Welcome to GuideLines, the publication that will keep researchers informed of current University policies and federal regulations as well as the latest updates, revisions and suggestions from the Office of Research Compliance. GuideLines will be available to faculty and graduate researchers on a quarterly basis, or more often when needed.

Issues of Importance to All Researchers

Special Reminder About New Training Requirements for Faculty and Staff

Commencing this semester, a new set of training programs are required to be completed by faculty and staff at the University of Connecticut. This training is required as a component of actions taken by the University to meet federal requirements and to ensure that all personnel are well-informed on policies related to the State Code of Ethics, the new University Code of Conduct, and principles of fiscal management of extramural grants and contracts.

The training consists of the following components:


This one and one-half hour session is required of all employees, and will be given online and in person.

♦ Fundamentals of Sponsored Project Administration Training.

This one and one-half hour session will be required of anyone who has any fiscal grant management responsibilities, including Principal Investigators, Co-PIs, department Grant Managers, Graduate Assistants and Special Payroll personnel. Training will be given in person.

♦ FAIT Training.

The University has also just commenced a nine-day training program, FAIT, for fiscal and administrative staff. Please note that employees who have completed the FAIT Legal/Ethics and OSP training modules of this nine-day training do not need to attend either of the sessions listed in column one during this academic year.

Scheduling of training sessions has already begun.

For more information, please consult the following website:
www.audit.uconn.edu/training.htm

A Word of Advice About Maintaining Research Files

In light of federal regulations on research misconduct, please note that the maintenance of research files is an important consideration. If an allegation of misconduct has been brought against a researcher, the researcher must be able to produce data, notebooks, computer records, scientific instruments, etc., supporting their research findings. The failure to produce data that should have been maintained may, in itself, be evidence of research misconduct. Documentation of destroyed records must been kept, if tapes, notes and other records have been destroyed, (for instance, to protect the identity of the human participants). The 2005 federal regulation on research misconduct may be reviewed on www.compliance.uconn.edu/link/1481.
An Overview and “Must Know” Facts

In January 2005 President Austin established and charged the ESCRO committee with the oversight of human stem cell research at the University of Connecticut. The establishment of the ESCRO committee follows National Academies of Sciences recommendations, and is required by the State of Connecticut for all Connecticut institutions conducting human embryonic stem cell (hESC) research.

If you or your students are planning a research project that uses human embryonic stem cells or their derivatives or aims to create new cell lines that are similar to embryonic stem cells in their pluripotency, here are some facts to keep in mind:

♦ All research projects that involve the use or creation of human embryonic stem cells must be reviewed and approved in advance by the ESCRO Committee, regardless of the source of funding.

♦ Visit the ESCRO website at www.escro.uconn.edu, and contact the ESCRO office at escro@uconn.edu or 860-486-2215 for information, advice, and forms for obtaining ESCRO approval of your project.

♦ To avoid delays in receiving funding, carefully plan your timetable for obtaining any required approvals from the IBC, IACUC, or IRB. ESCRO approval is the final sign-off after all other approvals are obtained. See the Research Compliance website at www.compliance.uconn.edu for the meeting schedules of these committees.

♦ All principal investigators and collaborating research personnel must complete the hESC research tutorial prior to submitting an application to the ESCRO. Contact the ESCRO office to obtain the tutorial (See 2nd bulleted item for contact information).

♦ Connecticut State law requires that prior to initiating any hESC research, the principal investigator notify the Commissioner of Public Health by submitting a signed “Verification” form, found on the ESCRO website, along with supporting documentation from the ESCRO committee.

Institutional Animal Care and Use Committee (IACUC)

IACUC FAQs

1. Do all research studies using animals require submission of an Animal Use Protocol Form?

No. Only studies using warm and cold-blooded vertebrates, either in the field, on the farm, and/or in the laboratory (for example, salamanders, birds, mice, cows, chickens, fish) for research/teaching activities require IACUC protocol review.

2. Do studies using snails, shrimp, bees, worms, microorganisms or related animals require submission of an Animal Use Protocol Form?

No. These animals do not have a vertebrae (backbone), and, therefore, such studies do not require IACUC review. You must submit an Animal Use Protocol Form only if you use animals that have a vertebrae (backbone).

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3. How long is an Animal Use Protocol approval good for?

Approval is for One (1) year. In order to remain active, a protocol must be renewed annually. It is important to note that all protocols must be rewritten and reviewed by the IACUC every three (3) years.

4. May the Institutional Animal Care and Use Committee (IACUC) administratively extend approval of a project that has expired?

No. According to federal regulations, IACUCs do not have the authority to administratively extend protocol approval — not even for a day. When IACUC approval expires, the protocol lacks valid approval. Continuation of animal activities in the absence of a valid approval is considered a serious violation of Public Health Service (PHS) Policy, and must be promptly reported to the Office of Laboratory Animal Welfare (OLAW).

5. If an investigator is awaiting an approval letter from the IACUC, may the animal work begin?

No. Starting the study without receipt of an approval letter from the IACUC would be research non-compliance.

6. If written notification that a project is “Approved” has been received, when can a project begin?

The approval date on the approval letter is the date the project may begin.

7. When would the IACUC send an investigator a letter with a notation, “Requires Modifications to Secure Approval”?

This statement means that, while reviewing a protocol application, the IACUC:

♦ had concerns that require more detailed explanation or clarification,
♦ found that some information was missing from the protocol which needed to be provided,
♦ found that training or occupational health and safety requirements still need to be fulfilled.

If a protocol is a new application, animal use cannot begin. If a protocol is being reviewed for renewal, all animal use covered by this application must cease beyond the expiration date of the previous protocol. In either case, animal work can only begin or continue after the IACUC accepts the written response to the committee’s concerns.

8. Can graduate students and post-doctoral researchers submit Animal Use Protocols under their own name?

No. Only Principal Investigators (PI) may submit protocols. A PI is a faculty member defined as a person who is tenured, in a tenure-track position or in a non-tenure track position, holding the title of University Professor, Professor, Associate Professor, Assistant Professor, Research Professor, Associate Research Professor, Assistant Research Professor, Professor In-Residence, Associate Professor In-Residence, Assistant Professor In-Residence, Research Scientist, and Research Scholar. Additional eligibility details may be found on iacuc.uconn.edu/link/1482. The IACUC understands that a PI sometimes will have a graduate student or post-doctoral researcher prepare an Animal Use Protocol form for a project in which the graduate student or post doctoral researcher is expected to participate. However, the completed form must list the faculty member as the Principal Investigator. The PI will be the primary contact with the Office of Research Compliance/IACUC for all matters relating to the Animal Use Protocol.
IACUC FAQs

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9. Is completion of an animal user compliance training program required?

Yes. Every animal user must attend an initial introductory training seminar that will cover the federal laws, policies, and regulations that govern animal use for research and teaching. The training program will also cover the University’s own policies, the function of the IACUC, and administrative hierarchy and reporting lines. Once this requirement has been met, every animal user must pass a web-based training module on a yearly basis. See iacuc.uconn.edu/training.html for details.

10. How often is the IACUC classroom training session scheduled?

Usually, two classroom training sessions are offered each month. One of the two sessions is scheduled in advance for the first Wednesday of every month. A list of these dates is posted on the IACUC website (iacuc.uconn.edu/training.html). A second session is offered each month to accommodate people who cannot attend a prescheduled session. The date, time and location for this second training session are sent by email in a monthly announcement to all principal investigators with active animal protocols. Researchers in need of taking the classroom training session, but unable to attend one of the prescheduled sessions, are encouraged to contact Dr. Daniel Schwartz at 486-2467; or daniel.schwartz@uconn.edu to schedule an alternate date.

11. Is there a way to find IACUC training completion dates if the dates have been forgotten?

Arlene Jacobsen in the Office of Research Compliance/IACUC at 486-4110 or arlene.jacobsen@uconn.edu can provide the most current classroom or web-based animal care and use training information and completion dates.

12. What is the procedure for adding personnel to an approved Animal Use Protocol?

Personnel can be added to an approved animal use protocol at any time. To do this, start with the current version of an approved Animal Use Protocol, and proceed as follows:

♦ Insert the name of the person to be added to the protocol in Section O, and provide all requested information.

♦ Describe in a specific manner the procedures this person is expected to perform and how, and from whom, they will receive any training that will be needed to insure that they perform these procedures properly.

♦ Use bold type for all newly added information.

♦ Submit an electronic version of the revised protocol to the Office of Research Compliance/IACUC (iacuc@uconn.edu).

♦ Describe the nature of the modification in the cover email.

Please Note: Any person added to a protocol must complete the required training (see iacuc.uconn.edu/training.html for details) and Occupational Health & Safety forms (iacuc.uconn.edu/link/1483) before the protocol modification can be approved. These requirements should be completed as soon as possible, even before submission of the modification, if possible, in order to facilitate timely approval of the modification request.

Once the protocol modification requesting addition of personnel is received by the Office of Research Compliance/ (Continued on page 5)
IACUC FAQs

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IACUC, it is distributed electronically to members of the IACUC for comment. If any member of the IACUC requests full Committee review, the protocol will be presented at the next convened IACUC meeting. If no member calls for full committee review by the given deadline, the protocol will be reviewed by the designated reviewer (usually the Chair of the IACUC). The designated reviewer may approve, request clarifications/changes, or request full Committee review of the modification. Once the modification is approved, an “Approval” letter will be sent to the Principal Investigator.

13. How are animal welfare concerns handled?

Researchers are urged to notify any IACUC member, any OARS veterinarian or staff member, or any ORC staff member with animal concerns or to report an incident of non-compliance. A list of IACUC members and staff members is available at iacuc.uconn.edu/membership.html. Contact information for OARS personnel is available at http://www.oars.uconn.edu/contacts.html. Additional information regarding reporting animal concerns or incidents of non-compliance can be found at iacuc.uconn.edu/concerns.html.

Institutional Biosafety Committee (IBC)

New IBC Policy on Generation and Breeding of Transgenic Animals

The Institutional Biosafety Committee (IBC) reviews research and teaching activities that involve recombinant DNA (rDNA), biological agents or toxins. The purpose of the IBC review process is to ensure that University activities comply with government regulations, and provide appropriate safeguards for human health and the environment. IBC policies and procedures apply to all Principal Investigators (PI) and University of Connecticut personnel at the Storrs and regional campuses. Companies operating in University facilities are expected to comply with the same procedures.

In February, 2007, the IBC approved a policy that outlines the review and approval process for all research and teaching activities that will alter an animal's genome by introduction of recombinant DNA. The policy applies to research using vertebrates, invertebrates, insects and all other members of the animal kingdom. In some limited situations, IBC approval is required for breeding transgenic animals. The full policy is available on the IBC web site (http://ibc.uconn.edu).

Before initiating any research project that is expected to generate transgenic animals, the Principal Investigator (PI) must notify the Institutional Biological Safety Officer (IBSO) in writing about the proposed experiments. Written notification must include the purpose of the project and the following information:

♦ animal species
♦ transgene name
♦ transgene function
♦ transgene source
♦ vector(s) used
♦ method of animal transformation
♦ physical location of the laboratories

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and research animals at the University.

- indication if the introduced gene(s) encodes a toxin or other potentially hazardous agent.

Based on this information, the IBSO will determine the appropriate review procedure. In very rare cases, the project may need to be referred to the NIH Office of Biotechnology Activity for federal review. In most cases the project will require either: 1) submission of a Memorandum of Understanding and Agreement (MUA) to the IBC for approval, OR 2) no further institutional review.

Other sections of the new policy address issues such as procedures for approving the transfer of transgenic animals and their tissues to scientists at other institutions, and the proper disposal of transgenic animals. The PI is responsible for reporting the inadvertent release of animals, improper disposal of transgenic animals or other incidents to the IBSO.

Investigators are strongly encouraged to contact the IBSO to discuss research or teaching activities that are expected to produce new transgenic animals or breed existing transgenic animals. For information or assistance with research activities, please contact Leslie Delpin (lm.delpin@uconn.edu), the Biological Safety Officer or Carol Auer (carol.auer@uconn.edu), the IBC Chairperson.

Institutional Review Board (IRB)

IRB Basics (Tips for a Smooth Protocol Application and Review Process)

- Photocopying Applications for Submission to the IRB

Trying to save paper by photocopying a protocol application and other materials in double-sided format makes it harder to review these documents. This, in turn, slows down the review process and the IRB’s response to the investigator. The ORC strongly suggests that single sided copies be submitted for IRB review.

- Language on Consent Forms

Use everyday language and avoid technical terms and professional jargon as much as possible. Consent Forms need to be understood by all subjects.

- Re-approval Request When the Grace Period is Over

A research study that was initially reviewed by the full IRB or by expedited review by an IRB member must be re-reviewed annually. Each study has an expiration date that is designated on the approval letter. The ORC extends a grace period of thirty (30) days. However, if re-approval information from an investigator is not received within thirty (30) days of the expiration date, the study will be terminated. Any re-approval information submitted after the grace period expiration date will not be accepted. As a courtesy, the ORC sends out re-approval reminder notices, but the responsibility for submitting material for-approval remains with the investigator.

- When Can A Study Be Considered Completed?

Research can be considered ‘complete’ when data analysis is done, when the identity of participants has been separated from the research data, and there is no additional research beyond the original intent planned for the data. If some minor tweaking of the data is necessary for publication purposes, this is (Continued on page 7)
acceptable after a study has been closed. As long as participants do not have to be re-contacted, and the essential work of the study is done, a study can be considered to be “CLOSED”.

♦ When Can A Study Be Considered in Data Analysis?

A study should stay open for as long as data needs to be accessed. A study may be considered in “Data Analysis Only” when new participants are not being enrolled into the study, when all participants have completed all interventions, when data are being analyzed or maintained, when there is no further contact with participants, but the identity of participants has not yet been separated from the research data; (i.e., a coding system linking participants to research data).

♦ If you have a problem with this process, please call 486-9428 or 486-8802.

Important Reminder: In order to be credited with a CITI completion report, it is necessary to sign up for either the Social Behavioral or Biomedical learner groups. There are additional learner groups that are used for other purposes, and do not generate completion reports.

Who Needs to Take the CITI Program Training?

All Investigators and "Key Personnel" who are "engaged in" research with living human beings, human tissue samples or identifiable private information, are required to take the CITI Training Program.

Key Personnel who are "engaged in research with human subjects" are staff or students who:

♦ Enroll participants;
♦ Obtain participants’ informed consent by doing more than handing out or collecting forms or telling subjects how to get in touch with the Investigators;

Collaborative IRB Training Initiative (CITI) Course in the Protection of Human Subjects Certification Period is Extended

In 2005, faculty, staff and students at the Storrs and regional campuses overwhelmingly complied with the requirement to complete the CITI on-line training program in the protection of human participants in research. Certification upon completion of the course was given for two years. The University has now extended that certification to three years from the date of completion of the CITI on-line course.

A refresher course is required by the University every three years. In order to keep track of course completion dates, it is suggested that CITI participants print out their completion reports by the following steps:

♦ Logon to www.citiprogram.org
♦ Enter user name and password
♦ Select completion reports and proceed to the name of the Learner Group(s) for which you registered, e.g. Social Behavioral, Biomedical, IRB reference, IRB member.
♦ Select and print report.

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“Help” Office Hours and Training Sessions

ORC staff will continue to offer “help” office hours every Tuesday, Wednesday and Thursday. Stop by the Whetten Graduate Center, Room 207, between 12 and 1:30 p.m., or call 486-9428 for an appointment for one-on-one help with IRB applications, questions on consent forms, or to decide if a study is actually “human subjects research”. Any other compliance questions are also welcome.

Additionally, if a department or class has specific IRB issues, ORC staff will provide compliance related training sessions in the department or classroom. Last semester thirteen departments had full presentations for faculty members as part of their departmental meetings, and IRB staff visited many classrooms for informal informational discussions with instructors and students. To set up a session, please call Christine Malloy, IRB Compliance and Education Monitor at 486-9428.