\*\*\* Please note that it may take ORAMS several seconds to load the next screen after clicking an action button (e.g., Submit, Create, etc.). Do not refresh your browser during that time. Additionally, please note that the use of DUO Multi-Factor Authentication is required to connect to ORAMS.\*\*\*

- Submitting a <u>Protocol Modification</u> Modified protocols will now be given a letter suffix to denote the modification. For example, the initial approved version will be Version A. The first modification will result in Version B, and so on. While previous versions of the protocol are accessible, please make sure that you and your personnel are always working off the most recent version.
  - 1. Login to ORAMS using your UCSB NetID.
  - 2. Click on the Protocol icon in the Dashboard to view a list of your currently approved protocols.







Personnel Training



= ORAMS						
A Home Protocol List						
	Protocol Number	Protocol Title	PI	Status		
	76.	Example Protocol	ORAMS PI	Approved by Designated Members	View	

4. Click the 'Create Modification' button under the 'Protocol' tab.

Save and Close

### = ORAMS • **Example Protocol** <u>76</u> Protocol General Info Animal Census Procedures Roster Facilities Drugs Disposition Hazards Permits Excep Click 'Open Protocol' to view the current version of this protocol in Google Docs. Use the buttons below to complete various protocol actions, including submitting modifications to the IACUC Office for review. DO NOT use the 'Request edit access' button in the Google Doc to make a modification. Current Protocol: Version: A (Approval Notice) Open Protocol Approval Notice • Create Modification Create Renewal

5. Write a brief summary of the revisions to be made in the Modification Description field. Click the 'Save and Close' button to save the Modification Description.

Modification Status:	
Please edit protocol file before submitting: Modification Google Document Modification Description	
Increasing animal numbers	

6. Click on the 'Open Protocol' button in the 'Protocol' tab to open the approved protocol in a new browser tab.

### 

<u>76</u>	<u>76</u> Example Protocol								
Prot	cocol General Info	Animal Census Roster							
Click 'Open Protocol' to view the current version of this protocol in Google Docs. Use the buttons below to complete various protocol actions, including submitting modifications to the IACUC Office for review. DO NOT use the 'Request edit access' button in the Google Doc to make a modification.          Modification, Version: B (Pending)       • Open Protocol									
Submit Modification Withdraw Modification									
	Version	Action		Performed by	Performed on				
1	Α	Created		ORAMS PI	1/31/2023 1:43 PM				

7. Make any necessary changes to the Gdoc protocol. Your revisions to the protocol will be in Suggestion Mode (similar to Track Changes in Word). The revisions will be accepted by the IACUC at the end of the modification review process. Once all the necessary changes have been made, close the browser tab with the Gdoc protocol application.

2 A Submitted for Dro Doviour ODAMS DI 1/21/2022 1.60 DM

- 8. Click the 'Submit Modification' button on the 'Protocol' tab to send the modification for review. A window will open with several assurance statements that the PI must read and confirm that they will adhere to.
  - Only PIs may submit a modification for review.

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2 Δ

## 76 Example Protocol

|--|--|

Click 'Open Protocol' to view the current version of this protocol in Google Docs. Use the buttons below to complete various protocol actions, including submitting modifications to the IACUC Office for review. DO NOT use the 'Request edit access' button in the Google Doc to make a modification.

Modification, Version:	Modification, Version: B (Pending)			
-				
Submit Modification	Withdraw Modification			
Version	Action		Perfo	
1 A	Created		ORA	

Submitted for Pre-Review

- 9. Depending on the modification description and revisions to the protocol, the modification will be classified as either Major, Minor, or Administrative.
  - If the modification is classified as either Major or Minor, the protocol will go to the Veterinarian for pre-review.
  - If the modification is classified as Administrative, the protocol will go to the IACUC Office for review.

ORAMS PL

- 10. Once the Veterinarian or IACUC Office have finished adding their comments and revisions to the modified protocol, the protocol will be sent back to you for revisions. An email notification will be sent to you and the Lab Manager when this happens.
- 11. Click the 'Open Protocol' button in ORAMS and revise the modified protocol based on the questions and comments. Once all the necessary changes have been made, close the browser tab with the Gdoc protocol application.

Performed on 1/31/2023 1:43 PM

1/31/2023 1-58 PM

# **■ ORAMS**

# 76 Example Protocol Protocol General Info Animal Census Roster Click 'Open Protocol' to view the current version of this protocol in Google Docs. Use the buttons below to complete various protocol actions, including submitting modifications to the IACUC Office for review. DO NOT use the 'Request edit access' button in the Google Doc to make a modification. Modification, Version: B (Pending) Open Protocol Resubmit to Vet

	Version	Action	Performed by	Performed on
1	А	Created	ORAMS PI	1/31/2023 1:43 PM
2	٨	Submitted for Dro Doviow	ODAMS DI	1/21/2022 1.60 DM

12. Click the 'Resubmit to Vet' button on the 'Protocol' tab to continue the pre-review process. This cycle of sending revisions back-and-forth will continue until all of the questions and comments have been adequately addressed. An email notification will be sent to you and the Lab Manager when this happens.

<u>76</u>	Example Protocol	
Protocol	General Info Animal Census Roster	
Click 'Oper actions, inc	Protocol' to view the current version of this protocol in Google Docs. Use the buttons below to complete various protocol luding submitting modifications to the IACUC Office for review. DO NOT use the 'Request edit access' button in the Google is a difference.	Doc

Modification, Version: B (Pending)	•	Open Protocol
Resubmit to Vet		

	Version	Action	Performed by	Performed on
1	А	Created	ORAMS PI	1/31/2023 1:43 PM
2	٨	Submitted for Dre-Deview	ODAMS DI	1/31/2023 1-58 DM

- 13. Once the revisions are determined to be complete, the <u>type of modification</u> is determined by the IACUC Office.
  - If a protocol modification is determined to be Administrative or Minor, the modification will be administratively approved by the IACUC Office.
  - If the modification is determined to be Major, the modified protocol will be reviewed by the IACUC, either through email (i.e., <u>Designated Member Review</u>) or, if Full Committee Review was requested during the pre-review or DMR, at a convened IACUC meeting.
- 14. If the IACUC has any questions or additional revisions during their review of a major modification, you will receive an email notification. These comments must be addressed before the review process can continue. Click on the 'Open Protocol' button in the 'Protocol' tab to open the modified protocol in a new browser tab. Make any necessary changes to the Gdoc protocol. Your revisions to the protocol will be in Suggestion Mode. Once all the necessary changes have been made, close the browser tab with the Gdoc protocol. Click the 'Resubmit to IACUC' button on the 'Protocol' tab.
  - A modification sent for Designated Member Review may still be brought for further review at an IACUC meeting if requested by any of the members.
- 15. Once the IACUC has no additional comments or revisions on the major modification, you and the Lab Manager will receive an email notifying you of this and that the modification has been approved. The approved modified protocol and modification approval notice will be available to view/print in ORAMS.
  - Once a modification is approved, an automated email will be sent to all personnel listed on the protocol's roster informing them that there is a new version of the protocol that they are required to read before continuing to work on that protocol. The information in the ORAMS tabs will be updated by the IACUC Office.
  - PIs are responsible for ensuring their personnel read each version of the protocol. The PI and Lab Manager can determine if a person on the roster has reviewed the latest version of the Gdoc protocol. Navigate to the protocol's 'Roster' tab. In the top table that lists the people that are approved to work on the protocol, there is a column that lists the last time each person accessed the Gdoc protocol. If the listed date and time are from before the latest modification approval, that person still needs to read the latest version of the protocol.

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<u>76</u>	76 Example Protocol				
Protocol	General Info 🖌	Animal Census	Roster		

Below is a list of all the personnel approved to work on this protocol, the procedures they will be performing on the protocol, and information about their training. All personnel listed on this roster are expected to have read the current version of the protocol and be properly trained in the animal procedures listed for them. The 'GDoc Last Access' column below indicates the last time a person used ORAMS to view the protocol. It is the responsibility of the PI and/or Lab Manager to keep the roster up-to-date.

Ro	Roster Add						
		Name	Role	GDoc Last Access			
	1	ORAMS PI	PI	Version A: Jan 31 2023 2:09PM	Training Record		

Assigned procedures will be visible here when the IACUC Coordinator assigns procedures to this protocol