# myResearch Radioactive Drug Research Committee (RDRC) Training Guide

November 2024

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## Questions and Issues

For policy related questions and issues including how to fill out the application, please contact the **Stony Brook University Radioactive Drug Research Committee** (631) 632-9036; or Email ORC\_OVPR@stonybrook.edu

## What is myRESEARCH?

MYRESEARCH is the electronic system. It will automate the development, review, and approval processes of your study while managing all major administrative aspects of the research and compliance lifecycle – from application submission, through amendments, and any type of compliance reporting (i.e., protocol deviations, etc).

## Getting a myRESEARCH Account

Faculty and staff users will log into the system using their **SBU NetID and password**. If your login attempt is unsuccessful, please contact ORC\_OVPR@stonybrook.edu.

#### **Overview**

This training pertains to the following:

Research Study	Details related to the specific information related to a study
Research Study Site	Details related to a specific institution's site (study team, consent forms, etc.)
Modification	Details related to changes made to a study
Continuing Review	Details related to the review of an already approved study

myRESEARCH integrates the following aspects of research management into a single system:

- Conflict of Interest (COI) applications
- IRB applications
- IACUC applications
- Safety applications
- Grant applications
- Research Agreements

#### Roles in myResearch

Registered User	Individuals authorized to input information in MYRESEARCH (must have an SBU NetID Single Sign On)
Principal Investigator	Individual in charge of the research. Only this person can submit the initial study, continuing review application, or amendments. This is also the only person that can submit a response.
Study Personnel	Individuals involved in developing the study application and listed on the application as a study team member. A co-investigator or a laboratory assistant could be a study team member.

## **Submission Process**

- Pre-submission state: Principal Investigator (PI) or study team members are working on an application
- Pre-Review: RDRC staff reviews the application for completeness
- IBC Review: RDRC members review the application and make a determination about the study
- Post Review: RDRC staff sends the determination information back to the PI and study team members

## Logging into myResearch Portal



Stony Brook Research | Office of the Vice President for Research

## Accessing the myResearch Portal

All SBU-affiliated personnel can access the portal using their **SBU NetID and password**. If your login attempt is unsuccessful, please contact ORC\_OVPR@stonybrook.edu.

## 

When you first log into the system, you will see your inbox (**My Inbox**). From this page, click **Safety** from the top menu bar. The tabs available to you on the menu bar are based on the user roles that you have for your account.

COI	Facilities	Safety			
		1			Components
My Inbox					
Filter by 😧 ID	Enter text to search for	Add Fi	lter 🔉 Clear All		
ID	Name	Date Created	▼ Date Modified	State	Coordinator
PROTO201900022	stem cell test 2	9/27/2019 8:53 AM	9/27/2019 8:56 AM	Pre-Submission	
	My Inbox Filter by O D	My Inbox Filter by O D V Enter text to search for ID Name	My Inbox Filter by D Enter text to search for Q + Add Fil ID Name Date Created	My Inbox Filter by D T Enter text to sealwrior Clear All ID Name Date Created The Modified	My Inbox Filter by D Enter text to seals for Q + Add Filter x Clear All ID Name Date Created • Date Modified State

## Safety Main Screen Navigation

On the Safety page, you can do a variety of functions including "Create Safety Submission". You can also search for specific study applications (through the use of the filter bar) and sort the data based on column name (by clicking on the respective column heading). To view details of a particular study application, click on either the ID or the study name.

» My	Inbox	COI	Facilities	Sa	afety				
Submissions	Incidents	Inspections	Meetings Re	aports	elp Center				
Submissions					Sort s	tudies by colu			
Create Safety Submis	In	-Review Active	Archived Susper	nded or Lapsed	All Submission	s	Search	Search projects	Q
		Filter by 😧 ID	Enter text	to search for		d Filter 🗰 Clear Al	1		
	_	ID	Name	- D	ate Modified	State	Submission Type	Safety Review Type	
		PROTO201900003	Rob Simple IBC prot	tocol. 10/	4/2019 12:34 PM	BSO Review	Initial Protocol	Biosafety	
		Ente	<b>r text to se</b>	earch (e.	g. word	<b>in the title)</b>	]		

## Main Workspace

The Main Workspace page can be subdivided into the left navigation area and the main content area on the right.

» My Inbox Submissions In	COI cidents Inspections	Facilities Meetings	Reports	Safety Help Center			
BSO Review	PROTO201900003						
	Rob Simple	e IBC pr	otocol				
ext Steps	Principal Investigator: Safet	y PI			Submission Type:	Initial Protocol	
View Protocol	Specialist: Safety Primary Contact:	y Specialist			Safety Review Type: Letter:	Biosafety	
	Admin office: Safety	4			Last day of continuing review	period:	
Printer Version	PI proxies:				Approval Date:		
View Differences	Pre-Submission	Specialist Review		ittee Review		Review Complete	
Assign PI Proxy	4	Clarification Requested		rification equested	- ( Modifications )◀ Required )◀		
Assign Primary Contact			$( \  \  \  )$				
Manage Guest List	History Documents	Reviews	Reviewer Notes	Contacts	Snapshots Follow-on Submis	sions Related Projects	
Add Comment	•						
Copy Submission	Filter by O Activity	▼ Enter t	ext to search for		Q + Add Filter ≭ Clear All		
Withdraw	Activity				Author	<ul> <li>Activity Date</li> </ul>	
Discard	Response Submitte	ed			PI, Safety	10/4/2019 9:29 AM	
Manage Related IACUC	good to go?						
Protocols	Clarification Reque     here is some more info	sted by Specialist			Specialist, Safety	10/4/2019 9:26 AM	
Manage Related IRB Studies	here is some more into				1		
1							

Stony Brook Resear	rch myRESEARCH
» My Inbo	x COI Facilities
Submissions	Incidents Inspections Meetings Repo
Specialist Review	PROTO201900003
Next Steps	Rob Simple IBC proto
View Protocol	Specialist: Safety Specialist Primary Contact:
	Admin office: Safety PI proxies:
Printer Version	ripioxies:
View Differences	Pre-Submission Specialist Review Clarification
Assign Primary Contact	Requested
Manage Guest List	History Documents Reviews Reviewer
Copy Submission	Filter by 😢 Activity 🔹 Enter text to se
← Withdraw	Activity
Ø Discard	Response Submitted
Manage Related IACUC Protocols	good to go? Clarification Requested by Specialist
Manage Related IRB Studie	s here is some more info

Within the main workspace, you can view the **Current State** of the application on the left navigation area and the main content area. The left navigation area contains all the buttons and activities that are available to you based on the state of the application. One of the buttons on the left navigation side of the **Main Workspace** is called "Copy Submission". This allows you to make an exact copy of an existing application.

» My In	ıbox	COI	Facilities	
Submissions	Incidents	Inspections	Meetings	Repor
Specialist Revie Next Steps View Protocol Printer Version View Differences	ew RC	nry Contact: n office: Safet	y PI y Specialist	oto(
🛃 Assign PI Proxy	+		Clarification Requested	
Manage Guest List	Hist	ory Documents	Reviews I	Reviewer N
<ul> <li>Add Comment</li> <li>Copy Submission</li> </ul>	Fi	Iter by ? Activity	▼ Enter to	ext to sea
← Withdraw		Activity		
O Discard	<b>&gt;</b>	Response Submitte	ed	
Manage Related IACUC Protocols	god	od to go? Clarification Reque	sted by Specialist	
Manage Related IRB Stu		re is some more info		

## **RDRC Module**

the application is ill in a state where ou can edit the plication, you can lit the application clicking on the lit Protocol button the left vigation area. In ldition, there will a View Protocol itton to enable ou to view the plication in a ad-only format. inter Version will low you to scroll rough the entire plication on one ige.

The right side contains the **Main Content**. The application title appears towards the left of the **Main Content** area and the application ID is contained above the application title. A summary box is displayed below the application title. Depending on the application, there is different information that is displayed in the summary box.



The **History** and **Documents** tabs always appear for all applications. The **History** tab contains a chronological log of all of the activities that have happened in the application. It includes the person responsible and the date/time the activity occurred. The **Documents** tab contains all documents that were uploaded into the application.



## **Creating a New Application**

To create a new application, click on the **Create Safety Submission** button on the left navigation area. After you click to create the new application, you will automatically be redirected to the first page of the "Formset" or area where the questions are located.

» My	Inbox	COI	Faci	lities	Safety					
Submissions	Incidents	Inspections	Meeting	s Reports	Help Center					
Submissions										
								Search Search	projects	Q
Create Safety Subr	nission	view Activ	re Archived	Suspended or Lap	osed All Submiss	ions In-Review	(w/ PI) All S	ubmissions (w/ PI Se	earch)	
	Filt	ter by 😯 🛛 ID	•	Enter text to search f	or	Q + Add Filt	er 🕱 Clear All			
					Date	State	Principal Investigator	Parent Submission	Submission Type	▲ Safety Review Typ
	ID		Name		Modified		investigator			
			Name Replimune, Inc.: R	P1-104	Modified 9/17/2024 12:35 PM	Modifications Required	Amna Sher		Initial Protocol	Biosafety

From there, you can navigate the page using the controls found at the top of the page.



A "Jump To" menu item will appear after you save the initial page of the application. This will enable you to jump to specific sections of the application.

Stony Brook Research myRESEARCH				$\sim$	Edit: Safety Submission - PROTO201900023
≪ Back	🖺 Save	🕩 Exit	A Hide/Show Errors	🕀 Print ( 🏞 Jump To 🕶	Finish

**IMPORTANT NOTE:** It is advised that you complete the application questions <u>in order</u> because the application shows questions/sections based on what was answered in earlier questions.

The "Hide/show Errors" menu item enables you to see if you have any unanswered questions on the application.

* Stony Brook Research	myRESEARCH					Edit: Safety Submission - PROTO201900023
<b>«</b> Back		🖹 Save 🕞 Exi	A Hide/Show Errors	Print	👼 Jump To 💌	Einish

When the "Hide/Show Errors" is clicked or when the click on "Submit Application" all of the questions that are unanswered will appear in an "Error/Warning Messages" section.

Error/Warning Messages		
Message	Field Name	Jump To
This is a required field; therefore, you must provide the required information.	Radioactivity Usage Type	Radiation Safety Summary
This is a required field; therefore, you must provide the required information.	Lab Security Procedures	Security and Waste Management
This is a required field; therefore, you must provide the required information.	Biological Waste Handling	Security and Waste Management
This is a required field; therefore, you must provide the required information.	Liquid Solid Animal Waste Handling	Security and Waste Management

≪ Back	🖺 Save 🛛 🕩 Ex	it A Hide/Show Errors	🔒 Print	Aump To 🕶	
Supporting Documents					
hank you for completing the information required to submit this prot	ocol to the appropriate Sa	fety Committee.			
1. Attach additional supporting documents: 😧					
+ Add					
Document Name		Date Modified			
There are no items to display					
Take this opportunity to review the information you have provided. complete all personnel requirements will result in a delay in the review					
Note that this protocol has not yet been submitted for review. Upor orotocol workspace in order to forward this submission for review.	n completing the informat	ion in this protocol and clicki	ng the "Finis	h" button below, the principal investig	ator must also click the "Submit" ac
≪ Back	🖺 Save 🛛 🗭 Exi	it A Hide/Show Errors	🔒 Print	产 Jump To 🔻	

At the end of the application, you will be able to upload/attach a file (if applicable).

## **Overview of the Application SmartForm**

- Each question on the SmartForm is numbered and those questions that have a red asterisk
   (\*) must be answered.
- A question mark appears beside many of the SmartForm questions. If you click on the question mark, information will appear that will assist you in answering the question.



If you need to leave the application for any reason, you can save the document and return to the application at a later time.

#### Manage Ancillary Reviews

#### **IMPORTANT NOTE:** New studies require Department Chair approval prior to submission.

- The PI's Department Chair can be selected as an ancillary reviewer.
- <u>Submission of new studies prior to Department Chair approval is not permitted in</u> <u>myResearch. The PI must wait for an email notification of Department Chair</u> <u>approval before submitting the study.</u>

#### Submitting the Study

Once an email notification of Department Chair approval is received, the study can be submitted for review. **The PI** must click on the **Submit** button in the study's left navigation area. An **Investigator's Assurance** page will pop up. The PI must carefully read the assurance page and click the **OK** button on the bottom-right hand side of the page.

## **RDRC Module**

😌 Execute "Submit" on PROTO201900003 - Google Chrome  $\times$ safety-test.myresearch.stonybrook.edu/Safety\_Test/sd/ResourceAdministration/Activity/form?ActivityType=com.webridg.. Submit Investigator's Assurance The Principal Investigator is responsible for the following: Providing adequate training and supervision of staff in good laboratory techniques and practices required to ensure safety and for procedures in dealing with accidents. • Enforcing federal regulations regarding laboratory safety for all persons who work under his/her direction, ensuring appropriate physical containment and for the proper disposal of all hazardous waste such as radioactive material, chemical waste, recombinant or synthetic nucleic acids, bacterial, viruses and other biohazardous agents. Reporting adverse events such as a work related injury or spill of hazardous and/or radioactive material, that could result in unexpected exposure of laboratory personnel and /or the public to the relevant institutional oversight committee. Ensuring that co-investigators, if any, employ the necessary safeguards to protect laboratory personnel, students and the community from potential hazards posed by the project. Complying with shipping requirements for hazardous materials including recombinant or synthetic nucleic acids, bacterial, viruses and other biohazardous agents. I understand my responsibility with regard to laboratory safety and certify that the protocol, as approved by the relevant institutional oversight committee, will be followed during the period covered by this research project. Any future changes will be submitted for committee review and approval prior to implementation. I understand the protocol will be reviewed periodically; it is my responsibility to complete and submit the continuing review form used for the periodic oversight committee review in a manner in accordance with deadlines communicated by the relevant committee. If you have finished filling out your application, click "OK". Afterwards you will no longer be able to edit the application. You will receive email when each approval is granted or refused, and again when all the required approvals are received.

#### **Clarification Requested**

Click the submission ID link in the email to open the document. Click the "History" tab and review the "Clarification Requested" activity. NOTE: if the reviewer attached a document, a link to open it appears on the "History" tab.

## **RDRC Module**

<b>»</b>	My Inbox	COI	Facilities	Safety		
Submissions	Incidents Inspe	ections Meetings	Reports Help Center			
BSO Review	PROTO201900	‱ mple IBC pr	otocol			
Next Steps	Principal Investiga		010001.	Submission Type:	Initial Protocol	
View Protocol	Specialist: Primary Contact:	Safety Specialist		Safety Review Type: Letter:	Biosafety	
Printer Version	Admin office: PI proxies:	Safety		Last day of continuing review Approval Date:	period:	
View Differences	Pre-Submission	Review	Committee Review	Post-Review Complete		
Submit Biosafety Risk Assessment		Clarification Requested	Clarification Requested	Modifications Required		
	BSO					

#### **Respond to Clarification Requests**

On the submission workspace, click "Submit Response". In the Notes box, explain your response to the review. Click "OK". The study has now moved back to the reviewer's inbox to continue the review.

Requested (Specialist Review) Next Steps Edit Protocol	TEST SAFETY SUBMISSION 10/1 Principal Investigator: Safety PI Specialist: Safety Specialist Primary Contact: Admin office: Safety PI proxiee:	4/2019-2 Submission Type: Safety Review Type: Letter: Last day of continuing review p Approval Date:	Initial Protocol Biosafety <b>Seriod:</b>
Printer Version View Differences Submit Response	Pre-Submission Specialist Review Clarification Requested Clarification Requested Clarification Requested Clarification Requested Social	Post-Review Review Complete Modifications Required Analysis Relate	) sd Projects
🛃 Assign PI Proxy	History Documents Reviews Reviewer Notes Contacts 5	napshots Follow-on Submissions Relate	ed Projects
🛃 Assign Primary Contact	Filter by 😢 Activity 💌 Enter text to search for	Q + Add Filter * Clear All	
🖀 Manage Guest List	Activity	Author	- Activity Date
Manage Ancillary Reviews	<ul> <li>Clarification Requested by Specialist</li> </ul>	Specialist, Safety	10/14/2019 4:11 PM
♀ Add Comment	TEST		
Copy Submission	A Submitted	PI, Safety	10/14/2019 4:10 PM
	R Protocol Created	PI, Safety	10/14/2019 4:09 PM
Ø Discard			
Manage Related IACUC Protocols			
Manage Related IRB Studies			

#### **Amendment Request**

Click on **Create Amendment** in the left navigation area if you are submitting an amendment request. Enter data in all required fields. Submit the amendment



## Safety Incident Report

<mark>Click o</mark> r	<b>Create Safety Incident</b> in the left navigation of the left navigati	ation area if you are submitti	<mark>ng an incident</mark>
<mark>report.</mark>			

Stony Brook Research myRESEARCH		New: Safety Incident
« Back	🖺 Save 🔒 Print	Continue »
Basic Information		
1. * Select the admin office: O Safety <u>Clear</u>		
2. * Incident name: 🕢		
3. ★ Select the type: ● Biosafety ○ Chemical Safety ○ Radiation Safety ○ Other <u>Clear</u>		
This area of the Safety Incident w	vill ask you to describe the incide	

This area of the Safety Incident will ask you to describe the incident, the nature of the incident any associated principal investigators, any related safety research protocols, where it was discovered and if there are any additional supporting documents.