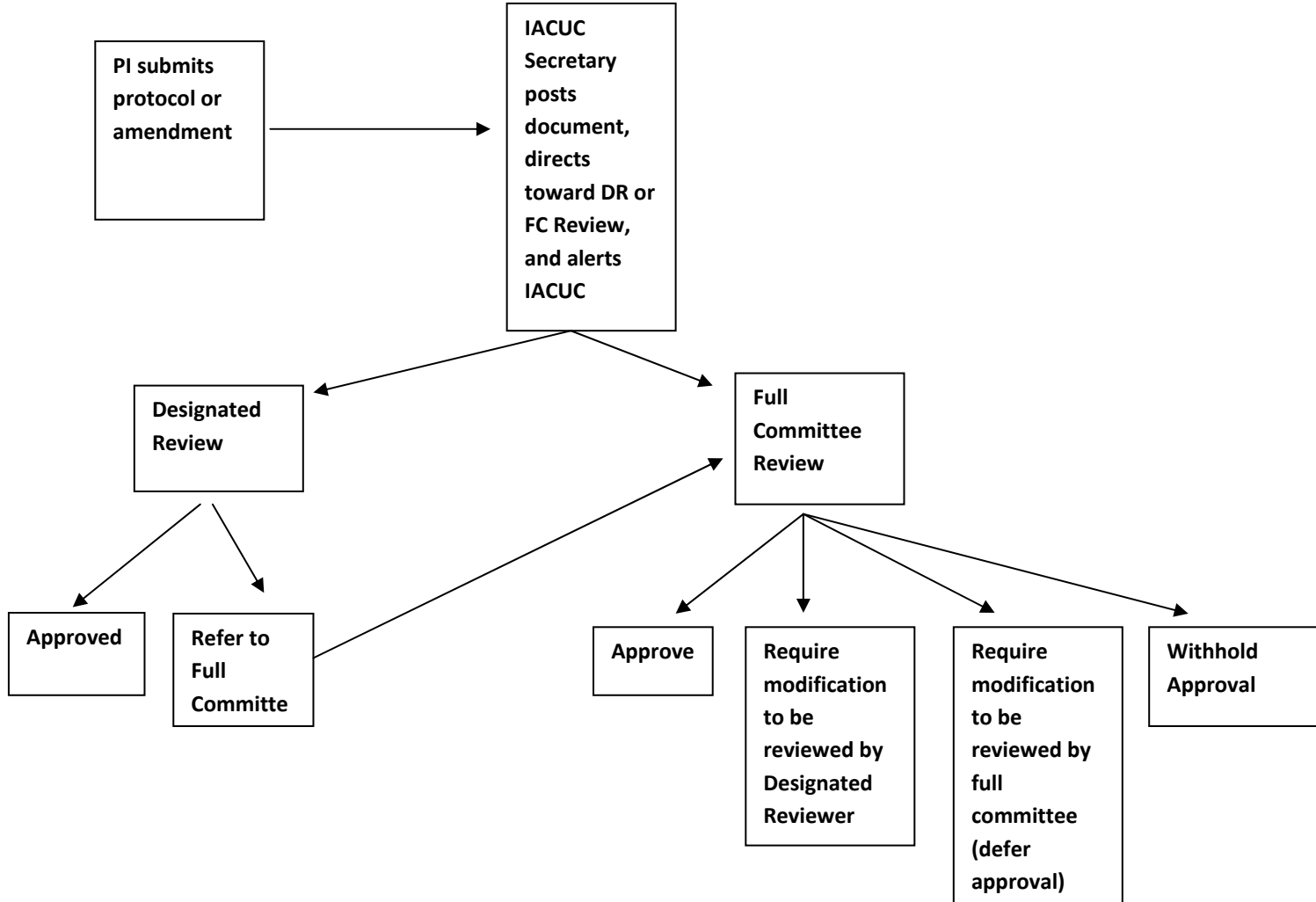


## IACUC Protocol and Amendment Review Process



### Key Points

1. IACUC secretary sends notice to renew protocol to PI beginning 60 days before expiration of protocol.
2. IACUC Secretary directs **protocols** toward DR or FC Review. DR is appropriate when all animal work will be done by FLSC staff (non-FLSC PI); and/or work will not cause greater than momentary pain or distress, even if such pain or distress is relieved by anesthesia/analgesia/sedation.
3. IACUC Secretary directs **amendments** toward DR or FC Review. DR is appropriate for minor changes such as increase in animal number is not greater than 25% of that originally approved; addition of test compounds that are of the same class as those originally approved and would not be expected to harm the animal. Major changes require FC Review and would include addition of invasive procedure; change in specie; an increase in animal numbers greater than 25% of that originally approved; any change that

would represent risk to animals or humans and which has not yet undergone review as part of that protocol.

4. Designated Review will occur when the IACUC Secretary directs a protocol or amendment to the DR process and posts it for all the IACUC to view. IACUC members are allowed five working days to offer comments or flag the protocol or amendment for full committee review. If not flagged for full committee review, the Designated Reviewer may approve (or call to full committee review).

5. If the full committee defers approval, the PI has 45 days from the date of notification to respond. If no response is received within that time frame, the protocol or amendment will be considered withdrawn.

6. Amendments for personnel changes only (other than the PI) may be approved by the Occupational Health and Training Coordinator, who is a voting member of the IACUC, serving as the designated reviewer. In this case, the amendment will not be posted for consideration by the entire IACUC.

7. Protocols are approved for three years; amendments are approved for the duration of the base protocol to which they are attached. Failure to renew a protocol by the date of expiration will result in animals not being available for use until a relevant protocol has been approved.

8. An approved Annual Review is required as a condition of continued use of animals on the protocol. Note that after three years, an entirely new protocol must be submitted.

9. The responsibilities of the IACUC Secretary in this process include:

- Evaluating submitted protocols, amendments, and annual reviews and directing them toward full or designated review.
- Alerting IACUC members when protocols, amendments, and annual reviews have been posted for review.
- Assuring the designated reviewer completes his/her review in a timely manner.
- Notify PIs as expiration dates and Annual Review dates for protocols approach.
- Notify PIs that work on expired protocols or protocols for which Annual Reviews have not been submitted in time is to be halted.
- Notify FLSC and PIs when protocols, amendments, or annual reviews are approved (or approval withheld).