Compliance Updates

Changes in Staffing

IACUC (ARC): Ms. Kathy Bryant joined the Office of Research Compliance as IACUC Administrator on March 26. I hope you will join us in welcoming her to this role. Together with Ms. Bridget Owens (IACUC Program Assistant) and Dr. Jeff Foltz (IACUC Chair), Kathy will provide guidance and assistance to those units on campus who use animals in research, teaching and testing. Contact Kathy at 656-4538 or email address kbrynt@clemson.edu.

IT (InfoEd): Mr. Daniel Harris, who has served as IRB Program Assistant since August 2005, has accepted the role of IT Coordinator in the Office of Research Compliance. Daniel will work with the IACUC and IRB to develop and implement online submission of protocols via InfoEd. Please help us in welcoming Daniel to this vital new role. Contact Daniel at 656-1450 or email address dharri2@clemson.edu.

Animal Research Committee

IACUC training changes: Our current provider of online training for animal care and use will be closing their site early May 2007. We have arranged for our training materials to be hosted by another online training provider. During this transition, self-enrollment into the Level 2 (required for participation on an AUP) will not be possible. Those individuals who need training must submit an email request to Kathy Bryant (kbrynt@clemson.edu) to be enrolled. They will then receive an email message advising them how to access and complete the required training. By the end of summer, we are hopeful self-enrollment in all available courses will be possible. We will update PIs as we obtain relevant information. Thank you for your patience during this transition.

Institutional Biosafety Committee

Updated IBC application: The IBC updated its IBC application on 11/10/06. Changes include: the inclusion of additional space for the names of personnel conducting the research, addition of an item under “safe handling procedures” that asks for initial “risk assessment based on the risk group (RG) of the agent”, removal of some items that were duplicative, streamlining Section C for use of chemicals to remove the request for information that would normally be on the MSD Sheet. There were no changes made to the recombinant DNA section. See http://www.clemson.edu/research/orcSite/orcIBC_Forms.htm

Updated Hantavirus Policy: An updated Hantavirus Policy is available on the IBC website at http://www.clemson.edu/research/orcSite/orcIBC_Reg.htm. As a reminder, this updated policy is intended to replace the standard IBC protocol application when the field study involves only “catch and release” practices. It is based on practices used by the Center for Disease Control, and has been modified for fieldwork. The policy is intended to give information about the best work practices to provide protection against hantavirus infection during fieldwork that involves the catch and release of small mammals. This policy outlines safe handling practices for research staff, specific practices for field studies, and important occupational health and training issues. If biological samples are to be collected, or invasive pro-
Guidance document for research work with animal specimens from uninspected sources: A guidance document for research work with animal specimens (preserved and unreserved) obtained from unclassified sources (not USDA inspected). The purpose of this document is to provide information to minimize occupational exposure to zoonotic diseases, focusing on contact with animal tissue or products. Clemson University is currently recommending that researchers submit an application for the animal specimens are from non-USDA inspected sources or if the specimens are being cultured. See [http://www.clemson.edu/research/orcSite/orcIRB_Reg.htm](http://www.clemson.edu/research/orcSite/orcIRB_Reg.htm)

**Arthropod Containment Levels (ACLs):** The IBC has placed on its website two published articles regarding guidelines for laboratory work with arthropod vectors of pathogenic agents. These documents were written in response to concerns related to an accidental release of arthropods. These published articles are titled: “Arthropod Containment Levels (ACLs)” and “Containment of Arthropod Disease Vectors”. See [http://www.clemson.edu/research/orcSite/orcResources.htm#IBC](http://www.clemson.edu/research/orcSite/orcResources.htm#IBC)

**OSHA requirement for annual blood-borne pathogens training:** OSHA mandates annual training for individuals working with human body fluids including blood and cell lines. This will be verified at the time of initial IBC review and yearly after that at the time of continuing review. Online training for bloodborne pathogens (BBP) training can be accessed at: [http://ehs.clemson.edu/training/BBP/index.htm](http://ehs.clemson.edu/training/BBP/index.htm)

**Fifth Edition of the BMBL:** CDC and NIH have issued the 5th edition of the BMBL (Biosafety in Microbiological and Biomedical Laboratories). It can be found on our IBC website or at: [http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm](http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm). The new 5th edition has a revised chapter on risk assessment that provides more emphasis on the importance of this process in selecting the appropriate practices and level of containment. The chapter on bio-security addresses the security of microbiological agents and toxins and the threats posed to human and animal health; the environment and economy by deliberate misuse or release. The section on vertebrate animal bio-safety level criteria for vivarium research facilities has been expanded. There have been substantial revisions to the Influenza Agent Summary Statement that addresses non-contemporary human influenza strains and recommended safeguards for research involving reverse genetics of the 1918 influenza strain. Additional updates have been made to the section on arboviruses and related zoonotic viruses.

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**Institutional Review Board**

**Two Institutions But Only One IRB Review?**

Researchers may not know it, but Clemson University (CU) has agreements with various other institutions that allow CU researchers to conduct human subjects research in collaboration with colleagues from other institutions or at other institutions without having to navigate two IRB systems. The general agreements CU has with other institutions can be summarized as follows:

**Health Sciences South Carolina (HSSC):** This is a consortium of six South Carolina institutions that have agreed that collaborative human subjects research among these institutions will be subject to only one IRB review. The participating institutions are: Clemson University, Greenville Hospital System, Medical University of South Carolina, Palmetto Health, Spartanburg Regional Healthcare System, and University of South Carolina. Which institution will serve as the IRB-of-Record is decided on a case-by-case basis, based primarily upon the following criteria: where the human subjects will be enrolled; where most clinical research interactions (if any) with subjects will take place; where the principal investigator is employed/affiliated, including any connection to grant funding, and; which IRB has the requisite expertise to review the study.

**Greenville Hospital System (GHS):** CU has an agreement with GHS for the GHS IRB to be the IRB-of-Record for biomedical research conducted by CU faculty, staff, and students. The term biomedical research refers to laboratory-based and clinical research which is aimed to define, treat, and/or prevent human diseases or conditions. It may include human participation, records-based studies, clinical samples, or technology development for clinical trials. Please note, the CU IRB still reviews some health-related research protocols that are mainly in the areas of social and behavioral sciences.

The recently revised procedures to follow when applying to the GHS IRCs are available here: [http://www.clemson.edu/research/orcSite/IRBforms/doc/GHS_SubmittingResearchProtocols.doc](http://www.clemson.edu/research/orcSite/IRBforms/doc/GHS_SubmittingResearchProtocols.doc).

**Oconee Memorial Hospital (OMH):** In the past, GHS has been the IRB-of-Record for all research studies conducted at OMH or its components. However, since last Fall the CU IRB is now the appropriate IRB-of-Record for all social and behavioral science research studies conducted at OMH by CU faculty, staff, and students.

**General guidelines when conducting research with/another institution:** While the specific procedures may vary somewhat from one situation to another, whenever you will be conducting research involving collaboration with another institution, the following general guidelines hold true.

- The CU IRB is held fully responsible for all human subjects research activities carried out by CU-affiliated personnel. Therefore, the CU IRB needs to know about all human subjects research being done by CU faculty, staff, and students.
- CU researchers should consult with the CU IRB regarding specific procedures to follow and who will be the IRB-of-Record before an IRB application is submitted to any institution. For instance, the new submission procedure in our agreement with GHS is that all CU-affiliated research studies must be submitted to the GHS IRCs or the GHS Nursing Research Council through the CU Office of Research Compliance (ORC).
- If the CU IRB is referring to another IRB for review of the
research protocol, an administrative review will be conducted in the CU ORC before the protocol is approved for submission to the IRB to which the CU IRB is deferring. This is simply to ensure that the CU IRB is aware of what CU researchers are doing and to ensure that other IRBs are not being asked to approve activities that the CU IRB would absolutely not approve.

- Notification of initial IRB approvals and approvals of all continuing reviews and amendments on research protocols approved by other institutions’ IRBs must be submitted to the CU IRB so the IRB is up-to-date with the status of research being conducted by CU researchers, but the CU IRB will not formally review these documents.

Other institutional agreements:
In addition to the general agreements outlined above, CU has various other institutional agreements linked to specific research studies. If you will be conducting collaborative human subjects research with colleagues from another institution, please contact the CU ORC to discuss whether or not an IRB deferral is appropriate for your research study.

For specific questions regarding institutional agreements and IRB deferrals, please contact Laura Moll, the IRB Administrator, at lmoll@clemson.edu or 656-6460.

Educational Research and FERPA
FERPA, the Family Educational Rights and Privacy Act, which was established in 1974, often has to be considered when planning to conduct research involving the use of educational records. While FERPA seeks to provide parents or students with the rights to inspect files and request the correction of information they feel to be incorrect, the law also acts to ensure the privacy of such records. This guarantee of confidentiality of educational records often, by its very nature, has repercussions on the conduct of research on educational practices.

While schools can release directory information without explicit consent, all other information is protected. Generally, any information outside of directory information may only be released with explicit, signed consent. Some important exceptions to this rule are:

- School officials with legitimate educational interest
- Organizations conducting certain studies for or on behalf of the school
- Researchers, with the holder of the records must specifically cite the exception to the regulation in writing. The exceptions that may be used for educational research are:
  - If the researcher is a school official with legitimate educational interest [34 CFR 99.31 (a)(1)]; or
  - If the researcher is conducting studies for or on behalf of the school [34 CFR 99.31(a)(6)].

When planning to conduct research involving educational records, the FERPA exception letter should be submitted to the IRB along with the IRB application. In most cases involving educational records held by elementary and secondary schools, this letter should come from the school district’s superintendent. The University Registrar is usually the official from whom this letter should come for research involving educational records held by a university. The use of personal, identifiable data for research purposes must always be approved by the IRB prior to the researcher obtaining access to such data.

Additional information on FERPA may be found at the website of the Department of Education at http://www.ed.gov/policy/gen/guid/fpcd/ferpa. The specific language of FERPA can be found at http://www.access.gpo.gov/nara/cfr/waisidx_04/34cfr99_04.html.

For specific questions regarding FERPA and educational research, please contact Laura Moll, the IRB Administrator, at lmoll@clemson.edu or 656-6460.

Are You Actually Conducting Research?
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 "a 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.

For specific questions regarding the definition of research, please contact Laura Moll, the IRB Administrator, at lmoll@clemson.edu or 656-6460.
The Office of Research Compliance (ORC) 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.