



UCConn

# GuideLines

## From the Office of Research Compliance

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March 2008

Welcome to the 2nd issue of "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" welcomes questions from researchers that may be submitted through the Office of Research Compliance.

### Research Compliance

[www.compliance.uconn.edu](http://www.compliance.uconn.edu)

- Institutional Review Board (IRB)
- Institutional Animal Care and Use Committee (IACUC)
- Institutional Biosafety Committee (IBC)
- Embryonic Stem Cell Research Oversight Committee (ESCRO)

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## Issues of Importance to All Researchers

### Faculty Consulting

Consulting is an activity performed by a faculty member for compensation, as a result of his/her expertise or prominence in his/her field, while not acting in his/her official capacity as a State employee (i.e. in his/her own time.) The University's Laws and Bylaws prohibit faculty from consulting on "time due to the University".

Prior to engaging in consulting activities, including any part-time or full-time outside employment, based on professional expertise or prominence in the field, regardless of when such activity is set to occur, a faculty member must complete and submit the "Request for Approval of Consulting Activities" form that may be found on <http://www.compliance.uconn.edu/facultyconsulting.php>.

The form must be submitted sufficiently in advance of the start of the consulting activity to allow for its appropriate review. Further, new forms must be completed and approved prior to making substantial changes to a previously approved activity.

### Consulting Activities FAQs

#### 1. What Is "Academic Activity"?

- ◆ Attendance at professional meetings,

- ◆ Reviewing books, articles, manuscripts, dossiers and research proposals,
- ◆ Giving occasional lectures, speeches and colloquia,
- ◆ Service on review panels for federal funding agencies.

#### 2. Can I Be Paid When I Engage In An "Academic Activity" In My Capacity As A State Employee?

No. You may be paid for "necessary expenses" only.

#### 3. What Constitutes "Necessary Expenses"?

Travel, lodging and food, at approximately the current federal and state per diem rates.

#### 4. What Can I Do With An Honorarium That Includes "Necessary Expenses"?

Accept the pay for necessary expenses made out to you personally, and put the remainder in a departmental research support account.

#### 5. Whom Should The Check Be Made Out To, If It Is To Be Deposited In A Departmental Account?

The check should be made out to the University of Connecticut.

## Consulting Activities FAQs

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### 6. What Is “Material Use” Of State Resources ?

- ◆ Anything that would incur cost to the state,
- ◆ Anything that one could NOT comfortably justify as part of routine, “academic activity”.

### 7. How Is The One-Day-A-Week For Consulting Calculated?

Generally, as one day in a five-day work week.

### 8. How Does One Count Consulting Days, If The Activity Is Done On Time “Not Due The University”?

Days that are not due to the University do not count against the one-day-a-week allowed for consulting.

### 9. What If I Initiate My Consulting Activity Before I Receive Approval From The University?

Without prior University approval, you do not have the benefit of the legislative carve-out and are subject to the jurisdiction of the Office of State Ethics.

### 10. Do New Forms Need To Be Completed And Approved Prior To Making Changes To A Previously Approved Activity?

Yes. Forms on file must always be the most current for the consulting activity.

### 11. How Can Approval Be Obtained For Last Minute Offers To Consult?

Presently, the procedure is the same as for last minute grant submissions. It may be necessary to hand-carry the consulting form to the Office of the Vice Provost for Research. Once the computer-driven on-line approval system is operational, this issue should be resolved.

### 12. Can A Person Who Is Not A Member Of The Faculty And Not A Member Of The AAUP Bargaining Unit Consult?

The word “consult” is being used only when this type of activity is carried out by a faculty member or a member of the AAUP bargaining unit. Employees who are not faculty or members of the AAUP bargaining unit may be allowed compensation for services rendered, provided that rules such as time due to the University are not violated. The Office of State Ethics would have jurisdiction over determining if there were a conflict of interest, inappropriate benefits resulting from state employment, violation of rules on confidential/proprietary information, etc.).

### 13. How Does The State Ethics Code Define A Conflict Of Interest?

The primary source of conflict in consulting would be any activity that would impair one’s ability for independent judgment as a state employee. Another way of stating it is that you or your family may not financially benefit from your state position.

### 14. Can A Faculty Member Or A Member Of The AAUP Bargaining Unit Use The University’s Name When Consulting?

Yes: However, the consultant may not speak, act or make representations on behalf of the University, or express institutional endorsement for an activity or product.



## Institutional Review Board (IRB)

**Note to Researchers:** Discussion and results of the IRB Researchers' Assessment Tool (RAT) will be on the IRB website, <http://www.irb.uconn.edu/> in mid-March, 2008.

### Your Questions and Tips for a Smooth Protocol Application and Review Process

1. **Good News For Researchers:** The Office of Research Compliance has revised the IRB forms. The most significant change involves the removal of the form field Text boxes (gray boxes), because the form fields were difficult to edit and spell check. The forms are now fully editable Word documents, and are capable of tracking changes. Please remember to always download and use the most current version of each form when submitting to the IRB. Please read the instructions attached to the revised application forms for more information.
2. **What Can I Do To Make Sure That My Submission Receives A Timely Review And Approval?**
  - ◆ IRB forms and templates have recently been updated. Download the current version of the protocol form and consent form templates to avoid delays in the review process.
  - ◆ Submit the correct number of copies of the protocol, consent documents and other supporting documents based on the level of review (original plus one for expedited review and original plus sixteen for full board review).
  - ◆ Make sure all investigators have completed the CITI on-line training.
  - ◆ Spell check all documents.
  - ◆ Sign all documents, where indicated.
3. **What is the Purpose of Attaching the "Face Page" to the Protocol Application?**
  - ◆ One Face Page attached to one signed copy of the protocol describes to the Office of Research Compliance (ORC) staff what is being submitted. This eliminates that chance that revised documents can be mistaken for new study material.
  - ◆ The Face Page is also a document check list for the benefit of the researcher and the ORC staff.
- ◆ Lastly, the Face Page is returned to the correspondent or the principal investigator as a receipt, to verify that the IRB office has received your materials.
4. **Do I Have To Have Letters Of Permission From All My Potential Sites Before My Study Can Be Approved By The IRB?**

No: The Principal Investigator (PI) must submit one letter of permission from one site before the IRB will approve a study. Additional sites may be added by filing an Amendment Review Form (IRB-3). Requiring the researcher to negotiate at least one site for the study demonstrates to the IRB that the PI is able to begin the study after IRB approval. Please contact the ORC office for assistance, if there are extenuating circumstances.
5. **Does A Researcher Need To Report An Adverse Event That Involves Research Personnel, Or Just Adverse Events Involving Study Participants?**

Events that involve both the participants and the researchers, including the PI, must be reported to the IRB within five days. The IRB is required by federal regulations to have written procedures for ensuring prompt reporting of any unanticipated problems involving risk to subjects or to any member of the research team. For example, unanticipated adverse events may include exposure of a research technician to a low level of radiation or an accidental finger prick during a blood draw. Unanticipated risks do not require that actual harm has occurred.
6. **If An Investigator Is Teaching A Course That Requires Students To Conduct Individual Research Projects As A Way Of Teaching Research Methods, And The Researcher Has Submitted A Protocol Application For The Involvement Of Human Participants In A Research Methods Course (IRB-7) To The IRB, Does Every Student Enrolled In The Course Need To Complete The CITI On-Line Training?**

No: Students enrolled in a research methods course are not required to complete the CITI training. How-

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## Institutional Review Board (IRB)

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ever, the IRB does suggest that, as part of the course, instructors offer students training in research ethics. The CITI program offers the IRB Reference Group modules, which enables the instructor to select specific modules, without requiring students to complete the entire CITI program.

### 7. If A Researcher, Who Is New To UConn, Completed The CITI Training At Their Last Institution, Can The CITI Coursework Be Transferred To UConn, So That The ORC Has A Record Of Completion?

Yes: The researcher can log into CITI, using the log-in and email from his or her last institution, and “re-affiliate” with UConn.

### 8. When Does An Amendment Form Need To Be Filed?

The Amendment Form (IRB-3) must be submitted to the IRB prior to instituting any changes to a research study. Changes that are being made need to be described on the IRB-3 form, and on each form affected by the changes, (e.g. IRB-1, consent forms etc.) These changes may not be put into effect until the amendment is approved by the IRB.

### 9. If A Protocol Application Has Been Submitted To The IRB For Review, May The Study Procedures Begin?

No: Participants may not be recruited, and the gathering of data may not commence until an approval letter and validated consent forms or information sheets have been issued by the IRB.

### 10. Researchers Asked That Two Items On The Protocol Application Form (IRB-1) Be Clarified. Here is The ORC’s Response:

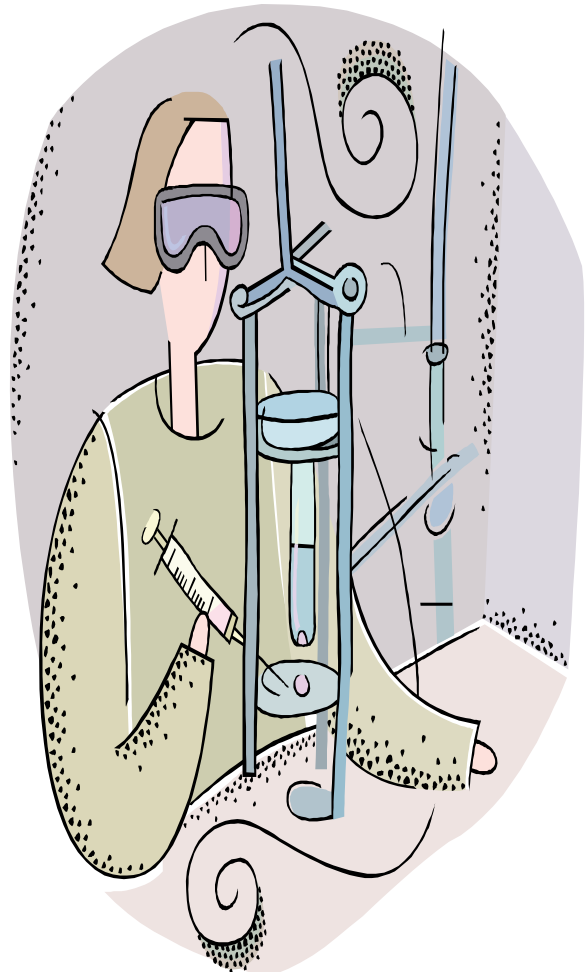
#### ◆ “Anticipated” Participant Enrollment” (Found in Section IV of the IRB-1)

The IRB-1, found on the IRB website, <http://www.irb.uconn.edu/forms.html>, has been revised. The IRB has removed the word “anticipated” from Section IV of the IRB-1. The question now clearly asks, “How Many Participants Will Be Enrolled?”. Once a study has been approved, this number of par-

ticipants may not be exceeded without amending the protocol. Participants are generally considered to be “enrolled” when they sign the consent form or have gone through an oral consent process. Therefore, be sure to account for attrition in enrollment numbers.

#### ◆ “Data Analysis/Justification of Sample Size” (Found in Section VI of the IRB-1)

In describing how data will be analyzed or giving a “justification of sample size”, the IRB suggests the following: For qualitative and pilot studies, describe how the proposed sample size is appropriate for achieving the anticipated results. For quantitative studies, provide a power analysis and references for how the sample size was determined.



## Institutional Review Board (IRB)

**April 11, 2008**

**Save the Date**

**You are invited to attend**

**“EMERGING ISSUES & ETHICS IN MEDICINE,  
SCIENCE AND RESEARCH”**

**A Forum on a Diversity of Ideas and Opinions to Inform and Engage  
the Campus Community and the Public**

**Presented by**

**The University of Connecticut**

**Office of Research Compliance**

**Dodd Center, Konover Auditorium, 9 a.m. – 1 p.m., April 11, 2008**

**Refreshments will be provided.**

**FREE to the public and to all UConn employees and students**

**A complete list of speakers and topics can be found at**

**<http://irb.uconn.edu/emergissues.html>**

## Institutional Animal Care and Use Committee (IACUC)

### Questions That Are Most Frequently Asked of the IACUC

#### 1. Do I Have To Complete An Animal Care And Use Protocol Form If I Am Only Using “Animal Parts/Tissue?”

It depends on the source of the animal(s) being used to provide the animal parts/tissue and the frequency with which this occurs.

- ◆ If you obtain animal parts/tissue from any live animal that has been specifically bred or purchased so that you can acquire the parts/tissue, then an Animal Care and Use Protocol form (IACUC-1) must be completed and approved before you can euthanize the animal to obtain the parts/tissue. If you are using animal parts/tissue from euthanized animals that are used in another study and are covered by your own approved protocol, then the protocol should be modified to reflect this additional animal use.
- ◆ If you obtain animal parts/tissue from another investigator who has a protocol with approved procedures for euthanizing animals, and obtaining such parts/tissue is an infrequent occurrence (once or twice), then an Animal Care and Use Protocol form (IACUC-1) is not required. However, if you obtain parts/tissue from another investigator with an approved protocol on a more frequent basis, you are advised to submit a completed copy of the “Petition to Exempt Activities Using Biological Materials From Animals” (Appendix A) in order to document that live animals were not bred or purchased by you obtain these parts/tissue. A copy of this form can be downloaded at <http://iacuc.uconn.edu/forms.html>. Alternatively, the PI providing the parts/tissue can submit a modification to his/her protocol to indicate this new use of parts/tissue from their euthanized animal(s).

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### 2. Do I Need To Submit Anything Else Besides The Animal Use Protocol Form (IACUC-1) When I Submit A New Protocol?

All individuals associated with an approved protocol must have submitted Occupational Health & Safety forms to the appropriate offices before a protocol will be approved.

- ◆ Beyond that, depending on the nature of the animal study, you may need to submit forms that cover special requirements of the project. For example: an Owner Consent form will be needed if you are using an animal owned by a private individual; a Special Husbandry form is needed to describe any special housing, feeding, or care requirements of the animals in the proposed study; a Hazardous Agents form is required if you will be exposing animals to radioisotopes, toxins, recombinant DNA/RNA chemical carcinogens or any potential pathogenic agent; a Consideration of Alternatives form is required if any of the animals in your study is classified as Category C or D; a Surgery form is required if you will be performing survival surgery (major or minor) on any of your animals; a Stress form is required if you will be exposing any of your conscious animals to conditions that have the potential to induce stress (for example, prolonged restraint); a copy of any Record Form you plan to use (other than those provided by OARS).
- ◆ If you are performing animal use activities that require special permits for work with endangered species or species collection permits, you should submit a copy of your permit along with the protocol form to the IACUC office. If you are working in cooperation with an investigator at another institution, you may be required to furnish a copy of that institution's protocol approval letter. If you have any question(s) about what documentation is required, consult the IACUC website and/or or contact the IACUC office

### 3. Do I Have To Resubmit A Protocol If The Same Animal Model (i.e., Procedures) Will Be Used In A New Grant Application?

A single protocol can be used to cover work described in multiple grant applications. The protocol must indicate the title, source and status of all grants that are cov-

ered and all sections of the protocol (animal numbers, project description, procedures, personnel, etc.) must be written to reflect all of the grant applications that are covered by the protocol. This information can be added as a modification(s) as new grants are submitted and/or approved.

### 4. What Is The Meaning Of The Different Pain Categories?

The USDA requires that all covered animals be classified as to the potential for pain and distress. This information must be reported to the USDA annually. The PHS Assurance for the University of Connecticut-Storrs extends this requirement for animal classification to all vertebrate animals used in research and teaching.

- ◆ **Category A:** This category includes any animal being bred, conditioned, or held for use in teaching, manipulations, research or surgery, but not yet used for such purposes. This category is used for animals only when there has been NO live animal contact by study personnel and NO experimental procedures of any kind involving these animals have been initiated.
- ◆ **Category B:** Animals in this category are expected to experience no more than mild or transient pain (or distress) and there is no need for any pain-relieving drugs. If you need to use an anesthetic or tranquilizer to perform any procedure, then the animals should be placed in Category C.
- ◆ **Category C:** Animals in this category are expected to experience some pain, distress, and/or discomfort as part of their participation in this protocol and appropriate pain relieving drugs or treatments (anesthetics, analgesics, tranquilizers) will be provided.
- ◆ **Category D:** This category includes animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. The withholding of such pain relieving drugs or treatment must be explicitly scientifically justified in the protocol and approved by the IACUC.

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## Institutional Animal Care and Use Committee (IACUC)

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### 5. Who Should Be Listed On A Protocol?

All faculty, staff, students and visiting scholars involved in any of the live animal procedures described in a protocol need to be listed in the Personnel section. New personnel should be added to a protocol as they join the project prior to their use of animals. All personnel should have appropriate and required training before use of any animal commences.

### 6. Must I Have An Approved Protocol Before I Can Order Or House Animals In An OARS Facility?

OARS will accept orders for animals at any time. However, orders will not be placed with an approved vendor until OARS receives confirmation that the PI has an approved protocol.

### 7. Can My Newly Submitted Protocol Be Granted Preapproval Status If I Am In A Rush To Do My Animal Work Or If My Grant Has Just Been Funded?

No. Animal work cannot begin until the IACUC approves your protocol. All new or 3-year renewal protocol applications must undergo full committee review before a decision can be rendered. Please note that modifications to an approved protocol can not be implemented until the modification has been approved by the IACUC also.

### 8. When Should I Report Changes Or Modifications To My Protocol?

Changes or modifications to an approved protocol may be requested at any time during the life of the current protocol. By federal law and University Policy, PIs are required to notify the IACUC of any change(s) made to any currently active protocol. Typical changes may include project personnel, numbers and species of animals, modifications to the experimental methods or procedures, changes in drugs administered, special requirements for animal husbandry and housing, etc. Be advised that if the change(s) is considered SIGNIFICANT (see below), the modified protocol must be reviewed and approved by the full committee.

### 9. How Do I Submit A Modification To My Protocol?

Modification of an approved protocol must be approved before the modification can be implemented. Approval for a modification does not change the existing expiration date of an approved protocol. Starting with a clean copy of the protocol, modifications are made by including new text in bold and showing deleted text with strikeout. A copy of the modified protocol should be submitted to the IACUC office along with a cover letter (or email) itemizing the changes. **Instructions for Completing a Protocol Modification are as follows:**

- ◆ Unprotect the document: All protocol forms are provided as locked documents. This limits your use of some features of your word processing program, such as boldface and strikethrough, features you need if you are going to submit a Modification to an approved protocol. If you plan to submit a Modification to an approved protocol, open a copy of the protocol using the "unlocked" setting of your word processing program. To unlock the document in Microsoft Word, go to the Tools menu and select "Unprotect Document." This will allow you to edit the document fully. You may only unlock the document if you have saved it to your computer and opened it in your word processor application. The option to unlock the document is not available from within the web browser (i.e. Netscape or Internet Explorer). If at any point you have difficulty using the IACUC forms, please contact the IACUC office.
- ◆ Use boldface for any newly added text.
- ◆ Use strike-out to line out any unwanted text.
- ◆ A protocol form modified from the original format may not be accepted. Please do not adjust the font type or size, nor should you change the margins.
- ◆ Please submit the modified protocol electronically to [IACUC@uconn.edu](mailto:IACUC@uconn.edu).
- ◆ Provide a brief summary of any changes made to the protocol in a letter or email to facilitate the review process

### 10. What Is The Difference Between A Significant And Minor Change To A Protocol?

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## Institutional Animal Care and Use Committee (IACUC)

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- ◆ Examples of minor changes include (but are not limited to) a change from jugular vein to tail vein for obtaining a blood sample, or a change in the anesthetic agent to be used.
- ◆ Examples of significant changes include (but are not limited to) a change in the project PI, a change in experimental objective of a study, a switch from non-survival to survival surgery, a change in the species or in the number of animals used, a change in the method of euthanasia, the withholding of analgesics, and an increase in degree of invasiveness of a procedure or potential discomfort to an animal. If you are unsure if a change is minor or significant, contact the IACUC office.

### 11. Will I Be Notified When It Is Time For Me To Renew My Protocol?

Yes. The IACUC office will first notify you approximately 2-3 months in advance of your protocol expiration date.

### 12. My protocol has expired and I still have animals. What happens now?

- ◆ Your animals will automatically be transferred to the OARS animal holding protocol for up to 60 days. This will allow time for you (as PI) to secure approval for a new protocol or transfer the animals to another IACUC approved protocol. At the PI's request, OARS can euthanize some or all of the remaining animals in the manner described in the original protocol.
- ◆ During the 60 day holding period, OARS will care for the animals in the manner described in the original protocol. Breeding colonies will also be maintained to ensure viability. The PI will not be allowed to have contact with these animals (unless the IACUC requests that they provide some or all of the required daily animal care) or proceed with any ongoing experiments until a new protocol has been approved by the IACUC.
- ◆ Animals remaining on the OARS holding protocol longer than 60 days will be reevaluated by the IACUC with respect to their disposition.

### 13. Can I Transport My Own Animals Around Campus?

It is permissible to transport your own animals if it is within the same building in which they are housed or in a building that is contiguous with where they are housed as long as you have IACUC approval to do so. In most other circumstances, the Office of Animal Research Services will provide transportation.

### 14. What Will Happen If I Do Not Follow My Protocol?

If a protocol is not followed, an IACUC investigation may follow. The PI may be asked to take corrective action or the PI may be suspended from using animals for a period of time or both. These incidents will be reported to the Institutional Official, and possibly the USDA, the Office of Laboratory Animal Welfare (OLAW), and the PI's funding source as required.

### 15. Can The IACUC Suspend My Animal Use Activity?

YES. Federal regulations specifically give the IACUC the authority to suspend a previously approved activity after review of the matter at a convened quorum of the IACUC. Further, regulations are interpreted to allow the IACUC the authority to suspend either a full activity or a portion of such an activity.



## Institutional Biosafety Committee

### The Responsibilities of a Principal Investigator

1. Principal Investigators conducting research (with or without grant support) involving recombinant DNA (rDNA), potentially hazardous biological materials and/or biological toxins must obtain approval from the IBC. Teaching activities using these methods and materials must also be reviewed and approved by the IBC.

2. Principal Investigators shall comply with University policies, state regulations and federal regulations regarding biosafety. The General Responsibilities of the Principal Investigator, outlined in the NIH Guidelines (Section IV-B-7-a) are as follows:

- ◆ **Section IV-B-7-a-(1).** Initiate or modify no recombinant DNA research which requires Institutional Biosafety Committee approval prior to initiation (see Sections III-A, III-B, III-C, III-D, and III-E, Experiments Covered by the NIH Guidelines) until that research or the proposed modification thereof has been approved by the Institutional Biosafety Committee and has met all other requirements of the NIH Guidelines;
  - ◆ **Section IV-B-7-a-(2).** Determine whether experiments are covered by Section III-E, Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation, and ensure that the appropriate procedures are followed;
  - ◆ **Section IV-B-7-a-(3).** Report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable) within 30 days. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax);
  - ◆ **Section IV-B-7-a-(4).** Report any new information bearing on the NIH Guidelines to the Institutional Biosafety Committee and to NIH/OBA (reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax));
  - ◆ **Section IV-B-7-a-(5).** Be adequately trained in good microbiological techniques;
  - ◆ **Section IV-B-7-a-(6).** Adhere to Institutional Biosafety Committee approved emergency plans for handling accidental spills and personnel contamination; and
  - ◆ **Section IV-B-7-a-(7).** Comply with shipping requirements for recombinant DNA molecules (see Appendix H, Shipment, for shipping requirements and the Laboratory Safety Monograph for technical recommendations).
3. Principal Investigators are obliged to disclose all relevant information about rDNA, biological materials and experimental protocols. Collaborators outside of the University who provide materials to the Principal Investigator may be required to provide information so that the IBC can assess the potential hazards. Upon request, 'Material Transfer Agreements' (MTAs) for research materials must be provided to the IBC.
4. Prior to initiation of experiments, Principal Investigators are strongly encouraged to discuss their experiments with the Institutional Biological Safety Officer, Leslie Delpin ([lm.delpin@uconn.edu](mailto:lm.delpin@uconn.edu)), and/or IBC Chairperson, Carol Auer ([carol.auer@uconn.edu](mailto:carol.auer@uconn.edu)). Principal Investigators with experiments deemed to require IBC approval must submit a MUA application. Experiments determined to be exempt from the NIH Guidelines do not require IBC review.
5. Principal Investigators and all other employees are responsible for observing safe practices when handling hazardous biological materials in teaching and research activities. Principal Investigators, instructors and laboratory supervisors have an obligation to instill in their students and laboratory personnel an informed awareness and responsibility concerning practices that will ensure safety.



## Embryonic Stem Cell Research Oversight Committee (ESCRO)

**Attention Principal Investigators:** The next round of State stem cell grants will be awarded on April 1, 2008. Please be advised that ESCRO approval requires prior approval from IBC and IA-CUC, if applicable.

### Current Happenings

#### 1. Tutorial Available

The Stem Cell Research Compliance Tutorial is now available on the ESCRO website: [www.escro.uconn.edu](http://www.escro.uconn.edu), and is no longer available through the UCHC Office of Research Compliance. To view the tutorial, quiz questions, and answer sheet, click on the link “Training” on the ESCRO website. Print and sign completed answer sheets and return them to [escro@uconn.edu](mailto:escro@uconn.edu), or fax sheets to 860-486-5381.

#### Who Must Complete The Tutorial?

In accordance with University Policy, all researchers and research staff, including students, post-docs, visitors and faculty, who are working with hESC at the University of Connecticut must pass the tutorial with 100% accuracy, prior to engaging in hESC research.

#### What Is The Intention of the Tutorial?

The tutorial is intended to educate researchers on ethical issues associated with hESC research, and to inform them of relevant institutional, state and federal policies and procedures.

#### 2. New ESCRO Amendment and Renewal Forms Are Now Available

The ESCRO Amendment Form is posted on the ESCRO website: [www.escro.uconn.edu](http://www.escro.uconn.edu) under “forms”.

#### When are Amendments Required?

Amendments are required for changes in staff, rooms additional cell lines, or changes in experiments. Minor changes can be addressed administratively.

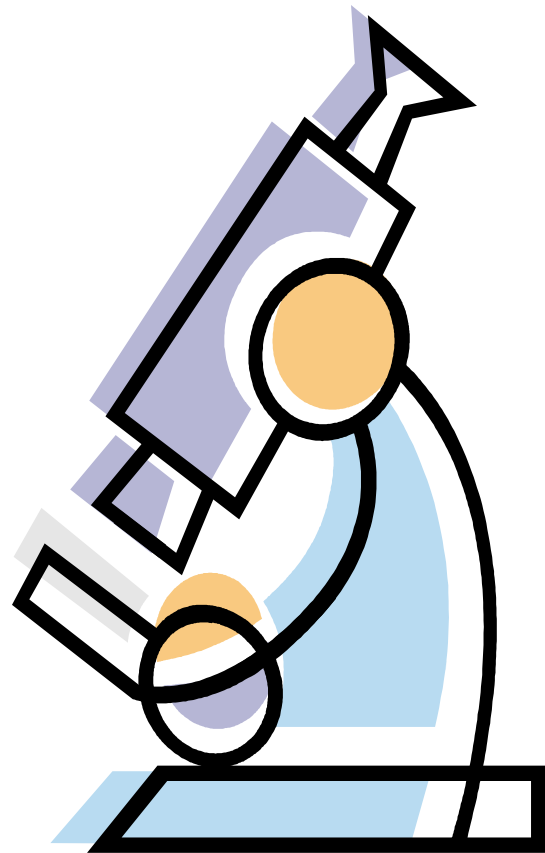
Two ESCRO renewal forms are also posted on the ESCRO website: [www.escro.uconn.edu](http://www.escro.uconn.edu).

**Form AC1** is for projects in the expedited review category (e.g. in vitro work with pre-existing anonymous hESC lines).

**Form AC2** is for projects that originally required full committee review.

#### 3. Review Criteria Update

ESCRO has been refining its review criteria for the use of parthenogenesis as a source of stem cells and the use of animals in testing the effects of transplantation of human stem cells and progenitor cells. At a recent meeting, the ESCRO agreed to move the review of parthenogenesis from the stringent review category down to the category of full committee review. Researchers who submit a state grant involving the creation of animal-human chimeras are asked to forward their state grant applications to the ESCRO to assist it in refining the review process.



## Help Sessions for Researchers

### Office of Research Compliance (ORC)

ORC staff continue to offer “IRB help” office hours every Tuesday, Wednesday and Thursday. Stop by the Whetten Graduate Center, Room 207, between 12 and 1:30p.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 IRB compliance questions are also welcome.

Also, representatives from the Institutional Review Board (IRB) would be happy to come to your classroom to provide information and training. Just call the ORC office at 486-8802 to make arrangements.

### Additional Help For Researchers Is Provided By The Center For Science And Technology Transfer Commercialization (CSTC)

The CSTC transfers new technologies to the private sector. Responsibilities of the CSTC include review of invention disclosures, licensing agreements and new company spin-outs for the entire University and the regional campuses.

Donna Cyr handles technologies in physical sciences and engineering, and is on the Storrs campus every Tuesday and Friday (other days by appointment). Dr. Cyr can be reached at 486-8330, 860-679-8185 or [dcyr@uchc.edu](mailto:dcyr@uchc.edu). Her office is Room 306 in the Whetten Graduate Center.

Greg Gallo handles technologies in life science, and is available by appointment. Dr. Gallo may be reached at 860-679-8774 or [ggallo@uchc.edu](mailto:ggallo@uchc.edu).

Mansoor Khan handles technologies in engineering, and is available by appointment. Dr. Khan may be reached at 860-679-8772 or [makhan@uchc.edu](mailto:makhan@uchc.edu).



## Protocol Submission Deadlines

**Protocols Must Be Received By 4:30p.m. on the following dates in order to be placed on the agenda for Protocol Review Meetings.**

### IRB Deadlines

Friday, March 21, 2008

Friday, April 11, 2008

Friday, May 2, 2008

Friday, May 23, 2008

### IACUC Deadlines

Tuesday, April 8, 2008

Tuesday, May 13, 2008

Tuesday, June 10, 2008

Tuesday, June 10, 2008

### IACUC Deadlines contd.

Tuesday, July 8, 2008

Tuesday, August 12, 2008

### ESCRO Deadlines

Monday, April 14, 2008

Monday, May 12, 2008

Monday, June 9, 2008

