Institutional Animal Care and Use Committee (IACUC)

جامعة الملك عبدالله
للعلوم والتقنية
King Abdullah University of
Science and Technology

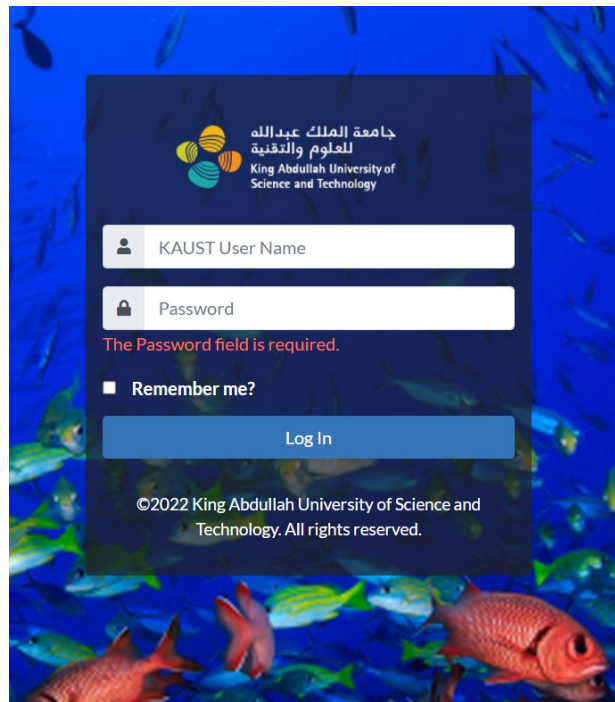# IACUC ELECTRONIC PORTAL
PRINCIPAL INVESTIGATOR USER GUIDE

Contents

Access to the IACUC system

1. Email iacuc@kaust.edu.sa to request Portal access.
2. Research Compliance (RC) will provide confirmation that your account has been activated.
3. Log into the IACUC Portal with your KAUST credentials.
   NOTE: when outside of the KAUST network, you are required to be on KAUST VPN to access the IACUC Portal.

# Nominate a Delegate to draft your IACUC protocols

1. To designate a Delegate, send a request email to iacuc@kaust.edu.sa with the nominated delegate email address.
2. Only senior staff are recommended to be nominated as a Delegate.
3. The Delegate has the ability to
   o draft a new protocol,
   o see the Committee's comments and edit the protocol during the review process
   o edit approved protocols to create draft amendments/renewals
   o clone approved/expired protocols, **cannot** clone closed protocols
   o view all the PI approved protocols
   o **cannot** create and manage a Continuing Review Report
4. The **PI has the ultimate responsibility in signing and submitting the protocol** to the Committee through the IACUC Portal.

Institutional Animal Care and Use Committee (IACUC)

Create your IACUC Protocol

1. Log into the IACUC Portal with your KAUST credentials.
2. There are three ways to create a new research protocol:
    a) From the main screen "Action Panel", click on "New Research Protocol":
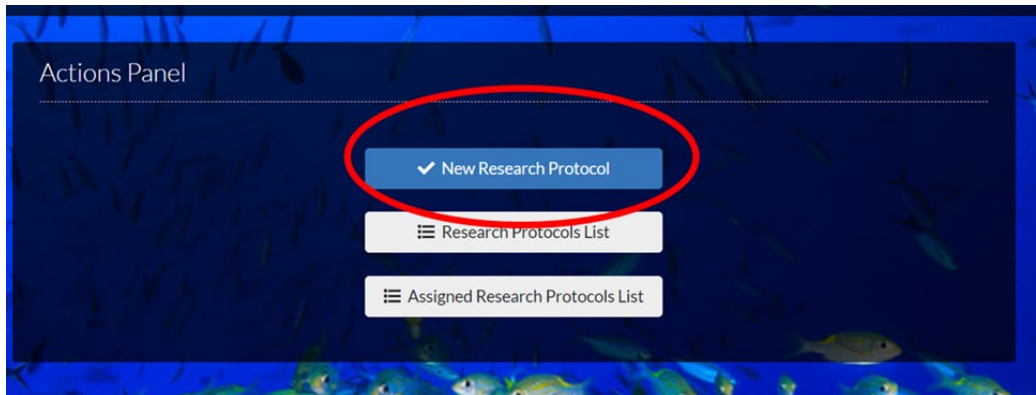
    b) From the Research Protocol List. Click on "+ Create New Research Protocol"
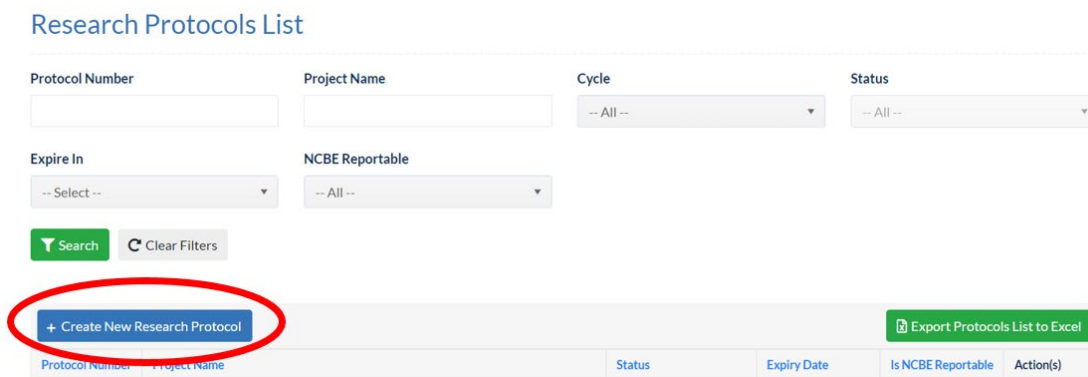
    c) Click on the Principal Investigator dropdown menu, then select 'New Research Protocol':

   NOTE: The system is autosaving regularly.If you don't submit the protocol, you can access it at a later stage the same ways described above to update and/or submit it.

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Complete your IACUC protocol

Once completing your protocol, see how to:

- **Navigate Between Sections**
- **Mandatory Sections and Mandatory Fields**
- **Add Repeating Items (i.e. Research Team, Summary Of Animal Use)**
- **Add Research Team Members**
- **Submit and Sign your IACUC Protocol**

Navigate Between Sections

- To navigate between sections, use the navigation pane on the left side or the "next" and "previous" buttons at the bottom of each section.
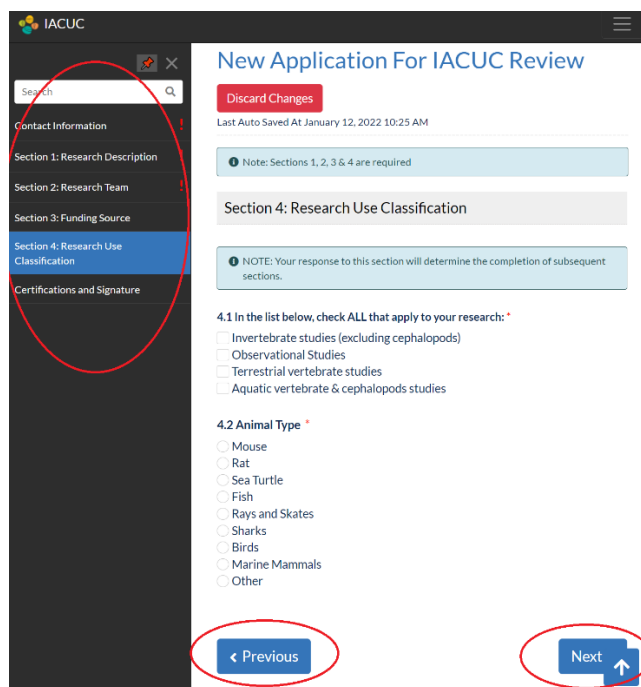
- The system **auto-saves content** of each page.

- You will see an ❗ exclamation mark sign in the sections where information needs to be completed. You will not be able to submit the protocol until this information have been entered.

- If you leave a protocol without submitting, you can find it as a **draft** when selecting "new research protocol". You can discard it by clicking on "Discard Changes".
  NOTE: you cannot create several drafts at the same time in the Portal.

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Mandatory Sections and Mandatory Fields

Mandatory Sections

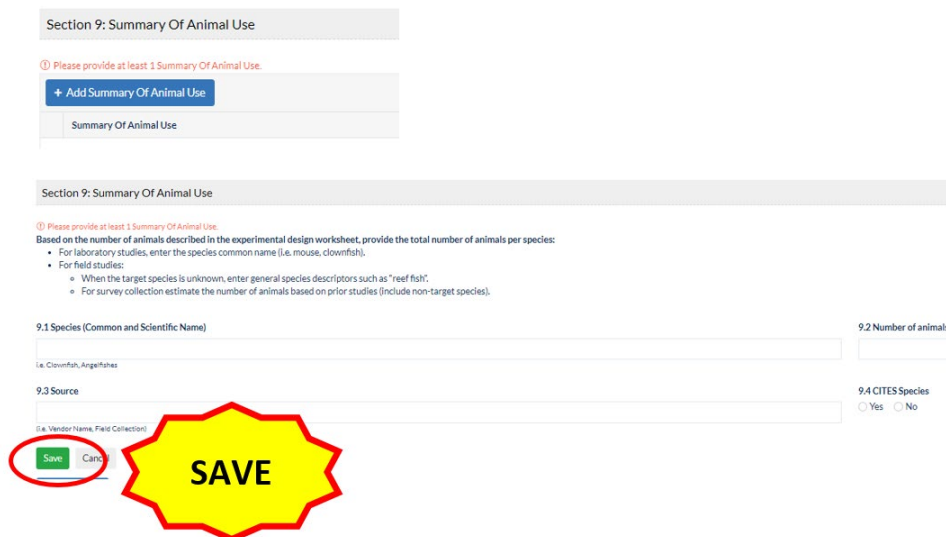The protocol cannot be submitted without completing the following sections:

- ✓ Contact Information
- ✓ Section 1: Research Description
- ✓ Section 2: Research Team
- ✓ Section 3: Funding Source
- ✓ Section 4: Research Use Classification
- ✓ Certifications and Signature

Mandatory fields

- Mandatory fields are indicated with a red "*" asterisk sign and the protocol cannot be submitted with unanswered mandatory fields.

Add Repeating Items

- In some sections of the protocol, you will be able to add multiple items (i.e. Research Team, Summary Of Animal Use).
- To create a new item, you must:
    1. Click the **ADD** button,
    2. Enter the required data
    3. Click **SAVE**.

Institutional Animal Care and Use Committee (IACUC)

Add Research Team Members

- By default the PI and the alternate contact are listed here, and you have to complete the 2.4, 2.5, and 2.6 fields for each.
- You add a team member by entering their KAUST ID; the name will be auto-populated.
- You must complete the following for each team member:
    - 2.4 Role
    - 2.5 Summary of experience with animal studies
    - 2.6 Responsibilities in this project

NOTE: this item can be repeated as many times as needed to include all the members of your research team.

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Submit and Sign your IACUC Protocol

- Once you have added all the information in your IACUC protocol, go to the **Certification and Signature** section to submit the protocol.
- Clicking on the **"Submit"** button is considered as **your signature**. A pop-up window will appear to confirm the protocol submission.

- To submit a draft sent by your delegate: from your research protocol list, select "edit" in the "Actions" dropdown menu of the draft.

- Then you can review, edit, and submit the protocol as described before.

Institutional Animal Care and Use Committee (IACUC)

- You can send back the protocol to your delegate for revision by clicking "Send to PI Delegate" on the top right side.
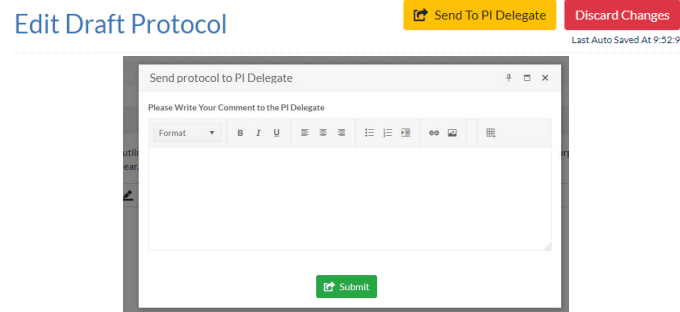
- The PI has the ultimate responsibility in signing and submitting the protocol in the Portal. Delegates can only send a draft to the PI for final submission.

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Respond to IACUC Comments

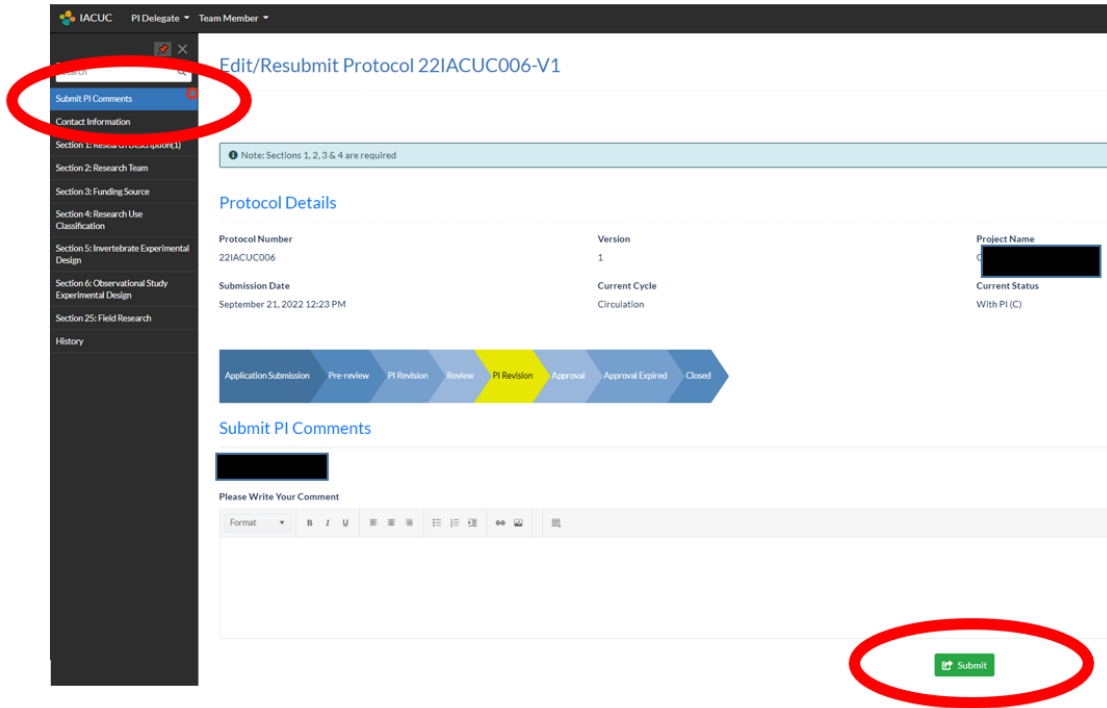During the review of your protocol, the IACUC Members and/or Research Compliance may raise some questions to clarify details within the protocol. These comments can be addressed by either the PI or the Delegate.

1. You will receive an automatic reply from no-reply@kaust.edu.sa informing you have comments awaiting to be reviewed.
   **Make sure this email address does not go to your Spam inbox so important notifications are not missed. **
2. Log in into the IACUC system with your KAUST credentials.
3. Go to your protocol: In the pending tab of the "Research Protocol List" select "View" from the "Action" dropdown to see the protocol and comments only and select "Edit" to view the comments and edit the protocol prior resubmission.
4. On the left menu bar, you will see a comment sign to highlight the section where comments have been raised and need your review.
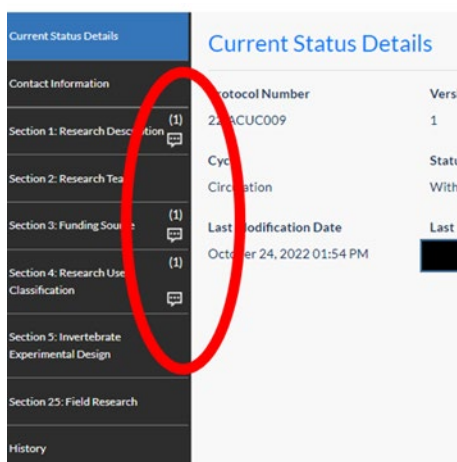
5. Your responses will need to be added directly into the application by editing your protocol.
   NOTE: The system should save the changes until the protocol is resubmitted, but we recommend you do all the changes in one session only.
6. Once you edited your protocol, go to the 'Submit PI Comments' section at the top of the left-hand side tab.
7. There you can add any other information you would like to share with RC and/or the Committee. Then click 'Submit'.
8. **Only PIs can submit a protocol.** Clicking on the **"Submit"** button is considered as **your signature**. A pop-up window will appear to confirm the protocol submission.

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Notice of Approval

- Once IACUC approves a protocol, you will receive an email notification from no-reply@kaust.edu.sa with a Notice of Approval attached.
  **Make sure this email address does not go to your Spam inbox so important notifications are not missed. **

- If a protocol is **'Approved with stipulations'**, the stipulations are visible in the email notification and the Notice of Approval.

- You have the ability to request the approval email notification to be <u>resent at any later time</u> by clicking "resend the approval email" from the "**Action**" dropdown menu of the protocol.

View all your IACUC Protocols

- Log in into the IACUC system with your KAUST credentials.
- Click on the '**Research Protocol List**' from the "Action Panel" or the PI dropdown menu.
- In this table, all continuing review reports will be visible in two separates tabs:
    ➢ **Pending**: List of all draft, submitted and under review protocols
    ➢ **Approved**: List of all approved, expired or archived protocols

- You can use the search tool at the top of the page to filter or sort the protocols.
- Clicking on the header of each columns of the table allows you to sort the protocols (descending/ascending)
- Your protocol list can also be exported to Excel.

- For each protocol, clicking on the Action button gives you access to the following options:

Actions ▾	Function	Pending Protocols not with Committee	Approved Protocols	Draft created by Delegate
View	Allow the view/edit of the protocol	👍	👍	👍
Edit	Allow the edition of an approved protocol to submit an amendment	👍	👍	👍
Clone	Creates a copy of the protocol that can be edited	👎	👍	👎
Renew	Allow the edition of an approved protocol to submit a renewal	👎	👍	👎

Resend the approval email	Resend the email with the Notice of Approval	👎	👍	👎
Export to PDF	Export a pdf copy of the protocol	👍	👍	👍
Print	Print a copy of the protocol	👍	👍	👍
History	Display previous versions of the protocol	👍	👍	👍

Continuing Review Report

What is a Continuing Review Report?

The National Committee for Bioethics (NCBE) requires the review of research progress at least once a year. This is 'to ascertain safety' and 'to ensure there is no reason for discontinuation or modification of the research.'

When to submit a Continuing Review Report?

You will receive a notification email from no-reply@kaust.edu.sa when a continuing review report is due.

Make sure this email address does not go to your Spam inbox so important notifications not are missed.

Who can submit a Continuing Review Report?

- The PI is the only one able to start, complete, and submit a Continuing Review Report.
- Delegates cannot view or create a continuing review report.

How to submit a Continuing Review Report?

- Log in into the IACUC system with your KAUST credentials.
- Click on **'New Continuing Review'** from the "Action Panel" or the PI dropdown menu.
- Select the protocol reference number from the top dropdown.
- A 'Continuing Review Report' will be generated. You will be able to disclose any changes in your project (study design, procedures or personnel), or any adverse events.
- When changes are disclosed, you **must** edit and submit an amendment to your protocol.

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Continuing Review Report

Section 1

Select the identification Number of the protocol for which you would like to complete the Continuing Review Report

IACUC Identification Number

22IACUC003

Project Title

IACUC Protocol Title

Is your research project still going?

● Yes ○ No

Section 2

Was there any change in this project that you have not reported to the IACUC?

○ Yes ● No

Have you added or removed staff which have not been reported to the IACUC?

● Yes ○ No

If any of these questions are answered "Yes", you have to complete an amendment to the protocol following the link that appears below

❗ Please create a new form with the form changes (and/or) staff changes from <u>Here</u>

Section 3

Was there any adverse or unanticipated consequences of the research?

○ Yes ● No

By submitting this form, I certify that the information I have provided is complete and correct, to the best of my knowledge. I am familiar with and agree to abide by the provisions of KAUST policies and guidelines on biological safety and bioethics as issued by IACUC, as well as other specific granting agency instructions, pertaining to the proposed project.

I will ensure all personnel under my supervision have appropriate training to conduct their research.

I agree that modifications to the originally approved protocol will not take place without prior review and approval by appropriate KAUST committees.

Name, on January 18, 2022

↪ Submit

View all your Continuing Review Reports

- Log in into the IACUC system with your KAUST credentials.
- Click on the **'Continuing Review Report List'** from the "Action Panel" or the PI dropdown menu.
- In this table, all continuing review reports will be visible in two separates tabs:
  - ➢ **Pending**: List of all submitted and under review continuing review report
  - ➢ **Approved**: List of all approved, expired or archived continuing review report

Continuing Review Reports List

| Pending | Approved |

Form ID	Protocol Number	Project Name	Due Date		
			After	Before

Cycle	Status
-- All --	-- All --

🔻 Search   ⟳ Clear Filters

+ New Continuing Review Report   📄 Export Continuing Review Reports List to Excel

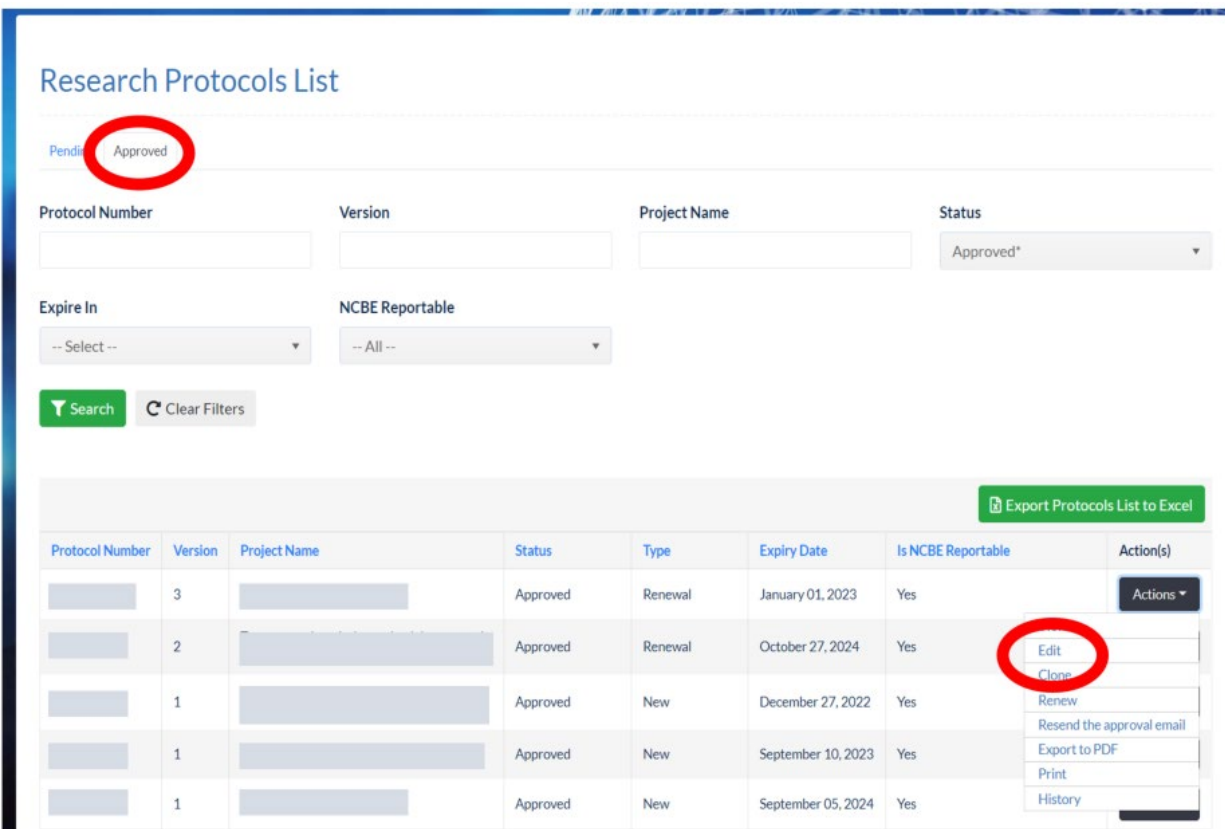| Form ID ↓	Protocol Number	Project Name	Due Date	Status	Action(s)
1	22IACUC005	IACUC Protocol Title	January 11, 2023	Submitted	Actions ▾

| ⏮ ◀ **1** ▶ ⏭ | 10 ▾ items per page | | 1 - 1 of 1 items |

- For each Continuing Review Report, clicking on the Action button gives you access to the following option:

Actions ▾	Function
View	View the continuing review report. When With PI, report can be edited
Export to pdf	Export a pdf copy of the report
Print	Print a copy of your report
History	Display previous versions of your report

Amend my approved protocol

You are able to amend your protocol once it has been approved.

1. Log in into the IACUC system with your KAUST credentials.
2. Click on the '**Research Protocol List**' from the "Action Panel" or the PI dropdown menu.
3. Go to the "**Approved**" Tab.
4. Click the option for "Edit" from the "Actions" dropdown menu of the protocol you want to amend. This will open your protocol in editing mode.

5. Once you have added all the information in your IACUC protocol, go to **Certification and Signature** as explained in Submit your IACUC Protocol.
   NOTE: The system should save the changes until the protocol is resubmitted, but we recommend you do all the changes in one session only.
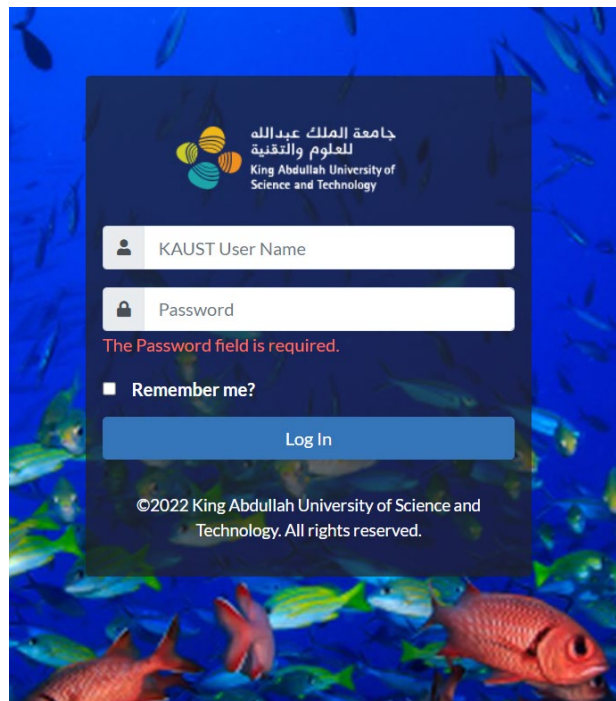
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PI DELEGATE USER GUIDE

Contents

How to access the IACUC Portal

1. Your PI should email iacuc@kaust.edu.sa to request your access to the IACUC Portal as their delegate.
2. Research Compliance (RC) will provide you with confirmation that your account has been activated.
3. Log into the IACUC Portal with your KAUST credentials.
   NOTE: when outside of the KAUST network, you are required to be on KAUST VPN to access the IACUC Portal.

PI Delegate Capabilities

1. The PI Delegate has the ability to
   o draft a new protocol,
   o see the Committee's comments and edit the protocol during the review process,
   o edit approved protocols to create draft amendments/renewals,
   o clone approved/expired protocols, **cannot** clone closed protocols,
   o view all the PI approved protocols.
2. The PI Delegate **cannot** create or manage a continuing review report.
3. The **PI has the ultimate responsibility in signing and submitting the protocol** to the Committee through the IACUC Portal.

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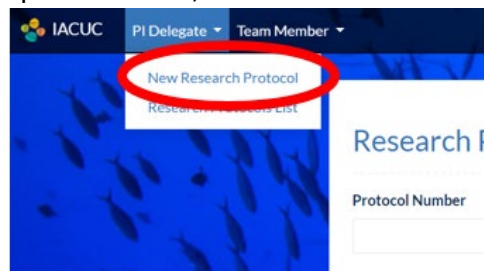
Create a draft IACUC Protocol for your PI

1. Log into the IACUC Portal with your KAUST credentials.
2. There are three ways to create a new research protocol:
   a) From the main screen "Action Panel": click on "New Research Protocol":
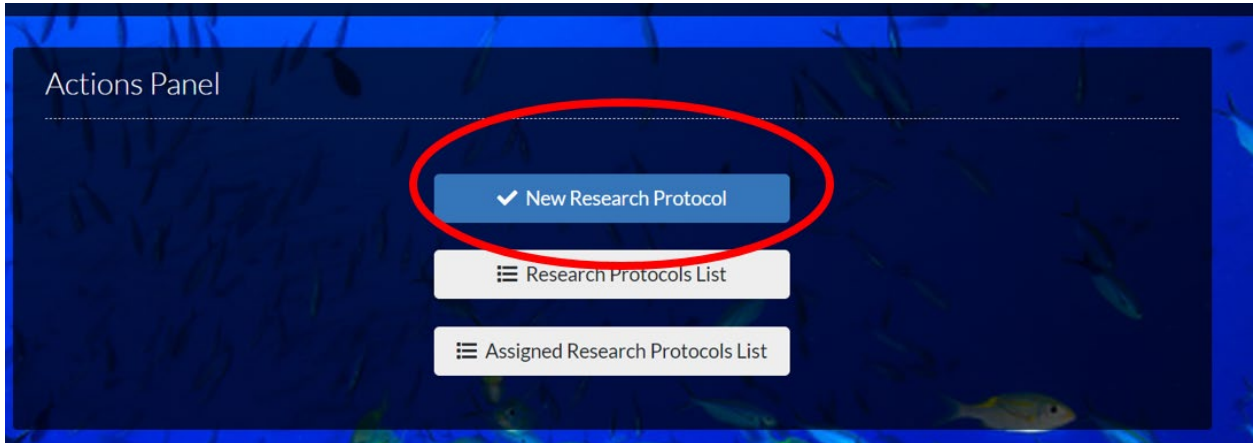
   b) From the Research Protocol List: click on "+ Create New Research Protocol":
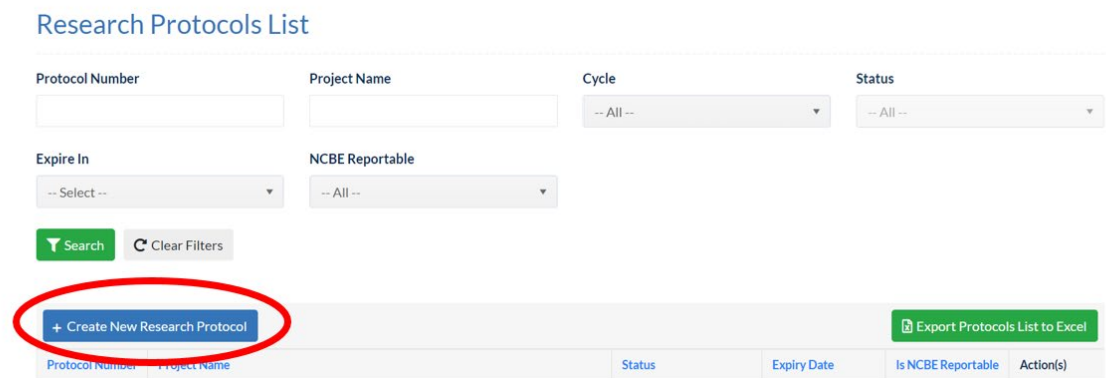
   c) From the PI Delegate dropdown menu, click "New Research Protocol":

Complete an IACUC protocol

1. Log in into the <u>IACUC Portal</u> with your KAUST credentials.
2. Follow the instructions below to:
   - **Navigate Between Sections**
   - **Complete Mandatory Sections and Mandatory Fields**
   - **Add Repeating Items (i.e. Research Team, Summary Of Animal Use)**
   - **Add Research Team Members**
   - **Send the draft Protocol to your PI**

Navigate Between Sections

- To navigate between sections, use the navigation pane on the left side or the "next" and "previous" buttons at the bottom of each section.

- The system **auto-saves content** of each page.

- You will see an ! exclamation mark sign in the sections where information needs to be completed. You will not be able to submit the protocol until this information has been entered.

- If you leave a protocol without submitting, you can find it as a **draft** when selecting "new research protocol". You can discard it by clicking on "Discard Changes".
  NOTE: you cannot create several drafts at the same time in the Portal.

Complete Mandatory Sections and Mandatory Fields

Mandatory Sections

The protocol cannot be submitted without completing at minimum the following sections:
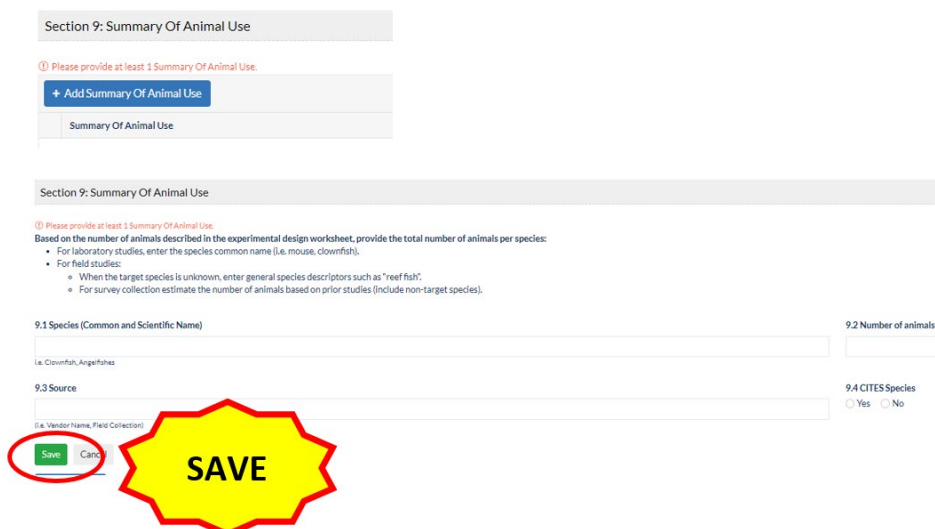
- ✓ Contact Information
- ✓ Section 1: Research Description
- ✓ Section 2: Research Team
- ✓ Section 3: Funding Source
- ✓ Section 4: Research Use Classification
- ✓ Certifications and Signature

Mandatory fields

- Mandatory fields are indicated with a red "*" asterisk sign and the protocol cannot be submitted with unanswered mandatory fields.

- You will see a red ! exclamation mark sign in the sections where information needs to be completed. You will not be able to submit the protocol until this information has been entered.

Add Repeating Items

- In some sections of the protocol, you will be able to add multiple items (i.e. Research Team member, Summary Of Animal Use, etc).
- To create a new item you must:
  1. Click the **ADD** button,
  2. Enter the required data
  3. Click **SAVE**.

Institutional Animal Care and Use Committee (IACUC)

Add Research Team Members

- By default, the PI and the alternate contact are listed here, and you have to complete the 2.4, 2.5, and 2.6 fields for each.
- You add a team member by entering their KAUST ID; the name will be auto-populated.
- You must complete the following:
  - 2.4 Role
  - 2.5 Summary of experience with animal studies
  - 2.6 Responsibilities in this project

NOTE: this item can be repeated as many times as needed to include all the members of your research team.

Send the draft protocol to your PI

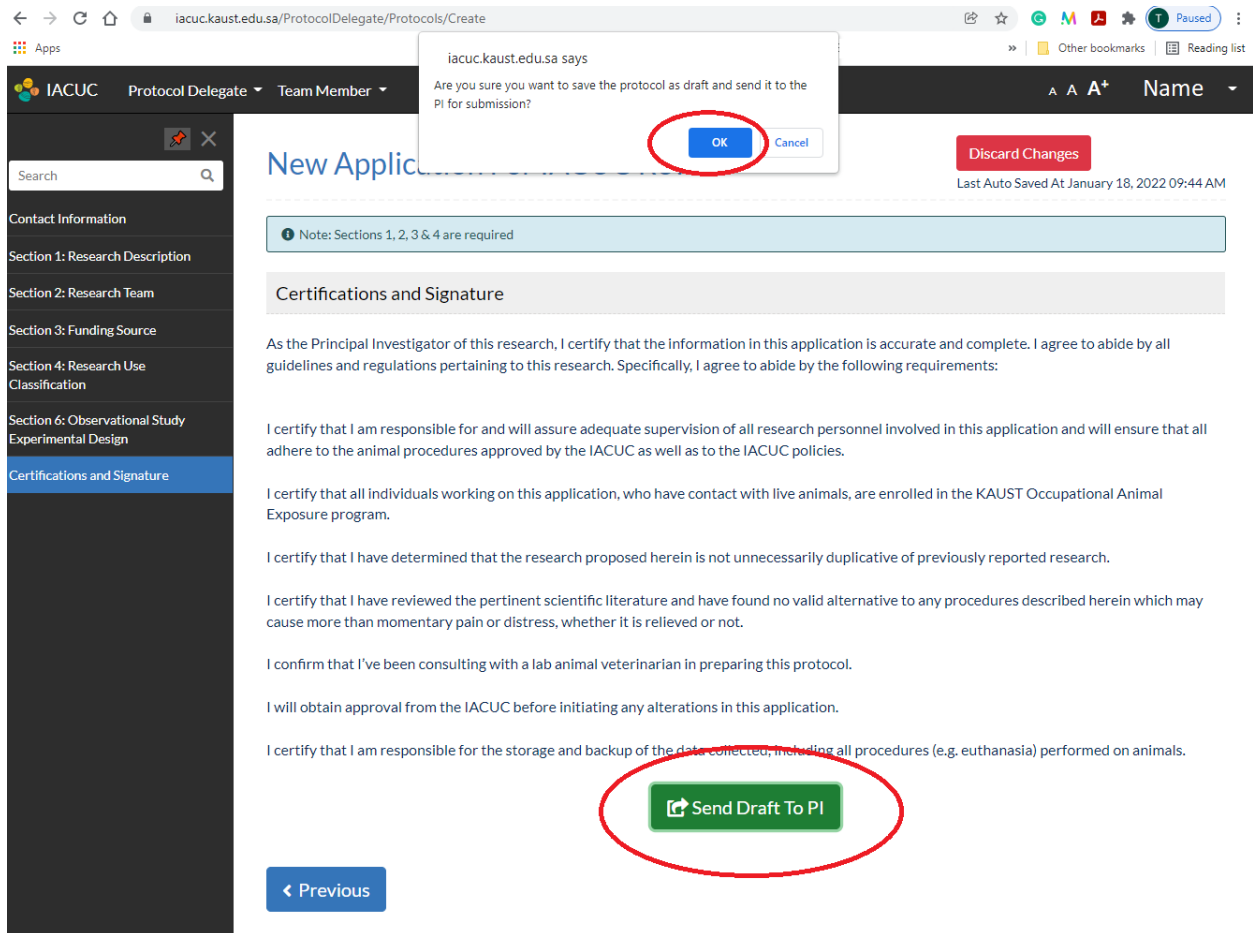- Once you have added all the information in your IACUC protocol, go to the **Certification and Signature** section.
- You can send the draft protocol to your PI for review, but **only PIs can submit a protocol to the IACUC.**

Institutional Animal Care and Use Committee (IACUC)
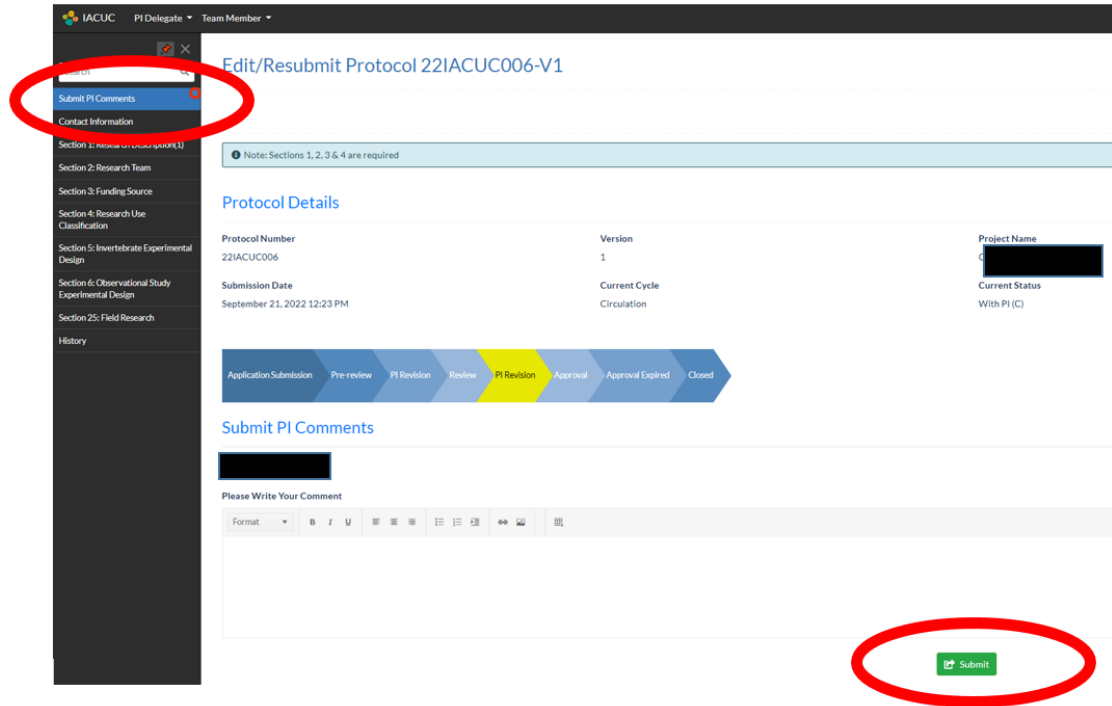
Respond to IACUC Comments

During the review of your Protocol, the IACUC Members and/or Research Compliance may raise some questions to clarify details within your protocol. These comments can be addressed by either the PI or the PI Delegate.

1. You will receive an automatic reply from no-reply@kaust.edu.sa informing you have comments awaiting to be reviewed.
   **Make sure this email address does not go to your Spam inbox so important notifications are not missed. **
2. Log in into the [IACUC system](#) with your KAUST credentials.
3. Go to your protocol: From the "Research Protocol List" select "View" from the "Actions" dropdown to see the protocol and comments only, and select "Edit" to view the comments and edit the protocol prior resubmission.
4. On the left menu bar, you will see a comment sign to highlight the section where comments have been raised and need your review.
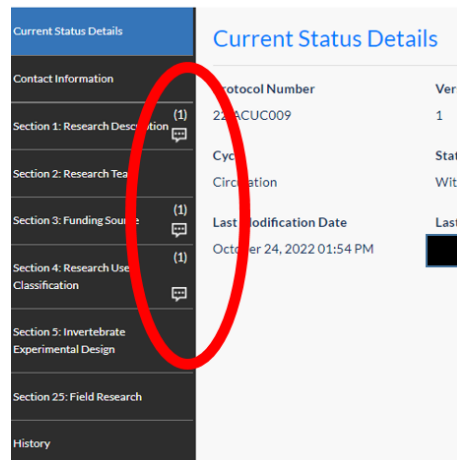
5. Your responses will need to be added directly into the application by editing your protocol.
   NOTE: The system should save the changes until the protocol is resubmitted, but we recommend you do all the changes in one session only.
6. Once you edited the protocol, go to the 'Submit PI Comments' tab at the top of the left-hand side menu.
7. There you can add any other information you would like to share with your PI, RC and/or the Committee. Then click 'Submit'. A pop-up window will appear to confirm the protocol submission. This will go to your PI as a draft.

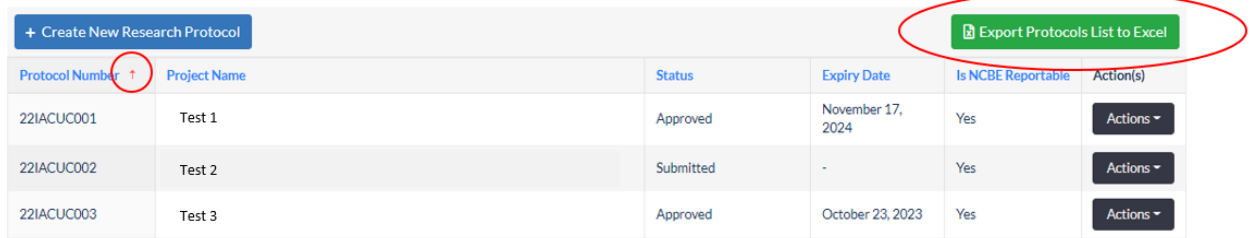# Institutional Animal Care and Use Committee (IACUC)

8. **Only PIs can submit a protocol.** The PI has the ultimate responsibility in reviewing the changes and submitting the protocol to the Committee through the IACUC Portal.

View all your PI's IACUC Protocols

- Log in into the IACUC system with your KAUST credentials.
- Click on '**Research Protocol List**' in the Action Panel or the PI Delegate dropdown menu.
- Here you can see all drafts, pending, approved, and closed protocols.
- You can use the <u>search tool</u> at the top of the page to filter or sort the protocols.
- Clicking on the header of each columns of the table allows you to sort the protocols (descending/ascending)
- The protocol list can be <u>exported to Excel.</u>

+ Create New Research Protocol					Export Protocols List to Excel
Protocol Number ↑	**Project Name**	**Status**	**Expiry Date**	**Is NCBE Reportable**	**Action(s)**
22IACUC001	Test 1	Approved	November 17, 2024	Yes	Actions ▾
22IACUC002	Test 2	Submitted	-	Yes	Actions ▾
22IACUC003	Test 3	Approved	October 23, 2023	Yes	Actions ▾

- If you click on the "**Actions**" button, you will have access to the following functions depending on the status:

Actions ▾	Function
View	Allow the view of the protocol
Edit	Allow the edition of a protocol (to be used on approved protocol to create amendment)
Clone	Creates a copy of the protocol that can be edited and submitted as a new one
Renew	Allow the edition of an approved protocol to submit a renewal
Export to PDF	Export a pdf copy of the protocol
Print	Print a copy of the protocol

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Amend an approved protocol

You are able to amend a protocol once it has been approved.

1. Log in into the IACUC system with your KAUST credentials.
2. Click on the '**Research Protocol List**' from the "Action Panel" or the PI Delegate dropdown menu.
3. Click the option for "Edit" from the "Actions" dropdown menu of the protocol you want to amend. This will open your protocol in editing mode

4. Once you have added all the information in the protocol, go to **Certification and Signature** as explained in "Send the IACUC Protocol Draft to your PI".
   NOTE: The system should save the changes until the protocol is sent to your PI, but we recommend you do all the changes in one session only.