UCONN HEALTH



V1.1 Updated 12/27/2016

How to Create a Modification/Amendment to an Approved Animal Protocol

This guide assumes you are logged into Topaz Elements and have an Approved Animal Protocol within the system.

- 1. From the Main Home Screen under the Compliance Menu, click Animal Protocols.
- 2. On the Protocols Menu, select **Create Amendment Protocol.**
- 3. A dialogue box will generate which will list all your approved protocols. **Select the desired protocol** from the grid to amend and modify by clicking on it.

Select	Protocol For Am	endment Q		🖶 😰 🥦 Filter: Not Set			ot Set	• 🐺 🕄		
	Protocol #	Reference #	Protocol Type	Principal Inve	Title	Author	Version #	Protocol Stati		
	101286-1218	101286	Amendment	Cook, Matthew	Test Protocol fo	Tomassi, Rolo	3	Approved		
Page 1 of 1. 1 total record(s) found.								K Ø Cancel		

- Click on the Modification/Amendment form from the Select Protocol for Amendment grid.
- Your approved protocol will generate with a modification header in Section 12 Modification/Amendment of the outline. Click on the box(es) that state(s) what the modification(s) are associated with your protocol.

Name	Description	Туре	
Amendment form v.20130101	Animal care and use amendment form	Amendment	

TOPAZ | Elements is maintained by the Office of the Vice President for Research at UConn Health. For technical issues, please email <u>eRA-support@uconn.edu</u>, call 860-486-7944, or visit <u>http://research.uchc.edu/about/research-it/topaz/</u>.

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C Animal Protocols - 1 🟠 Main Protocol Forms Protocols						
X Create Amendment Protocol -	Copy	y Compare Presubmit Submit Signoff Reports				
Outline 않윤이도	7	0 100039 1.	2 - *			
Filter Outline 1.2 +		/erdana 🔹 12 🔹 B I U 🛝 🗄 🗄 🗄 🖶 🚍 🖷 🤫 🏟 📾 🖓 🏷 Σָ				
1 Modification/Amendment Modification/Amendment Type		Modification/Amendment Type Select all that apply.	-			
Addition of animals	9	Addition of animals				
Additional Animals		Addition/change of experimental procedures				
2 Administration		Addition of hazardous substances				
Title		Addition/deletion of personnel				
Reference Number		A NOTE: you must update appropriate sections within the protocol below.				
Protocol Number		Addition/change of drugs and/or dosing regimen				
Created By		Change in laboratory location				
Principal Investigator	Ш	Addition/change in method of euthanasia				
Protocol Associates		A NOTE: you must update appropriate sections within the protocol below.				
Associates Authorized to Order Animals		Addition/change in surgical procedures				
Funding/Grant Source		Other				
Funding Details						
Study Initiation	F	Addition of animals				
Accounts						
- 3 Project Overview		Additional Animals How many additional animals are being requested? NOTE: You must also update the "Authorized Amounts" in the Animal Subjects see	tion			
Lay Summary		within the protocol.	cion			
- 4 Animal Subjects						
Species						

6. Amend the protocol by going to the section of your protocol that is associated with each change and modify your protocol. For example, if you need to add animals, you must go to the animal section and change your animal numbers in the "authorized amounts" section (a) and also put in a justification for the additional animals you are requesting in the "rational for requested animal numbers" section (b).



NOTE: You need to make the changes in the document for each modification requested. Modification requests will be returned to you if this is not done.

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7. Once you are sure the protocol is ready to be submitted, click the **Submit** button. The Set Status dialog box appears.

Animal Protocols		Main	Prot	ocols	7		
Create Original Protocol	Save	Сору	/// Compare	o Presubmit	Submit	Signoff	Reports

- 8. On the Set Status dialog box, click **Submitted** and then **Set Status** 2 button.
- 9. An e-Signature dialog appears, please
 - a. Click Sign Via Shibboleth button.
 - b. Enter your UConn Health domain account username.
 - c. Enter your UConn Health domain account password.
 - d. Click Login button
 - e. After successful login, you will be returned to the protocol.

Set Status	_	-		0
-	-	E-Signature Informatio	n	
-	Z >	Current User	(manufacture)	
Submitted		Current Date/Time	3/22/2016 12:40:20 PM	UCUNN HEAT
		Item Name	101289	Please login with your UConn Health network
		E-Signature Event	Animal Protocol Submitted For Approval	username password.
		Description		Log in to Unspecified Service Provider
				b Username
				C Password
				Login
		a	a Sign Via Shibboleth @ Cancel	
			Set Status	Cancel

10. Your protocol has been submitted. To confirm that your protocol was submitted using the Product Selector go to My Dashboard > My Protocols. Look for the protocol you just submitted. The Protocol Status should report "Submitted". If it doesn't, then something went wrong. Simply go back into the protocol by clicking on it and re-submit by repeating steps 7-9 above.