

## Protocol Review Form for Animal Care and Use

IACUC approved August 27, 1999

Provost and Academic Vice President approved March 29, 2000

Third revision May 18, 2011

The Institutional Animal Care and Use Committee (IACUC) is charged with oversight of animal use at John Carroll University to ensure compliance with federal regulations protecting the welfare of animals. A major function of the IACUC is to review teaching or experimental protocols and, where appropriate, recommend protocol modifications to improve the welfare of the animals. IACUC review is required for all laboratory and fieldwork administered by the University in which live vertebrates are captured or held in captivity. The IACUC approval is required before any such project may begin.

The IACUC consists of scientists from several disciplines as well as non-scientists, members of the University community, and persons who have no other affiliation with the University than as members of the Committee. The protocol should therefore be described in terms understandable by an audience of educated non-specialists. Please return the completed protocol to the Chair of the IACUC by the 5<sup>th</sup> of the month. Projects will be reviewed and the appropriate faculty member notified of the committee's initial decision within three weeks of submitting the Protocol Review Form. This decision may be "approved," "disapproved," or "revision requested." Investigators who submit protocol forms after the 5<sup>th</sup> of the month may find the project review will be delayed until the following month. Projects not approved in the initial review process will be re-reviewed upon modification of the protocol to address concerns expressed by the Committee. Revised protocols also will be reviewed within three weeks of submission. Work may proceed only after the project has been fully approved. Please call the IACUC Administrator at (216) 397-1527 if you have questions.

Project title: \_\_\_\_\_

Date submitted: \_\_\_\_\_ Project start date: \_\_\_\_\_ to \_\_\_\_\_

Project type: Teaching \_\_\_\_\_ Student research \_\_\_\_\_ Faculty research \_\_\_\_\_

Is this project a field study? Yes \_\_\_\_\_ No \_\_\_\_\_

Faculty instructor/supervisor/investigator: \_\_\_\_\_

Student investigator: \_\_\_\_\_

Department: \_\_\_\_\_ Is this a grant proposal? \_\_\_\_\_ Funding agency: \_\_\_\_\_

---

Faculty Signature:

I, the responsible faculty member, assure that this project will be conducted in accordance with this protocol, and that proposed changes to the procedure will be submitted to the IACUC for review before implementation. To the best of my knowledge this project does not unnecessarily duplicate previous work.

Faculty \_\_\_\_\_ Date \_\_\_\_\_



- 3) Explain how the number of animals required for this proposal fits your study design. Give the rationale for the number in terms of statistical methods to be used. Address the issue of reduction by explaining why the proposed number is sufficient, but not excessive. State the statistical method used for selecting the sample size. (A simple statement that the number proposed is required for statistical significance is not an adequate response.)

#### 4. **Alternatives to Painful Procedures**

If your project involves using a methodology that causes more than momentary or slight pain or distress to animals, document what information source(s) or literature searchers were used to locate alternative methods. The Animal Welfare Act requires that a minimum of 2 or more searches must be conducted (i.e., Pubmed and Medline.) Please provide the following information regarding your search: 1) list databases used, 2) keywords used in the search, 3) years covered by search, and 4) date on which current search was conducted. (For more information go to the USDA's Animal Welfare Information Center at <http://www.nal.usda.gov/awic/alternatives/alternat.htm>. JCU's IACUC website also provides additional resources and links to alternative method databases at <http://www.jcu.edu/research/iacuc>).

#### 5. **Endpoints**

Indicate what endpoints other than experimental parameters could lead to early termination of the experiment to prevent unnecessary pain or distress to the animal(s) (i.e., pain that cannot be controlled with analgesics, tumor size, stage of disease, 15 to 20% loss of body weight, etc). Include interventions that will be used such as euthanasia, treatment, or discontinuance of procedure.

#### 6. **Unnecessary Duplication**

Please provide evidence that the proposed activities do not unnecessarily duplicate previous experiments, and outline the basis for your statement(s). If applicable, explain the need to duplicate previous experiments. Please include as evidence 1) a list of databases used, 2) keywords used in the search, 3) years covered by search, and 4) date on which current search was conducted.



- b. Provide a statement about the qualifications of project personnel including technicians and students. If personnel are not adequately trained, explain your plan for training them.

**10. Procedures To Be Used**

Respond to all items; for items marked “yes,” provide requested details in the project description under IACUC Protocol item 1.

YES	NO	
_____	_____	Special diets ( <i>describe diet and any anticipated nutritional deficit</i> )
_____	_____	Restraint ( <i>describe method, duration</i> )
_____	_____	Blood sampling ( <i>describe techniques, volumes, frequency, anesthesia</i> )
_____	_____	Invasive sampling of urine/feces ( <i>describe techniques, frequency, anesthesia</i> )
_____	_____	Collection of tissues ( <i>describe method, anesthesia</i> )
_____	_____	Nonsurvival surgery ( <i>describe procedure, duration, anesthesia</i> )
_____	_____	Single survival surgery ( <i>describe procedure, duration, anesthesia, postoperative care provisions</i> )
_____	_____	Multiple survival surgeries involving an individual animal ( <i>justify the need for multiple surgeries and describe procedures, duration, anesthesia, post-operative care provisions for each procedure; explain how surgeries are related</i> )
_____	_____	Indwelling catheters or implants ( <i>describe site, type, maintenance/monitoring protocol</i> )
_____	_____	Administration of drugs/reagents/cells/etc. ( <i>describe agent, route of administration and frequency, anesthesia, anticipated side effects, monitoring protocol</i> )
_____	_____	Antibody production ( <i>indicate route of administration, adjuvant use and frequency, collection protocol</i> )
_____	_____	Tumor transplantation ( <i>describe any anticipated functional deficit to the animal, monitoring protocol, endpoint</i> )
_____	_____	Behavioral testing <u>without</u> significant restraint or noxious stimuli ( <i>describe</i> )
_____	_____	Behavioral testing <u>with</u> significant restraint or noxious stimuli ( <i>describe; provide rationale for degree of restraint or stimulus</i> )
_____	_____	Human safety concerns or hazards, such as ether ( <i>describe intended use, means available to ensure safety</i> )

**11. Biohazardous Agents**

Please check if any biohazardous agents will be used. If the answer is yes to any of the questions, name the biohazardous agent.

- \_\_\_\_\_ a. Chemical Carcinogens \_\_\_\_\_
- \_\_\_\_\_ b. Highly Toxic Compounds \_\_\_\_\_
- \_\_\_\_\_ c. *In Vivo* Infectious Organism \_\_\_\_\_
- \_\_\_\_\_ d. Radiation, Radioisotopes \_\_\_\_\_
- \_\_\_\_\_ e. Other \_\_\_\_\_

**12. Controlled Substances**

A controlled substance is a drug or chemical whose manufacture, possession and use are regulated by the Federal and State government. Will controlled substances be used for this research?

Yes                       No

If yes, please complete the information below (the current official list of DEA-controlled substances can be found in 21CFR §1308 at <http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm>):

Name of Controlled Substance	Class

Note: Every activity with controlled substances must be recorded on the IACUC Controlled Substance Use form and made available for inspection by the IACUC or other authorized individuals for the duration of the research. The form is available at <http://www.jcu.edu/research/forms/iacuc/ControlledSubstanceLog.doc>.

**13. Animal Sources**

a. Please indicate source of animals:

Collected in Field     Purchased

Other (Explain): \_\_\_\_\_

**13. Animal Handling** (For animals collected in the field by researchers).

a. If animals are caught in the wild, where and how will the animals be captured?

b. If animals are trapped in the wild, where and how will the animals be trapped? How often will the traps be checked?

c. Will the animals be marked or tagged and if so how will this be done?

d. What other steps will be taken to protect the animals from exposure or other danger?

- e. Will animals be released or brought back to campus?
- f. If the animals will be brought to the campus, what precautions will be taken to prevent zoonotic diseases?
- g. If animals are released shortly after capture, state the release method and location.
- h. Does the research require federal or state permits? If so, please attach a copy of the permit application and issued permit.

#### 14. Animal Location

- a. Where will the animals be housed?
- b. Where will the procedures be conducted?

Send two copies of this packet (the protocol and any pertinent materials including permits) to:

**IACUC**

**John Carroll University**

**20700 North Park Blvd., Room AD250**

**University Heights, OH 44118**

Forms and policy guidelines are available at: [www.jcu.edu/research/iacuc](http://www.jcu.edu/research/iacuc). For questions, comments, or assistance in completing the form, contact the IACUC Administrator at 216-397-1527.