IACUC

FORMS

Volunteers needed to Pilot Animal Use Protocol Application
The updated Animal Use Protocol application is in its final stages of revision and we would like to ask a few Principal Investigators to pilot it and provide comments, so we may make final revisions and add it to the IACUC forms. If you will need to submit a new application soon and are willing to help pilot this form please contact Kathy Bryant at kbrnyt@clemson.edu or 656-4538. We would like to have a variety of laboratory, farm and field research and teaching applications submitted. The form has been consolidated into one document rather than multiple sections, which we hope will make it easier for investigators to use and eliminate many of the redundancies of the previous forms.

New Amendment Form to Change Principal Investigator
A new amendment form has been created to change the Principal Investigator of an Animal Use Protocol. Changing a PI is considered a major change and cannot be done administratively. It must be reviewed by designated or full committee review. Please use this new form if a PI must be changed.

Updates to Forms
When submitting a new IACUC application, or other form, please check our website to be sure you have the most recent version. The Office of Research Compliance updates these forms as needed and using the forms on the website will insure that you have the most current one. Using an outdated form could delay review.

ILAR ‘Guide for the Care and Use of Laboratory Animals’ Revised
The ILAR (Institute for Laboratory Animal Research)’ Guide for the Care and Use of Laboratory Animals’ has been revised and will be published in the near future. Once it is published, the IACUC will use it, in conjunction with other publications, to evaluate the Animal Care and Use Program at Clemson.

CU Public Health Service Assurance Renewed
The Clemson University PHS (Public Health Service) Assurance document has been renewed by OLAW (Office of Laboratory Animal Welfare). The assurance document number remains the same. Organizations receiving NIH funding for research involving vertebrate animals must negotiate an assurance with OLAW prior to the use of animals. Approval by OLAW of an organization’s animal care and use program requires that their facilities and procedures conform to PHS Policy, and that research involving animals within their facilities be monitored by a requisite IACUC.

While the IACUC considers the appropriateness of the proposed protocol to the investigator’s scientific goals, the primary goal of the IACUC’s detailed evaluation and oversight of the protocol is to assure that the procedures involving animals conform to all federal animal welfare requirements and PHS Policy. Clemson also has a responsibility to ensure that the protocol approved by the IACUC is congruent with the proposed use of animals described in the Research Plan. Our assurance document can be found on the IACUC website.
IBC

NIH OBA Listserv
OBA (Office of Biotechnology Activities) has a listserv (OBA_NEWS) which provides updates on current initiatives, policies and news from OBA. To subscribe, send an e-mail message to: listserv@list.nih.gov with the message: subscribe OBA_News.

IBC Policy on Transgenic Plant Research
It is the policy of Clemson University that all research conducted on the campus or sponsored by the University involving transgenic plants must receive approval from the IBC prior to the start of any work, which requires IBC approval prior to initiation of work. Although some projects may qualify as exempt from the NIH guidelines, all projects that involve transgenic plants must be registered. Research projects will be assessed by the IBC on an individual basis.

Disposal of Transgenic Plants
University policy requires that transgenic plants and materials from transgenic plants, including seeds, must be inactivated prior to disposal to prevent accidental environmental release. Typically, autoclave treatment is employed for transgenic plant and seed inactivation in the Greenhouse. There are no exceptions to this policy without prior notification and approval by the IBC. If you have questions regarding proper disposal, please contact EHS (Environmental Health and Safety).

Transfer of Recombinant DNA and Transgenic Materials
Intra- or inter-facility transfers of recombinant DNA and transgenic materials, including transgenic animals and transgenic plants, are prohibited without the written approval of the IBC.

Experiments with Transgenic Animals
Experiments with transgenic animals must be approved by the IBC. NIH OBA has created a table describing animal experiments covered under the NIH Guidelines. It can be accessed at: http://oba.od.nih.gov/oba/FAQs/Animal%20Experiments%20Covered%20under%20the%20NIH%20Guidelines .pdf.

When considering recombinant DNA work with large animals, the work is covered under Appendix Q of the NIH Guidelines. Appendix Q specifies containment and confinement practices when animals are of a size or have growth requirements that preclude the use of laboratory containment of animals. NIH Guidelines include provisions for tracking and inventorying these animals. Animal carcasses must be disposed of as to avoid their use as food for human beings or animals unless food use is specifically authorized by an appropriate federal agency. An acceptable method of disposal would be incineration.

Nanomaterials and the IBC
The International Society for Analytical Cytology has published a biosafety standard for sorting of unfixed cells. This document provides a “written standard that modifies or expands the 1997 guideline document for handling and sorting of potentially biohazardous specimens and includes methods to assess risk of exposure to biological and/or toxic aerosols that may be produced by deflected-droplet fluorescence-activated cell sorters”. Please see: http://www.isac-net.org/media/Biosafety_sorting_2007.pdf.

CDC Public Health Grand Rounds
CDC has created a monthly series to further strengthen CDC’s common scientific culture and foster discussion and debate on major public health issues. Each session focuses on key issues and challenges related to a specific health topic, including scientific evidence.
On April 15, 2010, the topic was “Preventing Adverse Health Effects from Nanotechnology”. This session is currently archived on the CDC website at:
http://www.cdc.gov/about/grand-rounds/archives/2010/04-April.htm

This session focused on the current state of knowledge in nanotechnology and discussed concerns about the harmful impact that exposure to some nanomaterials may have on humans and the environment. A helpful link mentioned at this video seminar is www.goodnanoguide.org.

Protecting Healthcare Staff from Risks Associated with Disinfectants and Cleaners
Disinfectants and cleaners are essential products for preventing disease transmission in healthcare facilities, but they pose risks for work-related eye and respiratory irritation, sensitization, asthma-like symptoms, and respiratory distress for workers. A NIOSH study published in the May 14 Morbidity & Mortality Weekly Report provides the first multistate report on work-related symptoms among healthcare staff in three states, with recommendations for preventing illness and injury. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5918a2.htm

For Individuals Using the Greenhouse
The Clemson University Greenhouse Complex is part of the BRC (Biosystems Research Complex). They have updated the Greenhouse Operating Procedures. It is the researcher’s responsibility to obtain IBC approval according to the NIH Guidelines and obtain the required authorizations from the institution and from the appropriate federal agency if needed for growing or transporting transgenic plants. In addition, researchers must follow the proper containment level practices and procedures identified in the IBC protocol. The PI is responsible for reporting immediately any Greenhouse accidents involving the inadvertent release or spill of microorganisms to the following:

- Greenhouse/BRC Director (864-656-7063)
- Director of EHS (864-656-1806)
- Director of the Office of Research Compliance (864-656-1525)

USDA/APHIS Permits
The USDA/APHIS (United States Department of Agriculture/Animal and Plant Health Inspection Service) requires permits for the export, import, and interstate transfer of animal or plant pathogens, pathogen vectors, animal and animal products, plant and plant products, and the introduction of genetically modified organisms into the environment. For more information go to www.aphis.usda.gov/.

IRB

“Science and Subpoenas” by Felice J. Levine
(adapted from “Inside Higher Ed Views” accessed on August 18, 2010)

On Friday [August 13, 2010], Inside Higher Ed sadly reported on an effort underway by the state superintendent of Arizona to use the subpoena powers of a federal court to obtain data from education research scholars at the University of Arizona and Arizona State University. The research in question examines the state’s approach to educating children who are not native speakers of English. If the pending cross-motion of the state superintendent to compel production of experts’ source data prevails, the outcome of that determination could compromise the privacy protection promised to research participants and the confidentiality of the data.

Today [August 18, 2010], a federal judge has an opportunity to issue an order that prohibits the release of any information that would directly or indirectly disclose the identities of teachers who participated in important education research studies. Or the court could strike a blow to science serving the public interest by ordering identifiable information to be disclosed and thereby making teachers who voluntarily participated in these studies vulnerable to harm (e.g., loss of jobs, public criticism). In addition, the court ruling may result in a broader and longer-term impact by chilling the willingness of others to participate in research or stifling researchers from
undertaking some of the studies most necessary to policy and public decision making... [Inside Higher Ed Views accessed on August 18, 2010: Read the full article at http://www.insidehighered.com/views/2010/08/18/levine. Felice J. Levine is executive director of the American Educational Research Association. She is associate editor of the Journal of Empirical Research on Human Research Ethics.]

Challenges with Internet Research
Internet research is on the rise due to the accessibility of data and participants, but there are some key ethical issues that researchers must consider:

- private vs. public spaces
- identifiability
- risk of harm
- informed consent

IRBs are constantly faced with the dilemma of determining the risks involved with internet research without impeding researchers’ ability to collect their data. Even with more information available, internet research is still a gray area and each study must be evaluated individually. Ultimately, it is researchers’ responsibility to protect their participants, whether online or in person.

The following list of articles/books is recommended reading for those who plan to conduct research via the internet:

Ethical Dilemmas in Research on Internet Communities [http://www.hawaii.edu/hivandaids/Ethical_Dilemmas_in_Research_on_Internet_Communities.pdf], by Sarah Flicker, Dave Haans, and Harvey Skinner

“Go Away”: Participant Objections to Being Studied and the Ethics of Chatroom Research [http://www.cc.gatech.edu/~asb/papers/hudson-bruckman-tis04.pdf], by James M. Hudson and Amy Bruckman

National Surveys Via Rdd Telephone Interviewing Versus the Internet: Comparing Sample Representativeness and Response Quality [http://poq.oxfordjournals.org/cgi/content/full/73/4/641], by LinChiat Chang and Jon A. Krosnick

Online Interviews in Real Time, by Janet Salmons, SAGE Publications, Inc.


Playing a Good Game: Ethical Issues in Researching MMOGs and Virtual Worlds [https://ijire.net/issue_2.1/IJIRE_2.1.pdf], by Heidi A. McKee and James E. Porter

Research Ethics in the MySpace Era [http://www.pediatrics.org/cgi/content/full/121/1/157], by Megan A. Moreno, Norman C. Fost, and Dimitri A. Christakis

Studying the Amateur Artist: A Perspective on Disguising Data Collected in Human Subjects Research on the Internet [http://www.springerlink.com/content/t01630466t132246/fulltext.pdf], by Amy Bruckman

The Ethics of Internet Research: A Rhetorical, Case-Based Process, by Heidi A. McKee and James E. Porter, Peter Lang Publishing, Inc.

Trust and Privacy Concern within Social Networking Sites: A Comparison of Facebook and MySpace [http://csis.pace.edu/~dwyer/research/DwyerAMCIS2007.pdf], by Catherine Dwyer, Starr Hiltz, and Katia Passerini


**Research Integrity**

**RCR (Responsible Conduct of Research) Training Requirements**

NSF mandates RCR training for all undergraduate, graduate students and postdoctoral researchers who receive support from NSF, no matter how long they are on the grant/project. Clemson University’s basic online training is accomplished by completion of any one of the following five (5) CITI RCR tracks: Biomedical, Social and Behavioral, Physical Science, Humanities, and Engineering. Registration can be accessed at: [https://www.citiprogram.org/default.asp](https://www.citiprogram.org/default.asp).

Advanced training consists of discussion-based general or discipline-specific seminars. Sessions from our Brown Bag series, described below, qualify as advanced training.

NIH also requires that all trainees, fellows, participants and scholars receiving support through any NIH training, career development award, research education grant and dissertation research grant receive instruction in RCR. Proposals for these NIH awards must include a section on how instruction of RCR will be provided. The ORC has developed a template and instructions for completing this RCR NIH requirement. For more information and for the designation of which training grants are included in this requirement go to: [http://www.clemson.edu/research/compliance/integrity/resources.html](http://www.clemson.edu/research/compliance/integrity/resources.html)

**Brown Bag Seminars**

The ORC is pleased to announce our fall Brown Bag Series on the RCR (Responsible Conduct of Research).

Please register for one or more of the presentations, and bring your lunch to join us in the Student Senate Chambers (5th floor - Edgar A. Brown Union):

- **October 14, 2010, 12:00 pm**
  “Plagiarism: What You Need to Know”
  Presenter: Bobby Hollandsworth from the University Libraries

- **November 4, 2010, 12:00 pm**
  “Issues in Authorship”
  Presenter: Dr. Julia Frugoli from the Department of Genetics and Biochemistry

- **December 2, 2010, 12:00 pm**
  “Issues in Data Management”
  Presenter: Dr. Julia Frugoli from the Department of Genetics and Biochemistry

**Target audience** - Faculty, staff, postdocs, graduates, undergraduate students and anyone involved in the research process.

For more details go to our website at: [http://www.clemson.edu/research/compliance/](http://www.clemson.edu/research/compliance/)

**Questions?** Please contact Tracy Arwood, 864-656-1525, tarwood@clemson.edu
An Educational Interactive Webcast on Dual Research

The ORC has arranged a viewing of an educational interactive webcast on dual research entitled "Strategies for Promoting Responsible Research in the Life Sciences," in G100 BRC Seminar Room (Biosystems Research Center) on Wednesday, September 22, 2010 from 8AM to 10:30AM (three independent sessions). It is being sponsored by the US Government and hosted by the NASBB (National Science Advisory Board for Biosecurity) in partnership with the European Molecular Biology Organization, the European Science Foundation, the European Society of Clinical Microbiology and Infectious Diseases, and the Institute Pasteur.

If you would like to attend, please register at www.clemson.edu/orc/. You may register for any one or all of these sessions and be eligible for one hour of RCR advanced training for each session.

The program will include three sessions:

8:10am SESSION I: “Understanding the Concept of ‘Dual Use Research’ and ‘Dual Use Research of Concern”
This session will focus on the general concepts of "dual use research" and "dual use research of concern." Two scientific presentations will discuss dual use research in the context of antimicrobial resistance and synthetic biology. Commentary and discussion sessions will explore the general concepts in practical terms. Questions from webcast participants will be addressed during the panel discussion.

9:15am SESSION II: “Strategies for Promoting Responsible Research”
This session explores some strategies that have been proposed or implemented to promote the responsible conduct of life sciences research in the context of research that has dual use potential. Relevant activities in Europe as well as recommendations of the NSABB will be presented. Questions from webcast participants will be addressed during the panel discussion.

9:50am SESSION III: “General Panel Discussion and Audience Q & A”
The final session will be a general question and answer session. Panelists will address questions from webcast participants and discuss concepts and issues that emerge during the webcast.

Target audience: Those who are engaged in or have an interest in life sciences research.

A detailed agenda is available here or visit the NIH OBA for more information.
# SCHEDULE OF EVENTS

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<tr>
<th>DATE</th>
<th>EVENT</th>
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<tr>
<td>Wednesday, September 22</td>
<td>NIH Webcast on Dual Research “Strategies for Promoting Responsible</td>
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<td>Research in the Life Sciences”, 8:00 – 10:30am, G100 BRC Seminar Room</td>
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<td>IBC Submission Deadline</td>
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<td>Tuesday, September 28</td>
<td>IACUC Submission Deadline</td>
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<td>Wednesday, October 6</td>
<td>IBC Meeting</td>
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<td>the University Libraries, noon, 5th floor, Edgar A. Brown Union</td>
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<td>Wednesday, November 17</td>
<td>IBC Submission Deadline</td>
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<td>Thursday, November 25 –</td>
<td>ORC office is closed, Thanksgiving Staff Holidays</td>
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<td>Friday, November 26</td>
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<td>Wednesday, December 22 –</td>
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<td>Monday, December 27</td>
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<td>Friday, December 31 –</td>
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<td>Monday, January 3</td>
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The Office of Research Compliance (ORC) promotes a culture of compliance, research integrity, and high quality research within the University community. This is accomplished through consultation and educational programs for all researchers. The ORC facilitates University research, teaching, and public service programs by providing oversight and coordination of research compliance areas involving human subjects, vertebrate animals, recombinant DNA, hazardous agents and research misconduct.

http://www.clemson.edu/research/compliance/

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