

January 19, 2001

**IMPORTANT NOTICE - RETAIN FOR FUTURE REFERENCE**

TO: Members of the University Community  
FROM: Michael Breton, Ph.D.  
SUBJECT: Review of Animal Care and Use Sections of Research, Instructional, and Demonstration Protocols

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**POLICY**

In accordance with the University's policy governing the use of animals in research, instruction, and demonstration, Public Health Service (PHS) requirements, and United States Department of Agriculture (USDA) regulations, the University's Animal Care and Facilities Committee (ACFC), reviews all protocols utilizing live vertebrate animals.

Before any work with animals commences, all procedures using live vertebrate animals, whether new, ongoing, or proposed for funding, and irrespective of source of funding, whether conducted at the University or elsewhere by faculty in the discharge of their University duties and responsibilities, must be reviewed by the ACFC. This shall include the use of animals for research, instruction, or demonstration purposes (with the exception of non-University farm animals utilized for demonstration purposes by Rutgers Cooperative Extension).

All faculty and other whose research projects and animal care and use protocols have not been reviewed must submit an "Animal Use Protocol Review Form."

**AGENCY REQUIREMENTS**

Under the terms of the PHS Policy, a 60-day grace period from the date of submission of a new application to the NIH is allowed for the requisite review of the animal care and use sections of applications. In the case of continuation applications, agencies wish to have the notice of approval for protocols submitted contemporaneously with the continuation applications.

However, in order to avoid problems and unnecessary delays, protocols should be reviewed and approved prior to the submission of grant applications.

*The Public Health Service Policy on Humane Care and Use of Laboratory Animals* (Section V.B) states that “PHS awarding units may not make an award for an activity involving animals unless the prospective awardee institution . . . has provided verification of approval by the ACFC of those components of the application or proposal related to the care and use of animals.” At Rutgers, the mechanism for such approval is the animal use protocol. In order to provide such verification to PHS or other funding agencies, the Committee must verify that the procedures in a proposal are in fact covered by an active, approved protocol. Submission of the “Vertebrate Animal” sections of the grant applications are required and should be submitted, whenever possible, contemporaneously with the protocol.

Procedures described in a grant application must be approved in one or more animal use protocols. There need not be a one-to-one correspondence between grants and protocols. While an approved protocol may cover one or more grants, all procedures in a grant application must be described in one or more current, approved protocols before the University can attest that the proposed use of animals has been reviewed and approved.

#### **DE NOVO REVIEW**

*The Public Health Service Policy on Humane Care and Use of Laboratory Animals* requires that protocols be reviewed completely every three years. The Association for the Accreditation and Assessment of Laboratory Animal Care - International (AAALAC) recommends that existing protocols be rewritten in their entirety every three years to comply with the PHS requirements. Investigators will be notified by mail when a protocol should be rewritten.

#### **CONTINUING REVIEW**

Several months prior to the end of the period of protocol approval, a copy of the form “Request for Continuing Review” will be sent to principal investigators. The form must be returned in a timely manner so that the protocol does not lapse. If animals are being housed in a Rutgers facility and a continuing review form is not renewed prior to expiration, Laboratory Animal Services will place the animals in quarantine.

#### **AMENDMENTS TO PROTOCOLS**

If a significant change from a previously approved protocol is to be made, a formal amendment must be submitted for review to the ACFC.

Significant changes include:

- Change in species
- Change in drugs administered
- Change in method of anesthesia
- Change in method of euthanasia
- Inclusion of new surgical procedures
- Procedures that cause pain or distress in conscious animals
- Prolonged restraint
- Use of hazardous substances that involve possible exposure of personnel or animals in the animal facility

The following changes would NOT be considered significant:

- Changes in strain, stock, or breed of the animal
- Moving an animal from one approved animal facility to another
- Changes in *in vitro* procedures involving animal tissues
- Changes in funding agency, grant, or account

### **EXEMPTIONS**

In contrast to the review permitted for human subjects, there exist no exempt categories.

### **EXPEDITED REVIEW**

There is no expedited review or “provisional review” of animal protocols. As set forth in Paragraph IV.C.2 of the PHS Policy and Part 2, Section 2.31 (d)(2) of the USDA Animal Welfare Regulations, each committee member must have the opportunity to request review by the full committee. The Office of Laboratory Animal Welfare (OLAW) considers the opportunity for any member to call for full committee review before approval is given and before animal work begins to be an important safeguard of the well-being of animals.

### **CUSTOM ANTIBODY PRODUCTION**

According to OLAW, if an investigator contracts a company to do **custom** animal work the investigator must verify that the company being used has an approved animal welfare assurance number form with NIH. OLAW requires that only one of the institutions involved need review the protocol. The company’s assurance number rather than Rutgers’ animal assurance number should be used on specific grant applications.

Under these circumstances it is not necessary to complete a Rutgers animal protocol review form since the company’s protocol review form will be completed. However, a copy of a description of the work that will be done, the name of the company to be contacted, and its animal assurance number must be submitted to the ACFC for review. The University requires this information in order to keep abreast of the type of research being conducted by its faculty.

### **OCCUPATIONAL HEALTH**

In the Spring of 2000, the Occupational Health Department, in conjunction with the Animal Care and Facilities Committee and Laboratory Animal Services, expanded the occupational health program for University students and employees who work with animals. The program is required by both AAALAC and the *Guide for the Care and Use of Laboratory Animals*.

Effective April 1, 2001 protocols that are on the Animal Care and Facilities Committee agenda for review will not receive a Notice of Approval unless the principal investigator has participated in the Occupational Health Program and has received appropriate approval by Occupational Health. In addition, other personnel listed on the protocol will only be allowed to participate in the protocol if they have been approved by Occupational Health. In certain cases Occupational Health may decide that a particular person is exempt from the Occupational Health Program. In other cases, a person may be restricted from working with a particular species. This determination is made in cooperation with Occupational Health and Risk Management on a case-by-case basis.

### **ANIMAL ISSUES COMMUNICATION PLAN**

The University has an Animal Issues Communication Plan that outlines the response to both crisis situations and the promotion of the beneficial aspects of animal research. In accordance with the plan, University representatives have been identified by the ACFC to serve as media spokespersons for each of the campuses. The spokespersons were selected based upon their extensive knowledge of animal issues. Spokespersons have received media training on how to effectively respond to the media and how to respond to questions relating to animal research at Rutgers.

If you encounter a situation that requires immediate attention (e.g. protests, vandalism) or are approached by the media regarding animal research at Rutgers, it is essential that a designated spokesperson be immediately contacted. The spokesperson will determine if the plan should be implemented and if other key University departments or individuals should be informed. It is essential that you do not respond to the media without guidance. This procedure should be closely followed since the outcome impacts on other researchers.

Robert L. Harris, DVM, Director of Laboratory Animal Services, serves as the primary contact for animal issues for the University, and can be reached at 732-445-4168. In the absence of Dr. Harris, Karen M. Janes, Assistant Director of Research Subjects Administration, should be contacted at 732-445-2883. If there arises an animal crisis on the Newark Campus, the Newark police should be contacted immediately at 973-353-5111. On other campuses, Dr. Harris serves as the primary point of contact, with Karen Janes serving as the secondary point of contact

From time to time faculty members receive requests for interviews regarding the use of animals in research conducted at the University. The communications department on your campus is available to assist you. On occasion a tour of an animal facility is also requested. Requests for tours within an animal facility must be submitted to the ACFC for review.

#### **WEB SITES**

Useful information can be found on the animal care section of the Office of Research and Sponsored Programs' web site <<http://orsp.rutgers.edu/animals1.html>>. The protocol form, schedule of deadlines, the latest copy of the animal care newsletter, and policies are some of the items found on the web site.

Laboratory Animal Services also supports a web page <[www.rci.rutgers.edu/~labanim/](http://www.rci.rutgers.edu/~labanim/)>. This comprehensive web site includes an updated version of *The Animal Care Manual*. Some sections of interest include Animal Research Vendors, Standard Operating Procedures (appendix 5), Laws and Regulations, and the Farm Animal Disposition Policy.

#### **AVAILABILITY OF PROTOCOL FORM**

Hard copies of the animal protocol form are available by contacting the Office of Research and Sponsored Programs. The form is also available on the web.

#### **SCHEDULE FOR SUBMISSION**

Protocols submitted by the 10<sup>th</sup> of the month will be considered by the ACFC during that month. Example: Protocols received by October 10<sup>th</sup> will be reviewed at the October meeting.

There are no meetings in August or November. Protocols must be received by November 15<sup>th</sup> to be reviewed at the December meeting.

It is important to plan your research needs accordingly. Following the proper procedure is essential to preventing delays. Any variations to this schedule will be published in *Grantnet* and *Animal Welfare Matters*.

**ADDITIONAL INFORMATION**

For further information on the review process, and to obtain and submit protocol applications, please contact Karen M. Janes, Assistant Director Research Subjects Administration, Office of Research and Sponsored Programs, Annex II, Busch Campus, phone: 732-445-2883; e-mail, <[janes@orsp.rutgers.edu](mailto:janes@orsp.rutgers.edu)>.