LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES DIVISION

IACUC APPLICATION GUIDE for THE RESEARCH CHANNEL

http://portal.luhs.org

July 2012

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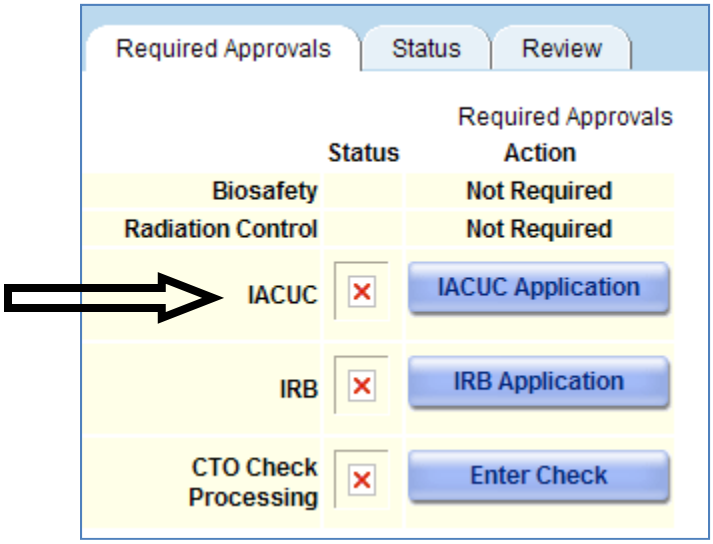
IACUC FORM (Version 2.00)

Creating a New IACUC

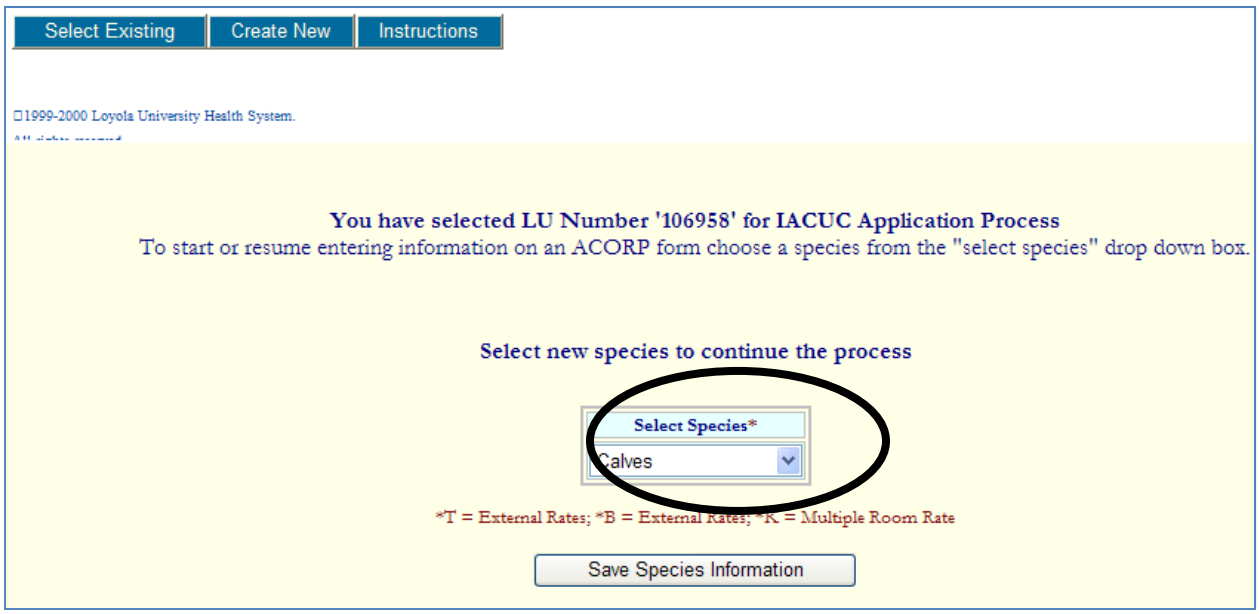
The IACUC form must be completed once you have entered in the project/proposal for animals. This form will generate Appendices based on what information is entered.
There are a total of 9 appendices.

1. Click on **IACUC** located under **New Proposal Form** on the menu. (NOTE: This option will only appear once you have generated a project/proposal with animals involved.)

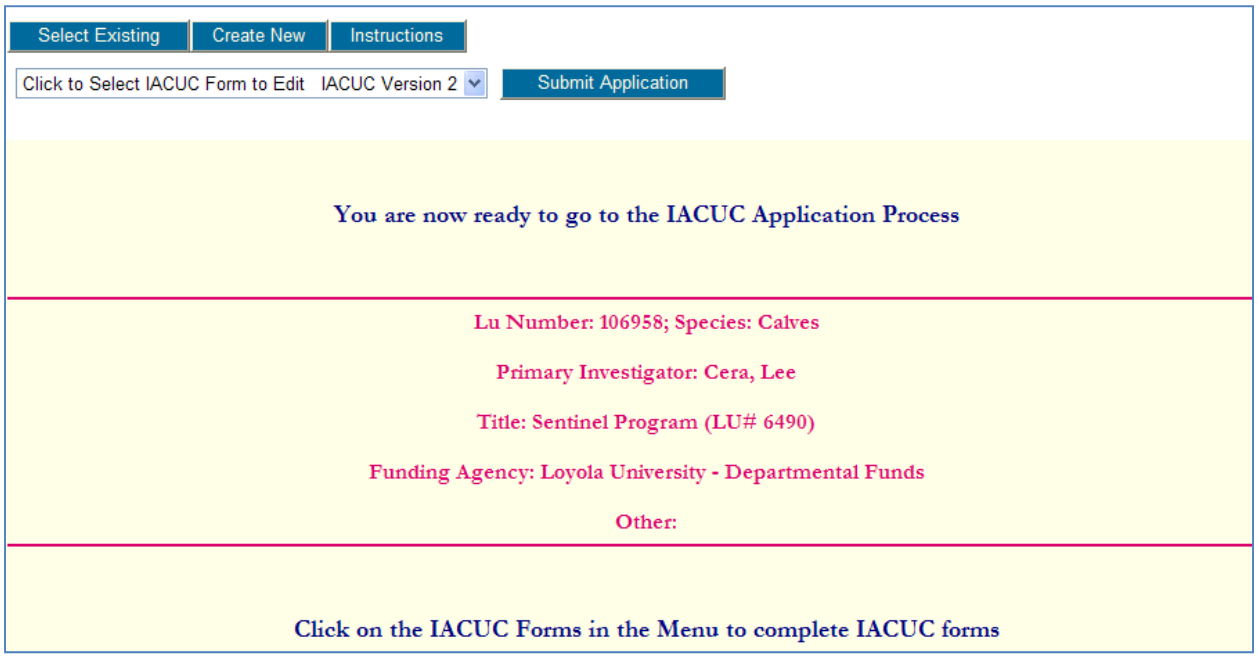


2. The IACUC menu will appear on the right. Click on **Create New Protocol**

3. Select your **species** from the drop down menu and click on **Save Species Information**

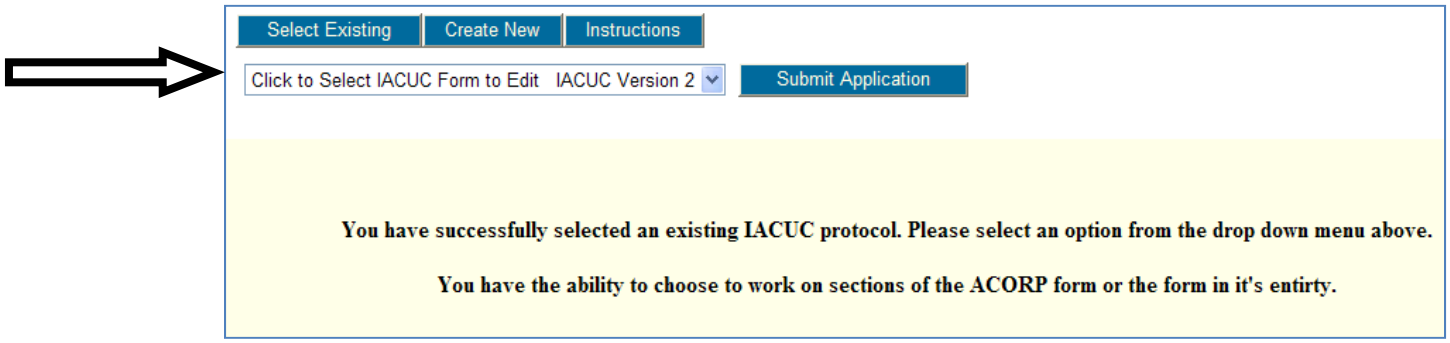


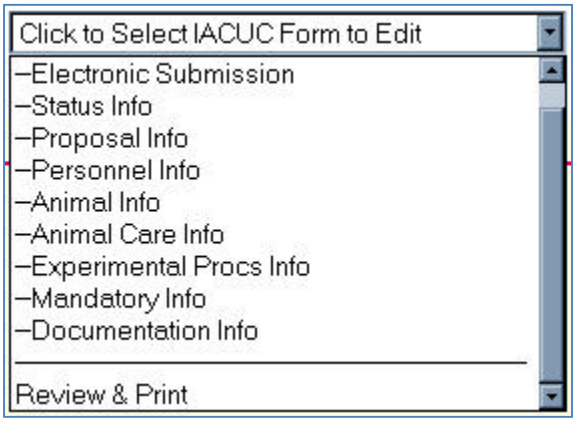
4. This IACUC message will appear.



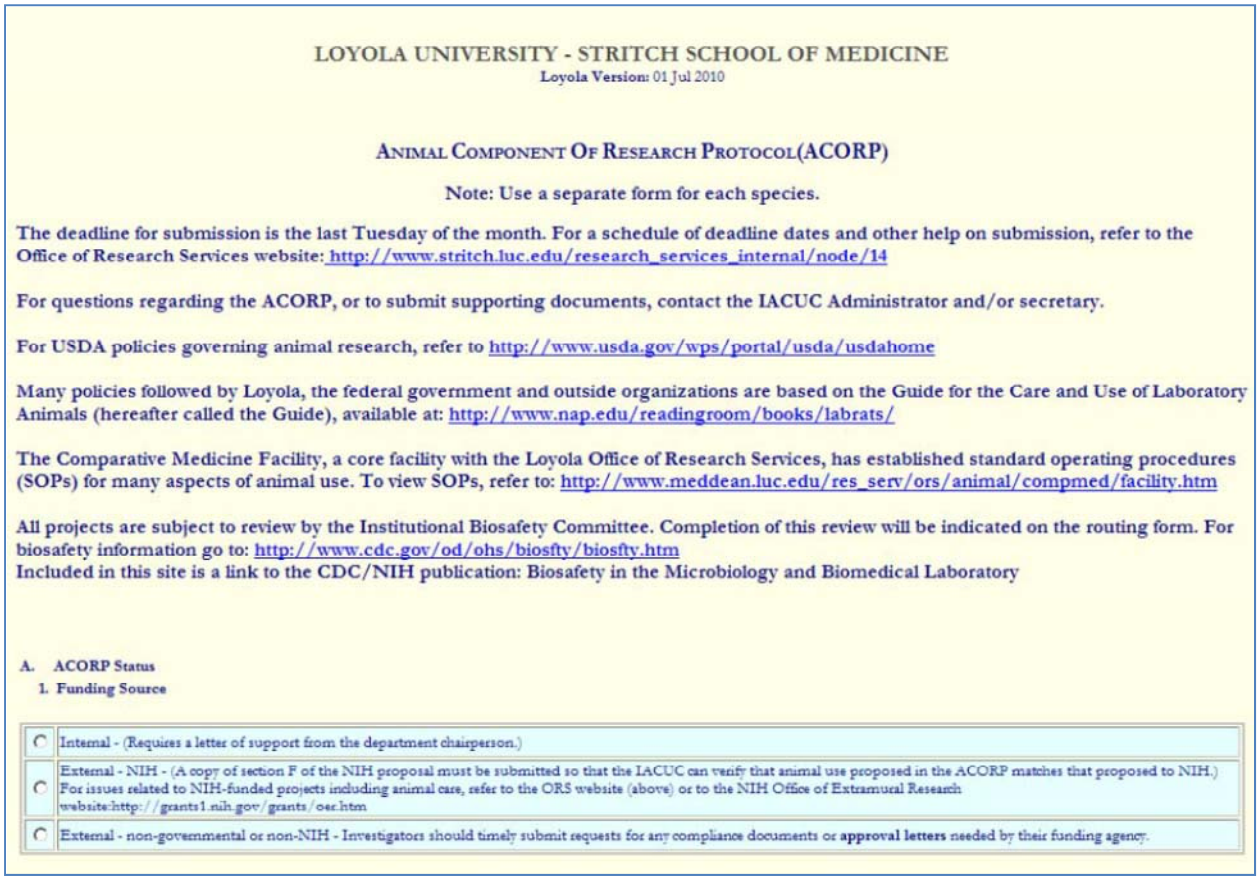
5. Click on **IACUC Form** and **the link will automatically load.**


Select Existing
Create New
Instructions


Select Existing
Create New
Instructions
Click to Select IACUC Form to Edit
IACUC Version 2
Submit Application
You have successfully selected an existing IACUC protocol. Please select an option from the drop down menu above.
You have the ability to choose to work on sections of the ACORP form or the form in it's entirty.


Click to Select IACUC Form to Edit
–Electronic Submission
–Status Info
–Proposal Info
–Personnel Info
–Animal Info
–Animal Care Info
–Experimental Procs Info
–Mandatory Info
–Documentation Info
Review & Print

4. The IACUC/ACORP form will now appear. Click on any of the categories and complete each field as needed. Click **Save** after completing each section.



LOYOLA UNIVERSITY - STRITCH SCHOOL OF MEDICINE

Loyola Version: 01 Jul 2010

ANIMAL COMPONENT OF RESEARCH PROTOCOL(ACORP)

Note: Use a separate form for each species.

The deadline for submission is the last Tuesday of the month. For a schedule of deadline dates and other help on submission, refer to the Office of Research Services website: http://www.stritch.luc.edu/research_services_internal/node/14

For questions regarding the ACORP, or to submit supporting documents, contact the IACUC Administrator and/or secretary.

For USDA policies governing animal research, refer to http://www.usda.gov/wps/portal/usda/usdahome

Many policies followed by Loyola, the federal government and outside organizations are based on the Guide for the Care and Use of Laboratory Animals (hereafter called the Guide), available at: http://www.nap.edu/readingroom/books/labrats/

The Comparative Medicine Facility, a core facility with the Loyola Office of Research Services, has established standard operating procedures (SOPs) for many aspects of animal use. To view SOPs, refer to: http://www.meddean.luc.edu/res_serv/ors/animal/compmed/facility.htm

All projects are subject to review by the Institutional Biosafety Committee. Completion of this review will be indicated on the routing form. For biosafety information go to: http://www.cdc.gov/od/ohs/biosfty/biosfty.htm
Included in this site is a link to the CDC/NIH publication: Biosafety in the Microbiology and Biomedical Laboratory

A. ACORP Status
1. Funding Source

○	Internal - (Requires a letter of support from the department chairperson.)
○	External - NIH - (A copy of section F of the NIH proposal must be submitted so that the IACUC can verify that animal use proposed in the ACORP matches that proposed to NIH.) For issues related to NIH-funded projects including animal care, refer to the ORS website (above) or to the NIH Office of Extramural Research website:http://grants1.nih.gov/grants/oer.htm
○	External - non-governmental or non-NIH - Investigators should timely submit requests for any compliance documents or **approval letters** needed by their funding agency.

IACUC FORM (Version 2.00)

LOYOLA UNIVERSITY - STRITCH SCHOOL OF MEDICINE

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A. ACORP Status

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○	External - non-governmental or non-NIH - Investigators should timely submit requests for any compliance documents or **approval letters** needed by their funding agency.

2. ACORP Status

○	This is new ACORP for a new project with a new LU#
○	This is a replacement of a previously approved ACORP which is being/has been completed. New studies are proposed which follow from and/or extend work completed under the previous ACORP. The project has a new funding source (i.e., a new LU#). The previous funding and LU# will not continue.
○	This ACORP is based on a previously approved ACORP but is associated with a new project and LU#, only for the purpose of adding a new funding source. The existing project (LU#) and funding will remain active. No significant revisions (e.g. additional animals or changes in experimental design) are proposed.
○	This is a minor revision (amendment) of an existing ACORP for an already approved project (e.g., changes in personnel, procedure location, etc).
○	This is a significant revision (amendment) of an ACORP for an already approved project (e.g., changes/additions in numbers or types of animals, number and type of experimental procedures and manipulations, etc, needed to accomplish the proposed work).
○	This ACORP is submitted as a three-year (3 year) renewal of an expiring ACORP, to continue existing approved studies. Complete Appendix 8, Status report for 3-year renewal ACORP, to indicate how the current proposal extends or expands any already completed work, without duplicating it. As appropriate, also address this issue in Section G and/or Section Y4
○	Other. Please Specify

Previous ACORP title (if different):	
Previous IACUC approval number:	

Will **Biohazardous Materials** be used in this ACORP?	○ Yes ○ No

3. Indicate the type of animal use:

(For multiple selections hold down CTRL key while highlighting choices)

- Research
- Teaching or Training
- Testing
- Sentinel animal use
- Breeding and colony management only; no experimental procedures
- Other.Please specify

B. Personnel

1. Principal and co-investigator(s)

Name of Principal Investigator		**Department**			
Building:	**Room:**	**E-mail:**		**Ext:**	

Name of Co-P.I(s):				**Co-P.I Dept:**			
Building:		**Room:**		**E-mail:**		**Ext:**	

2. Person(s) to be contacted with questions regarding this protocol

Contact Person: Last Name:		**Contact Person: First Name:**		**E-mail:**		**Ext:**	

3. Give the names of all research staff, including the PI and Co-PI, involved in this study. FOR EACH PERSON LISTED, describe their institutional affiliation, their specific role(s) in the project, their academic degrees, education, training, and experience with experimental animals in general AND describe their experience performing the exact procedures in the species described in this ACORP. For staff NOT having actual contact with animals, so state. This description must help the IACUC determine if all animal manipulations, including anesthesia, surgery, testing, blood collection, and euthanasia, are performed by individuals who are qualified to accomplish the procedures skillfully and humanely. A listing of academic degrees alone is not an adequate response.

Name/Academic Degree and Institutional Affiliation	Affiliation to this project and specific responsibilities	Education/training with procedure and experience with species	Email	Extension	Location

C. Training:

1. For all personnel listed in item B who do not have experience with the exact procedures and species described in this ACORP, state how will they be trained and who will train them. List persons providing the training in item B3 above. Once completed, proceed to item C 2.

2. Loyola University Stritch School of Medicine has access to a web-based training and certification program. Investigators should complete each required training module via the web site on which that module is offered. For clarification of requirements and additional training possibilities and information, consult the Comparative Medicine Facility or the IACUC office.

http://www.aalaslearninglibrary.org/ - The AALAS Learning Library provides training that is essential for technicians, veterinarians, managers, IACUC members, and investigators working with animals in a research or education setting.

Emphasizing the appropriate handling, care, and use of animals, the courses are designed to help you study for AALAS certification, meet training mandates of regulatory agencies, and improve your knowledge in technical areas.

Instructions for Personnel to Access the AALAS Learning Library: http://www.stritch.luc.edu/sites/default/internal_files/iacuc-aalas-learning-library-access.pdf

Required Levels of training:

All individuals listed on a protocol, including those without animal contact, including the PI and Co-PIs require:

1) Basic Training

2) Occupational Health

All individuals with animal contact ALSO require:

3) Species Specific Training

4) Anesthesia/Analgesics Training where applicable

5) Surgery Training where applicable

6) Post-Procedure Care where applicable

D. THIS SECTION IS CURRENTLY NOT IN USE

E. Procedure Location

List (in sequence where sensible) all animal procedures performed in this project and give their locations. Account for all time animals will be involved in procedures, including pre-treatment or pre-experiment holding periods, in vivo treatments or substance administration, behavioral observation periods, surgeries, euthanasia, and post-treatment observation/management for survival experiments. Describe how animals will be transported to and from these sites. Notes:

Procedures to be done within CMF housing facilities and/or procedure rooms, or procedures which may require removal and return of animals to CMF housing, must follow CMF SOPs and not compromise biosafety. Investigators are encouraged to plan such procedures with CMF staff.

Survival surgery on non-rodent species and survival surgery on rodent species may be performed in a procedure room or laboratory if approved by the IACUC.

Include any non-Loyola facilities (and complete Appendix 1 if appropriate).

Investigators not listed in B above, who plan only ex vivo procedures on animals prepared under this ACORP, such as experiments using only tissues harvested post-euthanasia, should complete a post-euthanasia tissue transfer form, available on the CMF web site.

Transportation must be in accordance with the *Guide*, USDA regulations, and PHS policy in climate controlled vehicles and sanitizable transport cages when appropriate. Transport through non-research areas must be discreet, i.e. secure animal cage or transport cage covered with a sheet or underpad. For transportation to Hines or any other off-campus location, contact the CMF (x 6-9179) for specific details.

If any patient procedural areas are to be used, complete Appendix 7, "Request to Use Patient Procedural Area". The principal investigator must also submit a letter of approval from the Director of the facility to be used and a similar letter of support from the Safety Manager and the Director of Corporate Compliance.

Procedure:		Duration:		Building #		Room #		Patient Procedure Area	○ No ○ Yes	Non-Loyola Facility	○ No ○ Yes

You can enter information in the text boxes and click on "Save F Info" or upload word documents by clicking on "To Upload File Click Here"

F. Lay Summary - describe in 2 brief paragraphs, using non-technical (lay) language that a high school student would understand:

1. How might this research improve the health of people and/or other animals?

2. Describe the experimental design, in a way that reveals what will actually happen to the animals.

Define all abbreviations the first time they are used.

G. Experimental Design and Procedure - In language scientific colleagues outside of your discipline would understand, describe the experiments and/or other procedures. Define all abbreviations. Include the following information:

1. The total number of animals requested.

2. Brief statement of major specific aims, rationale, objective or didactic/training value of the project. The numbers and types of animals to be used in each specific aim should be listed as accurately as possible, either here or in section L.

3. If this project continues or extends existing work, indicate briefly how the proposed work differs from the previous work.

4. The sequence of events to reveal what happens to the animal and their ultimate fate.

5. All procedures and manipulations; explain why they must be performed.

6. For complicated experimental designs, a flow chart, diagram, or table is strongly recommended to help the IACUC understand what is proposed. **Graphics such as flow charts, diagrams, and tables must be uploaded from a Word document.**

7. Mention any monoclonal antibody production, test substance administration, antemortem tissue harvesting, and surgery, but do not describe them in detail here. Such details are requested later in appendices 2-5, respectively (refer to sections P through T). Other specialized husbandry or experimental procedures should be mentioned here and described in Appendix 6(refer to section U).

H. Species Description.

Describe the characteristics of the selected species, strain, stock, mutant, or breed that justify its use in the proposed study. Consider such characteristics as body size, species, strain, breed, availability, data from previous studies, and unique anatomic or physiologic features. If animals with specific transgenes, gene knockouts, or prior experimental manipulations are required for the proposed work, describe and justify here.

I. Procurement of Animals-List all strains, including each distinct transgenic or mutant, one per line. Complete the following table; then **proceed** to **item J.** Animals from other than a licensed commercial source will require CMF approval. Contact CMF regarding required health certifications and/or other documents, shipment processing, housing availability, quarantine, etc.

Strain, Stock, Mutant, or Breed	Gender	Age/Size	Source (Vendor) Commercial or Non-commercial	Surgical Alterations
	Male Female Either			

Please input integers for all category animals for Years 1, 2 and 3. If you do not have the numbers, please put 0. Do not leave blanks.

J. Animal Numbers - In the table below, assign all requested animals by breed/strain/mutant to a USDA category of pain/distress. The list of strains and the total number of animals must match those in section I. If numbers within a category cannot be determined exactly, estimate as closely as possible. Please use the guidelines below the table to assign categories. If you have difficulty determining the appropriate category, please contact the attending veterinarian or IACUC Chair for assistance. ***The same animal cannot be assigned to more than one USDA category***. If an animal will undergo more than one procedure, it should be placed in the category for the most painful/distressful procedure.

Breed/Strain/Mutant	Pain/distress Category	Total requested for Year 1	Total requested for Year 2	Total requested for Year 3	Total number requested for Project
	B C D E				

USDA Category B - No experimental procedures:
Animals bred or purchased for breeding (parents and offspring), held in legal sized caging, and maintained in accordance with regulations.
Young that cannot be used experimentally because of improper genotype or gender. Animals being bred, conditioned non-aversively, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.
Animals held under proper captive conditions or wild animals that are being observed.

USDA Category C - Procedures performed by trained personnel, causing no or only very brief pain or distress, with no need for use of pain relieving drugs:
Observational studies.
Brief restraint(<15 minutes) for the purpose of a physical exam, radiography, ultrasound, etc.
Behavioral studies of an adapted animal.
Administration of electrolytes, fluids, non-irritating substances or oral medication.
Intravenous and parenteral injections of non-irritating agents.
Blood collections from peripheral vein (dog cephalic, cat jugular, rodent saphenous, mouse tail).
Euthanasia using methods recommended by the AVMA Guidelines on Euthanasia.
Post-euthanasia harvesting of cells and/or tissues.

USDA Category D - Procedures performed by trained personnel where potential pain or distress is relieved by appropriate anesthetics, sedatives, or analgesics:
Major and minor surgery performed under anesthesia (survival or non-survival), including but not limited to biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation, laparotomy or laparoscopy.
Surgical tissue or organ collections prior to euthanasia.
Painful procedures performed under anesthesia (such as retro-orbital blood collection in rodents).
Prolonged (>15 minutes) restraint accompanied by tranquilizers or sedatives.
Experiments involving infectious or other hazardous materials in animals, where there is a provision for immediate euthanasia for animals that become sick to effectively prevent pain and/suffering.
Invasive blood collection, such as intracardiac or periorbital collection from species without a true orbital sinus such as rats and guinea pigs.
Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics.

USDA Category E - Procedures causing pain or stress NOT relieved with the use of anesthetics, analgesics, tranquilizers, or by euthanasia.
Studies in which animals are allowed to die without intervention (i.e. LD50; mortality as an end-point).
Studies with endpoints that are painful or stressful.
Addictive drug withdrawals without treatment.
Thermal injury, noxious stimulation, aversive conditioning, or electric shocks which would cause pain in humans.
Animal undergoing painful/distressful procedures where use of anesthetics, analgesics, or tranquilizers will adversely affect the procedures, results, or interpretation.
Toxicity studies, microbial virulence testing, and radiation sickness.
Research on stress, shock or pain.
Invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.

K. Painful Procedures:

For all category D (and where appropriate, E) procedures, provide full details of anesthesia, analgesia, and/or euthanasia in the corresponding appendix (2,3,4,5, or 6) or in section W below.

Are any USDA Category D studies planned?

- (•) No, proceed to item L
- ( ) Yes, complete items K.1 - K.2, then proceed to item L.

1. List and describe all category D procedures by filling out the table below. If no category D studies are proposed, enter "N/A" and **proceed** to **item K.2.** For any surgical procedures you will describe in **Appendix 5** , enter only a brief description in the "Procedure" column, then enter "See Appendix 5 for details".

Procedure	Number of Animals (year 1)	Number of Animals (year 2)	Number of Animals (year 3)

Are any USDA Category E studies planned?

- (•) No, proceed to item L
- ( ) Yes, complete items K.1 - K.2, then proceed to item L.

2. USDA requires annual reporting of all category E procedures. If no category E studies are proposed, enter "N/A" and **proceed** to **item L.** List each procedure in the following table, and state where the details of the procedure are given (e.g. section G or appendices 2-6). If animals will undergo category D procedures as well, describe them in **item K.1** above.

For each procedure listed, provide detailed scientific justification for not using pain relief. Within your description of the procedures themselves (in Section G and /or any of Appendices 2-6), you may refer to the justifications you provide here. In these justifications, include references and/or any other information which will help the IACUC determine that you have considered available pain relief options thoroughly. If animals will be allowed to die naturally (e.g. infectious disease or oncology studies), or an endpoint is used that allows the animals to experience significant pain or distress, justify why an earlier alternate endpoint(e.g. endpoints described in section T, such as weight loss, clinical signs, tumor size, etc.) cannot be used.

Procedure	Scientific Justification for not using pain relief	Number of Animals (year 1)	Number of Animals (year 2)	Number of Animals (year 3)

L. Describe how the estimated number of animals needed for the experiments was determined. The following are some considerations which may apply:

- To the extent possible, each specific aim of the project should be listed, with numbers of animals of each type required for that aim (if not listed in section G above).
- If you are requesting significant numbers of additional animals or new strains for an approved project, state how the new numbers and/or types will enhance or allow completion of the studies.
- State if the exact numbers of animals cannot be determined prior, e.g. for pilot, exploratory or control studies where the variance of the data is unpredictable.
- If feasible, e.g. for hypotheses about differences among groups of data such as control vs treatment (having t, Gaussian, or Chi-square distributions), use a power analysis to determine sample size.
- If the experiments use a nonlinear or other statistical model for which power analysis is not available, or are expected to produce qualitative outcomes not amenable to statistical comparisons, so state.
- Indicate if numbers are based on a required yield of tissues, cells and/or isolates for in vitro studies, or on maximal attainable success or survival rates in experimental procedures.
- Indicate if operational constraints limit the rate of animal use, e.g. required minimum duration of experiment, required age/developmental stage of animals, success of breeding, availability/scheduling of research equipment and facilities.
- State any legal constraints based on contractual product testing or research.
- Other; explain.

The following considerations should be applied to help reduce numbers of animals:

1. Choice of statistical methods and software.
2. Use of standardized procedures.
3. Use of animals of known and/or controlled genetic background.
4. Multiple procedures per animal where permitted and justified.
5. Sharing of tissue in terminal and/or post-euthanasia procedures.

Animal Housing and Care

M. Laboratory Animal Veterinary Support. Complete **items M.1 - M.2**, then **proceed** to **item N.**

1. Give the name of the Laboratory Animal Veterinarian responsible for providing adequate care to the animals that will be used; include their institutional affiliation:

2. Policy requires that a Laboratory Animal Veterinarian be consulted during the planning stages of any procedure involving laboratory animals, before IACUC review. Give the name of the Laboratory Animal Veterinarian consulted during the planning of procedures involving animals. You may request that the Veterinarian perform a pre-review of the ACORP and provide comments to the PI so that the ACORP may be revised prior to full IACUC review. Also give the date of the veterinary consultation (meeting date, method of consultation, and/or date written comments were provided).

N. Husbandry.

Investigators are urged to consult with CMF regarding the availability of housing suited to the species and health status/risk factors of the animals to be used. Rodent users should consult the following link for updated housing information: http://www.meddean.luc.edu/res_serv/ors/animal/compmed/housing.htm

1. Caging needs. To help the animal care staff with caging needs, please consult with CMF staff at ext. 65162 and indicate the type of caging that you will need; then **proceed** to **item N.2:**

- ☐ Biohazard or other special hazard containment caging
- ☐ Sterile rodent microisolator caging, with filtered cage top
- ☐ Non-sterile rodent microisolator caging, with filtered cage top
- ☐ Standard non-rodent caging, appropriate for species
- ☐ Other. Describe:

2. ○ This protocol uses social animals but the animals will be housed singly. The *Guide for the Care and Use of Laboratory Animals* states that social animals should be housed in groups whenever possible.

Justify:
N/A

◉ N/A

3. ○ This protocol uses rodents which will be housed on suspended wire mesh floors or other flooring in which the animals do not rest on bedding. The *Guide* recommends the use of contact bedding (i.e., shoebox or microisolator cages).

Justify:
N/A

◉ N/A

4. ○ This protocol uses dogs which will be excluded from the USDA-required exercise plan.

Justify:
N/A

◉ N/A

5. ○ This protocol uses primates which will be excluded from the USDA-required psychological enrichment plan.

Justify:
N/A

◉ N/A

6. ○ This protocol uses genetically modified animals. Describe here any characteristic clinical signs or abnormal behavior related to their genotype. Include information on each specific strain.

Justify:
N/A

◉ N/A

7. ○ This protocol uses previously treated animals, e.g. animals obtained after experimental surgeries, induction of disease states, etc. Describe here any characteristic clinical signs or abnormal behavior related to their histories. Include information on each specific pretreatment.

Justify:
N/A

◉ N/A

O. THIS SECTION IS CURRENTLY NOT IN USE

P. Housing Sites. Will all animals purchased with LUC/SSOM Foundation funds be housed and otherwise used only in LUC/SSOM facilities?

○ Yes. **Proceed** to **item Q**
○ No. Complete and attach ACORP **Appendix 1**, "Use of Non-LUC/SSOM Animal Facility", then **Proceed** to **item Q**.

Experimental Procedures

Q. Test Substances. Will test substances be administered to animals? For the purposes of this question, test substances are defined as materials administered to animals. This includes, but is not limited to, radioisotopes, toxins, antigens, pharmacological agents, paralytic agents, drugs undergoing clinical trial, infectious agents, carcinogens or mutagens, biomaterials, prosthetic devices, and cells, tissues, or body fluids.

○ No. **Proceed** to **item S**.
○ Yes. Complete and attach **Appendix 3**, "Test Substances"; then **proceed** to **item S**.

Notes: the following substances do not need to be entered in **Appendix 3**: routine pre- or post-operative drugs described in the Surgery Appendix [Appendix 5], antigens, adjuvants, hybridomas described in the Antibody Production Appendix [Appendix 2], and anesthesia and/or euthanasia agents entered in Appendices, 2,4, or 5 or item V, Euthanasia.

Procurement and use of hazardous test substances is governed by the Loyola Institutional Biosafety Committee (IBC) and is contingent on IBC approval.

R. THIS SECTION IS CURRENTLY NOT IN USE

S. Body Fluid, Tissue, and Device Collection. Indicate which case applies.

☐ No body fluids or tissues will be collected in any invasive manner, nor will any devices will be implanted/removed. **Proceed** to **item U**

☐ Body fluids or tissues will be collected in an invasive manner, or devices will be implanted/removed, but these procedures will be done ENTIRELY post-euthanasia. **Proceed** to **item U**

☐ Antibody Production. Body fluids/tissues will be collected from animals used to produce monoclonal or polyclonal antibodies, or existing hybridoma cell lines will be injected into animals to harvest antibody. Complete and attach **Appendix 2** "Antibody Production", then **proceed** to **item U**

☐ Body fluids or tissues will be collected or devices will be implanted or removed BEFORE euthanasia, but using a NON-SURGICAL procedure. **Proceed** to **Appendix 4,** "Antemortem Specimen Collection"; **complete** and **return** to **Item U**

☐ Body fluids or tissues will be collected or devices will be implanted or removed BEFORE euthanasia, using a SURGICAL procedure. **Proceed** to **Item T**

T. Surgery. Will surgery (survival or non-survival) be performed?

For the purpose of this question, surgery involves penetration and exposure of a major body cavity, or a procedure producing substantial impairment of physical or physiological functions. Examples include laparotomies, thoracotomies, craniotomies, joint replacements, limb amputations, implantation or removal of sensors, catheters, pumps or other devices, surgical excision of organs or tissues, and exposure of tissues to insult such as burns, wounds, and/or sepsis.

- ○ No. **Proceed to item U**
- ○ Yes. Complete and attach Appendix 5, "Surgery", then **proceed to item U**

U. Special Procedures. Are any experimental procedures or special husbandry procedures planned that are not described in detail in section G or any of Appendices 2-5? Special procedures can include special restraint practices (including non-human primate chairing), special animal health monitoring, special diets (including food/water deprivation other than presurgical), special caging, environmental control or restriction (such as light deprivation, temperature extremes), use of special means of identification, use of noxious stimuli, forced exercise, or behavioral manipulation such as aversive conditioning.

- ○ No. **Proceed to item V**
- ○ Yes. Complete and attach Appendix 6, "Special Husbandry and Procedures", then **proceed to item V**

V. Humane Endpoints

1. What will be the normal fate of the animals in this study? (CHECK ALL THAT APPLY)

- ☐ Animals will survive and be available for adoption. Animals to be adopted must be of suitable species, and be healthy, not aggressive, have no implanted devices, and be neutered/spayed. Any proposal for adoption requires prior specific approval of the IACUC
- ☐ Animals will survive and be available for use in other protocols. Such transfer and use will require IACUC and CMF approval. These animals must be of suitable species and be healthy. No animals which have undergone any invasive procedures such as device implantation or other surgery may be used in any further invasive procedure, unless the initial procedure can be justified in specific detail as necessary preparation for the later procedure.
- ☐ Animals will be humanely euthanized using a specific procedure described in section W below during or after the study.
- ☐ Animals will be humanely euthanized as a result of nonsurvival surgery described in Appendix 5. Such euthanasia must follow the guidelines given in section W below.
- ☐ Animals will die as a result of experimental manipulations other than surgery, as described in Section G or Appendices 2,3,4 (with pain relief - category D).
- ☐ Animals will die as a result of experimental manipulations (surgical or other), as described in Section G or Appendices 2,3,4 or 6 (no pain relief-category E). Scientific justification must be provided in section J.

A. Provide here any information not given elsewhere which may help the IACUC determine that an appropriate endpoint has been chosen:

- ○ Section 1.A is N/A

2. Abnormal/unexpected endpoints: What criteria will be used to determine when sick, injured or otherwise compromised animals, *both on and off study*, will be euthanized or otherwise removed from the study? Examples include: (CHECK ALL THAT APPLY)

- ☐ Weight loss or failure of young animals to gain weight.
- ☐ Inappetance, anorexia, or inability to feed and obtain water.
- ☐ Weakness, ataxia, behavioral depression, seizures, paralysis, refractory pain, inability to stand, self-wounding.
- ☐ Low body temperature, dyspnea, cyanosis.
- ☐ Tumor growth or burden.
- ☐ Problems refractory to medical intervention, including infection, non-healing wounds, fractures, etc.
- ☐ Blood loss, vomiting, diarrhea, and/or other discharges.
- ☐ Surgical emergencies and/or failures of similarly complex procedures and treatments.

A. Describe specifically (In the case of surgical complications, you may refer to Appendix 5, item 16):

3. If any or all of these criteria are met, humane anesthesia is indicated. Only short-term monitoring is permitted to determine a course of action. Correction of surgical complications via additional surgical procedures will not be permitted. (CHECK ALL THAT APPLY)

For unexpected endpoints:

☐ Animals will be humanely euthanized immediately as described in section W below.

☐ Something else will be done, such as short-term monitoring and follow-up action.

A. Describe and justify. For the handling of surgical complications, you may refer to Appendix 5, item 16.

W. Euthanasia. The following apply to all studies involving euthanasia:

All personnel performing euthanasia must be listed in section B.3 with details of their training and experience.

All investigators must consult and COMPLY WITH the recommendations of the AVMA Guidlines on Euthanasia:

http://www.avma.org/issues/animal_welfare/euthanasia.pdf

Investigators are particularly reminded that any physical method of euthanasia such as decapitation, cervical dislocation, or use of carbon dioxide must be performed in specific accord with guidelines, and not by improvised or expedient methods. Anesthesia must be induced before euthanasia using a physical method where indicated in the AVMA guidelines.

Successful euthanasia must be verified specifically for each animal, particularly in any multiple animal procedure.

You are encouraged to consult with CMF veterinarians on all issues relating to euthanasia.

1. What method of euthanasia will be performed?

Acceptable:

Barbiturates
Carbon dioxide (MUST be performed using a gas cylinder and a suitable chamber or purpose-built apparatus)
Inhalant anesthetics
Potassium chloride (Only after verified induction of general anesthesia).
Other

Specify the agents used, dose and volume (as applicable), and route of administration. If complete information is given in Section G and/or one of Appendices 2-6, it need not be repeated here; in this case refer to the appropriate appendix.

Conditionally Acceptable:

Cervical dislocation
Chloral hydrate
Decapitation

Justify use of any conditonally acceptable or nonstandard methods. Include procedural details of the method; however if these are fully described in Section G or an appendix you may refer to that description.

X. DISPOSAL In case of animals found dead or those which must be euthanized immediately (for instance as a result of surgical complications), provide contact and carcass disposal information. Carcasses frozen rather than refrigerated may prove unsuitable for pathological studies.

Describe carcass handling	Immediately notify (name and extension)*

Mandatory Considerations

Y. Legally mandated information: USDA policy requires principal investigators to consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and provide written narrative of the methods used and sources consulted to determine the availability of alternatives, including refinements, reductions, and replacements. They must also provide written assurance that the activities do not *unnecessarily* duplicate previous experiments.

You should perform one or more database searches to meet these mandates, unless compelling justifications can be made without doing so. The Animal Welfare Information Center (AWIC) http://awic.nal.usda.gov/nal_display/index.php?info_center=3&tax_level=1 offers expertise in formulation of the search strategy and selection of key words and databases. If a database search identifies an alternative method (one that could be used to accomplish the goals of the animal use protocol) the written narrative should justify why this alternative was not used.

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training requires that the Institution ensure that animals selected for a procedure are of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and *in vitro* biological systems should be considered. http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples

Database searches should be performed before any ACORP containing new or substantially revised experimental aims is submitted. Searches should also be updated at the time of each annual review. The period covered by the search should be as long as necessary to ensure that relevant citations will be found. According to Policy 12 the principal investigator is expected to reconsider alternatives at least once every 3 years.

To demonstrate that alternatives to animals were considered, and that the proposal does not unnecessarily duplicate previous research, the following databases were searched:

Name of the Database(s)	Date Performed MM/DD/YYYY	Period (yrs) covered by each search	Key words and/or search strategy used

Due to special circumstances (as in a highly specialized field of study), the following other sources (conferences, colloquia, or subject expert consultants) were used in addition to or instead of database searches to provide relevant and up_to_date information regarding alternatives and non-duplication of previous work:

Name	Qualifications	Date	Institutional Affiliation	Content of Discussion

○ N/A - This section does not apply to this ACORP.

You must also consider the three principles of replacement, reduction, and refinement in designing your studies:

1. **Replacement** - State why the proposed work cannot be done by using non-animal systems (cell cultues, computer model or *in vitro* techniques) or less sentient animal species:

2. **Reduction** - State how you have ensured that the proposed work uses the minimum number of animals required to obtain scientifically valid data:

3. **Refinement** - State the methods used to refine animal use by lessening or eliminating pain or distress and, thereby, enhancing animal well-being (pain-relieving drugs, non-pharmacologic techniques, new diagnostic and therapeutic techniques, environmental enrichment programs, and establishment of humane endpoints):

4. **Duplication** - State how you have determined that the proposed work has not been done previously (you may refer to the above database searches and justifications). If this work DOES repeat a previous study, state why repeating the previous study is necessary:

5. Controlled Substances:

a. List all substances classified by the US DEA as controlled substances that will be used *in vivo* for this project.
For schedules of controlled substances go to http://www.deadiversion.usdoj.gov/. For licensing information visit this site or contact the Office of Research Services.

b. All controlled substances must be stored in a double-locked cabinet, and be *accessible only to authorized personnel* in accordance with DEA regulations.
The principal investigator is responsible for the dispensation of these drugs and must maintain a log to track their usage.
Give the building and room number where the drugs will be stored:

Z. Certification by Principal Investigator(s): To the best of my knowledge, I certify that information provided in this ACORP and its appendices and supporting documents is complete and accurate **and that the activities described within the protocol submitted for IACUC review are consistent with those described in the related grant, contract or subcontract.**

I understand that IACUC approval is valid for a three-year period, that approval must be renewed annually, and that every third year the IACUC must perform a completely new review of my protocol.

I also understand that IACUC approval must be obtained before I: 1) use additional animal species, increase the number of animals used, or increase the number of procedures performed on individual animals; 2) change procedures in any way that might increase the pain or distress category in which the animals are placed, or might otherwise be considered a departure from the written protocol; 3) Allow other investigators to use these animals on other protocols, or use these animals on another of my IACUC-approved protocols.

I further certify that no personnnel will perform any animal procedures until they have been fully trained and approved by the IACUC with the appropriate documentation of their training on file in the Office of Research Services. When new or additional personnel become involved in these studies, I will submit their qualifications, training, and experience to the IACUC and seek IACUC approval before they are involved in animal studies.

For projects including surgical procedures, I agree to all conditions listed at the end of Appendix 5.

I will ensure that all personnel are enrolled in the Institutional Occupational Health and Safety Program prior to their contact with animals. I will make clear to all personnel that they may consult with Occupational Health and Safety Program personnel regarding routine measures such as vaccinations for tetanus, rabies, and hepatitis B, and TB screening.

I have complied with/will comply with all requirements of the Institutional Biohazard Committee, Radiation Safety Committee, and/or other governing committees, which are applicable to this project.

Name of Principal Investigator	Signature	Date

Lu Number: 100811; Species: Calves

Primary Investigator: Tu, John

Title: new

Funding Agency: 3M Foundation

Based on the information in the ACORP form you may need to complete the following appendices.

Appendix 1

Appendix 2

Appendix 3

Appendix 4

Appendix 5

Appendix 6

Appendix 7

Appendix 8

Appendix 9

Loyola Appendix 1: 01 Jul 2010

LOYOLA UNIVERSITY - STRITCH SCHOOL of MEDICINE

ACORP - APPENDIX 1

Use of Non-Loyola Facility

Use this appendix to list any non-Loyola facility in which animals purchased with Loyola deposited funds will be used in the proposed project. Uses includes housing, quarantine, experimental procedures, production of custom antibodies or other biologicals, etc. Consider affiliated institutions as well as any contract facilities that purchase and house animals on your behalf. Consult with your veterinarian or IACUC to determine which institutions must be entered.

Loyola Stritch School of Medicine requires that all such facilities be accredited by AAALAC. (Association for Assessment and Accreditation of Laboratory Animal Care International) and/or other responsible bodies including US Public Health Service and US Department of Agriculture. Under exceptional circumstances, a waiver may be requested in writing from the IACUC, in which case the IACUC will review and forward it deliberations to the Associate Dean for Research for final determination.

Certain collaborating facilities including the Hines VA Hospital Veterinary Medicine Unit work with Loyola CMF under memoranda of understanding and/or standard operating procedures. These and/or other facilities may require that their animal care committees separately approve housing and husbandry plans. Investigators are encouraged to consult with CMF, and should consider the time which may be necessary for submission, review, and approval of documentation, as well as the availability of space.

Please Provide the following:

A. Indicate which non-Loyola facility you wish to house the animals purchased with Loyola deposited funds, for this project, and give the current AAALAC International Accreditation, USDA, and/or PHS accreditation status and/or numbers for each.

Non-Loyola Facility Name	Non-Loyola Facility Address	PHS AssuranceNumber	USDA Registration Number	AAALAC Status

B. In what non-Loyola building(s) and room(s) will the animals be housed?

Building	Room

C. Contact Person and Contact Information

Non-Loyola Facility Name	Contact Person	Building	Room

D. Any special needs regarding access, husbandry, etc. (if not described in Appendix 6)

Non-Loyola Facility Name	Building	Room	Special Needs
Please select	Please select	Please select	

E. Type of use (housing, quarantine, experimental procedure, etc. - investigators can refer to ACORP main body or appendices if already described there).

Non-Loyola Facility Name	Building	Room	Type of Use
Please select	Please select	Please select	

Loyola Appendix 2 : 01 Jul 2010

LOYOLA UNIVERSITY - STRITCH SCHOOL of MEDICINE

ACORP - APPENDIX 2

Antibody Production

Before completing this appendix, investigators should refer to CMF Standard Operating Procedure 02-18-5812, Use of Rodents and Rabbits in Antibody Production.

1. Monoclonal Antibody Production. Will monoclonal antibodies be produced in animals or harvested from hybridoma cell lines as part of this project?

- (•) No. Proceed to item 3
- ( ) Yes. Complete item 1.a

a. Is antibody harvest limited to existing hybridoma cell lines with no further immunizations or lymphocyte fusions planned?

- (•) Yes. Proceed to item 2 below
- ( ) No. Complete items 1.b and 1.c below; then proceed to item 2
- ( ) N/A

b. Complete the following table regarding the immunization protocol for the animals prior to lymphocyte harvest for hybridoma creation. For each antigen for which multiple immunization days will be used, use a separate row in the table for each immunization day.

Injection day (eg. Day 0, 7, 30, etc.)	Antigen	Total amount (mg) and volume (ml) of antigen injected	Identity and volume (ml) of adjuvant injected	Divided into how many injections	Injection route and location of injections on body

c. If feeder cells for supporting hybridoma colony growth will be collected from animals, describe the exact procedures that will be used to collect the feeder cells and the number of animals needed for this purpose.

2. You must consider alternate research methods that can replace the use of animals. Will any animals be used to expand hybridoma cell lines so that antibody can be harvested from ascites fluid?

- (•) No. Proceed to item 2.d
- ( ) Yes. Complete items 2.a-2.c below; then proceed to item 2.d
- ( ) N/A

a. Explain why in vitro cell culture systems for harvesting monoclonal antibodies are not adequate to meet the research objectives:

b. Complete the following table:

Hybridoma cell line designation	Number of animals used for ascites production	Priming agent and volume	Number and timing of priming injections	Volume of injected hybridoma cells	Number of abdominal taps before euthanasia

c. What criteria will be used to determine if animals should be euthanized prior to the last planned abdominal tap?

d. Blood Collection. Will survival blood collections be obtained from animals following immunization or as a "pre-bleed" prior to immunization?

- (•) No. Proceed to item 3
- ( ) Yes. Complete 2.d.1 and 2.d.2 below; then proceed to item 3.
- ( ) N/A

1) Complete the following table; include any "pre-bleeds" prior to immunizations

Site of blood collection	Amount of blood collected expressed as volume (ml) and % of body weight (assume 1 ml weighs 1 gram)	Number of blood collections	Interval between collections

2) Will anesthetics, tranquilizers, or analgesics be used prior to blood collection?

- (•) No. Justify the omission of pain-relieving agents; then proceed to item 3
- ( ) Yes. Describe the administration of pain-relieving agents including dose (mg/kg), volume (ml), route, and frequency/duration; then proceed to item 3
- ( ) N/A

3. Polyclonal Antibody Production. Will polyclonal antibodies be produced in this species of animal as a part of this project?

- (•) No. DO NOT complete items 3.a - 3.c; proceed to item 4
- ( ) Yes. Complete items 3.a - 3.c; proceed to item 4

a. Complete the following table. For each antigen for which multiple immunization days will be used, use a separate row in the table for each day:

Injection day (eg day 0, 7, 30, etc.)	Antigen	Total amount (mg) and volume (ml) of antigen injected	Identify, concentration and volume (ml) of adjuvant injected	Divided into how many injections	Injection route, and location of injections on body

b. List possible adverse effects in animals that might be seen from the proposed antigen or adjuvant injections and what measures will be taken should these adverse effects occur:

c. Blood Collection. Will survival blood collections be obtained from animals following immunization or as a "pre-bleed" prior to immunization?

- (•) No. Proceed to item 4
- ( ) Yes. Complete items 3.c.1 and 3.c.2; proceed to item 4
- ( ) N/A

1) Complete the following table; include any "pre bleeds" prior immunizations

Site of blood collection	Amount of blood collected expressed as volume (ml) and % of body weight (assume 1 ml weighs 1 gram)	Number of blood collections	Interval between collections

2) Will anesthetics, tranquilizers, or analgesics be used prior to blood collection?

- (•) No. Justify the omission of pain-relieving agents below; proceed to item 4
- ( ) Yes. Describe the administration of pain-relieving agents including dose (mg/kg), volume,(ml) route, and frequency/duration below; proceed to item 4
- ( ) N/A

4. Terminal blood collection. Will animals used for antibody production be exsanguinated as a method of euthanasia?

- (•) No. Proceed to item 5
- ( ) Yes. Complete items 4.a, b, and c; proceed to item 5

a. Describe the method of exsanguinations:

b. Will anesthetics, tranquilizers, or analgesics be used prior to exsanguinations?

- (•) No. Justify the omission of pain-relieving agents below; proceed to item 5
- ( ) Yes. Describe the administration of pain-relieving agents including dose (mg/kg), volume (ml), route, and frequency/duration here; proceed to item 5
- ( ) N/A

c. How will you make sure that the animals are dead following blood withdrawal?

5. How will the antigens or cell lines listed in items 1.b, 2.b, and 3.a be screened to make sure they do not harbor infectious agents that could infect other laboratory animals or people after injection? Documentation must be kept on file for the duration of the project.

Loyola Appendix 3 : 11 Feb 2002

LOYOLA UNIVERSITY - STRITCH SCHOOL of MEDICINE

ACORP - APPENDIX 3

Test Substances

1. Toxic Agents. Will toxic chemicals, toxic pharmacologic agents, known or suspected mutagens, carcinogens, teratogens, DNA-binding, or other similar agents be used in animals?

- ○ No. Proceed to item 2
- ○ Yes. Complete items 1.a - 1.d; then proceed to item 2

a. Table of toxic agents:

Agent	Diluent	Route of Administration	Dose (eg, mg/kg) and Volume (ml)	Frequency and Duration of Administration	Reason for Administration and Expected Effects

b. Indicate which of the above agents, if any, are known or suspected mutagens, carcinogens, or teratogens, then proceed to item 1c

c. Are any of the agents above on the CDC list of "select agents" that might have bioterrorism uses? Check the appropriate response below and proceed to item 1.d

- ○ No
- ○ Yes. Biosafety approval must be obtained.
- ○ N/A

d. Will the animals be anesthetized or sedated when these agents are administered?

- ○ No. Proceed to item 2
- ○ Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; the proceed to item 2

- ○ N/A

2. Infectious Agents. Will bacterial, viral, rickettsial, fungal, protozoal, or other infectious agents be used in animals? If the agent will have a radioactive label added, also complete item 4. Likewise, if the infectious agent contains recombinant nucleic acid, then complete item 6 for the agent as well

- ○ No. Proceed to item 3
- ○ Yes. Complete items 2.a - 2.d; then proceed to item 3

a. Complete the table below: then proceed to item 2b

Agent and Strain or Construct	CDC Biosafety Level of Agent (BSL 1, 2, 3 or 4)	Route of Administration	Dose (eg, CFU, PFU) and Volume Administered (ml)	Frequency of Administration

b. Has an anti-biogram, anti-viral drug sensitivity screen, or other appropriate drug sensitivity panel been determined for the agent(s) listed to assist physicians in selecting proper therapy if an inadvertent human infection occurs?, then proceed to item 2c

- ○ Yes, Proceed to item 2c
- ○ No. Please justify, then proceed to item 2c

- ○ N/A

c. Will the animals be anesthetized, or sedated when these agents are administered?

- ○ No. Proceed to item 2.d
- ○ Yes. Detail the method of anesthetic, sedative or tranquilizer administration including agent, dose and volume, and route; then proceed to item 2.d

- ○ N/A

d. Are any of the agents on the CDC list of "select agents" that might have bioterrorism uses? Check the appropriate response below and proceed to item 3

- ○ No, Proceed to item 3
- ○ Yes, Please identify. Biosafety Approval must be obtained. Proceed to Item 3

- ○ N/A

3. Biological Materials. Will serum, cell lines, tissue, nucleic acid or other biological materials be administered to animals?

- ○ No. Proceed to item 4
- ○ Yes. Complete 3.a - 3.c; then proceed to item 4

a. Table of biological materials:

Material (eg. Fluid, cells, tissues)	Diluent	Source (eg. vendor, other animals, colleague)	Route of Administration	Dose (eg. ml/kg, mg/kg, Cells/kg) and Volume (ml)	Frequency and Duration of Administration

b. Will the animals be anesthetized or sedated when these agents are administered?

- ○ No. Proceed to item 3.c
- ○ Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose, volume, and route; then proceed to item 3.c

- ○ N/A

c. How will these materials be screened to make sure they do not harbor infectious agents that could infect other laboratory animals or people? List source if materials are obtained from non-commercial sources, documentation must be kept on file of screening and pathogenic materials.

4. Recombinant Nucleic Acid and Recombinant Infectious Agents

a. Do any of the agents noted above in items 1 - 3 above have recombinant nucleic acid in them?

- ○ No. Enter Not Applicable (N/A) to 4.b; then proceed to item 5
- ○ Yes. Complete item 4.b
- ○ N/A

b. Are the recombinant constructs exempt from the animal research guidelines included in the latest version of the NIH Guidelines for Recombinant DNA and Gene Transfer publication?

- ○ No. You must conduct the animal experiments involving recombinant nucleic acid according to the NIH Guidelines for Recombinant DNA and Gene Transfer. Consult with your Biosafety Committee and Veterinarian to make sure you comply.

- ○ Yes. Proceed to item 5
- ○ N/A

5. Radioactive Agents. Will radioactive compounds or agents be administered to animals?

- ○ No. Proceed to item 6
- ○ Yes. Complete 5.a - 5.c; then proceed to item 6

a. Table of Radioactive Agents:

Radioactive Agent (include Isotope)	Diluent	Agent Dose (mg/kg) and Volume (ml)	Activity (eg. mCi/kg)	Route of Administration	Frequency and Duration of Administration

b. Which laboratory (investigator, bldg. # and Rm. #) has been approved by the Radiation Safety Committee, or equivalent committee, to utilize the isotope(s) indicated above? Please indicate approval number:

c. Will the animals be anesthetized or sedated when these agents are administered?

- ○ No. Proceed to item 6
- ○ Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose, volume, and route; then proceed to item 6

- ○ N/A

6. Other Agents. Will other substances not listed previously in this appendix be administered to animals? DO NOT include anesthetics/analgesics/sedatives, you will describe these elsewhere in the ACORP.

- ○ No. Proceed to item 7
- ○ Yes. Complete box below: then proceed to item 6a

Agent	Method of Administration	Dose and Volume	Route

a. Will the animals be anesthetized or sedated when these agents are administered?

- ○ No, Proceed to item 6.b
- ○ Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose, volume, and route; then proceed to item 6.b

- ○ N/A

b. How will these materials be screened to make sure they do not harbor infectious agents that could infect other laboratory animals or people? List source if materials are obtained from non-commercial sources, documentation must be kept on file of screening and pathogenic materials; then proceed to item 7

7. Hazardous/Toxic Agents. Are any of the agents listed above in items 1 - 7 hazardous or toxic to humans or animals, or covered by the NIH Guidelines for Recombinant DNA and Gene Transfer?

- ○ No
- ○ Yes

a. Table of hazardous agents, committee approvals, and personnel exposed:

Toxic or Hazardous Agents from items 1-7 above, or non-exempt agents from item 6 and HMIS Rating	Safety, biosafety, or radiation safety committee that has approved the use of this hazardous agent(s)	Is this an LU or affiliate committee?	Date Approved and LU #

8. Pain or Distress. Will animals potentially experience pain and/or distress as a result of the administration of agents listed above in items 1-7?

- ○ No. Proceed to item 9
- ○ Yes. Describe the nature of the pain and/or distress that animals might experience and describe measures that will be taken to alleviate any pain and/or distress. Proceed to item 9

9. Certifications. By submitting this ACORP, the Principal Investigator is "signing " the document using his /her electronic signature; and therefore, agrees to the following certifications

Before animal experiments involving the agents listed in item 8.a are performed, the PI in consultation with CMF will prepare a Standard Operating Procedure (SOP) designed to protect all of their laboratory personnel, the animal facility staff, as well as non-study animals. This document must be approved by the appropriate Loyola University/ Institutional Safety Committee and the IACUC.

Staff that might be exposed to test substances (including biological, toxic/hazardous, infectious, and radioactive agents) will be properly trained to follow SOPs and/or appropriate safety guideline to minimize the risk of exposure.

Cages will be appropriately labeled to identify the use of test substances to ensure that laboratory personnel and the animal facility staff are aware of any potential risk.

Provide SOP here:

Studies involving Infectious Agents: The Principal Investigator must submit a letter of support from the Biosafety Officer (Chairman of the Institutional Biosafety Committee) certifying the investigator has approval to use this agent(s) in animals. A PDF of this letter should be uploaded along with the IBC protocol.

Provide IBC Protocal here:

Studies involving Radioactive Agents: The Principal Investigator must submit a letter of support from the Radiation Safety Officer certifying the investigator has approval to use radioactive agents in animals. A PDF of this letter should be uploaded.

Loyola Appendix 4 : 01 Jul 2010

LOYOLA UNIVERSITY - STRITCH SCHOOL of MEDICINE

ACORP - APPENDIX 4

NON-SURGICAL Ante-mortem Specimen Collection

For all surgical procedures(survival and non-survival) use Appendix 5.

1. Blood Collection. Will blood be collected from live animals (anesthetized or awake) as a part of this proposal, OTHER than for antibody production which is described in Appendix 2?

- (•) No. Proceed to item 2
- ( ) Yes, but all collections are described in Appendix 2, "Antibody Production", so no further information need to be provided here; proceed to item 2
- ( ) Yes. Complete the table below; then proceed to item 2

Site and Method of Blood Collection	Amount of blood collected, expressed as volume (ml) and % of body weight (assume 1 ml of blood weighs 1 gram)	Number of blood collections	Interval between collections

2. Collection of other tissues. Will body fluids other than blood (cerebrospinal fluid, peritoneal fluid, urine, etc., or other tissues be collected from live animals (anesthetized or awake) as a part of this Proposal?

- (•) No. Proceed to item 3
- ( ) Yes. Complete the table below, then proceed to item 3.

Fluid or Tissue Collected	Site & method of collection; amount (if applicable)	Amount (g) or volume (ml	Number of collections	Interval between collections

3. Will anesthetics, tranquilizers, or analgesics be used to prevent pain or stress during collection of body fluids or tissues described in item 1 and 2 above?

- ( ) No, because the collection method involves no or momentary pain, or the omission of pain-relieving agents is fully justified scientifically in main ACORP section K. Completely describe the method of collection, including any physical restraint that will be used. If this appears elsewhere, e.g. in main ACORP section G or Appendix 5, you may refer to that description.

- ( ) Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route. If complete information has been provided elsewhere (e.g. in ACORP main body section G or Appendix 5), you may refer to that description.

Anesthetic, tranquilizer, or analgesic agent	Dose (mg/kg) & volume (ml)	Route	Frequency

4. Will the collection procedure enhance the likelihood of pain, distress, abnormal endpoints, or unexpected outcomes in ways not already detailed in ACORP main body sections G,K, or V, or Appendix 5? If so, describe here.

Loyola Appendix 5 : 11 Feb 2002

LOYOLA UNIVERSITY - STRITCH SCHOOL of MEDICINE

ACORP - APPENDIX 5

Surgery (survival or non-survival)

1. Multiple surgical procedures: If more than one surgical procedure will be performed on any one animal, provide a complete scientific justification, either here or in ACORP main body, section G. Include in your explanantion the interval(s) between the multiple surgeries, and the rationale for choosing the interval(s).

For non-survival surgery, the investigator must describe clearly in items 2 and/or later sections how euthanasia will be accomplished, so that the IACUC can verify that the euthanasia procedure conforms with the guidelines in the ACORP main body, section W.

a. Will more than one surgical procedure be performed on any one animal as part of the proposed experimental plan?

- ○ No. Proceed to item 2
- ○ Yes. Complete item 1.b - 1.c

b. Provide a complete scientific justification for performing more than one surgery on individual animals:

c. Give the interval(s) between the multiple surgeries, and the rationale for choosing the interval(s), then proceed to item 2:

2. Description of Procedure(s). Describe the surgical procedure(s) in enough details so that the IACUC reviewers can determine what procedure(s) are actually being performed. If several different surgeries are being performed, be sure to describe each one. When finished, proceed to item 3:

To Upload File '2' Click Here

3. Provide the names of the personnel who will perform the surgery; then proceed to item 4. Note that the surgical experience of each person involved in surgery should be listed in ACORP main body, item C.

4. Provide the names of the personnel who will perform the anesthetic induction and monitor the animal during surgery. Proceed to item 5: Note, the experience of each person involved in anesthetic induction must be listed in ACORP main body, item C.

5. Provide the building and room number(s) where the surgical procedure(s) will be performed. A dedicated surgical facility must be used for survival surgeries on non-rodent species. Non-survival surgery on non-rodent species and survival surgery on rodent species may be performed in a procedure room or laboratory if approved by the IACUC. Proceed to item 6:

6. Pre-Operative Procedures. Pre-operative procedures should include all preparations of the animal(s) for surgery. Check and describe which of the following procedures will be performed. Proceed to item 7:

○ None. Proceed to item 7
○ Yes, Enter information below

☐ **Fasting (not recommended in rodents or rabbits). Indicate the length of the fasting period:**

☐ **Withhold water. Indicate the length of time that water will be withheld:**

☐ **Catheter placement. Indicate the site(s) in which venous catheter(s) will be placed for vascular access during surgery:**

☐ **Other. Describe other pre-operative procedures:**

7. Pre-Operative Medications. Complete the following table. Include any antibiotics, sedatives, or tranquilizers, and the anesthetic agent(s) that will be used to induce anesthesia prior to surgical site preparation; proceed to item 8:

○ None. Proceed to item 8
○ Yes, Enter table below

Agent	Dose (mg/kg) and volume (ml)	Route	Frequency (e.g. times/day)	Duration (e.g. days)

8. Preparation of the Surgical Site. Describe how the surgical site(s) will be prepared prior to surgery. Include details of hair-clipping, skin disinfecting, and the use of surgical drapes. Then proceed to item 9:

9. Intra-Operative Medications. Complete the following table including any anesthetic agents, paralyzing agents, fluids, or other pharmaceuticals that will be administered to the animal during surgery. Also include experimental pharmaceuticals. Then proceed to item 10:

○ None. Proceed to item 10
○ Yes, Enter agent in the table below

Agent

10. Paralyzing Agents, are any of the above medications considered paralyzing agents (e.g. Tubocurarine chloride, Gallamine triethiodide, Pancuronium bromide, Alcuronium chloride, Atracurium besylate, Succinylcholine, Decamethonium)?

○ No. Proceed to item 11

○ Yes. Federal regulations prohibit the use of paralytics (neuromuscular blocking agents) for surgery unless other appropriate anesthetic agents are used to induce a surgical plane of anesthesia. Paralytics do not provide any pain relief; therefore, animals are unable to respond physically to pain because motor reflexes are paralyzed. Justify the use of these agents and indicate how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain. Then proceed to item 11

11. Physical Support. Indicate any physical methods used to support animals during surgery (e.g. heating pads, blankets, etc.); then proceed to item 12

12. Intra-Operative Monitoring. Describe methods used to monitor the state of anesthesia and general well-being of the animal during surgery. Then proceed to item 13:

13. Will animals regain consciousness following surgery?

○ No. You have completed this appendix. No further information is required. However, you must provide disposal information in ACORP main body, section X.

○ Yes. Proceed to item 14

14. Survival Surgery Considerations and Post-Operative Care. Complete items 14.a - 14.f below and proceed to item 15: Please note the requirement for a sterile/aseptic surgery facility in item 5 above.

a. How long will the animal(s) survive after surgery? (If multiple surgeries are planned, answer for the last surgery before euthanasia)

b. Indicate the procedures that will be used to maintain a sterile field during surgery.

- ☐ Sterile instruments
- ☐ Surgeon cap
- ☐ Sterile gloves
- ☐ Surgeon scrub
- ☐ Sterile Drapes
- ☐ Sterile gown
- ☐ Face mask
- ☐ Other. Describe:

c. List any physical methods used to support the animals in the immediate post-operative period (e.g. heating pads, blankets, fluids, etc.):

d. You are required to provide post-operative pain relief for all vertebrate animals undergoing survival surgery, unless this is scientifically justified to the satisfaction of the IACUC. List here the post-operative analgesic agent(s) that will be used after surgery to control pain.

If you do not intend to provide post-operative pain relief, you are performing a Category E procedure. Enter N/A in this table and provide complete justification in the ACORP main body, section K2.

Agent?	Dose (mg/kg) and Volume (ml)	Route	Frequency (e.g. times/day)	Duration (e.g. days)

e. Do any of the surgical procedures involve implanting cannulae, acrylic implants, venous catheters, telemetry devices, or other similar devices into an animal such that the device extends chronically through the skin, or any other treatments which may induce chronic injuries or infections?

- ○ No. Proceed to item 15.
- ○ Yes.

What wound management measures will be taken to minimize the chances of injury or chronic infections around the device(s) where they penetrate the skin:

15. Frequency and Responsibility for Post-Operative Care. Complete items 15.a - 15.c; then proceed to item 16. The names and after-hours telephone (or other contact) numbers of the personnel listed below must be provided to the CMF staff.

Name	Office/Laboratory Telephone(s)

a. Give the frequency of post-operative monitoring and how long the monitoring will continue:

b. Who will be responsible for post-operative care until the animal can ambulate without danger to itself? Note, the experience of each person involved in post-operative care must be listed in item B of the ACORP

c. Who will be responsible for post-operative care thereafter (including after-hours, weekends, and holidays)? Note, the experience of each person listed here must be listed in item B of the ACORP

16. Post-Operative Complications. Complete items 16.a - 16.d; then proceed to item 17

a. Describe any possible or expected post-operative complications and what will be done if these complications arise:

b. Provide criteria by which a decision to euthanize a surgerized animal post-operatively will be made:

c. In case there is an emergency medical situation and you or your staff cannot be reached, identify drugs or classes of drugs that should not be used as part of the treatment plan:

d. In the event that emergency euthanasia must be performed or an animal is unexpectedly found dead, indicate how the carcass should be handled (you may refer to ACORP main body section X if information has been provided there):

17. Responsibility for Maintaining Animal Post-Surgical Medical Records. Please indicate who will be responsible for maintaining accurate, daily, post-surgical written medical records. Proceed to item 18

NAME	EMAIL	TELEPHONE

18. Certifications:

By my certification in the ACORP main body, I also certify that:

*** Each animal under observation or treatment will be identified such that care for individual animals can be documented**

*** Daily post-operative medical records of the animal should be maintained in the individual or colony animal records held in the CMF, including an evaluation of overall health, a description of any complications noted, treatment provided, and the removal of sutures, staples, wound clips, or other such devices**

*** Records will document administration of all medications and treatments given to animals, including those given to reduce pain or stress**

*** As a minimum, daily records will cover the post-operative period as defined by local policy**

*** Each entry in the records will include a signature or the initials of the person making the observation or treatment**

*** All experiemental records will be readily available to the veterinary staff or the IACUC for review**

*** The names and contact numbers of persons to notify or consult in case of emergencies will be provided to the facility manager and veterinarian**

Name Investigator(s)	Signature	Date

Loyola Appendix 6 : 01 Jul 2010

LOYOLA UNIVERSITY - STRITCH SCHOOL of MEDICINE

ACORP - APPENDIX 6

Special Husbandry and Procedures

1. Special Husbandry. Are special husbandry practices required for this protocol that are notdescribed in the local Standard Operating Procedures (SOP) manual? Examples of special husbandry practices include temperature extremes, food or water deprivation, dietary manipulations, calorie restrictions, special housing/caging, modified light cycle, housing in Loyola facilities (see also Appendix 1), quarantine and/or special health monitoring, and unusual means of identification:

- (•) No. Proceed to item 2
- ( ) Yes. Complete items 1.a - 1.b; then proceed to item 2

a. Provide a complete description of all non-standard practices or procedures. Make sure that the frequency and duration of these practices or procedures are stated:

b. Justify the use of these non-standard practices or procedures:

2. Other Procedures. Are special procedures such as prolonged physical restraint, use of noxious stimuli, forced exercise, behavioral manipulations, total or partial body irradiation, radiography or other imaging studies planned but not described elsewhere in the ACORP?

- ( ) No. Proceed to item 3
- ( ) Yes. Complete items 2.a - 2.b; then proceed to item 3

a. Check which of the following procedures are proposed:

- ( ) Prolonged physical restraint, including chaining
- ( ) Noxious stimuli
- ( ) Forced exercise
- ( ) Behavioral manipulations
- ( ) Other: Describe:

b. Describe each procedure and the expected outcome(s) in detail. Make sure that the frequency, duration, and interval between repeated manipulations are described:

3. Identify the personnel who will perform the procedures and practices listed in items 1 and 2 and the personnel that will be responsible for monitoring the condition of these animals. After-hours telephone (or other contact) numbers of the personnel listed here MUST BE PROVIDED to the veterinary staff. Note that the experience of each person involved in these procedures must be listed in item E of the ACORP.

5. Will pain or stress-relieving agents be administered to the animals that experience pain, distress and/or discomfort? Then Proceed to item 6

○ No. You are required to provide pain and/or stress relief for all vertebrate animals, unless this is scientifically justified to the satisfaction of the IACUC. If you do not intend to provide this, you are performing a Category E procedure. Enter N/A in this table and provide complete justification in the ACORP main body, section K2.

◉ Yes. Fill out the table below:

Agent	Dose (mg/kg) and Volume (ml	Route	Frequency (e.g. times/day)	Duration (e.g. days)

6. Describe the methods used to monitor the condition of the animals during and after the practices or procedures and the criteria that will be used to remove individual animals from these practices and/or procedures should pain or suffering be present:

4. Do the practices or procedures have the potential to cause more than momentary pain, distress, and/or discomfort?

○ No. You have completed this appendix; no further information is required

◉ Yes. Describe the potential pain, distress and/or discomfort below; then proceed to item 5

Loyola Appendix 7 : 01 Jul 2010

LOYOLA UNIVERSITY - STRITCH SCHOOL of MEDICINE

ACORP - APPENDIX 7

Request to Use Patient Care Procedural Areas for Animal Studies

1. Describe the patient care area needed. Justify why this area is needed:

Building

Room Number

2. Identify the species and number of animals to be used:

Species of Animal	Numbers of animals involved in patient care area

3. Identify the equipment and location (building and room numbers) of the patient care area(s) to be used:

Equipment	Building	Room #

4. List the date(s) and time of day that the procedure(s) will be performed:

Day	Date	Time (a.m. or p.m.)

5. Discuss the method of transporting the animals to and from the procedural area. Include a description of the transport containers, any vehicles used, and precautions to be taken to avoid contact with patients, visitors, and other non-research personnel:

6. Provide a complete description of the measures to be taken to prevent the transmission of diseases or parasites from animals to patients and patient care personnel:

7. Provide a complete description of the measures to be taken to prevent disturbances (e.g., noise, odors) to patients and patient care personnel:

8. Provide a complete description of methods to be employed to prevent contamination of equipment and room surfaces by animal feces, urine, saliva, blood, or other body fluids:

9. Provide details of the procedures to be followed in cleaning and disinfecting equipment and room surfaces following use:

Loyola Appendix 8: 24 Feb 2009

LOYOLA UNIVERSITY - STRITCH SCHOOL of MEDICINE

ACORP - APPENDIX 8

Status report for 3-year renewal ACORP

Complete this appendix if the ACORP describes continuing work on an existing project which was not completed within the current 3-year ACORP approval period.

If the EXISTING ACORP has undergone approved ammendments, complete this appendix with reference to the latest approved revision.

1. In the ACORP main body, please be sure that the following sections correctly reflect your current and proposed practices: Indicate in which sections you have made changes since the last approved ammendment of the EXISTING ACORP.

- ☐ A. Status
- ☐ B. Personnel
- ☐ C. Training
- ☐ E. Procedure location
- ☐ F. Lay summary
- ☐ G. Experimental design
- ☐ J. Numbers of animals and Pain/distress categories
- ☐ K. Painful procedures
- ☐ L. Procurement of animals (including requested strains)
- ☐ M. Laboratory animal vetinary support
- ☐ N. Husbandry
- ☐ Q. Test substances
- ☐ S. Body Fluid/tissue collection
- ☐ T. Surgery
- ☐ U. Special procedures
- ☐ V. Humane endpoints
- ☐ W. Euthanasia
- ☐ Y. Mandatory considerations

2. How many animals (total) were requested in the latest amended version of the EXISTING approved ACORP?

☐

3. How many of that total were used during the 3 year approval period?

☐

4. Check which case applies:

☐ We reasonably expected the originally proposed work to require more than 3 years, and this renewal is to cover the additional time needed.
State which part(s) of the proposed work were and were not completed.

☐ We expected to complete the originally proposed work within 3 years but circumstances prevented this.
Explain here and state which part(s) of the proposed work were and were not completed.

5. Check which case applies:

☐ The animal request in ACORP main body Section J represents the balance of animals requested in the EXISTING ACORP but not used. This balance will be sufficient to complete work.

☐ We can not complete the originally proposed work with the originally requested numbers of animals and we are requesting more. The animal request in ACORP main body Section J represents ADDITIONAL animals beyond the balance of unused animals remaining from the request in the EXISTING ACORP.
Justify here, stating why you believe that the numbers and types of additional animals are appropriate for the completion of the studies.

6. Explain any other circumstances which you believe will help the IACUC evaluate your application.

Loyola Appendix 9: 01 Jul 2010

LOYOLA UNIVERSITY - STRITCH

ACORP - APPENDIX 9

Rodent Breeding and Weaning Appendix

A. INDIVIDUAL(S) RESPONSIBLE FOR COLONY MAINTENANCE

PI NAME:	Cara, Lee	DEPARTMENT:	Cell Biology, Neurobiology, and Anatomy
WORK PHONE #:		EMERGENCY PHONE (AFTER HOURS)#:	
E-Mail:			

Other individuals involved in Colony Maintenance (Must Also be Listed in Main Application)

Last Name		First Name		E-mail		Extension	

Please enter training and experience as it relates to colony maintenance & breeding of animals:

SECTION 1: BREEDING COLONY JUSTIFICATION

What Strains will be bred?

Provide a justification for establishing and maintaining a breeding colony of animals.

SECTION 2: HOUSING AND HUSBANDRY ISSUES:

List the location(s) where animals will be housed and bred.

Building		Room	

Are there any special husbandry requirements needed for the maintenance of the colony?	○ Yes	○ No

If you answered yes, please describe the needs (e.g., special diets, special housing, immunocompromized strains, etc.).

Will you be breeding genetically modified animals?	○ Yes	○ No

SECTION 3: COLONY MANAGEMENT INFORMATION

Please provide the following information below. Refer to the IACUC Policy on Breeding Colonies for additional instruction, found on the IACUC web site in the Policies section.

a. Breeding Scheme

- ☐ Harem Mating
- ☐ Pair Breeding - If this method is selected, what techniques will you use to properly manage litters within one cage?
  - Describe:
- ☐ Timed(hand)Mating
- ☐ Other - Describe and Provide Justification
- ☐ Post-Partum Breeding
  - Within 1-2 days after delivery

b. Weaning Plan

As per IACUC policy, no greater than one litter is to be kept in a cage. The Principal Investigator is responsible for weaning unless otherwise contracted.

- ☐ Animals will be weaned at 21-28 days
- ☐ The breeding requires additional time for weaning (beyond 28 days).
  - Please describe and justify:

c. Phenotype Information

Are there any health concerns associated with the development of the phenotypes for the strains described? ○ Yes ○ No

If yes, please describe the health concern(e.g., behavioral, anatomical and/or physiological) and describe how the health of these animals will be managed.

SECTION 4: GENOTYPING AND OTHER COLONY MANAGEMENT PROCEDURES

- The goal of this section is to identify techniques and procedures used to manage your colony.

a. Genetic Identification - Refer to the Guidelines for Genotyping of Rodents

Indicate how animals in the breeding colony will be identified genetically and the age of the animals for genotyping (if applicable).

Sample type:

- ☐ **Tail Clip** - If clipping is done on animals over 28 days of age, local or general anesthesia is required.

If this is the case what anesthetic method(s) will be used? Specify:

- ☐ **Blood sample - Describe the collection procedure:**
  - **Anesthesia** method (if applicable):
- ☐ **Other**, (e.g., ear notch, buccal swab). - Specify

b. Age of animals for genotyping:

- ☐ 0-21 days (anesthesia recommended)
- ☐ 21-23 days (anesthesia is highly recommended
- ☐ 21-28 days (anesthesia is strongly recommended)
- ☐ > 28 days and older (adult post-weaning-anesthesia is mandatory)

c. What method of animal identification will be used?

- ☐ Ear notch
- ☐ Ear Tag
- ☐ Tattoo
- ☐ Microchip implant
- ☐ Cage card identification only

d. Euthanasia

Will animals that cannot be utilized be euthanized in the same manner as described in the main part of the IACUC Protocol Application?	○ Yes	○ No
If no, please describe the alternate euthanasia method planned:		

e. Breeder Manipulations

Manipulations of breeder animals

Ovulation agents used?	○ Yes	○ No
Experimental Compounds?	○ Yes	○ No
In-utero therapies / therapeutics?	○ Yes	○ No
NOTE: All of these agents should be listed in the main protocol application		

SECTION 5: ESTIMATED NUMBER OF ANIMALS TO ESTABLISH AND MAINTAIN THE COLONY.

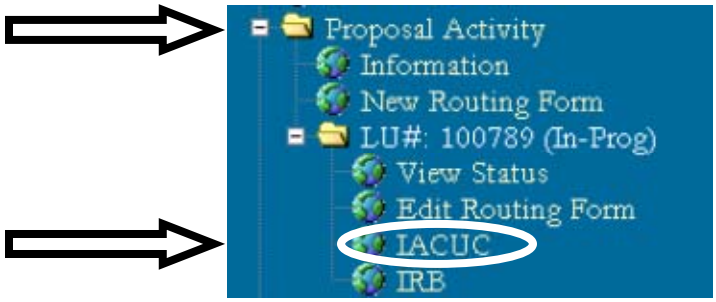
A mechanism for tracking colony management should be employed to allow review during semiannual IACUC inspections. If you need assistance in estimating numbers, please refer to *ILAR Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research (2003)*: http://www.nap.edu/books/0309089034/html

Enter Estimates:

Estimated number of weaned and adult animals to be subject to experimental manipulations	
Estimated number of suckling animals to be subject to experimental manipulations	
Estimated number of breeders held but not subject to experimental manipulations	
Estimated number of suckling animals to be euthanized at or prior to weaning, and **not** subject to experimental manipulations	
TOTAL ESTIMATE:	

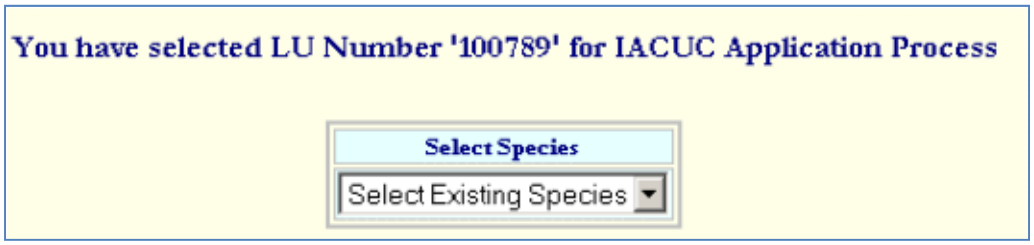
Selecting an existing IACUC form

1. Click on **IACUC** for the LU #. This is located under Proposal Activity, New Routing Form, and then the LU#.

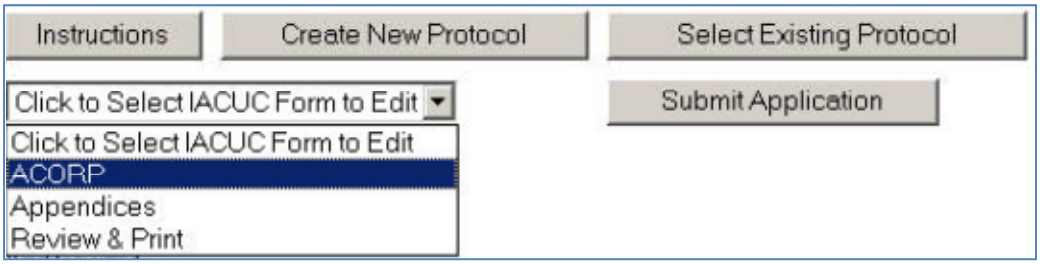


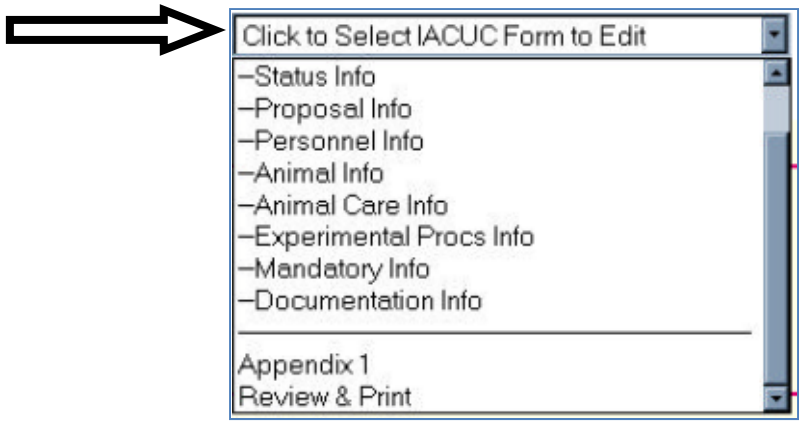
2. Click on the **Select Existing Protocol**

3. Click on the **Species** from the drop down menu. (If you need a new species, then you need to click on **Create New Protocol** from the IACUC menu.)



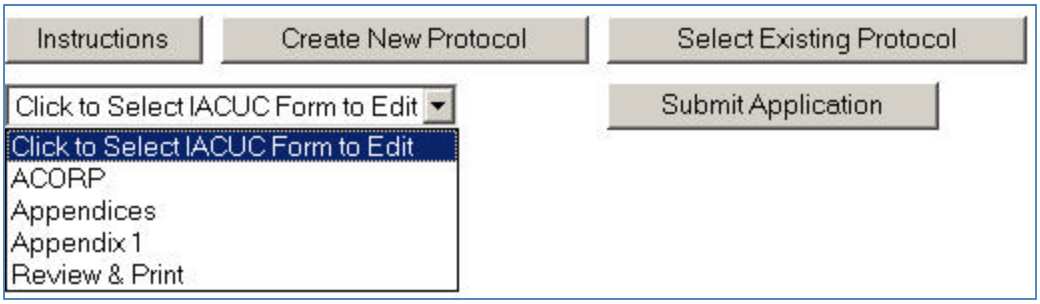
4. Choose **ACORP** from the drop down box**.** The form will now appear.

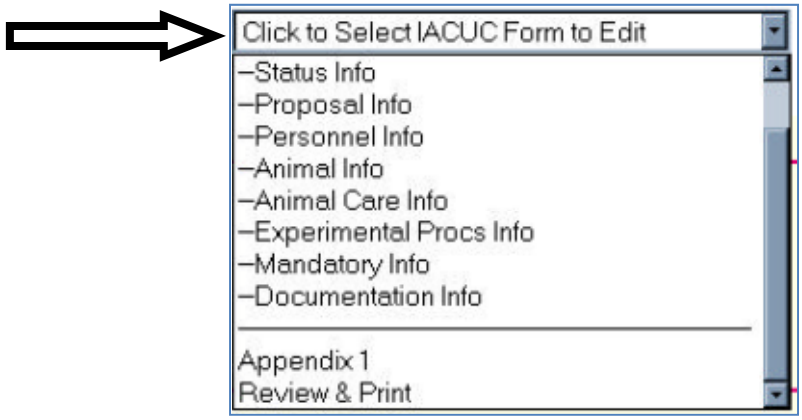




5. Appendices will appear, however they are not available until you complete fields on the IACUC form.

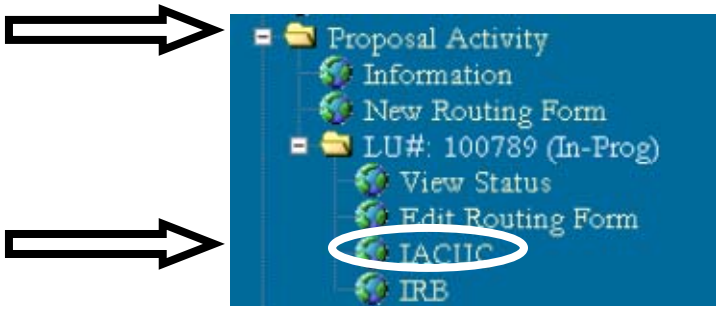
6. To complete the appendices, choose the appropriate Appendix from the dropdown box. The form will now appear.





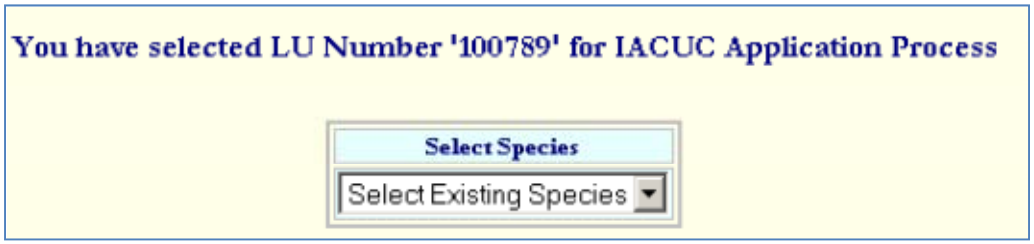
Duplicating Existing IACUC Protocols

1. Click on **IACUC** for the LU #. This is located under Proposal Activity, New Routing Form, and then the LU#.

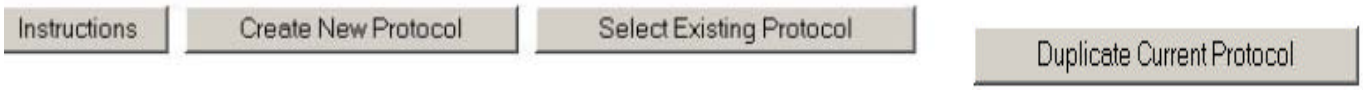


2. Click on the **Select Existing Protocol**

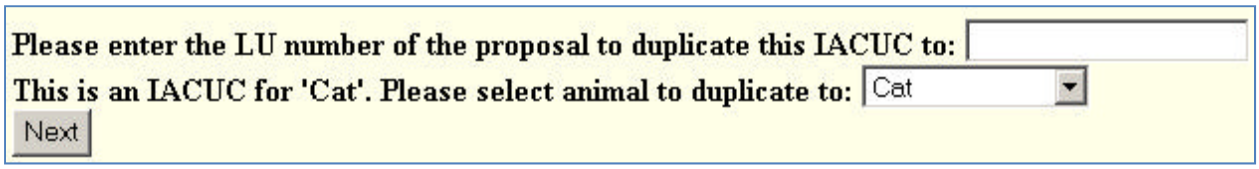
3. Click on the **Species** from the drop down menu. Choose the species that hasbeen submitted or approved to duplicate the protocol.



4. A new button appears to duplicate the protocol.

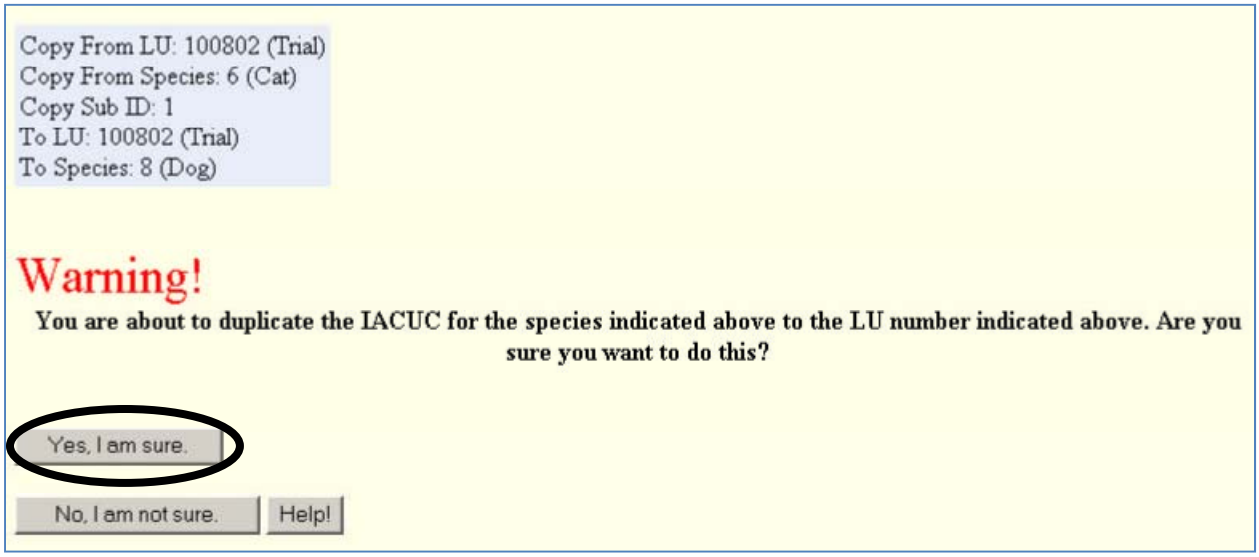


5. After the Duplicate Current Protocol has been chosen new options appear:



6. Enter the information needed. The drop down box lists all the species. Then click Next.

7. There is the availability of duplicating a current protocol to different LU numbers and to other investigators as long as the LU number is provided to you.
8. A verification screen appears.
9. This screen notifies the user of what is going to be duplicated. Once Yes, I am sure is chosen, the protocol is duplicated.



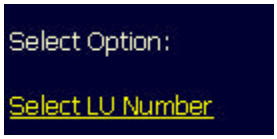
10. The IACUC has been duplicated and is ready to be edited and resubmitted to theIACUC Committee.

IACUC Amendment Process for the End User
Instituted as of 7/2012

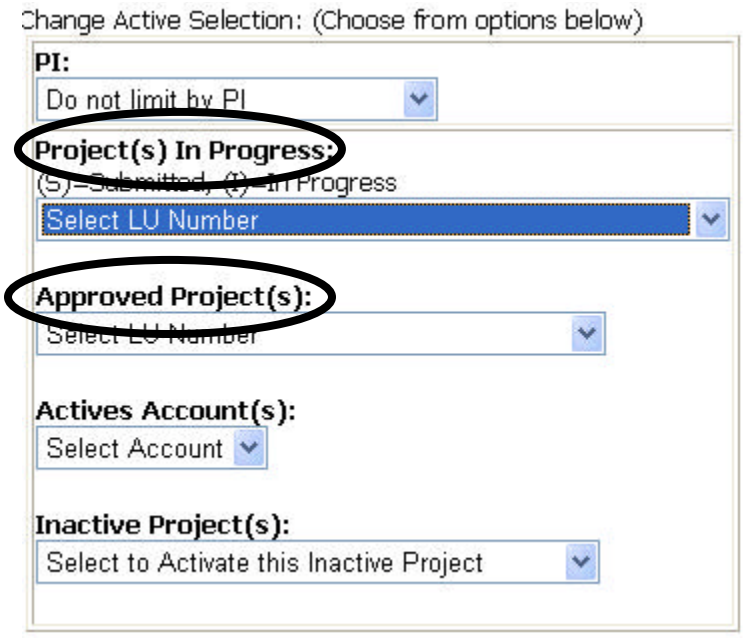
1. Log into the Loyola Information Portal.

2. Choose Research Channel

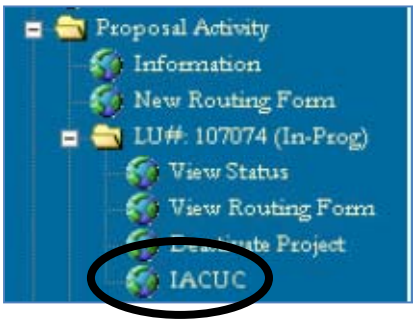
3. Choose Select LU Number



4. Choose the appropriate LU number under either Approved Projects or Projects in Progress that has the IACUC needing an amendment



5. On the left hand menu choose the IACUC option



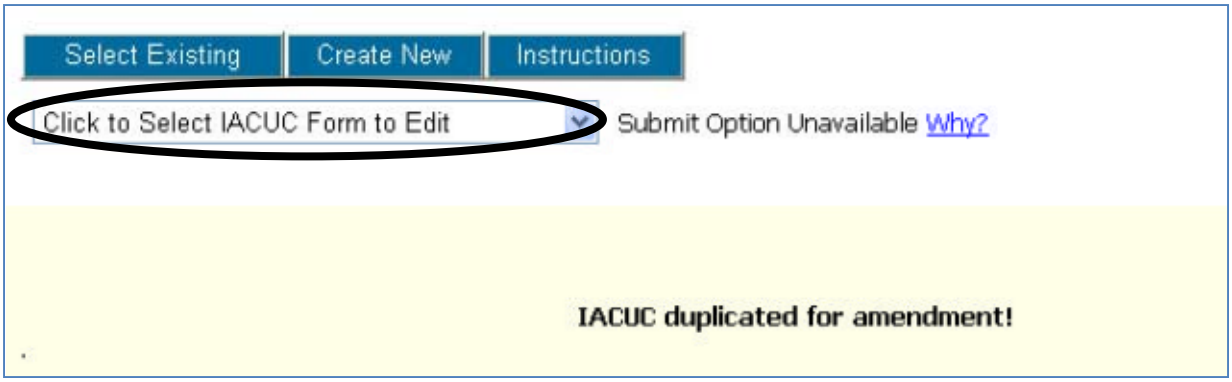
6. The IACUC options will appear. Choose Select Existing and then Under Select Species Choose the **APPROVED** ACORP that you wish to add an amendment to.

NOTE: The original ACORP will show your species as Calves (1.00). When this ACORP has been amended the species will show as Calves (1.01). This number will increase when there are new amendments created for this same ACORP (1.01, 1.02 etc.)

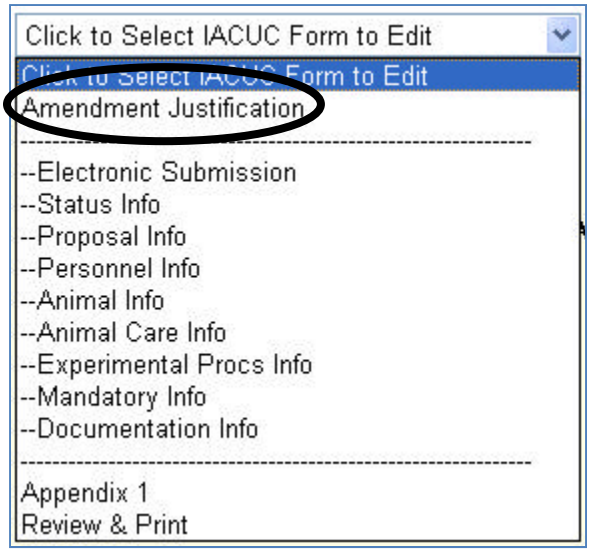
7. If the ACORP is approved these are the options that will appear. To make an amendment to the current protocol chooses Amend Current. This will duplicate yourcurrent protocol and give the ability to edit any information needed.

8. You will be asked if you are sure that you want to amend this application.

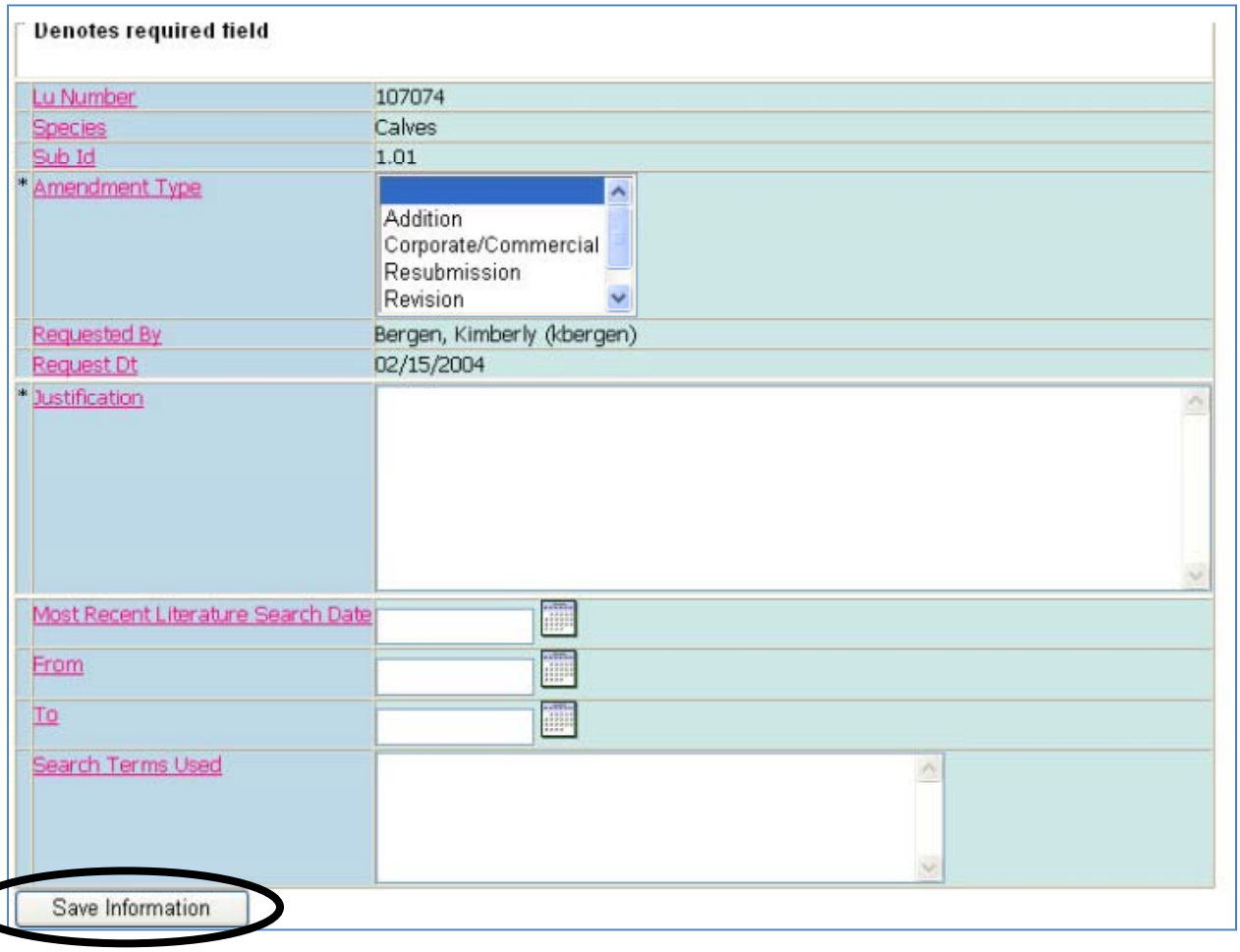
9. This is the new menu will appear. You are now able to work on the amendment. Just choose the IACUC form that you wish to edit.



10. After editing all of the necessary information you will not be able to submit the amendment until you have completed the **Amendment Justification**.



11. The Amendment Justification has a few sections that need to be completed:

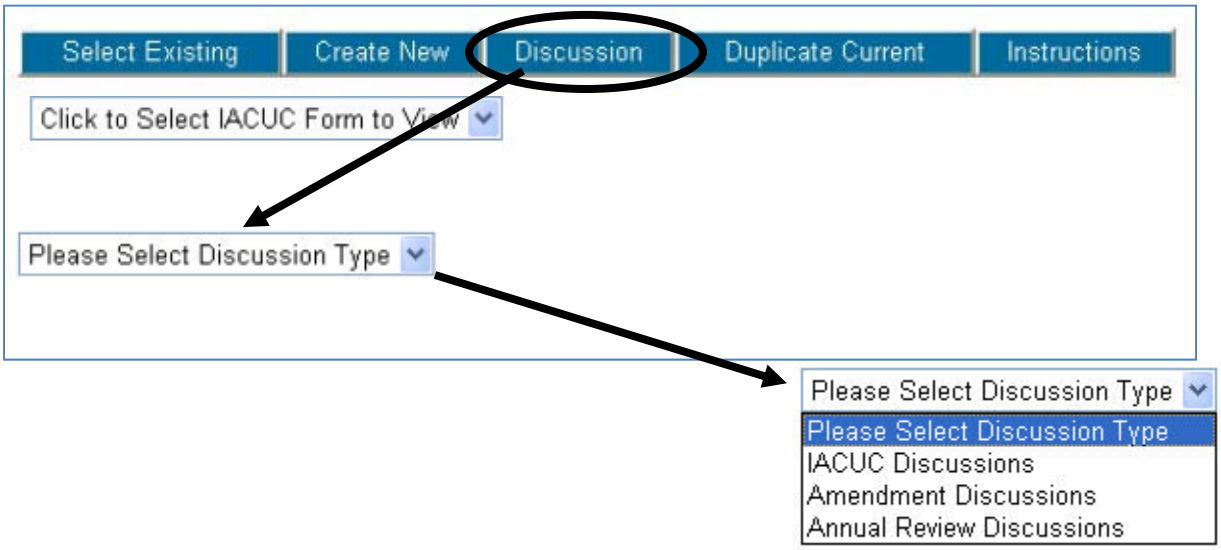


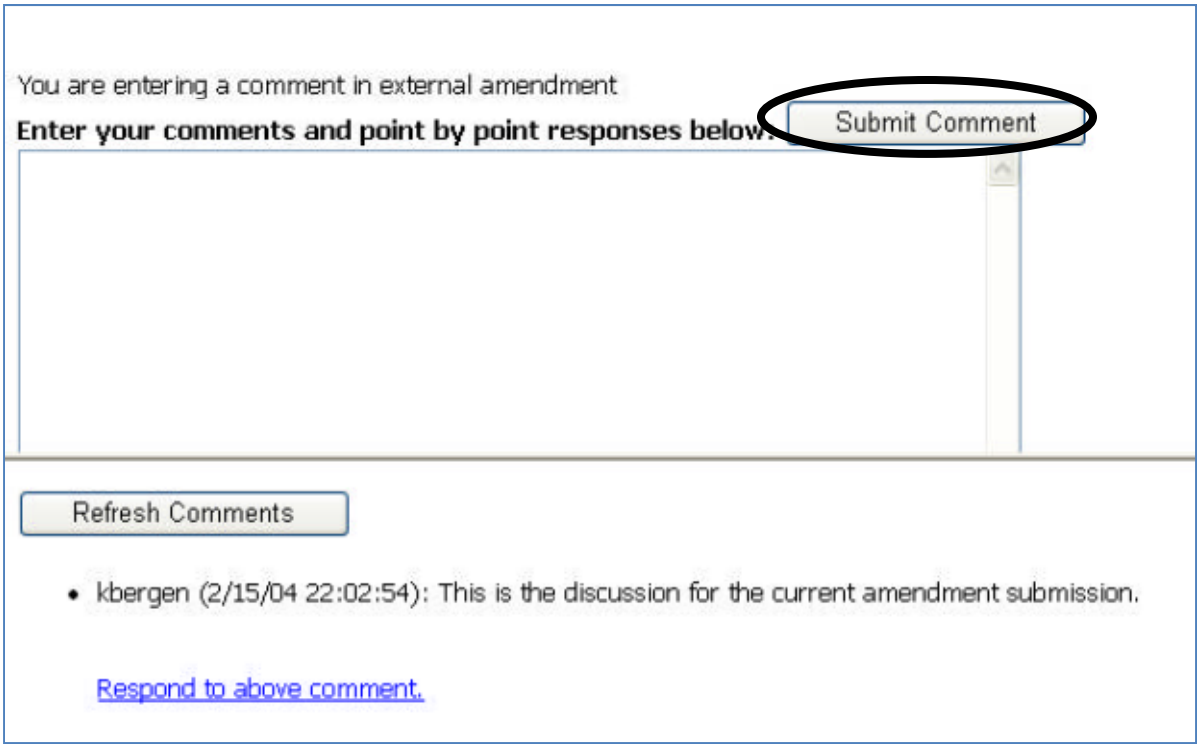
You will need to enter in your recent literature searches and terms used.

12. Once all of the above information is entered and the Save Information button is chosen you will then be able to submit the amendment. **Please remember that in order for the reviewers to be able to review your amendment you will need to submit the application. Once the amendment is submitted edits cannot be made.**

IACUC and Amendment Discussion Process

1. The review process is exactly the same as for an original ACORP submission. The discussion piece has changed. Once you click on Discussion you will have to choose your Discussion Type (ACORP, Amendment, and soon Annual Review)





Enter in your point-by-point response in the text box. If it is going to be a large document, type the information into a word file and then cut and paste into this section and then click submit comment.