2023-2024 IACUC Deadlines and Meeting Dates

Investigators are encouraged to submit protocols that are due for 3-year renewal early to allow time for pre-review of the protocol by the research liaisons and veterinarians. This will help expedite the review and approval of the protocol. Should you have any questions, please contact OARS at iacuc@yale.edu.

Research Liaison Department Assignments

New: Rodent Breeding: Colony Management, Identification & Genotyping Policy Review

The Office of Animal Research Support will offer a monthly meeting via Zoom to review IACUC policies on breeding, colony management, identification, and genotyping of rodents. The course will review starting a breeding colony, breeding schemes,
recordkeeping, identifying indicators of decline, and genotyping methods.

The first offering will be on Wednesday 5/17/23 at 1:00 pm. Click here to visit the TMS website to sign up for this training. A Zoom meeting invitation will be sent to all attendees prior to the meeting. If registering for this course off campus, VPN will be required to access the TMS database. Please contact OARS training specialist, Jeff Drozd, with any questions or for assistance registering.

**Reminder: Notifications from MAPS for Outstanding Competencies**

There have been an increased number of inquiries from the research community regarding notifications from MAPS for outstanding course competencies. Course information can be found in the IACUC Training Policy. If you receive a notification from MAPS, you can view your outstanding course requirements by:

1. Log into MAPS
2. Choosing Researcher Profiles in the header
3. Open your Researcher Profile
4. Choose the Outstanding Course Requirements tab on the profile home page

Medical Surveillance, YARC Facility Training Part 1, and YARC Facility Training Part 2 require communication with the Training Management System (TMS). To effectively communicate with MAPS, requirements for these courses must be in place. These requirements are put in place by answering “yes” to the animal related questions in the TMS compliance assessment. In the future, please ensure that the questions in your compliance assessment are answered properly. If your role has changed since you first took the assessment, you can request to retake it by logging into TMS (VPN required if off-campus) and choosing “Take Your Compliance Assessment” on the home page. If
you have already taken the assessment, you will have the option to request a retake. Please contact iacuc@yale.edu with any questions.

Reminder: YARC Facility Training Part 2 (Facility Tour) Requirements

The prerequisites to participate in a YARC facility tour have been updated. The new requirements are below:

- Listed as personnel on an approved protocol
- Working with the IACUC- [AALAS Learning Library (ALL)]
- Reporting Animal Welfare Concerns- [AALAS Learning Library (ALL)]
- Reporting Adverse Events- [AALAS Learning Library (ALL)]
- Euthanasia Policy- [AALAS Learning Library (ALL)]
- NEW Scientific Rigor and Reproducibility- [AALAS Learning Library (ALL)]
- YARC Facility Training Part 1- [TMS]
- Medical Clearance (email medical surveillance form to Employee Health; must receive confirmation of clearance)

USDA Inspection

On Monday and Tuesday, April 3rd and 4th, the USDA conducted a focused inspection of the university’s animal program. It focused on animal housing areas and associated documents, e.g., protocols, IACUC minutes, adverse events, etc. We are happy to announce there were no non-compliance findings, thus we received another clean USDA annual inspection report!

We would like to express our gratitude to all of you for helping us remain compliant with the Animal Welfare Act and Regulations. Our inspection history is a true testament
to your cooperation and attention in maintaining a high level of animal welfare while conducting ground-breaking research.

**MAPS Updates**

_Surgery Design Release 11_: went live March 16th. The update included the following:

- Replaced current surgery building blocks with options for Surgery for rodents, large animals, and non-mammalian.
- The new procedures will provide the recommended guidance and questions to the researcher based on the animal selection, pain classification, procedure length, and outcome.
- With the new building blocks, the user will be able to select a pre-approved multimodal analgesia regimen or propose a custom alternative for the IACUC to review.
- Pre-approved analgesic drugs will now be linked to the specific surgical procedure instead of at the experiment-level.
- Protocols that are approved or in the process will retain the existing surgery building blocks. Any additional surgeries being added to the protocol will use the new surgery selections.
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- Hard-coded information from our policies, but the text box for the surgical description & details remains unchanged.

**Personnel Modification Smart Form Adjustments: Personnel List**

The form will be converted from a multi-person to a single-person entry form. This change was made to improve the speed at which compliant users can be approved and added to the protocol. The detailed changes are:

- The Add Personnel screens will now only allow the selection of a single person as part of the personnel modification and set only that individual’s training assignments.
- After entering the personnel, the user can make the following selections:
Reminder: The Benefits of Switching to Ethiqa XR®
The benefits of up to 72 hours post-procedural pain relief with a single dose

Ethiqa XR® (buprenorphine extended-release injectable suspension) 1.3 mg/ml CIII is the only commercial pharmaceutical-grade extended-release buprenorphine FDA-indexed to control post-procedural pain in mice and rats up to 72 hours with just one dose.

Clinically proven, 72-hour pain relief with just a single dose. The long-acting, extended-release technology of Ethiqa XR® (buprenorphine extended-release injectable suspension) 1.3 mg/mL vastly reduces the risk of undue animal stress seen with short-acting formulations.
**Ethiqa XR®, the only commercial pharmaceutical-grade extended-release buprenorphine FDA-indexed to control post-procedural pain in mice and rats is your best choice:**

- Provides up to 72-hours of post-procedural pain relief in mice and rats
- Manufactured in the United States under cGMPs
- Pharmaceutical grade
- Not compounded, not diluted
- FDA-Indexed

[Click here to upgrade to Ethiqa XR®.](#)

[Click here for full prescribing information.](#)

**Important Safety Information**

**For Rats and Mice:**
Only administer Ethiqa XR® by subcutaneous injection. Ethiqa XR is not intended for intravenous, intra-arterial, intrathecal, intramuscular, or intra-peritoneal injection. Do not use on mice or rats with pre-existing respiratory deficiencies. Do not keep rats on wood chip-type bedding after administration of Ethiqa XR®. Use caution with
concomitant administration of Ethiqa XR® with drugs that cause respiratory depression.

For Humans:
Ethiqa XR® should only be administered by a veterinarian or laboratory staff trained in the handling of potent opioids. Protective clothing is recommended to avoid direct contact with human skin or mucus membranes which could result in absorption of buprenorphine and adverse reactions.

*Not for use in humans. Keep out of reach of children.*

*For more information, consult the Prescribing Information including the Boxed Warning.*

**WARNING: ABUSE POTENTIAL and LIFE-THREATENING RESPIRATORY DEPRESSION and ACCIDENTAL EXPOSURE**

**Abuse Potential**
Ethiqa XR® contains buprenorphine, a high-concentration (1.3 mg/mL) opioid agonist and Schedule III controlled substance with an abuse potential similar to other Schedule III opioids. The high concentration may be a particular target for human abuse. Buprenorphine has opioid properties that in humans may lead to dependence of the morphine type. Abuse of buprenorphine may lead to low or moderate physical dependence or high psychological dependence. The risk of abuse by humans should be considered when storing, administering, and disposing of Ethiqa XR®. Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (suicidal depression).

Because of human safety risks, this drug should be used only with veterinary supervision. Do not dispense Ethiqa XR®.

**Life-Threatening Respiratory Depression**
The concentration of buprenorphine in Ethiqa XR® is 1.3 mg/mL. Respiratory depression, including fatal cases, may occur with abuse of Ethiqa XR®. Ethiqa XR® has additive CNS
depressant effects when used with alcohol, other opioids, or illicit drugs that cause central nervous system depression. Because of the potential for adverse reactions associated with accidental injection, Ethiqa XR® should only be administered by a veterinarian or laboratory staff trained in the handling of potent opioids.

**Expectations for Minors**

Students/visiting undergraduates who are 16 to 17 years of age have additional IACUC training requirements.

If the student/visiting undergraduate is participating in animal-related activities, the responsible faculty member/PI must contact OARS and is required to register the minor with Environmental Health and Safety (EHS) via EHS Integrator. Please note that if animals will be present during the visit, the PI and senior lab personnel are responsible for the oversight of the student. Completion of additional forms from the Office of the Provost may be required.

Students/visiting undergraduates shall not have direct physical contact with live laboratory animals unless approved as personnel on an IACUC-approved protocol.

Students/visiting undergraduates observing or participating in activities in proximity of laboratory animals must obtain medical clearance from Employee Health.

Students/visiting undergraduates are also required to complete the following courses via the AALAS Learning Library:

1. Introduction to Laboratory Animal Medicine
2. Ethical Decision-Making in Animal Research

Instructions for institutional sign-in to the AALAS Learning Library can be found on the OARS Training page.

Students/visiting undergraduates must also complete species and procedure-specific
training prior to participating in animal-related activities. Please contact OARS to ensure that all the requirements are clear. Please review the Animal Care and Use Training Program Policy for additional information.

EHS instructional help guides are available to better assist you in the application process:

- Help Guide- Minors
- Help Guide- Visiting Undergraduates
- Frequently Asked Questions

Relevant University policies:

- Minors Participating in Research or Clinical Activities Policy
- Visiting Undergraduates Participating in Research or Clinical Activities Policy

Please let us know (OARS or EHS) if you have any questions or concerns.

**Special Instructions (SI) and Deviations from Standard Practice (DSP)**

There are two mechanisms by which researchers can specify the non-standard or special treatment of their animals.

1. A Special Instruction (SI) is directly related to the research being conducted and must be reviewed and approved by the IACUC as part of the IACUC protocol. SIs can be submitted via MAPS as part of a new or 3-year renewal protocol submission or as a modification to an approved protocol for review by the IACUC. Upon approval of the SI, OARS will then generate SI forms with the pertinent information and send them to YARC Operations.

2. A Deviation from Standard Practice (DSP) are deviations from YARC’s standard
practices. DSPs are not directly related to the research being conducted and are not part of the approved protocol. An example would be a request to use a different type of bedding or enrichment than normally supplied by YARC.

To initiate a DSP, please contact YARC.Operations@yale.edu or your facility manager. Once approved, SI and DSP forms are to be kept in the animal room with accompanying cage card stickers and Variation of Standard Care (VSC) forms generated by YARC. When a researcher wishes to “use” an SI or DSP, the appropriate sticker must be placed on the Special Instruction/Deviation of Standard Practice cage card and placed on the cage, ensuring the card is not blocked by any other cage cards. A Variation of Standard Care form is required when a PI is providing a service for either a DSP or an SI.

Examples of SIs and DSPs are below:

**Special Instructions**
- *Direct Care: Provided by Researcher*
- Cage Density
- Death as an Endpoint
- Enrichment: None
- Environment: housing in out-of-range temperature, humidity, or lighting
- Fluid Regulation
- Food Regulation
- Non-Standard YARC Caging
- Policy Exemption
- Sanitation Interval
- Single Housing
- Special Diet
- Special Water

**Deviation From Standard Practice**
- Bedding: Special
• Cage: Covering the front of cages with a towel
• Do No Enter – Experiment in Progress (procedure room, short duration)
• Enrichment: Extra
• Enrichment: Wooden blocks
• Food: Breeder diet
• Health Issues Expected
• Notify PI: Health concerns
• Save: Dead pups/animals

* New animal users providing direct husbandry and care to their animals will be required to complete the course, “Performing Animal Care and Husbandry Activities,” located in the AALAS Learning Library (ALL), to fulfill the PI Direct Care competency.

**Upcoming Facility Inspections**

The following facilities will be inspected in July 2023:

ESC (satellites), FMB (satellite), LSOG SB, LSOG B, LSOG 4 (satellite), LSOG 5, MEC, OML (satellite), SHM IG/BG (rodent and aquatics), SHM BG (NHPs), SHM 4, TAC, WWW and YSB.

Please contact Shannon Denison if you need further information. As always, please check your spaces periodically to ensure the fulfillment of IACUC expectations. The inspection checklist the IACUC utilizes to document findings is available on the OARS website.

**IMPORTANT:** If you have locked cabinets, drawers, or boxes that contain drugs or materials with expiration dates, please make sure that they are unlocked for the IACUC to inspect the contents. If you do not want to leave the container unlocked and unsupervised, then the IACUC’s expectation is that you be readily available to open
them. Contact Shannon Denison with your contact information and the areas of interest.

Policy Updates: January - March

Multiple Survival Surgery
• The definitions for “Non-Survival Surgery” and “Minor Survival Surgery” were removed.
• Under the “Requirements” section, the following statement was added:
  - The animal requires a surgical procedure prior to being adopted (e.g., spay/neuter, implant removal). The IACUC considers these as clinical procedures, because of cancer, population control, standard vet care, etc. and not part of any project.

Necropsy
• Reviewed and approved. No changes were made.

Reuse of Needles

The following statement was added to the below policies: All needles used for injections must be sterile. Reuse of needles in an individual or multiple animals is prohibited.
• Administration of Experimental Agents
• Analgesia
• Anesthesia
• Diluting and Compounding Drugs Used in Research and Teaching Animals
• Surgery-Non-Rodent Mammals-Survival-Non-Survival Surgery
• Surgery-Rodent Survival-Non-survival

As always, please contact OARS (iacuc@yale.edu) with any questions, suggestions, or concerns.
Stay safe everyone!

~OARS Team