

Overview of New Amendment Policy and Forms

The new animal protocol amendment policy - [ACUC05](#) - and new amendment forms are part of a continuing initiative to improve our animal protocol amendment process. Also, the new policy includes critical updates that are necessary to bring our animal care and use program into full compliance with [guidance from the Office of Laboratory Animal Welfare \(OLAW\)](#) on handling animal protocol amendments (specifically, significant changes).

OLAW has expanded the definition of the term "significant change." This term previously included animal protocol changes for which IACUC review was required - such changes were previously called Major Amendments under our animal protocol amendment policies. While the term still includes a set of animal protocol changes for which IACUC review is required, the term now also includes a subset of animal protocol changes for which veterinary review is permitted. This veterinary review track is similar to our Minor Amendment review track.

[Policy ACUC05, "IACUC Amendment Policy"](#)

New policy ACUC05 implements three key changes:

1. **Amendments are grouped into two categories - significant changes and minor changes** (this replaces our prior categorization system - major amendments, minor amendments, and administrative amendments)
 - **Significant changes** are changes that will or may negatively impact animal health and/or welfare. All amendments previously classified as Major Amendments fall into this category. In addition, most amendments previously classified as Minor Amendments (e.g., addition of a new study drug, addition of a procedure, addition of a strain) fall into this category. Examples include, but are not necessarily limited to:
 - Change from nonsurvival to survival surgery
 - Change resulting in greater pain, distress, or degree of invasiveness
 - Change in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC
 - Change in species
 - Change in anesthesia or analgesia
 - Change in use of experimental substances
 - Change in euthanasia
 - Increase in animal numbers
 - **Minor changes** are changes where administrative handling is permitted under animal welfare regulations or where animal health and/or welfare is not impacted. Examples include, but are not limited to:
 - Changes in personnel other than the PI
 - Changes in funding
 - Changes in off-hours access
 - Changes in lab locations used for animal work
 - Changes in vendor for approved strains
2. **Significant changes will not require a full protocol rewrite (i.e., Major Amendment)**
3. **All significant changes will be submitted using a new, comprehensive PDF amendment form**

For amendments previously categorized as Major Amendments, these changes are expected to significantly reduce the amount of time and effort involved in pre- and post-submission editing, as well as to reduce the approval timeframe. For amendments previously categorized as Minor Amendments, the amendment form will capture some new information not currently captured in the full animal protocol form (required under current regulations)*, but is expected to result in an overall reduction in time and effort in regard to post-submission editing (i.e., less back-and-forth during IACUC Office pre-review).

The policy also describes the review tracks that may be used to process animal protocol amendments:

- IACUC review by Full Committee Review (i.e., at a scheduled monthly IACUC meeting) or by Designated Member Review (i.e., review independent of the meeting schedule, but with the consent of the full IACUC)
- Veterinary review (Veterinary Verification and Consultation)
- Administrative review by the IACUC Office

Finally, the policy states which amendment form is used for each type of amendment:

- A change in PI (significant change) is handled through Amendment Form A
- Addition of personnel (minor change) is handled through Amendment Form B
- All other significant changes are handled through Amendment Form C
- All other minor changes are handled through Amendment Form D

*The IACUC Office will soon update the full animal protocol form to capture this new information

Amendment Form C (Significant Changes)

Amendment Form C (link available on 9/21) is a dynamic PDF form designed to capture the information necessary for the IACUC or veterinarian to review each significant change to an animal protocol. This form is expected to reduce the amount of post-submission editing required to process amendments by making clear up front what information is required for amendment submission. Like the amendment forms launched in January (Forms A and B), Form C will only work in Adobe Reader or Adobe Acrobat.

One small update reflected in Form C is that the preferred submission mechanism for all PDF amendment forms will now be Smartsheet. (Our other PDF amendment forms, A and B, will soon be updated to reflect this change.) The purpose of this change is two-fold:

1. Using Smartsheet to create an amendment submission portal avoids some persistent issues our Mac users encountered while submitting PDF amendment forms. (These issues have to do with the fact that Preview is the default PDF viewer for macOS and that our PDF amendment forms only work in Adobe Acrobat or Adobe Reader.)
2. The IACUC Office uses Smartsheet for task management. Recording amendment submission directly in Smartsheet simplifies the process of adding new tasks to the IACUC Office workflow.

Like Forms A and B, Amendment Form C must be completed in Adobe Acrobat or Adobe Reader.

Amendment Form D (Minor Changes)

Amendment Form D is a Smartsheet web form designed to capture changes in funding, off-hours access, and lab location, as well as other minor changes (i.e., small changes that do not impact animal health or welfare). As with Amendment Form C, the goal with this form is to make clear up front (as much as possible) what information is required for each minor change.

Note that changes in personnel other than the PI are also considered a minor changes, but addition of personnel is handled through [Amendment Form B](#) and removal of personnel simply requires emailing dfci_iacuc@dfci.harvard.edu with the numbers of the animal protocols to be amended and the name of the person to be removed.

For more information about the new amendment policy or new amendment forms, please contact the IACUC Office (dfci_iacuc@dfci.harvard.edu)