

Guidelines for the Designated Member Review and Expedited Review Processes

To ensure compliance with PHS Policy and Federal regulations, the following guidelines have been established for utilizing the Designated Member Review and Expedited Review processes at the Frederick National Lab. These review processes are utilized by the ACUC to assist an investigator in the timely initiation of modifications/refinements to his/her research project, but have been designed to ensure adequate review by the ACUC members for compliance with Federal regulations. Any ACUC member that opposes the use of the designated or expedited review process is always provided with the opportunity to call for full member review. Members are instructed to contact the ACUC Coordinator immediately if there are any questions or concerns regarding the requested review mechanism.

Designated Member Review Process:

The submitted modification undergoes the pre-review process by the Attending Veterinarian and ACUC Coordinator (as well as copies to the IBC, safety, and facility manager as applicable). Once the pre-review process has been completed, all information pertaining to the modification (proposal number, title, PI last name, and description of proposed modification) will be distributed by email to the entire ACUC. The ACUC members are given five workdays to respond back to the ACUC Coordinator. During this period, any ACUC member may reject the use of the designated review process and request that the modification be reviewed at the next convened ACUC meeting. No action is needed if an ACUC member does not have an objection to the modification and approves the use of the designated review process.

After five workdays, in the absence of a call for full committee review, the designated reviewers (consisting of the Safety Officer, Attending Veterinarian, and the Chair or Vice Chair) acknowledge acceptance of the modification in writing (signature review sheet) following consideration of any comments/concerns/queries that may have been raised during the five business day review. Once the signature review sheet has been completed by all designated reviewers, approval is granted, and the PI may proceed with the work. All modifications approved by the designated member review process will be listed on the next month's ACUC meeting agenda. Since multiple signatures are required before the final approval is released it may take several days to receive your official approval letter via email. For modifications that have been approved without stipulation and are simply awaiting signatures, please contact the ACUC office if a study needs to be initiated immediately. The ACUC office will send a notification to the facility staff, stating that there is approval to proceed.

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***NOTE:** Designated reviewers may approve the request, require modifications (to secure approval) or request full committee review. Designated reviewers may not withhold approval.*

During a convened ACUC meeting, the ACUC members may elect to “defer a proposal pending clarifications” and request that the clarifications to the proposal be reviewed and approved using the Designated Member Review process. In this situation, the Primary Reviewer obtains the requested clarifications from the Principal Investigator and forwards them to the ACUC Coordinator for distribution. The clarifications and/or revised animal study proposal form (along with the proposal number and PI last name) are distributed by email to the entire ACUC to undergo the *Designated Member Review* process as described previously.

Alternatively, the ACUC will entrust designated reviewers [Chair, LASP Director, Attending Veterinarian] the right to approve minor changes, not deemed significant (see below), without distribution to the entire committee [IBC will also be notified]:

- Changes in personnel involved with the ASP. If any individuals will be in contact with live animals, the PI must detail the procedures that they will be conducting and their experience with those procedures.
- An increase of up to 10% of the number of animals approved for use.
- Addition of or change in location where animals will be housed.

At the discretion of the designated reviewers any modification reviewed by this method can be forwarded to the full committee for review. If a designated reviewer submitted the modification, it must be distributed to the entire committee to avoid conflict of interest. Any modifications reviewed via this method will be reported at the next ACUC meeting.

Expedited Review Process:

As directed by the ACUC, this process is utilized at the discretion of the Attending Veterinarian and ACUC Chairperson. The investigator must provide justification indicating why the request cannot wait to undergo the designated member review process (five working days) or be reviewed at the next convened ACUC meeting (whichever comes first).

A modification is submitted with a request and justification for an expedited review and will go to the Attending Veterinarian and the ACUC Chair (as well as copies to the IBC, safety and facility manager as applicable) as the pre-defined ACUC designated reviewers. The Attending Veterinarian and ACUC Chair will review the document for acceptability/necessity to undergo the Expedited Review process. If the criteria for Expedited Review are met, information pertaining to the modification (proposal number, study title, PI last name, and description of proposed modification) will be distributed by email to the entire ACUC. The ACUC members will be requested to provide an immediate response. If an email response is not obtained within two hours of dissemination, the ACUC Coordinator will contact the outstanding ACUC members by phone for their responses. **IMPORTANT:** A positive response must be obtained from all ACUC members before approval can be granted. Any ACUC member may reject the

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use of the Expedited Review process and request that the modification be reviewed at the next convened ACUC meeting. If there are no requests for full committee review, then the modification is granted approval as soon as a positive response has been obtained from each ACUC member (there are no time limitations associated with this process). Upon approval, the Chair then signs and dates the modification for approval. The PI may then proceed with the work. All modifications approved by the Expedited Review process will be listed on the next month's ACUC meeting agenda. A contact listing (to include home phone, cell phone, pager, and home email addresses) will be maintained on file with the ACUC Coordinator.