

IACUC Process in InfoEd: Principal Investigator

Processing a New Protocol (or a Triennial Review)

- PI: log into the NIU eRA portal
 - For New Protocol: Hover over “Laboratory Animals” – select “create new protocol”
 - Select “Initial Protocol Submission” and “New Record” – continue
 - Type in the title of the study
 - Select yourself as the PI (unless it is someone else – e.g., your advisor)
 - You should land on an Initial Application submission page
 - For Triennial Review: log into the protocol record
 - Click on “Submissions” in the top left
 - Select “Triennial Review” from the dropdown option – click “add”
 - Click on “IACUC Initial Application”
 - Expand the application to fill up the page so that full questions are visible – this may take several seconds to load
 - Read the important information at the start
 - Complete the application all at once or save it and complete it later
 - Use “control P” or “command P” to print, if needed
 - When done, click “complete” and “close”
 - Upload additional documents using the “Add” button next to the words “Document/Form”
 - To add other personnel: before submitting, click on the “Personnel” tab on the left
 - Click “Add” in the upper right area
 - Type the last name of the person (a list of options will appear – click on the correct one)
 - If the person you would like to add is not in the system – email erahelp@niu.edu to get the person in the system
 - Once the person is listed in personnel, assign the appropriate role (usually “mentor” or “co-inv”)
 - The main PI should be assigned that role and have the radio dial under “PI” selected
 - Select “Save” in the upper left
 - Select “Submission” in the left-hand rectangle to get back to the Initial Protocol Submission page
 - **Select “SUBMIT”** when you are ready to send the application packet to your departmental chair (or advisor) for certification
 - Read through the certification and select “accepted” and “continue” if you agree with the statement and “continue” on the route page
 - Select “Submit” once more

ORCIS will route the protocol to the departmental chair (or surrogate). If the protocol is submitted by a student, the faculty advisor will be included in the routing. If changes are needed, the PI will be contacted.

- Advisor: an email is sent to the advisor indicating that a new protocol has been submitted and that their certification is needed
 - Click on the “Reviewer Dashboard” link in the email
 - Selecting the record number at the top left will take you to the complete protocol record
 - Selecting the “IACUC Initial Application” under Form/Document will take you directly to the application
 - If everything is satisfactory, change “Un-Reviewed” to “Reviewed”
 - Select “Approved” (notes can be added in the comments box if needed) and “ok”
 - a certification notice will appear – read it and select “accepted” if you agree with the statement
 - Close out of the Reviewer Dashboard
 - If everything isn’t satisfactory, change “Un-Reviewed” to “Reviewed”
 - add notes in the comments box to indicate what changes are needed
 - Select “Modifications Needed” and “ok”
 - Close out of the Reviewer Dashboard
- **PI (if Advisor or Dept. Chair determine that the submission needs work):** an email will be sent if changes are needed
 - Questions/requested changes are included in the email
 - Within the email, select the record link at the bottom
 - Select “Submissions” at the top left and go into the correct submission (Initial)
 - Modify the application or other materials in response to the comments provided in the email
 - Be sure to click “completed” again and re-submit the document (you will need to approve the certification again)
 - Submission goes through the same process – ORCIS, Advisor, Chair, ORCIS

The protocol will be reviewed by the IACUC at a convened meeting.

IF MODS REQUESTED

ORCIS will provide the PI with an email notification of modifications requested.

- **PI:** an email will appear when changes are needed
 - Open the letter attached to the email – the requested changes/clarifications will be indicated
 - To make the changes, select the clickable “Summary Submission Page” within the attached letter or access the protocol directly through InfoEd
 - Select “Respond to Change Requests” under “Initial Protocol Submission” on the Submission Summary Page
 - In the dropdown menu, select “Response to Mods Request” – click “Save”
 - Click on the Document/Form titled “IACUC Initial Application” to modify the application
 - You will need to unclick “Complete” in order to work inside of the document
 - Provide any necessary clarifications within the application at the very bottom (in the item under the word “STOP!!!”)

- Make any changes needed and then click “Complete” again followed by “Close”
- Add any necessary documents by clicking on the “Add” button next to “Document/Form”
- Click “Submit” on the far right
- Select “Continue” on the routing page
- Be sure to select “Done” (top left) when finished with the submission page

ORCIS will send the modified protocol to at least one IACUC member through email. The IACUC member(s) will provide feedback to ORCIS. The PI will be notified of IACUC approval through email.

IF TABLED

ORCIS will provide the PI with an email notification that the protocol was tabled and of any modifications/clarifications being requested by the IACUC.

- PI – an email will appear when changes are needed
 - Open the letter attached to the email – the requested changes/clarifications for the tabled protocol will be indicated
 - To make the changes, select the clickable “Summary Submission Page” within the attached letter or access the protocol directly through InfoEd
 - Select “Respond to Change Requests” under “Initial Protocol Submission” on the Submission Summary Page
 - In the dropdown menu, select “Response to tabled” – click “Save”
 - Click on the Document/Form titled “IACUC Initial Application” to modify the application
 - You will need to unclick “Complete” in order to work inside of the document
 - Provide any necessary clarifications within the application at the very bottom (in the item under the word “STOP!!!”)
 - Make any changes needed and then click “Complete” again followed by “Close”
 - Add any necessary documents by clicking on the “Add” button next to “Document/Form”
 - Click “Submit” on the far right
 - Select “Continue” on the routing page
 - Be sure to select “Done” (top left) when finished with the submission page

ORCIS will assign the protocol to the next IACUC meeting where the members will review the modifications/clarifications. The PI will be notified of IACUC approval through email.

Submitting an Annual Review

- PI: Access the protocol through the emailed letter sent indicating that an annual review is due
 - OR log into the NIU eRA portal
 - select “Locate My Records” along the top banner
 - Select the relevant record number from the list – hover over it, slide over to “edit” – slide over to click “Master Record”
 - [Or you can hover over “Laboratory Animals” – select “locate records”]
 - [Or you can hover over “Laboratory Animals” – select “Create New Protocol” then select “Annual Review” to find using the record number]

- Select “Submissions” in the banner running along the top
- On the right side of the Submissions box, select “Annual review” from the drop down menu – click “Add”
- In the Annual Review box in the center, select “IACUC Annual Continuation Form” under Document/Form
- Complete the application (you will need to expand it so the full document is visible) – select “Complete” then “Close”
- Upload any additional documents by selecting “Add” next to Document/Form
- When the application is ready to be submitted, select “Submit”
- Read the certification and select “Accepted” – click “Continue”
- Select “Continue” again on the routing page

ORCIS will route the protocol to those who “sign off” on the submission (e.g., faculty advisor, chair).

- Advisor: an email is sent to the advisor indicating that an annual continuation has been submitted and that their certification is needed
 - Click on the “Reviewer Dashboard” link in the email
 - Selecting the record number at the top left will take you to the complete protocol record
 - Selecting the “IACUC Annual Continuation” under Form/Document will take you directly to the application
 - If everything is satisfactory, change “Un-Reviewed” to “Reviewed”
 - Select “Approved” (notes can be added in the comments box if needed) and “ok”
 - a certification notice will appear – read it and select “accepted” if you agree with the statement
 - Close out of the Reviewer Dashboard
 - If everything isn’t satisfactory, change “Un-Reviewed” to “Reviewed”
 - add notes in the comments box to indicate what changes are needed
 - Select “Modifications Needed” and “ok”
 - [ORCIS will contact the PI for changes/clarifications]
 - Close out of the Reviewer Dashboard

ORCIS will send the protocol submission out for Designated Member Review. The IACUC members have one week to provide feedback. The PI will be notified of IACUC approval through email.

Submitting an Amendment

- PI: Access the protocol through the NIU eRA portal
 - select “Locate My Records” along the top banner
 - Select the relevant record number from the list – hover over it, slide over to “edit” – slide over to click “Master Record”
 - [Or you can hover over “Laboratory Animals” – select “locate records”]
 - [Or you can hover over “Laboratory Animals” – select “Create New Protocol” then select “Amendment” to find using the record number]
 - Select “Submissions” in the banner running along the top

- On the right side of the Submissions box, select “Amendment” from the drop down menu – click “Add”
- In the Annual Review box in the center, select “IACUC Amendment Form” under Document/Form
- Complete the application – select “Complete” then “Close”
- Upload any additional documents by selecting “Add” next to Document/Form
- When the application is ready to be submitted, select “Submit”
- Read the certification and select “Accepted” – click “Continue”
- Select “Continue” again on the routing page

ORCIS will route the amendment to a faculty advisor (if relevant) or begin the Designated Member Review process. The IACUC members have one week to provide feedback. The PI will be notified of IACUC approval through email.