released or “Exported” without a license. An “Export” includes:

- Training of foreign national students on controlled equipment
- Actual shipment or transmission outside U.S.
- Taking technology or technical data out of the U.S. (as when traveling with a laptop computer)
- Applying technical experience gained in the U.S. when abroad
- Written, visual or oral disclosure to a foreign national within or outside the U.S. (emails, telephone calls, photos, technical specifications/blueprints, training manuals, tours)
- Tours of Laboratories

Areas UConn must consider for Export Control compliance:

- Research Compliance
- Shipment of Controlled Technology Abroad
- Faculty/Staff Foreign Travel
- Deemed Exports: Exposure of foreign employees, and students, and visiting scientists/scholars to controlled Research
- Collaboration with and consulting for foreign researchers/institutions.

If you have questions about Export Control Regulations, please contact Nancy Wallach in the Office of Research Compliance (486-4164) or Antje Harnisch in the Office for Sponsored Programs (486-3994).
Institutional Biosafety Committee (IBC)

Biosafety Laboratory Competencies
by Leslie Delpin, Manager, Biological Health & Safety

The Centers for Disease Control and Prevention and the Association of Public Health Laboratories have released their [Guidelines for Biosafety Laboratory Competency](#). "These guidelines for laboratory biosafety competency outline the essential skills, knowledge and abilities required for working with biologic agents at the three highest biosafety levels (BSLs), (levels 2,3 and 4)". These guidelines are intended to be used in conjunction with a biosafety program and CDC/NIH guidelines Biosafety in Microbiological and Biomedical Laboratories (BMBL).

IBC Self-Assessment And NIH/OBA Site Visit Program

The NIH initially charged the Recombinant DNA Advisory Committee (RAC) with developing a set of guidelines that would govern the safe conduct of recombinant DNA (rDNA) research by outlining appropriate biosafety practices and containment measures. These guidelines, now known as the [NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)](#), were first published in 1976.

In response to the published guidelines, UConn established the Institutional Biosafety Committee (IBC) to oversee rDNA research. Yes, that's right; UConn's IBC has been in existence for over thirty years. As the NIH Guidelines evolved so have the IBC’s roles and responsibilities. The Office of Research Compliance (ORC), in partnership with Environmental Health and Safety, Biological Safety Section, is responsible for institutional biosafety at UConn.

The IBC is cognizant of the NIH/Office of Biotechnology Activities (OBA) site visit program aimed at enhancing compliance with the NIH Guidelines. The site visits will involve the evaluation and analysis of institutional systems of oversight of rDNA research. The site visits are meant to be informative not punitive in nature.

In January 2011, the IBC completed the [Tool for the Self-Assessment of the Institutional Biosafety Committee and Program of Oversight of Recombinant DNA Research](#). The assessment identified areas in need of improvement, one being the need to expand written documentation that clearly outlines the system of oversight to review and approve research and teaching activities that involve rDNA, biological agents or toxins at UConn. The IBC welcomes input from investigators to create a workable oversight process.

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**IBC Meeting Dates**

- Thursday March 22, 2012
- Thursday May 10, 2012
- Thursday July 19, 2012
- Thursday September 6, 2012
- Thursday October 25, 2012
- Thursday December 13, 2012

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Post Approval Monitoring (PAM): The What, When and Why

Post-approval monitoring ("PAM") of animal activities is required by federal laws, regulations and policies. In the broadest sense, PAM consists of all the continuing oversight activities undertaken by both internal and external groups, including the IACUC, EH&S, OAC, USDA/APHIS and AAALAC. This article will focus on PAM conducted by the IACUC at the time of annual continuation of protocols.

What is IACUC PAM?

PAM conducted by the IACUC is an opportunity for Principal Investigators and members of the IACUC to have a conversation about activities conducted under an approved IACUC protocol over the course of the preceding year. IACUC PAM sessions are conducted by at least one Faculty IACUC member and the Senior IACUC Coordinator, Karen Moré. Typically PAM sessions last between 40-60 minutes, depending on a protocol’s complexity. The PAM session is structured as an interview with questions designed to prompt discussion on topics including unexpected outcomes, need for modifications, pain and distress classification and risk/hazard assessment.

The IACUC representatives prepare for a PAM session by reading the protocol being monitored, with careful attention to procedures, guide exceptions, pain and distress classifications, necessary permits/approvals/licenses, hazards and personnel. Principal Investigators can prepare by familiarizing themselves with the activities conducted within the preceding year as well as reviewing any unexpected outcomes. The need for modifications will also be discussed. PAM is also a good time for Principal Investigators to informally test new ideas with current members of the IACUC.

Finally, the PAM appointment is an opportunity for Principal Investigators to provide feedback and constructive criticism regarding the Animal Care and Use Program as a whole. Investigator comments are compiled and provided anonymously as a monthly report to the IACUC entitled, “Stakeholder Feedback.” While investigators are always welcome to contact the IACUC Chair or an IACUC Member directly, we feel it is important to offer this informal alternative as part of the PAM conversation. The IACUC wants researchers to know that we value your input and believe it benefits the entire Program to provide this confidential opportunity for you to talk and for the IACUC to listen.

When can you expect to participate?

IACUC PAM is scheduled on or around the date of a protocol’s annual continuation. Principal Investigators should expect to receive an email communication from the Senior IACUC Coordinator to arrange a mutually convenient time to meet for PAM.

Why is PAM important?

As already mentioned, some form of PAM is required by federal laws, regulations and policies. Here at UConn we have decided to include encounters of many sorts as PAM, including EH&S audits, OAC animal health monitoring, semi-annual inspections and IACUC PAM. IACUC PAM is a unique opportunity for Principal Investigators to discuss their work with IACUC members face to face. It provides IACUC members the opportunity to learn more about a particular protocol, including any results or findings the protocol has generated. PAM also promotes conversation that may lead a researcher to recognize the need for a modification in order to remain in compliance. IACUC PAM provides a venue for the IACUC to communicate changes to policies or business practices that have occurred during the preceding year. Finally, the PAM process helps to ensure compliance by fostering positive collegial relationships between Principal Investigators and IACUC members that are based on trust and communication. By taking the time to meet with researchers, we hope to engender a feeling of mutual respect which will aid the institution in fulfilling its mandate to maintain animal welfare while conducting research, testing and teaching.
Revisions to IACUC Exemption Form: Formerly known as “Appendix A”

In our efforts to review and revise our IACUC forms, the IACUC exemption form (formerly titled “Appendix A”) has been updated. The exemption form is now titled “IACUC-2”, in order to more accurately denote its purpose as a petition for exemption from IACUC review, rather than a potentially necessary Appendix to the main IACUC-1 form. The form now clarifies that exemption is appropriate in the following cases:

The proposed activities involve the use of live invertebrate animals that will cohabit with vertebrate animals; or
The proposed activities only require the use of biological materials (blood, tissues etc.) obtained from animals NOT purchased, housed or cared for at the University of Connecticut; or the proposed activities involve the observation, filming or other documentation of animal activities with no interference on the part of the researcher, either directly or through environmental manipulation.

Earlier versions of the exemption petition were not well-defined and forced some Principal Investigators to try and fit the square peg of field observations (for example) into the round hole of tissue culture. By reinterpreting our forms and casting a careful eye to where IACUC oversight is required, we hope to enable researchers in their endeavors and reduce the amount of time and effort required from faculty while maintaining high standards in animal welfare.

IACUC Hints

Save time and Avoid Delays:

1. **Update your annual Occupational Health & Safety Status:** If there is no change, select, *Reply* and state “No change” to the email from Bill Field /EH&S. If EH&S doesn’t hear from you in a reasonable time, you will be removed from the list and will have to resubmit the paperwork even though there are no changes! If you have changes to report or wish to enroll in ongoing medical review services, you will have to resubmit the forms. The forms are on both EH&S and the IACUC websites. [http://www.ehs.uconn.edu/forms/index.php](http://www.ehs.uconn.edu/forms/index.php)

2. **When you know you want to add personnel to your protocol:** Before you submit the paperwork to the IACUC, tell them to take the IACUC Training [http://iacuc.uconn.edu/training.html](http://iacuc.uconn.edu/training.html) AND to fill out the Occupational Health and Safety Forms for animal handlers. [http://iacuc.uconn.edu/forms.html](http://iacuc.uconn.edu/forms.html)

3. **If you or your students are confused about the IACUC Training Options:** Read the information on the website: [http://iacuc.uconn.edu/training.html](http://iacuc.uconn.edu/training.html)

4. **If you or your student is still confused about which CITI Training course qualifies for IACUC Training credit, call the Office!** The Responsible Conduct of Research Course does NOT meet the requirement for IACUC Training.
The Geron Corporation, a pioneer in embryonic stem cell research, announced it is ending its stem cell research program and discontinuing its clinical trial testing of an embryonic stem cell derivative to treat spinal cord injuries. The corporation, which is under new management, has decided to shift its focus instead to cancer research. Geron had been conducting a first-in-human clinical trial of an embryonic stem cell product. Two other clinical trials are currently underway by Advanced Cell Technology to evaluate embryonic stem cell derived therapies to treat the blindness caused by macular degeneration.