

Submitting a new IACUC Protocol

To submit a new project for review and approval:

1. Click on “Create New Project” on the menubar on the left. Fill in the information requested on that page.
2. On the next screen click the button at the bottom (under Step 2) that says “Add New Document.” (You will not be using Step 1 at this point in the process.)
3. In the **lower** blue box, choose “UMCP – IACUC Animal Study Protocol” and click “Add.”
4. Click on “Create New Wizard.” This will create an online “smart form” core document that captures necessary reportable information for the IACUC to conduct their review. This document and “Section E: Experimental Design” are REQUIRED for all protocols.

NOTE: *If you are submitted a 3-year renewal and would prefer to clone your previous Animal Study Protocol, please see “How to clone your ASP,” below.*

NOTE: *Use the “Jump To” button to return to a previous page – using the browser back button creates problems.*

NOTE: *If at any time you need to stop, click “Save & Exit.” Upon returning, click on “My Projects” in the left menubar, select the project, then click “Designer.” In the listing on the next page, click the Pencil icon to return to editing your project.*

5. Click “Next.” Fill in the information requested regarding the PI on the protocol.
6. There are always Key Personnel – including the PI--so on the next page, click Yes.
7. Work your way through the pages that follow “Complete the Funding” and “Type of Protocol” pages.
8. On the Supplemental Sections page, check all that apply and make sure to fill out each each section required, indicated in brackets next to the check boxes.
9. Complete the “Lay Summary” section and click “Next.”
10. On the “Potentially Painful Procedures” page, indicate whether the protocol will involve potential pain. If the answer is “Yes,” click “Next” and provide an explanation why alternatives cannot be used.

NOTE: *In performing literature searches for alternatives to pain and distress, it is important to consider carefully your search terms, dates of the search, and provide sufficient information regarding the outcomes of your search. If no potentially painful procedures are contained in the protocol, click “Next.”*

11. Complete the “Animal Use Justification,” “Species Use Justification,” “Animal Information,” and “Number Justification” pages, clicking “Next” after each.

12. Complete the “Animal Housing and Procedure Locations” page.

NOTE: All animal housing facilities must be approved by the Attending Veterinarian and Facility Management staff prior to housing animals. Click “Next.”

13. Complete the “Conditions Requiring Exceptions” page. In this section, indicate whether the protocol contains exceptions from the *Guide for the Care and Use of Laboratory Animals*.

NOTE: If any of these exceptions are included in the protocol, you **MUST** complete “Section M: Exemptions from Animal Welfare Standards.” Click Next.

14. Complete the “Euthanasia and/or Disposition” and “Disposition of Live Animals” sections, clicking “Next” after each.

15. Read the Principal Investigator Agreement and click “Next.”

16. The second to last screen in the protocol form states the various signatures you will need in order to complete the submission and to confirm that you will uphold the assurances described at the end of the core protocol form (aka “cover sheet”). You will do this last, just prior to submitting your completed protocol package. (See below) For now, click “Next.”

REMINDER: If you are using hazardous agents (and are required to submit “Section F: Hazardous Agents”), you must obtain approval for your protocol through DES/IBC **first** and upload your IBC approval letter to your IACUC submittal.

Attaching supplemental section forms to your protocol package

Once you have reached “Form Complete,” you have finished the “smart form” portion of the protocol submission process. Now you need to complete all of the additional documentation that is associated with specific aspects of your protocol.

REQUIRED:

- a. Section E
- b. Personal Qualifications Form(s) for all Key Personnel
- c. PI/Animal User training documentation for all Key Personnel
- d. Occupational Health enrollment letter for all Key Personnel

ONLY WHERE APPLICABLE:

- e. Sections F-N
- f. IBC approval and registration number (if hazardous agents are used)

NOTE: Additional forms required for your submission are listed at the bottom of your Animal Study Protocol form.

17. To obtain copies of each form you need to submit, click on “Forms and Templates” under “Other Tools” in the left menubar Then, be sure to set the pull-down menu at the top to “University of Maryland College Park (UMCP) IACUC, Documents for Researchers.”
18. You will see a listing of the various forms available. These forms are not “smart forms” - you will need to download and fill out the appropriate forms, then re-upload them. You will not necessarily need **every** form, - use only the forms that are listed at the bottom of your protocol form (these are listed automatically, based on the checkboxes you mark). After downloading all the forms you need, click “My Projects” in the left menubar and return to your current project.

NOTE: Any time you want to view your protocol/documents, go the menubar on the left and click on “My Projects” then click on the project title you are interested in. Once you have selected the protocol, you must then click on “Designer.” In Designer mode, you can then examine your documents (paper icon), edit them (pencil icon), or delete them (red X icon).

19. Using the downloaded templates, complete the necessary forms in your word processing program. Please fill out each form *completely*. Please resave the file **with the original file name** (e.g., “Section E Experimental Design”). Keeping the file name the same helps the system present the IACUC staff with the most recent version of the file, if you make any subsequent changes.
20. When ready, click Designer to return to the Designer page and click the “Add New Document” button.
21. Under Document type, Select “Other.” You may enter a description of the document if desired.
22. Because you are uploading the Word/PDF forms you have filled out, you will next need to select File: “Choose” then select the title of the file you wish to upload. Click “Attach” to upload the document to the package. Repeat for all necessary forms.

Signing your submission

23. The next to last step in the protocol submission process is to sign the protocol. To do this, click on “Sign this Package” in the lefthand menubar. This takes you to a page that states that you “certify that to the best of my knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.” Select the appropriate title from the drop-down bar and click “Sign.” You will be required to provide your IRBNet login information when signing a package.

NOTE 1: *By this signature, you verify that you agree to the assurances stated in Section VIII. Principal Investigator Agreement and Signatures, which is found on page 5 of the smart form (“coversheet”).*

NOTE 2: *Please read Rights and Responsibilities of Principal Investigators in the Document Library.*

Submitting your protocol

24. When you are finished obtaining all necessary signatures and are ready to submit, click on “Submit This Package” in the lefthand menubar.
25. This page asks you to select a board . The UMD IACUC should be listed in the larger window, and you simply select that board and continue.
26. On the next page, use the pulldown menu to select the type of submission you are entering, and add any notes you would like to communicate to email recipients listed at the top of that window.

NOTE: *Once a package is submitted, it is locked and cannot be modified. Please do not submit until all documents are complete. In the event you accidentally submit the package before it is ready to be reviewed by the IACUC, please contact the IACUC staff immediately to request your package be unlocked. Be ready to provide the IRBNet ID number or internal R number (e.g., R-X-X).*

NOTE: *When submitting for the first time, or when submitting a protocol for a new area of method or study, please feel free to contact the IACUC office or the University Attending Veterinarian for advice on any procedure or submission process. This will allow you to take care of many problems before the protocol is reviewed, and will likely expedite the approval process.*