Introduction to a-tune tick@lab
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a-tune tick@lab – the IACUC and IBC’s New Electronic Submission and Review System

The Institutional Animal Care and Use Committee (IACUC) and Institutional Biosafety Committee (IBC) has transitioned to an electronic system for submission, review, and maintenance of IACUC and IBC applications. The software also integrates research, teaching and testing protocols, animal procurement and management, as well as veterinary medical records.

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  IACUC and IBC related topics
  Software functionality

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  Software functionality
What we will cover

• General overview
• Logging-in and orientation of software
• Creating a new protocol
• Completing an IACUC/IBC form
• Submitting for review
• Responding to review comments
• Filters – Finding your protocols
• Creating an IBC from an IACUC
• Compare feature
What is a-tune tick@lab?

- Web-based protocol submission system for IACUC and IBC
- Integrate protocols, animal procurement and management, veterinary medical records
- Track animal orders and use

IACUC and IBC applications are completed, signed, and submitted completely in the system – no more hand-written signatures or Word document-based applications.
Benefits

- One document, always current with amendments incorporated
- Available in one place 24/7 from anywhere
- Mobile friendly
- See where protocols are in review process
- Meticulously selected and customized to match current forms
- One-stop-shop

- Amendments are made within the existing approved protocols which means the most current version is always available
- Since this is a web-based system, you can access your protocols from anywhere at anytime with your username and password
- a-tune has a mobile version for tablets and phones
- You will be able to track the progress of your submissions based on the document status of your protocol
- We customized the software extensively to match our current forms and review processes as much as possible
- ORR, AV, and LAR have worked together to make this a one-stop shop from protocol submission to animal ordering and veterinary records
a-tune tick@lab is live at ISU

- Went live at ISU on April 4, 2018
- All IACUC and IBC Protocol submissions go in a-tune tick@lab as a new protocol
  - This includes any amendments and/or annual reviews to protocols currently approved in the paper format
- We continue to schedule trainings, please visit the ORR website for the latest offerings: [www.compliance.iastate.edu](http://www.compliance.iastate.edu)

The test environment at [https://vpr007.its.iastate.edu/tickatlab_test/default.aspx](https://vpr007.its.iastate.edu/tickatlab_test/default.aspx) is for PRACTICE.

For protocols that you plan to submit to their respective committee, you must use the production environment at [https://vpr009.its.iastate.edu/tickatlab/default.aspx](https://vpr009.its.iastate.edu/tickatlab/default.aspx).

There is no connectivity between the test environment and the production environment, so be sure when you go to add an actual protocol that you use the production environment. We will not be able to transfer a protocol from the test environment to the production environment. You would have to re-enter it in the production environment.

Register online for one of the a-tune training sessions, or, for more information, please contact Jen Walker ([jlwd@iastate.edu](mailto:jlwd@iastate.edu)) or Cara Loy ([cara@iastate.edu](mailto:cara@iastate.edu)).

Other ways you can help with the transition:
- Closing studies that are no longer active. Active studies will need to be entered in the system as new protocols – no need to do this if your study
is already complete.
Access for tick@lab software

- An account is required before you can log into a-tune tick@lab
- Request an account via the excel file on the ORR Website
- Once you have an account, log in with your ISU NetID and Password
- The software works in all web browsers
- Off campus, you will need a VPN connection

The system administrators must add users to the a-tune software before personnel, including the PI, are allowed access to the system.

Fill out the New User Request excel file that is available on the ORR website, under IACUC or IBC a-tune Program Information
https://www.compliance.iastate.edu/committees/iacuc/a-tune-program-information

The person listed in the PI column will have a team created and all personnel listed on the rows will be on their team.
Each excel file would have the same PI name in all rows and that PI's name will be the name of a Team.
To have Co-investigator status, mark the columns “Will be on IACUC or IBC protocols” AND “Will edit IACUC or IBC protocols.”
Use an X in the cells under the column headings that apply to each person
Email this file to iacuc@iastate.edu or bphc@iastate.edu

You will need to have ISU’s virtual private network (VPN) set up on devices to access the system when not connected to the ISU network. Instructions are found on the ITS website: https://www.it.iastate.edu/services/vpn
Emails

- Emails will be sent automatically from tickatlab@attune.com during status changes
  - Some emails do not require any action
- Emails will include a link to system
- Annual Review reminders will also come from this email
- No longer a 45-day waiting period between expired and closed protocols
- If your protocol expired, you will need to submit a NEW protocol for review
  - You can use the Duplicate file feature to do so

The software only sends one email for status changes. Please be sure to keep this in mind and respond promptly.

The IACUC and IBC Office won’t be reminding you if you have something pending.

Please note: you will receive emails as the protocol moves through the process. Some emails do not require any action. Be sure to read the email to determine if action it required.

If you let a protocol expire, you will have to submit a new protocol to reestablish approval. However, there is a duplicate file button in the right-click menu of the file-level that will make this quite easy.
TEST vs PRODUCTION ENVIRONMENTS

• The TEST environment is used for training and is a sandbox: https://vpr007.its.iastate.edu/ticketlab_test/default.aspx
  You can use it to practice and learn, but the information in this environment will NOT be transferred into our final PRODUCTION environment
  • Do NOT put your protocols in the TEST environment – this environment is only for training purposes

• The PRODUCTION environment: https://vpr009.its.iastate.edu/ticketlab/default.aspx
  • In this environment, ongoing and upcoming protocols are entered and reviewed.
Log in to tick@lab software

- Test environment: https://vpr007.its.iastate.edu/tickatlab_test/default.aspx
- A pop-up window will appear
- Use your NetID and password to log in
- If you do not see a pop up when visiting that site, allow pop-ups in your web browser

The exercises and practice should be done in this TEST environment.

The PRODUCTION environment must be used for any actual protocols: https://vpr009.its.iastate.edu/tickatlab/default.aspx
Place the URL on the slide into your browser’s address bar and hit enter.

The Log In Pop Up window will appear.

Enter your NetID in the field for Username Field.

Enter your normal password for your email in the Password Field.

By registering for this training session, a profile in the TEST environment was made for you. To gain access to the PRODUCTION environment, fill out the excel file for requesting new users and email it to iacuc@iastate.edu.
Pop up windows must be allowed in your web browser.
This is an example of a homepage in tick@lab for a PI.

Other roles may have slightly different modules visible and available for use.

Basic controls:
- Logout – logs out of a-tune
- Start – takes you back to the homepage
- Profile – user profile information (name, title, email, etc.)
- Refresh – refreshes the page (use this instead of the browser refresh)
- Help – pop-up with a lot of help information for the system. We recommend using this as a helpful resource.
- Info – information regarding the current version of the software
Right Click on Macs & iPads

- Macs can use CTRL + click to mimic a right click
- Macs and iPads can use “Switch to Mobile” to have a hand hover over right click menus

Many controls in a-tune tick@lab rely on right click drop down menus.

On Mac computers, the CNTL key can be held down while clicking to mimic a right click.

On iPads, you can switch to “MOBILE VIEW”, which will create a hover hand at sections where right clicking is required.

Click on the hand to open that menu and click again to select an option.
Navigate to Protocol Forms

- Click on the blue banner text “Files & Documents”

The IACUC and IBC protocol forms are located in the “Files & Documents” section of a-tune tick@lab.
Choose Committee

The tab that is darker blue is the one that is selected.

If you only see one tab, that means you have access only to that committee. You simply request access for the other one from ORR if you want to submit the other type of protocol.

The controls are the same for both tabs.

The IACUC tab holds your IACUC protocols. The IBC tab holds your IBC protocols.
Open the list of Files

- Click on the plus sign in a blue box just left of the word “Files”

A list of protocol files will open.
The File List

- You may have Files (protocols) in Test or Production that you did not put in
- Test has test data the a-tune admin team may have added
- Production has skeleton protocols that LAR added if you needed to order animals

If you have any protocols started, they will appear in this list.

You may have protocols that you have not put in. The a-tune administration team have added test data based on actual protocols in the TEST environment.

You may have protocols in the PRODUCTION environment that you have not added yourself. LAR staff have added skeleton protocols (with much of the protocol information missing) in order to utilize the animal management portion of the software. You will still need to add any such protocols to the PRODUCTION environment and the animals on the skeleton protocol will be moved over to the protocol you enter.
“SKELETON” Protocols – LAR Users

• Created by LAR for animal management of paper protocols
• May be used to place animal orders
• May NOT be used to modify or renew that protocol
• Animals on a SKELETON protocol will be transferred from it to the PI’s approved full protocol once it is submitted and approved in a-tune

The information included in SKELETON protocols is only the PI, IACUC protocol number, title, approved species, and animal numbers (no study information)

SKELETON protocols are not considered to be working protocols

Although you may see your protocol (with the word SKELETON in the title) in a-tune, the protocol is NOT complete and approved in a-tune

SKELETON protocols should only be used by the PI or their staff to place animal orders with LAR procurement and are not to be edited or used in any other way

When you submit a new protocol in a-tune that is complete and approved, LAR will transfer any live animals you’ve had on the skeleton version to the new protocol and close the skeleton version of the protocol
The file is the protocol which contains a group of documents. Documents are different versions of the protocol. The user must open the File in order to see the list of documents inside.

Files are opened by clicking on the blue text of the protocol number. (Clicking on the folder icon does NOT open the folder)

Documents must be checked out for the user to be able to edit them. Documents must be checked back in for other users to be able to check them out and then edit them.

Left clicking on the File title opens or closes it. Right clicking on a File title opens a menu of actions.

Left clicking on the Document title opens the document. Right clicking on a Document title opens a menu of actions.
The File right click menu allows you to Duplicate the File or Create an IBC from an IACUC.

The Document right click menu allows you to open the document, print it, Check-IN or Check-OUT the document, and move the document to the next Workflow step, like For Signature.
Check out a Document to Edit it

- Right click on the document title and select “Check-out document”
- When creating a NEW protocol, it is automatically checked out to the creator
- Only one person can have a document checked out at a time

Only one person may have a document checked out at a time, and only that person may edit the protocol at that time.
Icons for Checked out documents

- No Icon = No one has it checked out
- Green Checkmark = You have it checked out
- Red Circle/line = Another user has it checked out

You can tell who has a document checked out in the Checked-out by column.

If you wish to edit a protocol that another user has checked out, please contact them.

If a colleague has the document checked-out and they are out of the office (not working on the protocol), ORR also has the capability of checking-in a document for you.
Pre-set filters are available in the “My Filter Sets” drop-down menu. These are common filters used across all users.

If instead you set the filters manually, you must also Click on the Apply Filter Button.

If you are seeing a list that has been filtered and then want to see all files, click on the Reset Filter button.

You can also make custom filters by choosing parameters in the Document filter, and then clicking on the Apply Filter button. The list of files and documents under the word files will populate with only protocols that meet your criteria.

Click the Reset filter button to clear the filter you’ve used to make the list of files and documents complete.

If “Last, Active” is engaged, you will only see the most recent version of that document listed under a file. If a protocol is approved, you will only see the approved version, unless you have started an amendment or annual review, in which case you will see the last approved version AND the amendment or renewal version that is in progress. If “Last, Active” is NOT engaged, you’ll see every version that protocol has gone through.
Create a New Protocol

Clicking on the New button launches a new protocol in a pop-up window.

If you click New, and nothing happens, be sure you have allowed pop-up windows and then click new again.

The type of protocol (IACUC or IBC) that is launched correlates with which tab you have highlighted. If the IACUC tab is darker blue, you have that tab highlighted and the New button will launch an IACUC protocol. If the IBC tab is darker blue, you have that tab highlighted and the New button will launch an IBC protocol.

If you can not see the New button, click on the + sign just left of the word “Files”. This opens the list of files and documents and that is where the New button is located.
Allow Pop Ups

- a-tune tick@lab uses pop up windows in many areas
- If something does not work as expected, always check that pop ups have been allowed
- Each browser type has its own way of allowing pop ups

Chrome: when a pop up is blocked, note the red box with a white x in the address bar
Click on this icon and allow popups for the tick@lab site

Chrome Popup information: https://support.google.com/chrome/answer/95472?co=GENIE.Platform%3DDesktop &hl=en

Firefox Popup information: https://support.mozilla.org/en-US/kb/pop-blocker-settings-exceptions-troubleshooting#w_pop-up-blocker-settings


Edge Popup information: https://www.isunshare.com/windows-10/enable-or-disable-block-pop-ups-in-microsoft-edge.html

Clicking the New button launches this “Initiate File and Document Wizard” window.

The Document template is automatically filled with IACUC if you were on the IACUC tab when you clicked the New button, or IBC if you were on the IBC tab when you clicked the new button.

Proceed by clicking the Next button.

If you want to create an IBC protocol but you see “IACUC Protocol” in the document template drop down, you must close that window. You go back to the list of Files and Documents, and then click on the IBC tab. Then click on the New button, and this “Initiate File and Document Wizard” window will now have the IBC template automatically in the Document Template area.
Creating a New Protocol

This is where you add your title. If you need to change the title later, you may do so within the document on the General Information tab.

Notice that the Protocol Number is auto-generated.

The number format will be either:

- IACUC – 2 digit year- a 3 digit unique ID number
- IBC – 2 digit year – 3 digit unique ID number

Click the “Save and open document” button. This takes you into the actual protocol form.
Orientation to the Protocol Structure

Tabs down the left side indicate categories.

Clicking on a tab changes the questions in the center of the page.
Notice in the middle section of the page there is a Protocol Category section with IACUC type. If you had created a new IBC, this would say IBC type. The drop down allows you to choose the type of protocol you would like to create. This mimics our current paper system so you may choose from the following options:

For IACUC:
- Research
- Teaching
- Breeding

For IBC:
- Research/Teaching
- Breeding
- Field Release
- Exempt

When you select a type, the tabs on the left and the questions throughout the form do change based on the content needed for that protocol type. For instance, breeding protocols are the only type with breeding related questions.
Overview of Controls

- The **Back** button returns you to the previous page of list of files & documents, but it does NOT save.
- The **Attachments** button allows you to attach a document.
- The **Review** button is used in the review process of the protocol.
The attachments window can be used to add any additional reference material to your protocol (i.e. grants, permits, tables, journal articles, etc.)

To add an attachment follow the following steps:

- Click the “Attachments” button in the menu bar
- In the pop-up, make sure the correct tab on the left is selected where the attachment is referenced in the protocol.
- Click “Choose File”, and find your attachment wherever it is saved on your computer
- Click “Open” in the search window
- Add a description of the attachment in the “Description” box
- Click the “Add” button
- Once the file is attached, it will show up in the bottom sections under “Attachments”
- Repeat if necessary for other attachments, or close the window
Overview of Controls

- The Action button displays a drop-down list of options
- This is where you SAVE the document

Save: Saves the file – use if you want to save and keep working in the protocol.
Save & Check-in: Saves the file and checks it in so that another person could check it out to edit it.
Save New Version: Saves a separate and new version of the file.
Print PDF: You would again choose your type of form. This prints a pdf of the file, and displays it in a pop up window. You can print to paper from the pdf.
Compare Version: Allows you to select a previous version of the file to compare this open version against.
Validation: Runs the file through a series of checks and will display messages at the top of the screen under “BACK TO MAIN MENU” that tell if validations were successful or not.
Overview of Controls

- The **Workflow** button displays a drop-down list of options
- This is where you **SIGN and SUBMIT** the document

The options that appear under Workflow change based on the status the document is in (Draft, For Signature, IACUC/IBC office review, etc.)

For Signature moves the protocol into the signatures state to be signed by the PI. This is the first step in submitting to the IACUC/IBC office.
This system does NOT auto save

• We recommend you save often
• Under the Action drop down menu
• The system times out after an hour, and any unsaved changes will be lost
• Closing your browser window does not save and unsaved changes will be lost
Notice tabs down the left side. These tabs help group the questions of the protocol.

When you click on a tab, it will turn a darker blue. The content in the middle section of the form will change to include the questions relevant to that tab.

Many of the questions are radio buttons or text boxes. Some questions use software specific controls that we will explain in this training.

We strongly recommend filling out the protocol form starting with the top tab and working down. Some of the questions build on information from previous questions. For instance, the Experimental Design tab questions may not be answered until you have entered information on the Species tab.
<table>
<thead>
<tr>
<th>Personnel Category</th>
<th>Roles</th>
</tr>
</thead>
</table>
| Principal Investigator                    | • Create a new protocol  
• Edit and view protocols  
• Order animals  
• Can only be one  
• Must also be signer  
• Signs to submit |
| Co-Investigator                           | • Create a new protocol, change PI  
• Edit and view protocols  
• Can be multiple  
• Order animals  
• Copied on emails |
| Research Personnel (including animal ordering) | • View protocols  
• Order animals  
• PI & Co-I(s) must also be listed here |
| Research Personnel (excluding animal ordering) | • View protocols |
| Signer                                    | • Signs to submit  
• Can only be one  
• Must also be PI |
| Pre-reviewer                              | • A colleague that provides comments prior to submitting  
• NOT pre-review from IACUC/IBC office  
• Vet pre-reviewers are assigned by IACUC office |
There are Edit selection buttons under each category of personnel and there are several categories. They each have different roles.

The Signers category personnel will be required to sign the protocol before it is allowed to be submitted to the IACUC or IBC Committees.

This system is eliminating the Department Chair signature that was required on the paper form.
Personnel Tab - Adding Teams

- To find personnel on a Team, click the “+” next to Teams
- Find your team name and click on it
- Add individuals by clicking their name
- Add entire team to category by clicking the green “+”

When you click on a person or team to select them, they appear in a list at the very bottom of this window. Be sure to scroll all the way to the bottom to see this list.

Be sure to add PI and CoPI to “research personnel animal ordering” group

Clicking the “+” sign shows a list of teams or groups. Clicking the word “Teams” shows a list of individuals in alphabetical order.

Clicking the green “+” to the right of a group name adds all members within that group.
For a list of all personnel in alphabetical order, click the **teams**

Click the name of the person you wish to select

When you click on a person or team to select them, they appear in a list at the very bottom of this window. Be sure to scroll all the way to the bottom to see this list.

Be sure to add PI and CoPI to “research personnel animal ordering” group

Clicking the “+” sign shows a list of teams or groups. Clicking the **word** “Teams” shows a list of individuals in alphabetical order.

Clicking the green “+” to the right of a group name adds all members within that group.
Adding Personnel - Finalizing

- A list of the selected personnel will appear at the bottom of the pop-up window (you will need to scroll down)
- Delete any personnel you need to
- Click “Apply current selection” to put those names into the personnel category selected

If you know that a person is in a-tune, but you can’t find them under this category, they likely do not have the role that you are trying to put them under. Contact ORR to give that person that role or put this information into the table at the bottom of the page for new personnel – just indicate which role you want this person to have.

Once a person is added to your team, they will always show up in your team, unless you ask ORR to remove them.
Co-Investigator Creating a Protocol

- Add yourself as Co-Investigator first
- Delete yourself and add correct PI in Principal Investigator and Signer categories
- Removing yourself from PI before adding yourself as Co-Investigator will lock you out of the protocol
Adding a New User

- The personnel tab has a table at the bottom where you can indicate you have additional users that are not already in the system.

The IACUC or IBC Office will add the people in this table as users in a-tune.
Adding Rows to a Table

- Click into the table and right click on text
- Hover over “Row” in the menu
- Select one of the “Insert Row” options
• Euthanasia training should also be selected for planned and unplanned euthanasia, as the individual performing this will need to have taken training.
• As a reminder, training must be completed prior to submission to the IACUC/IBC office.
• The clear grey boxes (not the blue) are the ones to select.
• Please do not select the grey boxes by the headings.
• Only the CITI and AALAS options are required.
• You may utilize the Optional trainings for your records.
• You must click the Refresh button to have the table populated. If adding personnel to an approved protocol or after the last "refresh", click Refresh button again.
• The PI and Co-Investigators must be added to the personnel category (on the personnel tab) in order for them to appear in this table. If they are not in the table, please go back to the personnel tab and add them to the category Research Personnel - Animal Ordering.
IACUC – Species Tab

- Click the Edit selection button
- In the pop-up that opens, click on the name of the species you are using (not the blue open box)
- Multiple species may be selected
- Click on the Apply current selection button at the bottom

Multiple species can be added in this pop-up. All species selected will appear under “Current selection” section of the page.

You must click on the text of the species name (not the blue box to the left).

When the species listed at the bottom of the window is complete, click the Apply current selection button.
Click the “Add new row” button. Fill in the pain category, species and number of animals.

If you need more rows, click the “Add new row” button and create as many rows as you need. If you have one species with different pain categories, you use multiple rows, one for each pain category.

**NOTE:** The numbers of each species here MUST match with the numbers of each species on the Animal Numbers Tab or the protocol will not be allowed to be submitted. This is one of the validation steps.
Repeat for each experimental design.

You may add one experimental design or multiple. The number is up to you and what fits best with your protocol.

Teaching protocols – it is recommended to use one experimental design per teaching lab.

Click on the + sign on the line for species to open a drop down list of species (that is from the species you selected on the species tab).

For each experimental design created, a tab will be made and questions under that tab will appear. Each tab needs to be filled out.
Notice that there is a tab for each experimental design you created on the experimental design tab.

You must add animal numbers on each tab (except on the total tab).

Click the Add/Edit Calculation button to launch a pop up window.

If the same animals are used for multiple designs, count the animals on the first design and indicate “0” for subsequent designs. Then, clarify this in the animal numbers justification question.
IACUC –Animal Numbers Tab

1. Move the species to the right-hand box
2. Click on the blue text “New row”
3. Enter maximum number of animals
4. Click the “Apply calculation” button

It is critical that you get the name of the species you want to do the calculation for into the right-hand box.

You can move a species to the right-hand box by double clicking on the species name, or by highlighting the species and clicking on the double arrow.

Click on the blue text that says new row.

The IACUC office only requires a **maximum** number of animals used. The animal number module has the function to use calculations, but this is not required.

If multiple experiments use the same animals, these animals should only be counted once. If the animals have been accounted for in the first experimental design, use “0” for subsequent calculations.

If you want to learn more about the calculator function of this module, please refer to the Help menu in a-tunes.
The total tab shows you all numbers for each experimental design.
IACUC – Animal Numbers Validation

- One major validation check is that the number of each species matches between:
  - The USDA Pain Category table on the Species Tab
  - The Animal Numbers Table on the Animal Numbers Tab

You can save your protocol before the validation is successful.

You can NOT submit your protocol to the Committee for review until the validation is successful.
Validation Check Examples

- Successful Validation:

- Failed Validation:
Click the Add/Edit Procedures & Surgeries button.

A pop-up window will open where you can add procedures and surgeries, and indicate which species will experience which procedure or surgery.

Two types of Procedures & Surgeries

“Procedures & Surgeries”
  Pre-entered
  Select, Apply, Add, Accept Selection

“Manually Described Procedures & Surgeries”
  You add the Name and Description
  Add, Accept Selection
In the top section, use the + sign to open a list of pre-entered procedures and surgeries. Locate the procedure of interest, click the check box next to it. You may select several at once. Once you have your list, it is important to select the Apply button, and ALSO click the Add button.

If you don’t see the procedure/surgery you want on your protocol, move down to the section labeled Manually Described Procedures & Surgeries. Ignore the Type drop down, we are not using it. Fill in the Name and Description, and click on the Add button just above the Name.

Each time you click Add, it will add that procedure or surgery to a list at the bottom of this pop-up window under the heading Selected Procedures & Surgeries.

If there are multiple species on an experimental design, be sure to select the appropriate species to each selected procedure or surgery on the “Assign species” tab.

*** It is important to click the “Accept Selection” button when you are done adding procedures and surgeries. This is what adds them into your protocol.
Procedures & Surgeries

Please read the pre-entered procedures or surgeries descriptions that are populated from the database, and edit them to reflect what you will actually do for your protocol.

The far right icon on the text box toggles on and off a track changes type feature.

- Red strikethrough indicates deleted text
- Green underline indicates added text
IACUC - Anesthesia & Analgesia Tab

- The top two tables are for pre-entered procedures/surgeries
- Third table is for manually-entered procedures/surgeries

<p>| Anesthesia | |
| --- | --- | --- | --- | --- | --- | --- |</p>
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Species</th>
<th>Drug</th>
<th>Friday (after morning pre-op)</th>
<th>Oral</th>
<th>Rectal</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>

<p>| Analgesia | |
| --- | --- | --- | --- | --- | --- | --- |</p>
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Species</th>
<th>Drug</th>
<th>Monday (after morning pre-op)</th>
<th>Oral</th>
<th>Rectal</th>
<th>Frequency</th>
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<td></td>
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</tbody>
</table>

<p>| Drugs for Non-anesthetized Procedures | |
| --- | --- | --- | --- | --- | --- | --- |</p>
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Species</th>
<th>Drug</th>
<th>Monday (after morning pre-op)</th>
<th>Oral</th>
<th>Rectal</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
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Protocol Submission for Review - Step 1

- Workflow Menu
  - Select “For Signature”
- A pop-up window will appear
  - You may make a comment, this is permanently there
- Click “OK”
- Changes Status to “Signatures”

Save one last time before submitting.

Must be in a state that includes a “For Signature” option under workflow (e.g. Draft, For Revision)

The “For Signature” option is the first step in the process for submitting for IACUC or IBC office review.

Adding a comment to the pop-up window is optional.

Do not select “Pre-Review” unless you have a pre-reviewer assigned on the personnel tab. **Pre-review is not a pre-review by the IACUC/IBC office.** It is intended for a colleague to review the protocol **prior to submission.** **USDA pre-review is administered by the IACUC office.**
It may seem redundant to send the protocol to the “For Signature” state and then to the “Signatures” state, but this flow is in place for situations where a graduate student or scientist has created and drafted the protocol. They would send the protocol to the “For Signature” state, and the PI of the protocol would need to log in and sign the protocol in the “Signatures” state.

If you are both the drafter of the protocol and the PI, you do both steps.

As the PI, within the protocol that is in the “Signatures” status, go to Workflow. Click on “Signatures”. A pop up appears. As the PI, sign with your NetID’s password. Click the “Sign” Button.

A timestamp of your signature will appear in the pop-up window.

Close the window by clicking the text “Close Window” in the top left corner. This refreshes the database. Closing the window with the top right “X” does not refresh the database. You would want to click on the word Refresh to do so if you closed it that way.

The protocol is then routed to the office in IACUC or IBC Office Review status.
Protocol Review Process

- Once signed, the document moves from the Status “For Signature” to the status “IACUC Office Review” or “IBC Office Review”
- The protocol is now in the review process and the PI/Personnel may not make any further changes until or if it is sent back for revisions
- The Office will review the protocol and if there are any questions, they send it back to you in the “For Revision” state
- You will get an email that there are comments to address

If you realize you need to make a change after it’s been submitted, you will need to contact ORR at 294-6288. You won’t be able to make any changes when the protocol is under review.

Any document in the status “For Revision (xxx)” is ready for you as the PI to respond to review comments.
Address the comments within the protocol itself, but also respond to the comment in the review module to state if the item has been updated/corrected/etc. OR respond with information or justification for not making recommended changes in the protocol itself.
Comments are made on the tabs that are specific to where the concern is in the protocol.

Note that the “All” tab at the bottom is selected, which is why all comments appear in the main window.

Address the comment within the protocol itself, then say fixed or done in response to a comment.

If you need to provide justification, please do so in the responses area of the comment.
You must have the document checked out to make any changes into the protocol itself. If you are in the document (protocol), go to the Action menu drop down and select “Check out” to check it out.

Remember to use the Action Menu to Save it before you submit it back to the office for review.

Response to comment can be as simple as “addressed”. The most important thing is making the changes **within the protocol itself**.

Note once you have clicked IACUC/IBC Office Review, the document will now be in the IACUC/IBC Office Review state again.

The workflow menu does change based on the state the document is in.
### Statuses that Require PI Attention

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<th>Status</th>
<th>Meaning</th>
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| Draft  | • Protocol is in progress  
         | • Has not been submitted |
| For Signature | • Protocol has been sent to for signature  
                     | • PI needs to review, send to “Signatures” and sign |
| Signatures | • PI signs the protocol in pop-up window  
          | • Automatically sent to Office Review after signing |
| For Revision (IACUC/IBC Office Review or Pre-Review) | • The committee, office, or pre-reviewer has comments that need to be addressed and sent back to the office |
| Amendment/Annual Review | • An editable version of the protocol  
                         | • Fill out the amendment and/or annual review tabs  
                         | • Make any changes to protocol before signing and submitting |
| Pre-review | • Not a pre-review by the office, contact the IACUC/IBC office if sent to inadvertently  
             | • If USDA-covered protocol, the protocol is in review by a veterinarian  
             | • If not your protocol, you may have been assigned as a pre-reviewer |

Please note: you will receive emails as the protocol moves through the process. Some emails do not require any action. Only the above document statuses require your attention.

**Both Committees:**
- **Draft Status:** A user has created and saved a protocol
- **For Signature:** A user has completed the protocol and the PI needs to sign it
- **Signatures Status:** The PI signs the document
- **For Revision Status:** May occur following IACUC (IBC) office Review, DMR review, or a pre-review

**IACUC:**
- **IACUC Office Review Status:** The document has been submitted to the IACUC office
- **IACUC eReview and DMR:** the committee is currently reviewing the protocol
- **Full Committee Review Status:** The document will be reviewed at the next full
committee meeting

IBC:
IBC Office Review Status: The document has been submitted to the IBC office
Subcommittee Review Status: The committee is currently reviewing the protocol (annual reviews and minor amendments)
Full Committee Review Status: The document will be reviewed at the next full committee meeting
Annual Reviews and Amendments

From an approved protocol document:
- right click to select annual review or amendment
- This creates a new version, which is editable
- Make changes throughout the form as desired and fill in the appropriate amendment and/or annual review tab
- Once approved, the amendment or annual review version will replace the approved version, becoming the new approved version

Reminder: only one submission can be submitted and in the review process at a time. Keep this in mind if your annual review date is approaching or you have multiple amendments.

You may NOT have an amendment under review and then submit another amendment or annual review concurrently. You will have to wait until the first amendment is approved before you may start another amendment or an annual review.

Only approved protocols have the option to do an annual review or amendment.

Clicking on the annual review or amendment option creates a new version of the document.

If the controls within the protocol are greyed out, go to the Action Menu and click on Check-Out.
Make changes as desired throughout the form and also fill in the appropriate amendment and/or annual review tab, which have questions specific to an amendment or annual review, respectively.

You can do an annual review **and** an amendment at the same time:
- Select “Annual Review” on the right click drop down menu from the document list.
- Make desired changes in the protocol.
- Complete both the amendment and annual review tabs.

Only one submission (version) may be in the review process at one time.

Once changes have been made and the protocol is ready for submission, use the workflow menu to send it to For Signatures, then again to Signatures. Once you put in your password, the document will automatically be submitted to the IACUC or IBC office.
Closing Protocols

• From an approved protocol document, right click to select amendment or annual review
• This creates a new version, which is editable
• Go into the protocol and navigate to the Protocol Closure tab
• Select “Yes” to the Protocol Closure question
• Sign and submit the protocol
  • The IACUC/IBC office will then close your protocol in the system
Duplicating a File

Right click on the file title to get a drop down menu

- After clicking the “Duplicate File” button, a new draft will be added to your list of protocols
- The new protocol has a new number
- Review the protocol and edit as applicable to the new project
- You can change the file title by selecting “Edit File” on the new protocol

The File level of a protocol has a drop down menu (from a right click) that includes an option to Duplicate File. The Documents of a file do not have this option. You must right click on the text of the File level of a protocol to have this option.

When you choose the Duplicate File option, a new file is generated and it will have a new protocol number and appear in your list of files and is automatically checked out to you.

This new file will have all of the information in it that the file you used to create it did. Now you can go in and edit the information to meet any changes you need.

This is especially useful for 3-year (IACUC) and 5-year (IBC) renewals, and for protocols that you may be taking over for another PI.

Please do thoroughly review all of the information in the new document to ensure it reflects how you want to carry out this current protocol.
Creating an IBC from an IACUC

- Select “Create IBC Form” from file menu
- This creates an IBC with a one-time data transfer
- Any changes going forward need to be made on both the IACUC and the IBC
- Joint IACUC and IBC protocols will need to be 1:1

Right click on the file title to get a drop down menu

This feature is available from the Files and Documents list.

You must left click on the FILE level of the protocol. This does not work for the document level of the protocol.

This is a one-time transfer, so be sure your IACUC is as complete as possible before you create an IBC from it. Any amendments made to either protocol must be made to both, if relevant.

You will now need to have one IACUC for each IBC and vice versa.

Data from the IACUC from the Personnel, General Information, IACUC Information (or Breeding information for a breeding protocol) and EH&S is transferred to the IBC.

However, additional questions are asked on those tabs in the IBC protocol form, so please review those tabs and ensure all questions are completed.
Creating an IBC from an IACUC

- Please leave the auto populated title. You may add a descriptive title after this.
- Relevant info will be populated into the IBC protocol draft.
- Review all tabs to ensure all questions are answered.

Please leave the auto populated title. You may add a descriptive title of your choice AFTER that title.

Data from the IACUC is transferred to the Personnel, General Information, IACUC Information (or Breeding information for a breeding protocol) and EH&S tabs in the IBC.

However, additional questions are asked on those tabs in the IBC protocol form, so please review those tabs and ensure all questions are completed.
The compare feature is available from within a protocol (IACUC or IBC).

Under the Action menu, click Compare Version.
The “Open all” button expands the pop-up window to list all changes found between the two versions.
Compare feature

- Changes are also highlighted within the protocol
- Click the arrow to collapse/hide details
- Click “Stop comparison” to turn off the compare feature

Within the protocol itself (versus the pop-up window), changes are also highlighted with yellow orange boxes with the same green underline for insertions and red strikethrough for deletions.

The compare feature will remain on until you click the “Stop comparison” button.
Contact Information

- Cara Loy - ORR: 294-4673, cara@iastate.edu
  - IACUC and IBC related topics
  - Software functionality

- Jen Walker, a-tune project manager - AV Office: 294-8964, jlw@iastate.edu
  - Attending Veterinarian related topics
  - Software functionality

- Brian Carney - LAR: 294-0536, bscarney@iastate.edu
  - Laboratory Animal Resources related topics
  - Software functionality