

IACUC Protocol Submission and Review Procedures

SUBMISSION AND CERTIFICATION OF PROTOCOLS

IACUC approval is required for all animal activity at the College of Charleston facilities and for all field studies conducted by College of Charleston investigators. Investigators must submit their protocols to and receive approval from the IACUC before any animal activity begins. Investigators who engage in activity at Ft. Johnson research facilities (Grice Marine Laboratory [GML], Department of Natural Resources ([DNR], National Oceanic & Atmospheric Administration [NOAA], National Institute of Standards & Technology [NST], Hollings Marine Laboratory [HML] and associated research vessels and facilities) must submit protocols and receive approval from the College of Charleston IACUC.

All new and de novo protocols for IACUC review must be submitted by the PI via our eForm platform.

Principal Investigators (PIs) and faculty sponsors of student PIs certify that they responsible for the reporting of modifications, annual reports, adverse events, and final reports upon initial submission. This includes being responsible for following the CofC procedures for Animal Ordering and Delivery in the protocol application and once approved. Any changes to procedures or adverse events must be promptly submitted to the IACUC.

TYPES OF SUBMISSIONS

New Protocols

PIs must complete submit new protocols through the eForm platform. A complete application may include the following attachments, when needed:

- Required permits for field research
- Species chart for assemblage research
- Technical section of funding proposals
- References

The approval process for new protocols is typically 4-6 weeks. Once approved, the IACUC protocol is valid for 3 years after the initial approval date, with annual reporting requirements. If the research will continue beyond the approved three years, a de novo application must be submitted and approved prior to the expiration of the existing protocol.

Continuations

A continuing review (CR, also known as annual review) must be submitted annually for years 1 and 2. A final report must be submitted for year 3. We request that CRs and final reports be provided 2-4 weeks prior to the deadline.

De Novo Protocols

All protocols must be reviewed once every three years. PIs must submit a new application prior to the current protocol expiration (recommend 8 weeks). PIs may make a copy of the approved protocol to

submit as a De Novo protocol through the eForm platform. The *de novo* protocol will be assigned a new protocol number, and additional changes may be made prior to submission to the IACUC.

Modifications

If a PI would like to make changes to the approved protocol, a protocol modification must be submitted through the eForm platform. Depending on the type of change, the modification may undergo administrative, DMR or FCR review. The timeframe of review and approval will depend on the type of review required.

Adverse Events

An Adverse Event Report must be submitted following the occurrence of an unforeseen adverse event that negatively impacts the welfare of research animal(s), involving pain, distress, and/or death of the animal. By definition, adverse events have not been identified as potential risks or outcomes in the approved IACUC protocol.

TYPES OF REVIEW

Full Committee Review (FCR)

Review by the full committee at an IACUC meeting is required under the following circumstances:

- USDA-covered species
- Pain and distress category E
- When requested by an IACUC member following Protocol Vote or DMR procedures
- Significant Modifications if the protocol was originally approved under FCR procedures

Designated Member Review (DMR)

DMR Review by two designated members and attending veterinarian under the following circumstances:

- New or de novo protocols that do not fit the FCR criteria AND no member votes for FCR

DMR Review by the IACUC Chair and/or their designee under the following circumstances:

- Minor Modifications that do not qualify for Administrative Review
- Significant Modifications if the protocols were originally approved under DMR procedures
- CRs that do not qualify for Administrative review.
- DMR following FCR, when approved by the IACUC during the vote of a protocol at a convened meeting.

Administrative Review (AR)

Review of minor modifications to previously approved protocols and the annual review portion of post-approval monitoring may qualify for administrative review by IACUC staff. See Administrative Review procedures for details.

IACUC REVIEW PROCEDURES

ORGA Staff Procedures:

Once a new protocol is submitted, it will be assigned to the CofC IACUC panel. The pain/distress level and animal housing requirements will also be reviewed for the following purposes:

- If the pain/distress is category E, it will automatically be assigned FCR.
- From there a Voting Solicitation email will be sent to all members. Members have 5 business days to request FCR, otherwise the application will be reviewed DMR.
- The Voting Solicitation notice will state:
 - Please review the protocol and cast your vote for either DMR or FCR: <link to protocol>. You have 5 days to cast your vote. If there are no votes for FCR after 5 business days, the protocol will be assigned designated reviewers.
- Following the link in the email, the IACUC members will then vote on the review level using the drop-down function, located at the top of the protocol information.
- All protocols involving housing in CofC Facilities will also be assigned to IACUP staff for IACUP review, regardless of DMR or FCR review status.
 - The notification will be the “common reviewer assigned notification” template
- ORGA staff will send the notices to the IACUC reviewers (DMR or FCR).
- Any revisions requested by reviewers will be sent to the PI by ORGA staff. The requested revisions will be saved to the protocol and available to IACUC reviewing members when reviewing revisions once they are submitted by the PI.
- ORGA staff will provide the approval letter once all revisions have been reviewed and approved as indicated by IACUC members.

IACUP Review Procedures

- Upon receipt of the review notification of a new protocol, continuing review or modification that involves housing changes, the IACUP director will review the application and respond to the reviewer survey.
 - The IACUP reviewer survey will ask 6 yes/no questions:
 1. Do we have facilities that are adequate for the proposed species? Air quality, temp, light, etc.
 2. Do we have adequate caging/microenvironments for these species?
 3. Do we have the sanitation capabilities to care for these species?
 4. Do we have staff that are adequately trained to provide care for the species listed?
 5. Do we have adequate veterinary expertise to include these species?
 6. Can this application be approved with the animal husbandry procedures provided?

If the answer is “No” to any of the above IACUP questions the reason for the response must be communicated with ORGA staff and shared with the Chairs of the IACUC and Department Chair of the PI. It may also be necessary to include the IO with information related to institutional facilities. Reasonable efforts will be made to accommodate research plans and alternate research plans can be suggested.

IACUC Member Review Procedures

Protocol Vote

- Upon receiving the vote notification, login and review the submitted application within 5 days.

- If you think DMR is appropriate, no response is required.
- Request FCR if you believe it is appropriate.
 - Once any member request FCR, it will automatically be assigned to the IACUC and put on the agenda for the next meeting.
- If no vote for FCR after 5 business days, it will be assigned to two IACUC members and one veterinarian for DMR.
 - An alternate IACUC member can be assigned DMR if one full member is also assigned to review the protocol.
 - Note that DMR reviewers may still request FCR during their review process.

Designated Member Review (DMR)

- Review the application linked in the notification email.
- Leave reviewer comments in the application sections if any revisions are needed to that section.
- Once the protocol review is complete, press the DMR Button at the top of the application.
 - 1. Answer the Reviewer Survey:
 - 2. Leave any additional comments.
 - 3. Complete the review
- If you selected options 1 or 2 in the reviewer survey, it will automatically be reassigned to you once the revisions are submitted. The steps above will be repeated until approval is obtained.

Full Committee Review (FCR)

- Review the application linked in the notification email.
- Leave reviewer comments in the application sections if any revisions are needed to that section prior to meeting to include on the agenda. Additional comments/revision requests can also be made during the meeting.
- IACUC members will vote on the protocol after discussion. Any members with conflict of interest will be removed from the internal discussion and vote. A quorum must be present for a vote on a protocol.
- Vote outcomes:
 - Approve
 - Approve with stipulations- DMR following FCR allowed
 - Approved with stipulations- request for FCR of revisions
 - Disapprove
- The vote outcome and any requested revisions will be communicated to the PI by ORGA staff.

IACUC REVIEW PROCEDURES for MODIFICATIONS and CONTINUATIONS

Significant Modifications/Protocol Deviations

- Significant modifications, which include the (non-exhaustive) list below, will be reviewed according to original review status.
 - Change in pain/distress category
 - Addition/removal of species
 - Change in PI
 - Change in study objectives

- Changes that impact personnel safety, such as the use of hazardous agents
- New procedures that will result in pain or distress.
- Change in method of anesthesia, sedation, or analgesia.
- Protocol from non-surgery to surgery, from minor to major surgery, from non-survival to survival surgery, or from single to multiple survival surgery.
- Deviations from The Guide
- Changes in animal numbers
- If the pain/distress has been changed to category E, it will automatically be assigned FCR and put on the agenda for the next IACUC meeting.
- If originally approved by DMR, then the modification will be reviewed by DMR-Chair or their designee(s). The DMR reviewer(s) may request FCR of the modification.

Minor Modifications

- The following minor changes qualify for administrative review.
 - Change in CofC personnel other than change in PI
 - Change in funding source
 - Change in title
- All other minor modifications will be reviewed by DMR-Chair, or their designee(s), following the DMR procedures indicated above. These include:
 - Change in housing location
 - Euthanasia procedures, from one AVMA approved method to another

Continuations/Annual Renewal

- The IACUC staff may approve the annual review portion of post-approval monitoring following the Administrative Review procedures, provided that no USDA-covered species are included on the protocol and there have been no adverse events within the last year.
- If USDA-covered species, review of the CR will correspond with original level of review.

Approved by the IACUC: August 25, 2023

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