



A Checklist for Submitting Animal Use Applications

Dear Colleague: Welcome to Duke! This is an exciting place to do animal facilitated research. Your research is important to you, and it is important to us. To assist with getting started on the right foot and getting started quickly, please review the following steps describing the protocol approval process at Duke. We want your transition to our program to be a pleasant experience and the process of obtaining protocol approval to be as smooth as it can be. If you have any problems along the way, please email me at ron.banks@duke.edu. The Office of Animal Welfare Assurance will do all we can to facilitate your smooth transition to our campus.

GETTING STARTED:

- VISIT THE DUKE ANIMAL PROGRAM WEB SITE** at: <http://vetmed.duhs.duke.edu/>
 - Familiarize yourself with this web site. This is the principle site for all forms, policies, guidelines, and directions for training or other procedures used in the Duke animal care and use program.
 - For more specific protocol development guidance click on the link at the left titled "Protocol Development." You may access the protocol template from this page, or by using the next step.
 - The protocol template may be found on the page (http://vetmed.duhs.duke.edu/index_of_new_protocol.htm).
 - Review the protocol template instructions.
 - Download the appropriate version on the template for your animal protocol (most researchers select 'Option A').
 - Visit the 'IACUC Meeting Deadlines' web page to confirm the review and approval schedule that best meets your need (http://vetmed.duhs.duke.edu/index_of_iacuc_meeting_deadlines.htm). While most protocols are approved at the first IACUC meeting, you should plan on a 2 month approval process, just to be safe.
- OBTAIN YOUR DUKE 'NetID' AND 'Password'**: While the animal program site is freely accessible, you will need your NetID and Password for other steps in this process. NetID and Passwords are automatically created when you initiate a relationship with Duke (e.g. grad students' fees are paid at the registrar; faculty position acceptance letter has been received by Duke HR). If you have problems or don't know your NetID or Password, call the Office of Information Technology (OIT) at 919.684.2200.
- COMPLETE THE HEALTH REVIEW**: The web form for 'Health Review for Animal Handlers' is located at: <https://www.hr.duke.edu/secure/eohw/animal.php> Once submitted, the assessment usually takes a few days, but may take longer if EOHW (Employee Health) determines additional medical assessment or immunizations are necessary prior to working with animals, animal tissues, or animal byproducts.
- COMPLETE WEB TRAINING**: Visit the OESO (safety office) web site at: <http://www.safety.duke.edu/>. Select the link on the left 'On-line Training.' Enter your NetID and Password. Select 'Courses Available On-Line.' All animal users must complete Animal Handlers I and Animal Handlers II. If you are working with rodents and will use CO₂ for euthanasia, you must also complete 'CO₂ Euthanasia of Rodents.' You may complete any of the other courses you feel are appropriate or may be necessary. The IACUC, OESO, or EOHW may require specified web courses (e.g. biosafety work may require completion of the biosafety web module) during the protocol review.
- FACILITY ORIENTATION**: Access to animal vivaria requires an approved protocol and Facility Orientation. Contact Peg Hogan, RLATG, CMAR (ph: 684-3885) or Email hogan012@mc.duke.edu for scheduling.
- QUESTIONS OR PROBLEMS**: Call the Office of Animal Welfare Assurance at 919.668.6720 or Email ron.banks@duke.edu or michelle.keys@duke.edu.

PROTOCOL SUBMISSION:

- **PRE-REVIEW:** To assist researchers with protocol development, the Office of Animal Welfare Assurance (OAWA) provides a pre-review service. Just complete your protocol as best you can, and Email it to IACUC@DUKE.EDU. An OAWA veterinarian will review your protocol and offer suggestions for improvement.
- **SUBMISSION FOR IACUC REVIEW:** When ready, submit all protocols to IACUC@DUKE.EDU. Once a protocol is submitted, DO NOT revise the protocol, only reply to Emails. Emails become part of the protocol file. A revised protocol will require re-review and may delay protocol approval.
 - **ADMINISTRATIVE REVIEW:** You will receive a confirmation from one of the Protocol Specialist that your protocol has been added to the IACUC's agenda. The Protocol Specialist will also perform an 'Administrative Review' and may suggest enhancements (e.g. missing contact information, missing housing or procedure location, etc.). Please reply by Email with the information requested.
 - **VETERINARY REVIEW:** All protocols receive a review by a Duke veterinarian prior to going to the IACUC. This review will include the entire protocol, but will focus on animal care, anesthesia, analgesia, and other animal care activities. The reviewer may identify specific concerns and offer suggestions to reconcile the concern. Please reply to the Email with the information requested.
 - **OESO / EOHW REVIEW:** All protocols and amendments are reviewed by OESO and EOHW to assure compliance with Duke requirements for a safe workplace. You will receive an Email notice from OESO/EOHW concerning any issues that require attention. Please do not delay in responding to OESO/EOHW. Animal protocols may be reviewed by the IACUC, but the approval will not be granted until PROTOCOL CLEARANCE has been received from OESO and EOHW.
 - **PRIMARY IACUC MEMBER REVIEWER:** A member of the IACUC will be assigned as the PRIMARY REVIEWER. A few days before the IACUC meeting you may receive an Email from the PRIMARY REVIEWER requesting clarification of certain points. Please reply to the Email with the information requested. The PRIMARY REVIEWER will be your advocate at the IACUC meeting.
 - **NOTICE OF IACUC REVIEW:** Within 3 business days of the IACUC meeting you will be advised of the outcome of the Committee's review. If approved, you will be given a protocol registry number and instructions on annual reporting of your animal use activity. If additional clarifications are required to secure approval, you will receive a point by point breakdown of necessary actions to secure approval.
- **QUESTIONS OR PROBLEMS:** Call the Office of Animal Welfare Assurance at 919.668.6720 or Email ron.banks@duke.edu or michelle.keys@duke.edu

PROTOCOL MAINTENANCE:

- **ANNUAL PROTOCOL REPORT:** A request for an annual report of your animal use activities will be sent via Email during the 10th month of the protocol. You must complete the report, return the report, and the report must be approved prior to the protocol approval anniversary date, or the protocol may be suspended by the IACUC.
- **USDA REPORT:** The Duke animal program must report animal use to the USDA annually. A request for your animal numbers used will be sent via Email each fall. Please reply as soon as possible.
- **AMENDMENTS TO APPROVED ACTIVITY:** Any change of research direction, addition of new procedures or personnel, or changes in approved procedures must be IACUC approved prior to performing the changed activity. The Amendment form is available on the animal program website under 'FORMS AND REPORTS.' Depending upon the nature of the change, amendments may take up to 14 business days for approval.
- **DE NOVO REVIEW:** According to NIH/PHS Policy, all protocols have a life cycle of 3 years. Projects continuing beyond 3 years must have a new protocol approved by the IACUC. At the 33rd month of your protocol life cycle, we will alert you by Email that you should submit a new protocol. Please reply promptly.
- **POST APPROVAL MONITORING:** Duke has an active program of Post Approval Monitoring (PAM). Compliance Liaisons will occasionally monitor animal procedures and confirm that the laboratory practices are as described in the approved protocol. Most laboratories will receive one visit per year, but depending upon the type of research, more monitoring sessions may be required. Researchers should view this process as partnering with the IACUC assuring program integrity. Deficiencies noted will be addressed quickly and in a collegial manner.
- **QUESTIONS OR PROBLEMS:** Call the Office of Animal Welfare Assurance at 919.668.6720 or Email ron.banks@duke.edu or michelle.keys@duke.edu