Guidelines
From the Office of Research Compliance
Welcome to the 4th issue of Guidelines

Ten Tips for Streamlining IRB Review

Here are ten easy steps to help you.

1. Become familiar with the IRB website – http://www.irb.uconn.edu and the following sections, in particular - Forms, Meeting Dates and deadlines, and Researcher’s Guide.

2. Submit the protocol at least 2 months before the anticipated start date of the research. The IRB makes every effort to review protocol submissions in a timely manner, but heavy volume can push back turn-around times. Do not wait until the last minute to submit the protocol.

3. Attend an IRB application help session. Sessions are held 2x/month in the Whetten Graduate Center, Classroom 200. Check the IRB website for specific dates - http://irb.uconn.edu/viewnews.cfm?articleid=503.

4. Download and use the most current versions of the application forms and consent document templates.

5. Contact the IRB with questions, particularly, if you are uncertain what information is required in the protocol application.

6. Read each section of the protocol application carefully, including the instructions in small print, to be sure that you are providing the IRB with the information requested and where the information is requested. We strongly suggest that you read the entire protocol application before completing it; doing so will give the IRB the information it needs to process your application.

7. If you use the InfoEd electronic submission system, review the manual and/or the instructional video before using InfoEd. The training material is available on the IRB website - http://www.irb.uconn.edu/infoed.html. Hard copies (with appropriate signatures) are also accepted.

(continued on page 2)
Institutional Research Board (IRB)

8. When submitting hard copies, assemble the protocol application for review in the following order:
   a. Face Sheet
   b. Protocol Application
   c. Appendix A
   d. Supplemental Application Forms (i.e. IRB-1A)
   e. Consent Documents
   f. Recruitment Flyers
   g. Appendix Materials
   h. Grant Application

9. When submitting hard copies, submit the required number of copies for review. Submit the original + one copy for protocols that require expedited review. Submit the original + 16 copies for protocols that require full board review. Collate the copies in the order described in #8.

10. Faculty members who serve as PI on protocols submitted by student researchers are asked to do the following:
    • Help students to prepare the protocol – offer advice, wisdom and criticism. Their work is a reflection of you.
    • Read the protocol application, consent documents, etc. before you sign the protocol. As PI you are ultimately responsible for the protocol and research conducted by the student.

Dear Colleagues:

The National Institute for Health and the International Committee of Medical Journal Editors (ICMJE) have issued laws and directives on the subject of clinical trial registration.

ClinicalTrials.gov is a service of the NIH, developed by the National Library of Congress to facilitates registration of trials in accordance with the International Committee of Medical Journal Editors (ICMJE) initiative requiring prior entry of clinical trials in a public registry as a condition for publication. The ICMJE defines clinical trials as, “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.” A listing of the relevant ICMJE journals can be found at: http://www.icmje.org/journals.html. The University of Connecticut has registered with ClinicalTrials.gov to facilitate the public registration of clinical trials conducted at UConn (separate from those trials conducted at the UConn Health Center).

If you have questions, please refer to the ClinicalTrials.gov information page on the Research Administration website, http://research.uconn.edu/clinicaltrials.cfm or contact Doug Bradway at 6-0986 or by email at doug.bradway@uconn.edu. Thank you.

Suman Singha
The purpose of this article is to update University researchers about the streamlined oversight process now in place for all research and teaching activities utilizing recombinant DNA (rDNA), potentially hazardous biological materials and/or biological toxins. The Institutional Biosafety Committee (IBC) at the University has been active for more than three decades in helping researchers comply with federal biosafety guidelines, achieve safe lab practices, and protect the environment.

Common types of experiments that require IBC review and approval include expression of recombinant proteins in bacterial cultures, the use of viral vectors to transform animal cell cultures, the production of transgenic plants and insects, and nanotechnology involving biological materials.

The faculty and community representatives on the IBC have worked to make this federally-mandated oversight process as easy and efficient as possible. The following list outlines some of the changes that are already helping researchers comply with all relevant University policies and federal biosafety guidelines:

- A new Memorandum of Understanding and Agreement application form (called the MUA) has been implemented. Only one MUA form is needed for research projects that occur under multiple grant titles or receive funding from more than one agency.

- The new MUA has check boxes and tables so that researchers can rapidly enter names of cell lines, laboratory personal protective equipment, and other information.

- After submission of the MUA, there is an internal pre-review process with feedback to the applicant. This allows investigators to modify their application before it goes to the quarterly IBC meeting. This has proven to be very effective in speeding up the approval process.

- Researchers with active MUAs can ask for amendments or modifications of their MUA at any time. This can be done through an email or a phone call to Leslie Delphin (EH&S). These administrative modifications allow the MUAs to remain current and accurate without requiring a new MUA application.

- A brief ‘IBC Policies and Procedures’ statement has been placed on the IBC web site to help everyone understand their roles and responsibilities. The new MUA form and deadlines for MUA applications are also on the web site. Please go to: www.ibc.uconn.edu.

Contact Information:

Nancy Wallach  
Director, ORC  
nancy.wallach@uconn.edu  
Phone: (860) 486-4164

Carol Auer  
Chair, IBC  
carol.auer@uconn.edu  
860-486-1878

Leslie Delphin  
Institutional Biological Safety Officer, EH&S  
lm.delphin@uconn.edu  
860-486-2436

Cindy Hall  
Compliance Coordinator, ORC  
cindy.hall@uconn.edu  
860-486-5813

Office Fax: 860-486-1044
Beginning November 1, 2009, the Institutional Animal Care and Use Committee (IACUC) will be requiring the use of an updated protocol form for all new protocol submissions and the renewal of protocols in their third year. This form will be on the IACUC website shortly.

You will notice several changes to the form itself. We have made the changes to bring the University's program current with changing standards of animal care and use. It is hoped that the new forms will greatly reduce the amount of time required for review, and will ask the questions that most frequently hold up protocol review. In short, it is our hope that the new form will more comprehensively cover all of the required information.

In addition to the new form, several reference resources and checklists for required content have been provided, and will continue to be provided. We are working diligently to ensure you have adequate resources for your use. We are also modifying the process for protocol review.

Please note the expected chain of events, as numbered:

1. You will submit your protocol to the IACUC office, via hard copy or e-mail (preferred) to iacuc@uconn.edu.

2. Your protocol will receive a pre-review in the IACUC office for required content, general structure, and items that will require further input from our side (Veterinary consultation, EH&S review, state and/or federal permits, etc.). It will also be assigned a number.

3. Rachael Shenyo, Senior IACUC Coordinator, will contact you if there are any required modifications prior to the protocol being submitted for primary review. A primary reviewer member of the IACUC with sufficient knowledge to review the protocol) will be assigned by the chair or vice chair.

4. In an effort to streamline the process, once the protocol is deemed ready for primary review, the primary reviewer and veterinarian will receive it at the same time, and will coordinate the comments and questions on the protocol. They may choose to contact the PI for clarification and discussion at this point, as happened previously.

5. The primary reviewer will discuss only outstanding questions and concerns at the meeting where the protocol is presented, and will provide an overview of the proposed research and its importance.

(Continued on page 5)
It is hoped that the new system will reduce the time necessary for protocol approval, and will also reduce handling time by including all necessary review pieces upfront. In order to facilitate the new process, we have posted new deadlines for submission. Please do not hesitate to contact the IACUC office if you have any questions regarding either the new process or forms that are being used.

The IACUC staff are planning to hold formal training sessions for using the new form and leveraging the new process, and the Senior IACUC Coordinator will be available by appointment to assist with protocol preparation during the transition time while the new form is being used.

AAALAC Update

What is AAALAC and why is the University going through its accreditation process?

UConn/Storrs is seeking accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). AAALAC is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. More than 770 companies, universities, hospitals, government agencies and other research institutions in 31 countries have earned AAALAC accreditation, including Sloane Kettering Cancer Center, the NIH and the American Red Cross. In the scientific community, AAALAC International accreditation shows that an institution is serious about setting, achieving, and maintaining high standards for animal care and use in science. Accreditation promotes scientific validity in animal research because reliable results depend on a quality animal care and use program. Both private and public funding sources view AAALAC International accreditation as assurance that animal use will be scientifically justified and humane, and that appropriate regulations and policies will be followed. Accreditation also assures the public and potential employees that the institution is committed to the responsible care and use of animals in science.

Mock Inspections Offered.

Staff from OARS and the IACUC and from several departments have been working to get the paperwork for the AAALAC application submitted by the December 1 deadline. The accreditation process also includes inspections by AAALAC council members which will occur in February or March of 2010. We are fortunate that our OARS Director, Dr. Cecile Baccanale, has served as an AAALAC Inspector and has been on site visits across the country. OARS and IACUC personnel have also been working with animal researchers in departments on campus to do self assessments of labs and other facilities where animals are housed and used for research or teaching. To help prepare their departments for the AAALAC inspectors, some departments (Psychology, Pharmacy) have requested that mock inspections be scheduled. These mock inspections will be done by Dr. Baccanale and an IACUC member and will include an in-depth review of two protocols from the department. Mock inspections will be done as time allows in the order that they were requested. If your department is interested in arranging one, please contact OARS or the IACUC office.
Once again the Connecticut Stem Cell Researchers Grants Program is committed to supporting researchers in the advancement of Human Embryonic and Adult Stem Cell research here in Connecticut.

The intent of this program is to aide in supporting all forms of stem cell research, its primary focus is human embryonic stem cell research that is not currently eligible for federal funding. Priority of these grants will be given to studies with a clear relevance to human health. Animal models will also be considered in this pool of applicants, however a direct relevance to human stem cell biology along with its therapeutic implications must be demonstrated.

**Four types of awards will be granted:**

1. **Seed Grants**: Intended to support early stages of projects that are not ready for larger scale funding.

2. **Establish Investigator Awards**: Intended for Investigators with a track record of independent research including prior grant support and regular peer reviewed publications.

3. **Group Project Awards**: Intended to support coordinated approaches to ambitious strategic goals that are beyond the scope of a typical single laboratory.

4. **Core Facilities Awards**: Intended to provide shared core facilities for stem cell researchers at eligible Connecticut Institutions, hospitals or companies.


(Information obtained from the RFA)

**Please Note**: Stem cell researchers planning iPS projects using chimeras should be prepared to provide documentation to the ESCRO regarding the informed consent of the somatic cells from which the iPS lines were derived.

Attention Investigators: All ESCRO research grants need to be reviewed by the ESCRO Committee before awards can be accepted.

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**New ESCRO Chair**

The ESCRO would like to welcome our new ESCRO Chair, Dr. Audrey Chapman

**Brief Biography:**

Dr. Chapman is a Professor in the Division of Public Health Law and Bioethics and the first Healy Endowed Chair. Dr. Chapman is responsible for developing medical humanities at the UConn Health Center.

She is the author, coauthor or editor of 18 books and numerous articles and reports dealing with ethical, human rights, theological and intellectual property issues related to health, genetic developments and pharmaceuticals.

Further she has published works on ethical, social and cultural rights; healthcare reform and transitional justice; reconciliation and development.

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**Contact Information:**

**Audrey Chapman**
Chair, ESCRO
achapman@uchc.edu
Phone: 860-679-1590

**Dana Howard**
Administrator, ESCRO
dana.howard@uconn.edu
Phone: 860-486-1725

Office Fax: 860-486-1044