

Just In Time Submissions

Summary/Purpose: To define and establish the principles of “Just-in-Time” research proposal submissions.

Definition:

The Division of Research Integrity and Compliance uses the “just-in-time” (JIT) process for submission of Institutional Animal Care and Use Committee (IACUC) approval of a federally funded research proposal. Using this process, the University may defer IACUC approval until it is determined that the proposal will likely qualify for an award. **To avoid delays in activating awards, it is the PI’s responsibility to submit the Animal Study Application to the IACUC as soon as they receive a score that may be within the fundable range. This will ensure an adequate amount of time for the PI to make any revisions to the protocol application and for the IACUC to conduct the review.** All investigators should review the NIH guidelines described at

<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-064.html> and listed below.

NIH Principles And Expectations (Applies to all funding sources)

The NIH has emphasized certain principles and expectations of the “just-in-time” process for IACUC review and approval.

- The fundamental PHS Policy requirement that no award may be made without an approved Assurance and without verification of IACUC approval remains in effect. This change only affects the timing of the submission of the verification of that review.
- This change is intended to permit flexibility and discretion on the part of the institution. It is not a requirement that IACUC approval be deferred. Institutional officials retain the discretion to require IACUC approval prior to peer review in certain circumstances of their choosing if they so desire.
- Under no circumstances may an IACUC be pressured to approve a protocol, or be overruled on its decision to withhold approval. NIH peer review groups will continue to address the adequacy of animal usage and protections in their review of an application, and will continue to raise concerns about animal welfare issues. However, in no way is peer review intended to supersede or serve as a replacement for IACUC approval. An institution that elects to use IACUC “just-in-time” bears the responsibility for supporting the role of the IACUC.
- It remains incumbent upon investigators to be totally forthcoming and timely in conveying to their IACUCs any modifications related to project scope and animal usage that may result from the NIH review and award process. Should an institution find that one of its investigators disregards his/her responsibilities, the institution may, for example, determine that all animal protocols from that investigator be subject to IACUC approval before it will permit submission of an application from that investigator.

The University of Mississippi

- The existing PHS Policy requirement that modifications required by the IACUC be submitted to the NIH with the verification of IACUC approval remains in effect, and it remains the responsibility of institutions to communicate any IACUC-imposed changes to NIH staff.
- The NIH understands its responsibility to ensure that institutions are given adequate notice to allow for timely IACUC review prior to award, and will take appropriate internal measures to fulfill its responsibility to establish timely feedback.

Source: Federal Register (67 FR 51289), PHS Policy IV.D.2.