

## **Description of the Human Studies Council and the Institutional Animal Care and Use Committee**

### **USE OF HUMAN PARTICIPANTS OR ANIMAL SUBJECTS IN YOUR RESEARCH**

In keeping with current federal standards and regulations, **all research involving human participants or animal subjects must be approved by the appropriate campus committee:** the *Human Studies Committee (HSC)* or the *Institutional Animal Care and Use Committee (IACUC)*. These groups function to insure that appropriate safeguards are used to protect the rights and wellbeing of research subjects.

#### ***Human Studies Council - Institutional Review Board***

ALL graduate program final projects - theses, dissertations and special projects- that involve human research participants, must be reviewed by the Human Studies Council (HSC).

**WHY?** The HSC is CCSU's Institutional Review Board (IRB), the body federally mandated to protect the welfare and autonomy of human participants in research conducted by CCSU faculty, students and staff. The function of the Human Subjects Council is to protect the rights and welfare of human research participants and to assist faculty and students in developing ethical research protocols.

**WHAT?** The HSC conducts a risk-benefit analysis in which committee members review the study's proposed objectives, recruitment process, interventions/measures, consenting process, data security plans and intended method of report reporting findings. The HSC works with an investigator to identify and minimize potential risks in study involvement –either by direct participation in the data collection phase, or due to breaches in data security/privacy after participation is complete.

**HOW?** Customarily, *minimal risk* studies with adult volunteers are approved quickly through an expedited review process. However, research projects with protected populations (such as children, prisoners, mentally disabled persons) or projects that involve deception or *greater than minimal* risk go through a full review process. The full review process can be done only at convened meetings of the Human Studies Council. These meetings occur throughout the year; the meeting schedule is posted on the HSC website.

**WHEN?** Before submitting a proposal for review, and to comply with federal regulations, researchers must complete a research ethics education module. CCSU endorses the National Institutes of Health [\*Protecting Human Research Participants\*](#) tutorial to meet this educational requirement. The student's *Certificate of Tutorial Completion* and all relevant proposal addenda must accompany a Protocol Submission Form before the HSC can begin the review process. The HSC recommends submitting proposals two to four weeks before study activities are scheduled to begin.

**WHERE?** Faculty Advisors are to review student proposal materials and submit them on their advisee's behalf to [hsc@ccsu.edu](mailto:hsc@ccsu.edu).

**For more information about the CCSU Human Research Protections Policy, graduate research requirements and HSC submission process and forms, contact the HSC Administrator at 860-832-2366 or [hsc@ccsu.edu](mailto:hsc@ccsu.edu) or visit the HSC website ([www.ccsu.edu/humanstudies](http://www.ccsu.edu/humanstudies)) or Office of Grants and Funded Research in Barnard 120.**

### *Institutional Animal Care and Use Committee (IACUC)*

The IACUC is responsible for oversight and evaluation of the animal care and use program at CCSU. Its functions include inspection of facilities; evaluation of programs and animal-activity areas; review of proposals for the use of animals in research, testing or education; and the review of concerns involving the care and use of animals at CCSU.

The following should be considered in the preparation and review of animal care and use protocols:

- ♦ Rationale and purpose of the proposed use of animals
- ♦ Justification of the species and number of animals requested. Whenever possible, the number of animals requested should be justified statistically.
- ♦ Availability or appropriateness of the use of less-evasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation.
- ♦ Adequacy of training and experience of personnel in the procedures used.
- ♦ Unusual housing and husbandry requirements.
- ♦ Appropriate sedation, analgesia and anesthesia.
- ♦ Unnecessary duplication of experiments.
- ♦ Conduction of multiple major operative procedures.
- ♦ Criteria and processes for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.
- ♦ Post procedure care.
- ♦ Method of euthanasia or disposal of animals.
- ♦ Safety of work environment for personnel.

The Application for Project Approval (APA) form is available from Ruth Rollins, Chair IACUC, located in Copernicus Hall. Each APA is reviewed by the IACUC, which includes a veterinarian. Some protocols may be approved by an expedited process and may require two to three weeks. Other protocols require a full review process that can be done only at a regularly convened meeting of the full IACUC. The full committee generally meets four times a year. Timely submission of proposals is especially important if approval is required before submission of research proposals for university or external grants.