

Creating a Protocol

ERMS - IACUC Job Aid



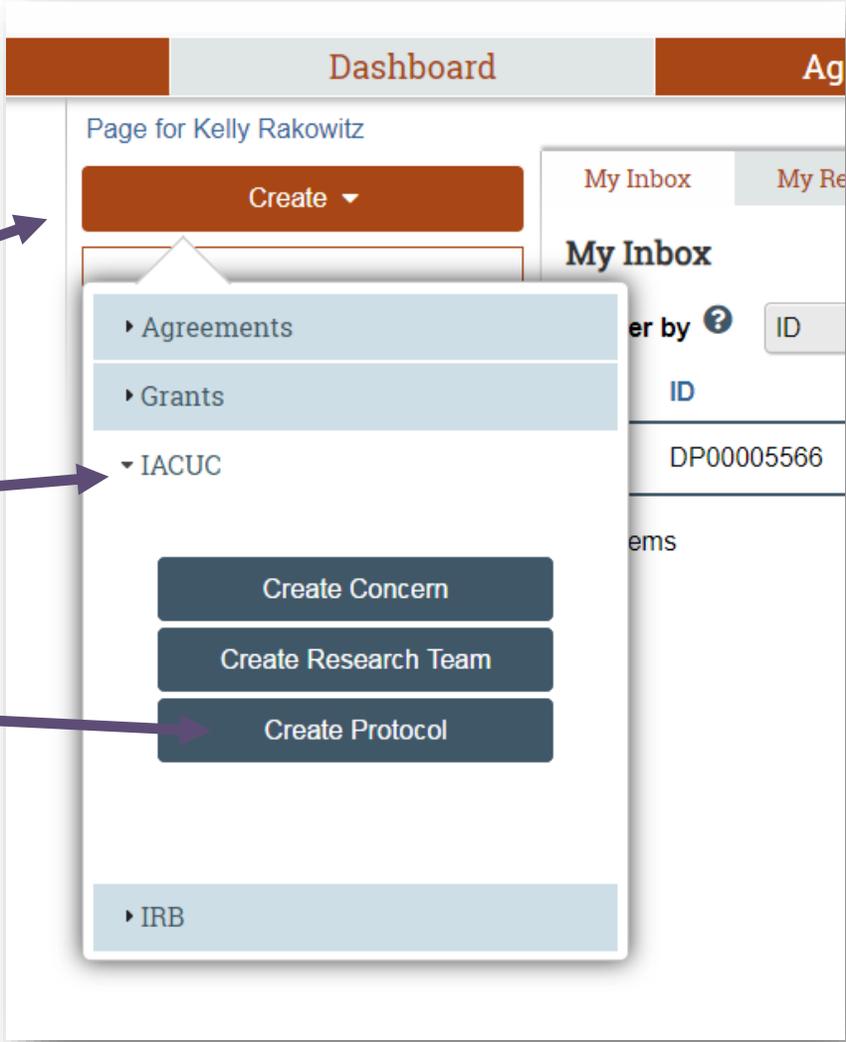
UT Health
San Antonio

Enterprise Research
Management System
(ERMS)

Creating a Protocol

You can create the Protocol from 2 places.

- 1. FROM THE MAIN DASHBOARD
 - Click the Create box.
 - Click the IACUC box for the drop-down menu.
 - Select Create Protocol.



Creating a Protocol

2. FROM THE IACUC DASHBOARD, RESEARCH TEAM WORKSPACE.

The screenshot shows the IACUC dashboard interface. At the top, there is a navigation bar with tabs for Dashboard, Agreements, COI, Facilities, Grants, and IACUC. Below this is a secondary navigation bar with links for Submissions, Standard Library, Concerns, Meetings, Reports, and Help Center. The main content area displays the details for a specific protocol, 'Test 1 KR', which is in an 'Active' state. The principal investigator is Kelly Rakowitz. On the left side, there is a 'Next Steps' section with buttons for 'Edit Research Team', 'Create Protocol', 'Create Procedure', and 'Create Substance'. The 'Create Protocol' button is highlighted with a purple box. Below the 'Next Steps' section, there is a search filter and a table of activities. The table has columns for Name, Execute Activity, Date Modified, State, Version, and Species. One activity is listed: 'Administer Prednisolone' with an 'Actions' dropdown, a date of '6/24/2024 5:02 PM', and a state of 'Active'.

... > IACUC > Test 1 KR

Active TEAM00000015
Test 1 KR
Principal investigator: Kelly Rakowitz
Phone: 210-562-6421
E-mail: RAKOWITZK@UTHSCSA.EDU

Next Steps

- Edit Research Team
- Create Protocol**
- Create Procedure
- Create Substance

Submissions Procedures Substances History Research Team Contacts Archived Procedures Archived Substances Training

Filter by ? Name [v] Enter text to search [Q] + Add Filter X Clear All

Name	Execute Activity	Date Modified	State	Version	Species
Administer Prednisolone	Actions ▾	6/24/2024 5:02 PM	Active	1	Dog(s)

Creating a Protocol

Basic Information Go to forms menu Help

1. * Select research team: ?

Name

PI

Test 1 KR

Kelly Rakowitz

Clear

2. * Title of protocol:

TEST Compare different steroids for the treatment of Glioblastoma

3. * Short title: ?

Steroid Treatments of Glioblastoma

4. * Summary of research: ?

This study compares different steroids that are used to treat Glioblastoma.

5. * Principal investigator:

Kelly Rakowitz ... +

6. * What is the intention of the animal protocol? ?

Breeding Only

Experimental Research

Field Research

Holding Protocol

Teaching

Clear

*Research Team

*Title

*Short Title

*Summary of research

*Principal Investigator

*The intention of the animal protocol

You can Save and return later or Click Continue to proceed to next steps.

Exit Save Continue

Creating a Protocol

 Enterprise Research Management System (ERMS)

Validating | Comparing | <<

Basic Information & Funding

- Basic Information
- Experimental Research Protocol Addition**
- Protocol Team Members
- Funding Sources

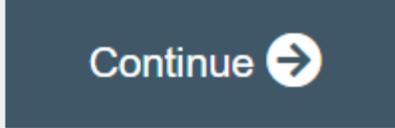
Experimental Design

Editing: IPROTO202400000028

Experimental Research Protocol Addition

1. * Will the protocol include breeding? 

Yes No [Clear](#)

Editing: IPROTO202400000028

Protocol Team Members

Research Team members are then auto-populated.

1. Identify each additional person involved in the design, conduct, or reporting of the research: 

+ Add

Name	Role	Involved in Animal Handling	Authorized To Order Animals	Email	Phone	
Barry Bridges	Research Assistant	no	no	BRIDGESB@UTHSCSA.EDU	210-562-6421	
Mark Parma	Statistician	no	no	PARMAM@UTHSCSA.EDU	210-567-0903	
Belinda Yaeger	Co-Investigator	no	no	YAUGER@UTHSCSA.EDU	210-567-4950	

2. External team member information: 

+ Add

Drag and drop files to upload

Document Name

Date Modified

There are no items to display

Creating a Protocol

Editing: IPROTO202400000028

Protocol Team Members

Add Research Team Members as Needed.

1. Identify each additional person involved in the design, conduct, or reporting of the research: ?

Remove Members.

+ Add

Name	Role	Involved in Animal Handling	Authorized To Order Animals	E-mail	Phone
Barry Bridges	Research Assistant	no	no	BRIDGESB@UTHSCSA.EDU	210-562-6421
Mark Parma	Statistician	no	no	PARMAM@UTHSCSA.EDU	210-567-0903
Belinda Yauger	Co-Investigator	no	no	YAUGER@UTHSCSA.EDU	210-567-4950

✕
✕
✕

2. External team member information: ?

+ Add Drag and drop files to upload

Document Name

Date Modified

There are no items to display

Team Members without IACUC system access, can be added by adding a document with his/her contact information.

Click Continue.

✕ Exit

Save

Continue →

Add Funding Sources to your Protocols.



Editing: IPROTO202400000028

Funding Sources

1. Identify each organization supplying funding for the protocol: ?



Funding Organization

There are no items to display

Click Add.
Enter all questions appropriately to your protocol.

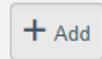
Add Funding Source

1. * Select the funding organization: ?

2. Sponsor's funding ID: (assigned by external sponsor) ?

3. Grants office ID: (assigned internally) ?

4. Attach files: (including any grant applications)



Document Name

Date Modified

There are no items to display

Enter all questions appropriately for your protocol.
Choose Funding Organization from the ellipsis option.

Click OK.

OK

OK and Add Another

Cancel

Creating a Protocol

Editing: IPROTO202400000028

[Go to forms menu](#) [Print](#) [Icons](#) [Help](#)

Scientific Aims

1. * Scientific aims of the research: ?

There are several goals of this research. They are as follows:

- 1) To determine the most effective steroid to use for reducing or improving Glioblastoma.
- 2) To determine which steroid to use for certain populations.
- 3) To determine which steroid causes the least number of side effects.

2. * Significance and benefits of the research: ?

This has a huge benefit to society and those with Glioblastoma, including improvement to human health and the advancement of knowledge.

The benefits are as follows:

- 1) A treatment that does not cause harm to people.
- 2) A treatment that is cost effective and easy to administer. |

Enter Scientific Aims of your research.

You can copy text from other documents and paste into these free space answer boxes.

Click Continue.

✕ Exit

💾 Save

Continue →

Creating a Protocol

Add Experiment Details to your Protocol.

Editing: IPROTO202400000028

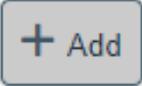
[Go to forms menu](#) [Print](#) [Icons](#) [Help](#)

Experiments

 **Important!** Make sure all procedures required for your protocol exist in the IACUC system before you add experiments.

If the procedure is not yet created: [Create Procedure](#)

1. * Define the experiments to be used in this protocol:



Click ADD to add details, new screen will appear.

Name	Species	Is USDA	Total	Pain Category	Procedures
------	---------	---------	-------	---------------	------------

There are no items to display

Continue to answer the Experiments details, click the ellipsis for additional options and add documents, if needed.

Add Experiment

1. Display order:

2. * Experiment name:

3. * Species: ?

Dog(s) ... +

4. * Describe the experiment: (including animal characteristics such as age, weight, and sex)

5. * Define humane endpoints for this experiment: ?

6. Justify the purpose of this experiment:

7. Select procedures: ?

Name	Type	Version	State	Scope
------	------	---------	-------	-------

There are no items to display

8. Describe any variations to the selected standard procedures: ?

9. Procedure timing: ?

10. * Total number of animals used in this experiment: (including all the animals to be produced)

11. If any of these animals will experience unrelieved pain or distress, provide a scientific justification why pain/distress cannot be relieved:

Select One or More Procedure Projects

Filter by Name

1-11 of 11

Name	Type	Version	Species	Scope
<input type="checkbox"/> Administer Prednisolone	Substance Administration	1	Dog(s)	Team
<input type="checkbox"/> Administration of Isoflurane	Substance Administration	1	Dog(s)	Standard
<input type="checkbox"/> Barbituate derivative (e.g. Euthasol)	Euthanasia	1	Dog(s)	Standard
<input type="checkbox"/> Euthanasia via Euthasol	Euthanasia	1	Dog(s)	Standard
<input type="checkbox"/> Fasting for Surgery	Food or Fluid Restriction	1	Dog(s)	Standard
<input type="checkbox"/> Inferior vena cava occluder placement	Non-Survival Surgery	1	Dog(s)	Standard
<input type="checkbox"/> Intrapericardial Chest Tube Placement	Non-Survival Surgery	1	Dog(s)	Standard
<input type="checkbox"/> Lateral thoracotomy	Non-Survival Surgery	1	Dog(s)	Standard
<input type="checkbox"/> Sonometric crystal placement	Non-Survival Surgery	1	Dog(s)	Standard
<input type="checkbox"/> A	Non-Survival Surgery	1	Dog(s)	Standard
<input type="checkbox"/> Test Administer Prednisolone	Substance Administration	1	Dog(s)	Team
<input type="checkbox"/> Vascular sheath placement via Seldinger technique, and placement of RA pacing catheter and LV pressure-volume catheter (or arterial pressure catheter)	Non-Survival Surgery	1	Dog(s)	Standard

Creating a Protocol

12. Number of animals by pain category: (include each animal only once in the highest pain category) ?

B:

C:

D:

E:

13. Identify husbandry exceptions:

+ Add

Exception Type

Description and Justification

There are no items to display

14. Supporting documents: ?

+ Add

Document Name

Date Modified

There are no items to display

Continue to answer the Experiments details,
add supporting documents, if needed.

Click OK.

* Required

OK

OK and Add Another

Cancel

Creating a Protocol

Experiments ?

Important! Make sure all procedures required for your protocol exist in the IACUC system before you add experiments.

If the procedure is not yet created: [Create Procedure](#)

Experiment is now listed.

1. * Define the experiments to be used in this protocol:

Name	Species	Is USDA	Total	Pain Category	Procedures	
TEST1	Dog(s)	yes	1	B: 1, C: 0, D: 0, E: 0	• Administer Prednisolone (Team - Substance Administration)	Copy ✕

You can copy your experiment to use it as a starting point for adding another experiment.

2. If the experiments include survival surgery, will any single animal undergo more than one survival surgery? (include any animal that underwent surgery prior to use on this protocol) ?

Yes No [Clear](#)

Click Continue.

✕ Exit

 Save

Continue 

Creating a Protocol

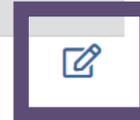
Editing: IPROTO202400000028

Go to forms menu Print Icons Help

Procedure Personnel Assignment

1. Select the team members who will be performing each procedure: ?

Procedure	Species	Is USDA Species	Team Members
Substance Administration: Administer Prednisolone, ver. 1 (Team)	Dog(s)	yes	Belinda Yauger Mark Parma Barry Bridges Kelly Rakowitz



Edit Protocol Team as needed for each procedure listed.

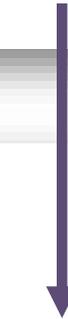
Click the Edit icon.

Procedure Personnel Assignment

1. Select the team members who will be performing each procedure: ?

Procedure	Species	Is USDA Species	Team Members
Substance Administration: Administer Prednisolone, ver. 1 (Team)	Dog(s)	yes	<input checked="" type="checkbox"/> Barry Bridges <input checked="" type="checkbox"/> Mark Parma <input checked="" type="checkbox"/> Kelly Rakowitz <input checked="" type="checkbox"/> Belinda Yauger

Unselect the team members not performing the procedure .



Team member training:

Name	Training
Kelly Rakowitz	No current training data to display
Barry Bridges	No current training data to display
Mark Parma	No current training data to display
Belinda Yauger	No current training data to display

Training is listed for each team member to show who is qualified to perform the procedure.

Click Continue.

✕ Exit

💾 Save

Continue →

Editing: IPROTO202400000028

◀ Go to forms menu 🖨️ Print ▼ ⓘ Icons ? Help

Strains

1. Identify background strains:

Is USDA Species	Strain	Genetically Modified Strain	Phenotype
There are no items to display			

Add any background strains, if possible.

Click Continue.

✕ Exit

💾 Save

Continue →

Creating a Protocol

Animal Justification 

Go to forms menu Print Info

1. Adjust the number of animals to be used or produced for this protocol as needed: 

Species	USDA Covered Species	Pain Category	Animals Identified in Experiments	Adjusted Animal Count	
Dog(s)	yes	Pain Category B	1	1	
Dog(s)	yes	Pain Category C	0	0	
Dog(s)	yes	Pain Category D	0	0	
Dog(s)	yes	Pain Category E	0	0	

2. If you adjusted the number of animals for this protocol, explain why:

You will begin answering questions on Animal Justification –count adjustments. You will see the numbers of animals you identified across your experiments by pain category.
Answer Questions 1-7.
Add any supporting documents.

Click Continue when done.

 Exit  Save **Continue **

Creating a Protocol

Editing: IPROTO20240000028

[Go to forms me](#)

Alternatives Searches and Duplication ?

1. Record all searches for alternatives for each procedure that causes pain or distress: ?

+ Add

Procedures Search Date Searched Databases Keywords Search Period Start Search Period End

There are no items to display

distre...

Version Species State Scope

Click Add.
New screen will appear.

Click the ellipsis to search through the databases for duplicate research.

Add additional information to help with your search.

Click OK.

Identify what you have done to make sure you are not duplicating research previously performed.

Click Continue when done.

Add Procedure Search Details

1. Procedures causing pain or distress:

...

Name Version State Approval Date Last Day of Approval Period

There are no items to display

2. * Date of search:

3. Databases searched:

Name Link

There are no items to display

4. Keywords used:

5. Summarize your search for an alternative procedure:

6. Time period covered by search:

Start:

End:

* Required

OK

OK and Add Another

Cancel

Creating a Protocol

Editing: IPROTO202400000028 Go to forms menu Print Icons Help

Alternatives Searches and Duplication ?

1. Record all searches for alternatives for each procedure that causes pain or distress: ?

+ Add

Procedures	Search Date	Searched Databases	Keywords	Search Period Start	Search Period End
There are no items to display					

Procedures causing pain or distress:

Name	Type	Version	Species	State	Scope
------	------	---------	---------	-------	-------

2. Identify any other references used to find alternatives: (such as periodicals, publications and consultation)

3. * The principal investigator asserts that the activities described in this proposal do not unnecessarily duplicate previous experiments:

Yes No [Clear](#)

Exit Save Continue →

Identify other references used to find alternatives.

Confirm activities in proposal are not duplicating previous experiments.

Click Continue when done.

Creating a Protocol

Housing and Use

1. Identify each vivarium location where animals will be housed or used:

Name	Species	Hours
There are no items to display		

2. Identify each non-vivarium location where animals will be housed or used:

Name	Species	Hours	Reason
There are no items to display			

Enter desired locations for animals.
Inside institutions vivarium or
Outside the vivarium.
Click Continue.

Creating a Protocol

Editing: Steroid Treatments of Glioblastoma

Disposition

1. Disposition plans for the animals when this research is complete: (check all that apply)

- The animals will be euthanized according to the procedures described in this protocol.
- The animals will remain with their owners.
- The animals will be transferred to another approved protocol held by this investigator.
- The animals will be transferred to another approved protocol by another investigator.
- Other (describe below).

2. If other, provide an animal disposition description:

Identify plans for the disposition of animals after your research is complete.

Click Continue.

 Exit

 Save

Continue 

Creating a Protocol

The screenshot shows the 'Supporting Documents' section of the ERMS interface. The page title is 'Editing: IPROTO202400000028'. The 'Supporting Documents' section is active, showing a list with a '+ Add' button and a 'Document Name' header. A callout box points to the '+ Add' button with the text: 'Enter supporting documents for your protocol you did not include on other pages.' Another callout box lists document types: 'These documents may include: Clinical trial documents, Safety information, Breeding or restraint device details, Flow charts'.

Last step - click Validate to check for errors in your protocol creation.

The screenshot shows the ERMS interface with the 'Validate' button highlighted in a purple box. The page title is 'Editing: IPROTO202400'. The 'Supporting Documents' section is visible below.

Click Finish when done.

The screenshot shows the ERMS navigation bar with three buttons: 'Exit', 'Save', and 'Finish'. The 'Finish' button is highlighted in a dark blue color.

Creating a Protocol

Dashboard | Agreements | COI | Facilities | Grants | IACUC

Submissions | Standard Library | Concerns | Meetings | Reports | Help Center

... > IACUC > Test 1 KR > Steroid Treatments of Glioblastoma

Pre-Submission ←

Steroid Treatments of Glioblastoma

IRB# 202400000028

Principal investigator: Kelly Rakowitz
Submission type: New Protocol Application
Primary contact:
Consulted vet:
PI proxies: There are no items to display

Letter:
Protocol type: Experimental Research
IACUC coordinator:
Admin office: IACUC
Grace period: -

```
graph LR; A[Pre-Submission] --> B[Pre-Review]; B --> C[IACUC Review]; C --> D[Post-Review]; D --> E[Review Complete]; B --> B1[Clarification Requested]; B1 --> B; C --> C1[Clarification Requested]; C1 --> C; D --> D1[Modifications Required]; D1 --> D;
```

Next Steps

- Edit Protocol
- Printer Version
- Submit
- Request Pre-Submission Assistance
- Assign Primary Contact
- Assign PI Proxy
- Manage Guest List
- Manage Ancillary Reviews
- Manage Related Safety Protocols
- Add Comment
- Discard
- Copy Submission
- Manage Related Agreements

History | Experiments | Documents | Reviews | Contacts | Snapshots | Training | Related Concerns | Change Log | Agreements

Filter by Activity + Add Filter × Clear All

Activity	Author	Activity Date
Protocol Created	Rakowitz, Kelly	6/25/2024 11:33 AM

For general ERMS-IACUC questions, please contact ermshelp@uthscsa.edu.



Enterprise Research
Management System
(ERMS)