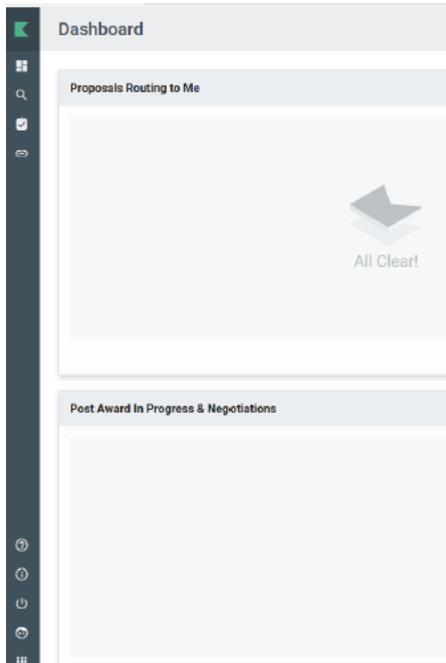
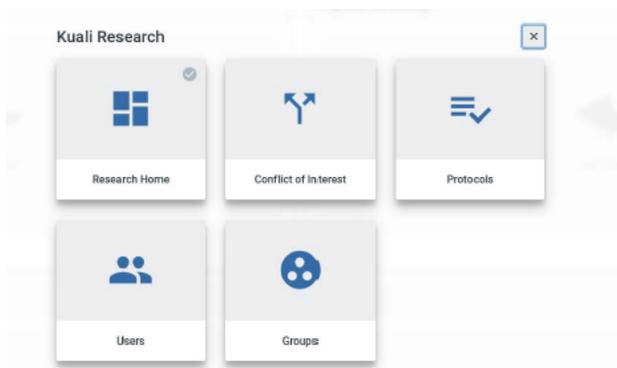


How to create an IACUC protocol

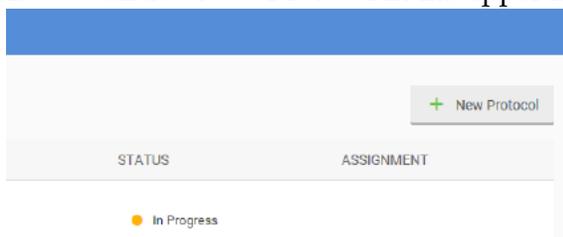
1. LOG IN: Go to https://www.umb.edu/orsp/kuali_research and log in using your NetID and Password.
2. Select Switch Apps on the lower left margin (the icon has 9 dots).



3. Click Protocols



4. Click + New Protocol in the upper right of screen. Then select IACUC.



5. Sections:

- General Information
- Administrative Inform...
- Project Personnel
- Special Considerations
- Project Summary
- Species
- Housing & Husbandry
- Substance Administratic
- Hazardous Agents
- Attachments
- Guidelines
- Certification

6. Type in your name in the Principal Investigator field; your name will populate from a drop-down list. Select your department in the Lead Unit field. Type in your protocol title, then click Next in the upper right-hand corner.
7. You will then be asked your application, protocol type, and funding.

Application Type:

Protocol Application

Field Research Application

Protocol Type:

Holding

Research

Teaching

Will this project be supported by any external sponsored funds? If yes, be sure to attach the Vertebrate Animal Section in the Attachments section.

Yes

No

8. The screen you see next will look like this:

The Animal Welfare Act and the PHS Policy requires that personnel are appropriately trained in animal care and use matters, and that the professional training is documented. The PI is responsible for ensuring that s/he has read and understands the approved protocol, completed all applicable CITI trainings, and enrolled in the Occupational Health and Safety Program.

List all personnel who will work with live vertebrate animals as part of this protocol below. Include PIs, Co-Is, Post-Docs, Students, lab technicians, etc. Select either Full Access or Read Only Access for each individual. Note: Full Access provides editing abilities to this protocol.

People

Columns + Add Line

	PERSON	DEPARTMENT	RESEARCHER ROLE	CONTACT ROLES
	Miles, Alison M	Dept: 4-H Youth Family Development	Principal Investigator	Administrative Editor

Other Personnel (Students/Externs)

Columns + Add Line

	PERSONNEL	EMAIL	RESEARCHER ROLE	ROLE ON THE PROJECT	TRAINING DETAILS
+ Add Info					

Emergency Contacts

Columns + Add Line

You will already be listed in the People section because you are the PI, however, you must click the Pencil icon to add information and answer additional questions about yourself. If you forget to do this, it will not let you submit your protocol. Here is what it looks like when you click the Pencil:

Special Considerations

Note: 'progressive disclosure' is used throughout this form which means by answering the questions displayed, required sections of the form will populate for completion.

Check all that apply:

9. Special Considerations: Note 'progressive disclosure' is used throughout this form which means by answering the questions displayed, required sections of the form will populate for completion.

Check all that apply:

<input type="checkbox"/> Animal Exercise	<input type="checkbox"/> Restraint (using conventional or novel devices) of any duration
<input type="checkbox"/> Assays or Antibody Production	<input type="checkbox"/> Anesthetic Agents (injectable or inhaled)
<input type="checkbox"/> Tumor Implants or Growth	<input type="checkbox"/> Survival Surgical Procedures
<input type="checkbox"/> Induced Disease	<input type="checkbox"/> Multiple survival surgeries
<input type="checkbox"/> Death as an endpoint studies (i.e. LD50)	<input type="checkbox"/> Procedures including minor manipulations, ligations, non-survival surgery behavior observation
<input type="checkbox"/> Moribund as an endpoint	<input type="checkbox"/> Paralytic Agents
<input type="checkbox"/> Burns or Trauma	<input type="checkbox"/> Food or water deprivation (other than required for pre-op)
<input type="checkbox"/> Breeding	<input type="checkbox"/> Special diet (high fat, low fat)
<input type="checkbox"/> Disease evaluation	<input type="checkbox"/> Study of pain, distress or stress
	<input type="checkbox"/> Unrelieved pain or distress

10. Project Summary

Please limit your answers to 2 to 3 sentences.

Using non-technical terms understandable to non-scientist IACUC members, provide a brief answer to each of the following questions.

What is the overall objective of this study?

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Why is this work important/significant?

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How will the animals be used to accomplish the goals of the study? Very briefly describe the general experimental plan

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How does this work build upon prior work with animals?

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What are the study endpoints for the animals and what are the expected results?

11. Species

Species

Include all species info related to this protocol here. Separate procedural information must be included for each species in the Procedures section. If you remove a species, be sure to remove the associated procedure from the Procedures section.

Total number of animals are approved for three years; therefore, the number of animals requested should be the total number of animals needed for the entire project (over the three-year period).

Columns + Add Line			
	SCIENTIFIC NAME	COMMON NAME	TOTAL NUMBER OF ANIMALS
+ Add Info			

Please enter any special characteristics of the selected species:

Example: If this is a rodent study, indicate the strain(s)/stock(s) including any abnormal phenotypes or behaviors exhibited. i.e. Strain-NOD, C57Bl, Transgenic, i.e. Stock- Swiss Webster, Sprague Dawley, i.e. Phenotype- animals will appear obese, exhibit tremors, grow spontaneous tumors and have respiratory difficulties as part of an induced genetic mutation.

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If the experimental goals of the proposed studies are accomplished with fewer animals than the number approved, any "EXTRA" animals ARE NOT to be used.

The number of animals requested must be based on the amount needed to answer a specific scientific question. Animals are not to be justified on the basis of how many experiments can be physically performed by a certain number of researchers in a given period of time.

Does the number of animals requested include extra animals to cover anticipated failures or to familiarize the staff with the procedures described?

- Yes
- No

Provide the sample size calculation or other justification for sample and group size. Include this info below, or attach a separate document in the Attachments section.

Example 1: Sample size needed to study differences in the means of two or more populations. Indicate expected variability, mean, "p-value", and power level supporting requested group/sample size.

Example 2: Sample size needed to study difference in frequency of an event. Indicate expected frequency, "p-value", and power level supporting requested group/sample size.

Example 3: Sample/group size needed to perform a pilot study or to provide procedural training. Justify the number requested.

Example 4: If the number of animals requested is based upon the need for detailed analyses of certain tissues, provide a detailed breakdown of assays to be performed, amount of material needed for each assay and amount of material available from each animal.

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The species selected is appropriate because:

- The process resembles that in humans.
- Prior research has been done in this species.
- Tissues or other substances to be harvested require an animal of this size.
- The size or anatomy of this species is best or uniquely suited to the procedure to be done.
- Tissues or substances needed are best or uniquely provided by this species.
- Species lower on the phylogenetic scale cannot be used.
- Other

12. Housing and Husbandry

Please check all applicable areas where animals will be housed:

- Animal Resources Core Facility
- Check this box if procedures will only take place in the animal facility
- Classroom
- Laboratory
- Other

Will the animals on this study require any special handling or husbandry requirements?

This includes anything outside of normal routine husbandry/handling services (i.e. alterations in bedding types, cage change frequencies, housing densities, special diets/fluids, deviations from currently approved IACUC policies, etc).

- Yes
- No

Will animals leave housing for more than 12 hours?

Please indicate what method(s) of identification will be used to track these animals. Select all that apply:

- Ear tag or notch
- Cage card
- Tattoos
- Implant
- Other

13. Substance Administration

Identify all substances to be used in this protocol below. This includes any anesthetics, analgesics, test substances or other agents to be administered to the animal.

 Columns

+ Add Line

	SPECIES	SUBSTANCE TYPE	SUBSTANCE ADMINISTERED	SOURCE
--	---------	----------------	------------------------	--------

+ Add Info

The IACUC requires that all chemical compounds administered to any animal species be of pharmaceutical grade. The FDA site, [orangebook](#), can be used as a resource to confirm if your compound is available is pharmaceutical grade. In situations where use of a non-pharmaceutical grade substance is necessary, a scientific justification is required.

Are nonpharmaceutical grade substances being proposed for use?

- Yes
- No

14. Hazardous Agents

All projects involving the use of any radiological, chemical, or biological hazard must be performed in accordance with UMass Boston safety protocol(s) for hazardous materials. When there is a risk of exposure within the vivarium, a Hazard Safety SOP must be developed.

Are you using biological material, human or animal products, infectious agents, or rDNA?

- Yes
 No

Are you using toxic or hazardous substances in animals (e.g., carcinogens, reproductive hazards, etc.)?

- Yes
 No

Radioisotopes

- Yes
 No

Controlled Substance

- Yes
 No

Other

- Yes
 No

15. Attachments

Attachments

Please attach all documents that provide direct support for this protocol. Please name all attachments as referenced in the narrative sections of the protocol.

[Columns](#)

[+ Add Line](#)

	ATTACHMENT	NAME	ATTACHMENT TYPE
--	------------	------	-----------------

[+ Add Info](#)

16. Guidelines

1. [Animal Facility Access](#)
 2. [Equipment Sanitization](#)
 3. [Rodent Anesthesia and Analgesia Formulary](#)
 4. [Use of Nonpharmaceutical Grade Compounds](#)
 5. [Assigning Pain Categories](#)
 6. [Spontaneous and Induced Tumor Production in Rodents](#)
 7. [Occupational Health and Safety](#)
-

I have read and agree to all applicable guidelines linked above.

17. Certification: The Care and Use of Laboratory Animals

UMass Boston has on file with NIH's Office of Laboratory Animal Welfare (OLAW) a written Assurance of Compliance which commits this institution to following the standards established by [Public Health Service \(PHS\) Policy](#). As part of the Assurance, UMass Boston has established an institutional animal care and use committee (IACUC) to review, require changes to, and/or grant approval to research protocols or teaching projects involving the use of vertebrate animals. The IACUC is also charged with ascertaining if research proposals are consistent with the "[US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)", the [Guide for the Care and Use of Laboratory Animals 8th Ed.](#), the [Animal Welfare Act/Regulations](#), and other applicable state and city public laws and regulations. These regulatory documents describe the minimal standards that must be met for humane care and treatment of research animals to assure that animals do not suffer unnecessary discomfort, pain, or injury, and that animals receive proper care and husbandry. Laboratory animals must be cared for and used in a manner that complies with the above documents to protect current and future sponsored support.

ANIMAL USER CERTIFICATION:

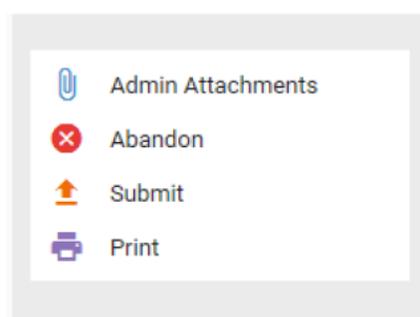
All personnel listed on this protocol are responsible for reading the above statement and will be held responsible for adhering to all regulations therein, and agree to make written notification in the form of a protocol amendment to the Institutional Animal Care and Use Committee (IACUC) of any proposed changes in the animal experimentation protocol for review and approval prior to proceeding with any animal experimentation.

All personnel working with animals on this protocol:

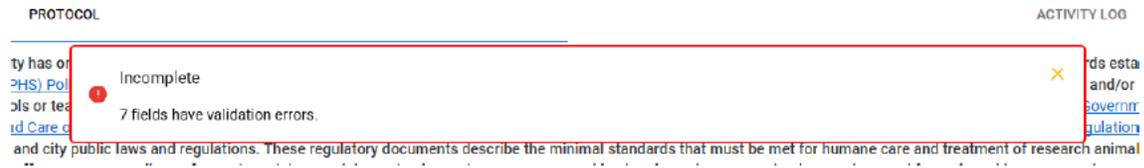
- must enroll in the University's Occupational Health Program to work with animals;
- will be held responsible for pursuing appropriate training; and
- must adhere to the terms and conditions of this protocol as approved by the IACUC.

I have read the above certifications and understand my responsibility to provide assurance of compliance with UMass Boston standards.

18. Once you feel you have completed the protocol, click Submit in the upper right-hand corner of the page.

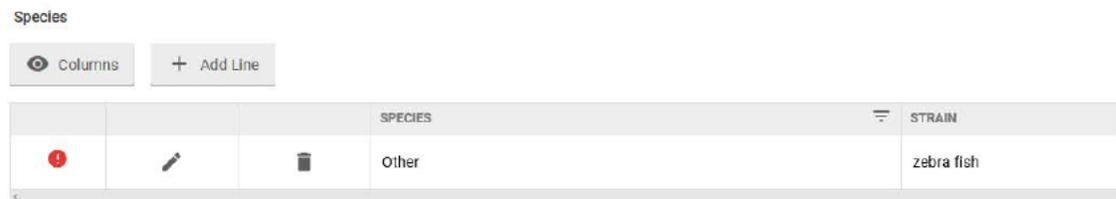


- If you have not completed areas of the form which are required, you will get something that looks similar to this:

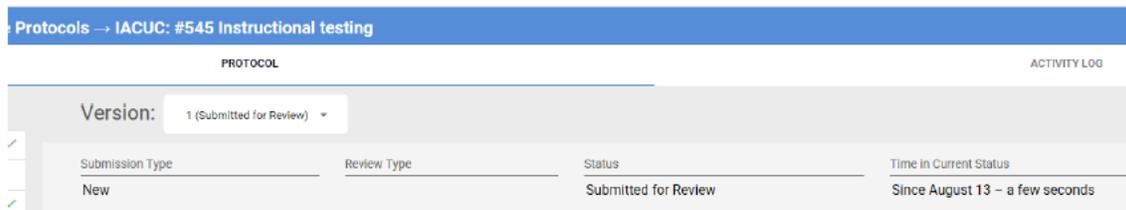


Scroll through the form to find the fields that need further completion.

For example you may see that species has a **red!** next to it. Click the Pencil icon to open the box to see what is missing.



- Complete the missing information.
- Click Submit
- Once your protocol has been submitted you will receive an email that it was submitted. The top of your form will look similar to this:



With the status and date that it was submitted.