New IRB Application - zebrafish

This form will serve as the application for IRB approval for a new project **involving zebrafish** that hasn't yet been reviewed.

If you'd like to **amend** an existing protocol that's already been approved, please use this form: https://forms.office.com/r/n4jzrnX5EY
If you'd like to **renew** an existing protocol that's already been approved, please use this form: https://forms.office.com/r/RpiEUGQUjv

* Required

* This form will record your name, please fill your name.

The Roanoke College Institutional Review Board (IRB) must review and approve all research, including research involving zebrafish, before data collection begins. Each of the items in the form that follows must be completed, which will serve as your application. Your responses will automatically be sent to the IRB for review, and their review will not begin until all required elements have been submitted.

Please allow at least 10 business days for the IRB to respond to your application. **You may not begin collecting any data until you have received an official Certificate of Action (CoA) from irb@roanoke.edu.** You should refer to the study number in your CoA for all future correspondence about your project, including general queries, amendments, and renewals.

Please direct any questions to irb@roanoke.edu.

Thank you!

Demographics

In this section, please submit basic project information before proceeding.

Project Title *

Is this project being funded by an external funding agency? *

- ◯ Yes
- ◯ No

Please indicate the funding agency and grant number supporting this project. *

Is this project being conducted by a student (or group of students) as part of a course you're enrolled in? *

Note: This may include an independent study, Honors Distinction Project, research practicum, capstone course, etc.

- ◯ Yes, this is a student-led project supervised by a faculty member
- ◯ No, this is a faculty-led project, but a student (or students) will also be involved with the process
- ◯ No, this is a faculty-led project with no student involvement

Please indicate the class you're conducting this project in. *

Project Lead First Name *

Note: Student co-investigators can be listed towards the end of this form

Project Lead Last Name *

Faculty Member/Advisor First Name *

Faculty Member/Advisor Last Name *

Faculty Member/Advisor RC Email Address *

Project Start Date *

Note: The start date **cannot** be backdated

Project End Date *

Notes: The end date should extend at least 3 weeks beyond the date of your submission, to ensure ample time for IRB review.

In addition, data analysis is still considered part of the research process. Therefore, your end date should cover the duration of data analysis in addition to data collection. If anything changes and you need more time, you can always submit a renewal (https://forms.office.com/r/RpiEUGQUjv) to grant yourself more time.

Animal Requirements

What species will you be working with? *

What is the age/weight/size of the animal? *

Which sex will you be studying? *

- [ ] male
- [ ] female

Please indicate the stock or strain you'll be studying *

What is the source of the stock or strain you're working with? *

Where will the animal(s) be housed? *

Note: If animals will be housed in lab or anywhere else outside the primary facility for more than 12 hours, you should provide building and room number

Where will animal procedures take place? *

Please indicate the number of animals required for each year, along with the total number *

Special Concerns or Requirements of the Project

Will your project involve any special housing, equipment, animal care (e.g., special caging, water, feed, or waste disposal, environmental enhancement, etc.)? *

- ◯ Yes
- ◯ No

Please list these special requirements below *

Will laboratory personnel be primarily responsible for animal care? *

- ◯ Yes
- ◯ No

Please upload a copy of the standard operating procedures laboratory personnel will follow *

Upload file

File number limit: 10 Single file size limit: 1GB Allowed file types: Word, Excel, PPT, PDF, Image

Transportation

Transportation of animals must conform to all institutional guidelines/policies and federal regulations.

Will animals be transported on public roads or out of state? *

- ◯ Yes
- ◯ No

Describe efforts the researchers will take to comply with USDA regulations *

Will animals be transported between facilities? *

- ◯ Yes
- ◯ No

Describe methods and containment to be utilized in transport of animals. *

Will animals be transported within a facility? *

- ◯ Yes
- ◯ No

Identify the route and elevator within the facility that will be utilized *

Will live animals be returned to animal facilities? *

- ◯ Yes
- ◯ No

Project Objectives

Purpose *

Briefly describe, **in non-technical terms**, the aim of the project and how the project may benefit human or animal health or advance scientific understanding of biological processes or educational objectives. (What do you expect it to achieve? Why is the project important?)

Rationale For Animal Use

Explain your rationale for animal use *

Note: The rationale should include reasons why non-animal models cannot be used

Justify the appropriateness of the species selected. *

Justify the number of animals to be used *

Note: You should describe how the number of animals to be used was determined, and why that number is necessary to achieve the goals of this project. If possible, summarize this information in a table giving 1) the number of different experiments, 2) the number of groups per experiment, and 3) the number of animals per group. Whenever possible, justify the number of animals statistically

Description of Experimental Design and Animal Procedures

In this section, you will briefly explain the experimental design and specify all animal procedures. This description should allow the IRB to understand the experimental course of an animal from its entry into the experiment to the endpoint of the project.

Describe the animal identification methods you will employ *

Examples: ear tags, tattoos, collar, leg band, cage card, implant, etc.

Will you be administering injections or inoculations? *

- ◯ Yes
- ◯ No

Describe the injections or inoculations *

Note: You should describe the substances (e.g., infectious agents, adjuvants, etc.), dose, sites, volume, route, and schedules

Will you be drawing blood from the animals? *

- ◯ Yes
- ◯ No

Describe the blood drawing processes *

Note: You should describe the volume, frequency, withdrawal sites, and methodology

Will you be using non-survival surgical procedures? *

Note: Details for survival surgical procedures will be requested later in this form

- ◯ Yes
- ◯ No

Describe the non-survival surgical procedures used *

Will you deliver radiation to the animals? *

- ◯ Yes
- ◯ No

Describe the dosage and schedule of radiation *

Will methods of restraint be employed? *

- ◯ Yes
- ◯ No

Describe the methods of restraint used *

Examples: restraint chairs, collars, vests, harnesses, slings, etc.

Are the animals expected to experience any resultant effects (e.g., pain or distress, ascites production, etc.)? *

- ◯ Yes
- ◯ No

Describe anticipated resultant effects *

Are the animals expected to experience other potential stressors (e.g., food or water deprivation, noxious stimuli, environmental stress, etc.)? *

- ◯ Yes
- ◯ No

Describe anticipated potential stressors *

Describe procedures that will be used to monitor and minimize distress *

Will the project involve any additional procedures not yet described? *

Examples: Behavioral studies, tail biopsies, etc.

- ◯ Yes
- ◯ No

Describe any additional procedures *

Describe the experimental endpoint criteria *

Note: tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal.

List the criteria to be used to determine when euthanasia is to be performed. **Death as an endpoint must always be scientifically justified.**

Records

Records should include animal or group identification, type of procedure (blood collection (amount, method), kind of surgery, euthanasia (method), administration of drugs (name, dose, route), etc.), initials of personnel, date, and observations relating to animal health and welfare.

Upload a copy of your records for the IRB to review. *

Upload file

File number limit: 10 Single file size limit: 1GB Allowed file types: Word, Excel, PPT, PDF, Image

Survival Surgery

Will your project involve survival surgery? *

- ◯ Yes
- ◯ No

Will minor surgery be involved? *

Examples: Cut-downs, needle aspirations, tail biopsies

- ◯ Yes
- ◯ No

Specify the minor surgical procedure(s) *

Will major surgery be involved? *

Examples: Entering a body cavity or producing substantial impairment of physical or physiologic functions (such as laparotomy, thoracotomy, craniotomy, joint replacement, or limb amputation)

- ◯ Yes
- ◯ No

Specify the major surgical procedure(s) *

Identify and describe the surgical procedure(s) to be performed *

Note: You should include:

- preoperative procedures (e.g., fasting, analgesic loading), anesthetic monitoring (e.g., corneal and pedal reflexes, heart and respiratory rates, etc.), and supportive care (ophthalmic ointment, methods to prevent dehydration and hypothermia, etc.) during surgery
- the aseptic methods (e.g., animal and human preparations, sterile instruments and field, etc.) to be utilized

Who will perform surgery and what are their qualifications and/or experience? *

Where will surgery be performed (Building and Room)? *

Will paralytic agents be used during surgery? *

- ◯ Yes
- ◯ No

Describe how ventilation will be maintained and how pain will be assessed *

Describe post-operative care required, including location, frequency of observation, consideration of the use of post-operative analgesics, and identify the responsible individual(s), and duration of survival after surgery. Describe what impairment can be expected from the surgery, any post-operative complications that may develop, and your plans to handle them. *

Has major survival surgery been performed on any animal prior to being placed on this project? *

- ◯ Yes
- ◯ No

Explain why this is the case *

Will more than one major survival surgery be performed on an animal while on this project? *

- ◯ Yes
- ◯ No

Justify why this is the case *

Pain or Distress Category and Consideration of Alternatives

Category A: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.

- Examples:
  - Breeding colonies of any animal species. Breeding colony includes parents and offspring.
  - Newly acquired animals that are held in proper caging and handled in accordance with applicable regulations.
  - Animals held under proper captive conditions or wild animals that are being observed.

Category B: Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.

- Examples:
  - Procedures performed correctly by trained personnel such as the administration of electrolytes/fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice or catheterization of same, standard radiography, parenteral injections of non-irritating substances, restrictions of food/water intake for less than equivalent to periods of abstinence in nature.
  - Euthanasia performed in accordance with the recommendations of the most recent AVMA Panel on Euthanasia, utilizing procedures that produce rapid unconsciousness and subsequent humane death.
  - Manual restraint that is no longer than would be required for a simple exam; less than 12 hours of physical restraint for an adapted animal.

Category C: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.

- Examples:
  - Surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation, laparotomy or laparoscopy.
  - Blood collection by more invasive routes 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.

Category D: Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

- Examples:
  - Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain.
  - Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
  - Negative conditioning via electric shocks that would cause pain in humans.
  - Physical restraint of animals not conditioned to the procedure for the time period used or in excess of 12 hours.

Will your project involve any of the above categories of pain or distress?

- ◯ Yes
- ◯ No

Which category or pain or distress will your project involve? *

- [ ] Category A
- [ ] Category B
- [ ] Category C
- [ ] Category D

Identify how many animals will be used within each category for each of 3 consecutive years. You should also calculate the total number of animals within each category for the entire 3-year period. *

If any animal will be subject to Category D, explain the procedures producing pain or distress in these animals and the justification for not using anesthetic, analgesic or tranquilizing drugs below. For USDA (Animal Welfare Act) AWA-covered animals, this information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act. *

Note: If no animals will be subject to Category D, please type "N/A" below

The project director must provide a written assurance that the activities do not unnecessarily duplicate research projects/courses and that there are no alternatives (such as less sentient animal species, computer models, tissue culture, etc.) to the use of live animals. *

Note: This narrative should include adequate information for the IRB to assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods. If the database search or other source identifies a bonafide alternative method (one that could be used to accomplish the goals of the animal use proposal), the written narrative should justify why this alternative was not used.

If any procedures fall into Categories C or D, causing more than momentary or slight pain or distress to the animals, 1) describe your consideration of alternatives and your determination that alternatives are not available and 2) involve the Attending Veterinarian in planning. *

Note: If no animals will be subject to Category C or D, please type "N/A" below

Alternatives include methods that (1) refine existing tests by minimizing animal distress, (2) reduce the number of animals necessary for an experiment, or (3) replace whole animal use with in vitro or other tests. Note that you must certify that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether relieved or not. Delineate the methods and sources used in the search. *

- [ ] Medline
- [ ] Agricola
- [ ] Biosis
- [ ] Embase
- [ ] AWIC
- [ ] CAB Abstracts
- [ ] CAB Vet & Medica
- [ ] Index Medicus
- [ ] Federal Research in Progress
- [ ] NML
- [ ] Science Citation Index
- [ ] Current Contents
- [ ] National Agricultural Library
- [ ] PubMed
- [ ] Periodicals
- [ ] Meetings or conferences
- [ ] Consultation with colleagues
- [ ] Other

Provide additional information, depending on the option(s) selected above *

- **Database references**: must include databases (2 or more) searched; list the date of the search, period covered, and the keywords used
- **Periodicals**: identify the names of periodicals or journals read on a regular basis
- **Conferences**: list names and dates of meetings attended
- **Consultation with colleagues**: identify the names and credentials of colleagues (i.e., M.D., Ph.D.), dates of consultations, and nature of discussions

Anesthesia, Analgesia, and Tranquilizers

Will anesthesia, analgesia, and/or tranquilizers be used in this project? *

- ◯ Yes
- ◯ Yes

Specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used *

Note: In this section, you should:

1. Include the name of the agent(s), the dosage, route and frequency of administration
2. Describe tracking and security of controlled drugs (Drug Enforcement Agency requirements)

Method of Euthanasia or Disposition of Animals at End of Project

Will euthanasia be used in this project? *

- ◯ Yes
- ◯ No

Provide the following details:

- the proposed method
- if a chemical agent is used, specify the dosage and route of administration
- the method of carcass disposal

*

What exactly will happen to the animals at the conclusion of the experiment or demonstration? *

Note: Techniques for euthanasia must follow the guidelines established by the latest report by the AVMA Panel on Euthanasia. Deviations must be justified for scientific reasons and approved by the IRB.

- ☐ Anesthetic injection overdose (state drug/dose per body weight/route of administration of drug)
- ☐ Exsanguination under anesthesia (state name/dose (per body weight)/route of administration of drug)
- ☐ Inhalation of carbon dioxide from a compressed gas cylinder
- ☐ Cervical dislocation
- ☐ Decapitation
- ☐ Other

In some animals exposed to gas, heartbeat can be maintained after visible respiration has ceased, and the animal might eventually recover. A thoracotomy or other physical method is recommended to assure death of animals after gas exposure. At minimum, check for both respiratory and cardiac arrest prior to discarding the carcass. Describe how death is verified. *

Hazardous Agents in Animals

Will hazardous agents be used with animals in this project? *

Note: Use of hazardous agents requires the approval of the institutional biosafety specialist. Registration Documents for the use of recombinant DNA or potential human pathogens may be attached at the discretion of the IRB.

- ◯ Yes
- ◯ No

Which hazardous agents will be used? *

- ☐ Radionuclides
- ☐ Biological agents
- ☐ Hazardous chemicals or drugs
- ☐ Recombinant DNA

List agents and registration document # (if applicable) for any choice selected above *

Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this project *

Describe methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity *

Describe any additional safety considerations

Biological Material/Animal Products for Use in Animals

Examples: Cell lines, antiserum, etc.

Will biological material(s) and/or animal products be used in this project? *

- ◯ Yes
- ◯ No

Specify the material used *

Specify the source of the material used *

I certify that the MAP/RAP/HAP tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original MAP tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens. *

- ◯ Yes

Transgenic and Knockout Animals

Will this project involve the use of transgenic and/or knockout animals? *

- ◯ Yes
- ◯ No

Describe any phenotypic consequences of the genetic manipulations to the animals *

Describe any special care or monitoring that the animals will require *

Field Studies and Wild Caught Animals

Will this project involve field studies and/or the use of wild caught animals? *

- ◯ Yes
- ◯ No

Describe how animals in the wild will be observed, any interactions with the animals, whether the animals will be disturbed or affected, and any special procedures anticipated *

Are Federal and/or state permits required? *

- ◯ Yes
- ◯ No

Have Federal and/or state permits been obtained? *

- ◯ Yes
- ◯ No

Additional Co-Investigators

Please list the full name(s) of any additional co-investigators. This should include any other student, staff, or faculty member involved in this project in any way. *

If none apply, please indicate N/A

CITI Training Certificates

Please upload the CITI training certificates for all individuals listed on this form. *

Being involved in a research project with zebrafish requires training in the rules and procedures governing ethical treatment and use of zebrafish. Each individual listed on this form must provide documentation of competence in this area by completing the "Working with Zebrafish (Danio rerio) in Research Settings" online course through the CITI training website: https://www.citiprogram.org/index.cfm?pageID=154&icat=0&ac=0&region=1&message=0.

Please register for a free account, add your affiliation as Roanoke College, complete all required modules within the Social & Behavioral Research Investigators course, save your certificate, and upload it here for everyone listed on this form.

This **must** include:

1. the faculty member/advisor
2. the project lead
3. all co-investigators

IRB review will not begin until all researchers' training certificates have been attached.

Upload file

File number limit: 10 Single file size limit: 1GB Allowed file types: Word, Excel, PPT, PDF, Image, Video, Audio

Project Director Certifications

Finally, please ensure all researchers have signed the Project Director Certifications form, which you should download, fill out completely, and upload here.

Project Director Certifications form: https://mailroanoke.sharepoint.com/sites/RC-InstitutionalReviewBoard/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x012000324972389611974 5A03E022D9DA0785F&id=%2Fsites%2FRC%2DInstitutionalReviewBoard%2FShared%20Documents%2FGeneral%2FIRB%20Application%20Signature%20Page%20%2D%20zebrafish%2Dfillable%2Epdf&parent=%2Fsites%2FRC%2DInstitutionalReviewBoard%2FShared%20Documents%2FGeneral

Please upload the completed certifications form here. *

Upload file

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