IRB
Ms. Jane Brison joined the Office of Research Compliance as IRB Program Assistant on May 18, 2007. I hope you will join us in welcoming her to this role. Contact Jane Brison at 864-656-0636 or email at brison@clemson.edu.

Toll-free Number
The Office of Research Compliance has established a toll-free number (1-866-297-3071) when you are calling from outside the local calling area.

IACUC/ARC
(Institutional Animal Care and Use Committee/Animal Research Committee)

IACUC/ARC Training Update. The new animal care and use training provider is now on-line and personnel are now able to self-enroll. The new training site is hosted by the Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org. Instructions for registration are posted on the Office of Research Compliance web page in the Training section at www.clemson.edu/research/orcSite/orcIRB_CITIHelpPage.htm. The courses contained on the CITI site fulfill the animal welfare training requirements for Administrators, IACUC/ARC Committee members, Principal Investigators, animal care staff, and personnel listed on teaching and research protocols. Faculty may also choose to document their students training by completing the Basic course rather than by in-classroom lecture or seminar. Modules for enrollment in the Medical Surveillance Program and the associated zoonotic disease training are also available at this site.

2007 Facility Award. The IACUC/ARC presented the 2007 Facility Award to the Simpson Station Beef Unit. This award includes a monetary award to be used for continuing education of personnel and/or improvements to the unit. Congratulations to facility manager Gary Burns, and all the personnel at the unit for a job well done.

Name change. The name transition of the Animal Research Committee (ARC) to Institutional Animal Care and Use Committee (IACUC) has been initiated to better reflect the role of the committee. In the coming months, you may see the Committee acronym listed as IACUC/ARC.

New workshop. A new Workshop titled “Navigating the IACUC/ARC Process” was held September 14, 2007. This session is designed to orient new faculty and facility managers to the regulatory requirements and the protocol submission process. The session will be held once each semester.

InfoEd Online Submission Update. A pilot study is planned for early this Fall to test the online submission process for animal use protocols using the InfoEd system. If you are interested in helping us test the system, please contact Kathy Bryant at kbrynt@clemson.edu.
IBC (Institutional Biosafety Committee)

Research involving the use of nanomaterials. The definition of nanomaterials “includes, but is not limited to, ultrafine structures (engineered or extracted from natural components), devices and systems that have a length scale of roughly 1 to 100 nanometers in one dimension such as fullerenes, quantum dots, carbon nanotubes, nanowires, etc. Research with
♦ recombinant DNA
♦ biological hazards, including but not limited to, a BSL2 agent or above, toxins, human blood and cell lines, and/or
♦ chemicals that are defined as highly toxic, mutagenic, teratogenic, carcinogenic (confirmed or suspected), explosive or involving Schedule I or II drugs requires that an IBC application be submitted to the Office of Research Compliance for review by the Institutional Biosafety Committee (IBC). For employees and students conducting research involving the creation, manipulation, or use of nanomaterials or devices not involving the materials listed in the previous paragraph, Clemson University recommends that researchers submit an IBC application. This is because of the potential exposure to ultrafine nanostructures, devices, and systems whose toxicity and health risks associated with nanoparticle exposure have not been defined.

A Guidance Document has been developed by the CU IBC and describes:
♦ a definition of nanomaterials,
♦ work practices
♦ safety concerns
♦ knowledge gaps
♦ reasonable control strategies for working with nanomaterials
♦ control of exposure by inhalation, dermal exposure and ingestion.

This guidance document may be accessed at: http://www.clemson.edu/research/orcSite/orcIBC_Reg.htm

IBC application. The IBC application has been revised as of 8/30/07 and is available on the IBC website. It can be accessed at: http://www.clemson.edu/research/orcSite/orcIBC_Forms.htm

Summary of some of the changes include:
− Updated definitions of what constitutes “highly toxic” and “toxic” chemicals (instructions section)
− Expansion of Section A.4.K. to include additional items relating to the use of nanomaterials
− Addition to Section A.4.C. information on the inspection of chemical hoods and certification of biosafety cabinets
− In Section C, clarified that MSD sheets that meet the IBC requirements be within the last 3 years
− Identified that if the PI has three or more hazardous chemicals that an alternate approach is available for the PI to submit the equivalent information in a single format (Excel Spreadsheet that is available on the forms page) and that contact should be made with the IBC Administrator, Marlene Ventura at 864-656-0118 or ventura@clemson.edu.

Key points that address problems that often delay approval of IBC applications.
− Chemical hoods need to be inspected/tested within the past 12 months by EHS. Contact Don Worthy (864-656-7557) to schedule an inspection. A yellow sticker showing air flow and operating height of the hood sash will be posted on the left side of the hood upon completion of EHS testing. If this sticker is not displayed, or a “Failed” notice is posted, the hood should not be used.
− Biological Safety Hoods (BSC) have to be certified every 12 months or whenever the hood is relocated. To schedule BSC inspections, contact EHS at Clemson University who will in turn coordinate inspections for investigators with a private vendor (Environmental Safety Professionals at (919) 217-2650).
− Safety goggles, not safety glasses, should always be worn whenever a splash hazard exists.
− MSDS that accompany the section Cs of the IBC application should be from the vendor that supplies the chemical(s) and should be no older than 3 years. If the vendor does not have a current one than resources like Sigma or Fisher can be used.
− Be specific regarding the type of PPE to be used and the type of glove to be used. Latex gloves cannot be used with chemicals. Nitrile gloves have a wide range of usage but in some cases a different glove may be necessary in handling the chemical. The glove-type should be specific to the chemical.
− Use of human cell lines necessitates an IBC application handled under BSL-2 containment practices regardless if the commercial vendor indicates that the containment level is BSL-1.

“Research with recombinant DNA, biological and chemical hazards as defined by CU requires an IBC application.”

“Key points that address problems that often delay approval of IBC applications.”
Disinfectants to be used with human cell lines and bodily fluids of human origin including, but not limited to blood, must be selected from the “D List” of the EPA Registered Disinfectants effective again HIV-1 and Hepatitis B viruses. This list can be found at:

http://www.epa.gov/oppad001/chemrepgindex.htm

**Minors Working on IBC approved research projects.** The IBC has developed a policy for minors working on IBC approved projects. Individuals under the age of 18 are considered minors and must attend to participation in IBC approved research and must have the written permission of their parent or guardian. This policy applies to all persons under the age of 18 whether students, employees or volunteers. No children under 16 years of age are allowed into any laboratory except with the special permission of the Environmental Health and Safety Officer (864-656-1806).  Whenever visitors are allowed into a laboratory, it is the responsibility of the laboratory supervisor to ensure that they are supervised at all times, and that they follow the same rules as laboratory personnel (Clemson University’s Chemical Hygiene Plan dated 4/15/05). This policy outlines Principal Investigator’s responsibilities and includes a “Minor’s Registration Form” http://www.clemson.edu/research/orcSite/IBCforms/Minors_Registration_Form.doc

Non-Clemson University persons working on approved IBC protocols. Individuals who are not employed by nor enrolled as a student at Clemson University but who are working on approved IBC protocols involving the use of recombinant DNA technologies, bloodborne pathogens, infectious agents or hazardous chemicals must complete an “Assumption of Risk and Release From Liability for Non-Clemson University Faculty, Staff or Students” Form. This form can be obtained from the IBC website under the “Forms section”. http://www.clemson.edu/research/orcSite/orcIBC_Forms.htm

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**IRB (Institutional Review Board)**

You may have a project that involves human subjects, but is your project considered to be “research” as defined by the federal regulations? This is an important question to consider when submitting an IRB application because projects that do not meet the criteria for research do not require compliance review. Under the Federal regulations, research is defined as “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” When applying the above definition to your project, special attention should be given to whether the project is intended to develop or contribute to generalizable knowledge. Generally, research data that is gathered solely for internal campus or course use would not need to be reviewed. However, if the results of your project are intended to be published, or presented to an audience and generalized to a larger population than the specific instances for which it was collected, that research would contribute to generalizable knowledge and would require prior review and approval. If the original intent of the project is not to develop or contribute to generalizable knowledge, but the possibility of future dissemination exists, the researcher would be advised to consult with the Office of Research Compliance before initiating the project. Examples of projects that may involve human subjects, but do not meet the definition of research would include:

- Class assignments for which the results would be presented in-class only
- Data collection limited to program development within the university
- Data collected under a service agreement with a company solely for that company’s use

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“Individuals under the age of 18 are considered minors and must assent to participate in IBC approved activities and must have written permission of the parent/guardian.”

“Under the federal regulations, research is defined as “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”
The ORC (Office of Research Compliance) provides support and training for faculty, staff, and students in regulatory requirements for research and teaching activities involving vertebrate animals, research involving the use of human subjects, and research involving the use of hazardous agents. The ORC is responsible for the development and implementation of University policies and for coordinating institutional compliance with federal and state law/regulations. The ORC supports the university community in promoting the responsible conduct of research.

Promoting ethical and responsible research involving vertebrate animals, hazardous materials, and human subjects.

http://www.clemson.edu/research/orcSite/indexComply.htm

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