

# BiosafetyNet Training Introduction For Research Staff

University of South Florida  
Research Integrity & Compliance  
October 2017.



HELLO  
my name is



**Debbie Howeth**  
Biosafety Manager  
dhoweth@usf.edu

**Farah Moulvi**  
Institutional Biosafety Officer  
fmoulvi@usf.edu

**Tony Marshall**  
IT technology

**ARC Help Desk**  
IT technology





## Background

- Going electronic with BiosafetyNet for Institutional Biosafety Committee (IBC) protocols online
- Research Integrity & Compliance has contracted with Huron Consulting Group to license the Click® Safety Portal for IBC submissions
- Anticipated soft-roll out August 2017
- Platform uses the same Applications for Research Compliance (ARC), single sign on process like eIRB, eIACUC and eCOI
- The Safety Portal is being implemented to assist principal investigators, students, compliance and research administration staff with administering Biosafety Applications
- Biosafety Office is leading the implementation of the Click Portal, working in collaboration with our vendor partner, Huron, Research Technologies, USF IBC members and USF faculty/staff Champions.

## Training Agenda & Materials

- Click Portal - Safety Module Training Setup/Agenda
- Work Instructions:
  - Login
  - Safety Protocol Workflow
  - Create and Submit a BiosafetyNet Safety Protocol
  - Clarification Requested and/or Reviewer Notes
  - Create and Submit a Follow-On Submission (Amendment and Continuing Review)
- Safety Quick Reference Guide
- Sample BiosafetyNet Safety Protocol



## User Roles and Responsibilities

- **Protocol/Study Team** - Individuals responsible for developing and editing the protocol. Includes PIs and their contacts, and other study staff.
- **Safety Administrators** - Individuals who guide submissions through the review process. Includes Safety Specialists and Safety Administrators. Committee Administrators oversee committees and meetings.
- **Reviewers** - Individuals responsible for reviewing protocols. Includes Biosafety Officers, Safety Committee Members, and the Committee Chair. Some protocols may also require an optional review by an Ancillary Reviewer.



## Key Actions By Role

Actions and State Transitions			
In this state...	These roles...	Can perform these actions...	Changing the submission state to...
<b>(No State)</b>	Any registered user	Create a new safety protocol	Pre-Submission
<b>Pre-Submission</b>	Principal Investigator or PI Proxy	Submit	Specialist Review
<b>Specialist Review</b>	Safety Specialist	Send to BSO Review	BSO Review
		Send to Member Review	Member Review
		Approve Submission (Admin)	Post-Review
	Safety Specialist, Safety Administrator	Request Clarification by Specialist	Clarifications Requested (Specialist Review)
	Safety Specialist	Submit Specialist Review	Committee Review

## BiosafetyNet Workflow - Pre-Submission

- **Pre-Submission:** During Pre-Submission, the PI or Research Staff will create the Safety protocol



- **Specialist Review:** In the Specialist Review state, the protocol has been submitted and is reviewed by the BioSafety Specialist



## BiosafetyNet Workflow - Committee Review

- **Committee Review:** In Committee Review, the Safety committee members will review the protocol for completeness



- **Clarification Requested:** The Safety Specialist and/or Safety Committee members may send a Request for Clarification during the Specialist and Committee Review states. This will send the protocol into the Clarification Requested state until the PI has responded to the request



## BiosafetyNet Workflow - Post- Review

- Post-Review:** The Post-Review state gives the Safety Specialist an opportunity to approve any attached documents, request any modifications. and prepare and send the determination letter



- Review Complete:** The Safety protocol will reach its final state, Review Complete, after the approval letter is sent



## ARC Registration for New Users

- If you are already an ARC user then use your login and password to access BiosafetyNet
- As a new user, to access/use BiosafetyNet, you must register at ARC  
<https://arc.research.usf.edu/prod>
- Complete all the fields on the registration form
- Your Username and Password will be e-mailed to you
- USF Personnel can login using their NetID



The screenshot shows the BiosafetyNet Home Page. At the top left, there are logos for USF University of South Florida, ARC, and Biosafety Net. On the right side, there is a 'Login' button highlighted with a red box and an arrow labeled '2'. Below the navigation bar, there is a search box with a 'Go' button and a 'Help' button. The main content area is titled 'Home' and contains a message 'USF Dev Site for Click Safety' and 'No items to display' under 'Folders' and 'Documents' sections. On the right side, there is a 'Need an account?' section with a 'Register Here' button highlighted with a red box and an arrow labeled '1'.

## From Main page

1. Select Register Here is you do not have an ARC account and first time system user
2. Select Login once you have an ARC account to access BiosafetyNet



**Register Here**

**Self Registration**

Prefix:

\* First:

Middle:

\* Last:

Suffix:

Title:

\* Department:

\* USF Campus or Affiliation:   
Indicate the USF Campus (e.g., Tampa or Sarasota) or Organization (e.g., Moffitt or TGH) that you are affiliated with.

---

\* Primary E-mail:   
(Please list your work or student e-mail address)

Secondary E-mail:

USF Net ID:   
Activate/Administer NetID

USF ID Number:   
(Student or Employee ID)

\* Roles Requested:

- Study Staff (PI, Co-I, Coordinator, Study Team)
- Supervisor
- Department Chair/Approver
- Department Scientific Reviewer
- Appointed IRB Member
- Appointed IACUC Member
- Appointed COI Member

---

\* Business Phone:

Mobile:

Fax:

\* Address:   
(Line 1)

Address:   
(Line 2)

\* City:

\* State:  \* Zip:

You will receive your username and a temporary password by e-mail.

**Note:** The first time you login, you will be prompted to change that password.

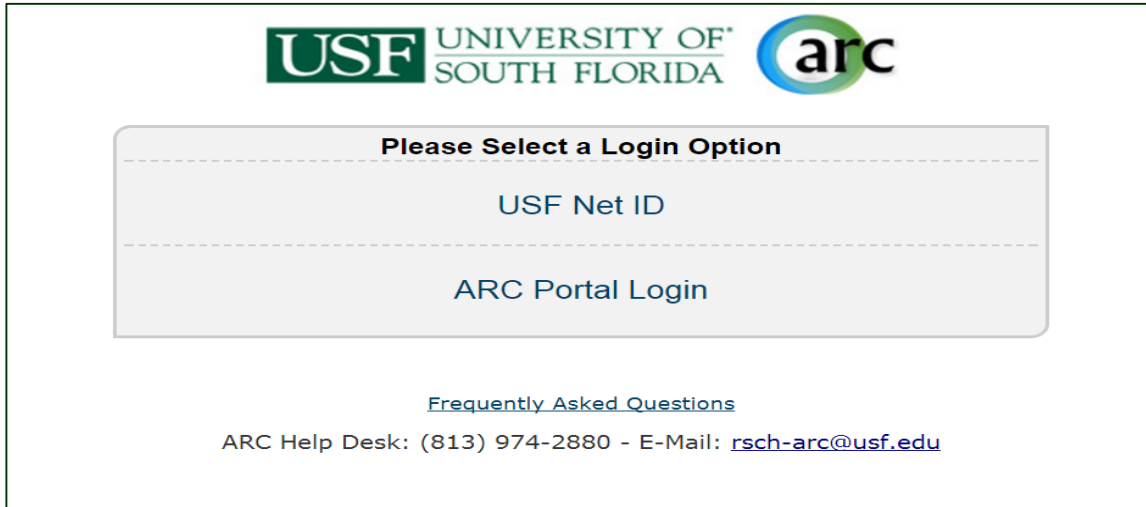
\* Required

- Required fields are marked with an asterisk \*
- PIs/Staff/researchers should select the “Study Staff” role
- You will receive your username and temporary password via email with 2-3 days



## Website

- Navigate to <https://arc.research.usf.edu/Safety>



**USF** UNIVERSITY OF SOUTH FLORIDA **arc**

Please Select a Login Option

USF Net ID

ARC Portal Login

[Frequently Asked Questions](#)

ARC Help Desk: (813) 974-2880 - E-Mail: [rsch-arc@usf.edu](mailto:rsch-arc@usf.edu)

- If USF affiliated you can use your NetID as single sign-on
- For all other use ARC Portal Login
- Enter a User Name and Password, and click the Login button.



## USF Net ID login prompt

**USF** UNIVERSITY OF SOUTH FLORIDA. MYUSF WEB TOOLS DIRECTORY

ABOUT USF ACADEMICS ADMISSIONS CAMPUS LIFE RESEARCH USF SYSTEM

### USF NetID Single-SignOn (Testing)

This site is for **TESTING PURPOSES ONLY!**

If you are not part of a group that is currently testing a new or updated application, you have been sent to wrong place. Please contact the developer or group responsible for your application and let them know you are seeing this message.

#### NetID Single-SignOn (Testing)

NetID

Password

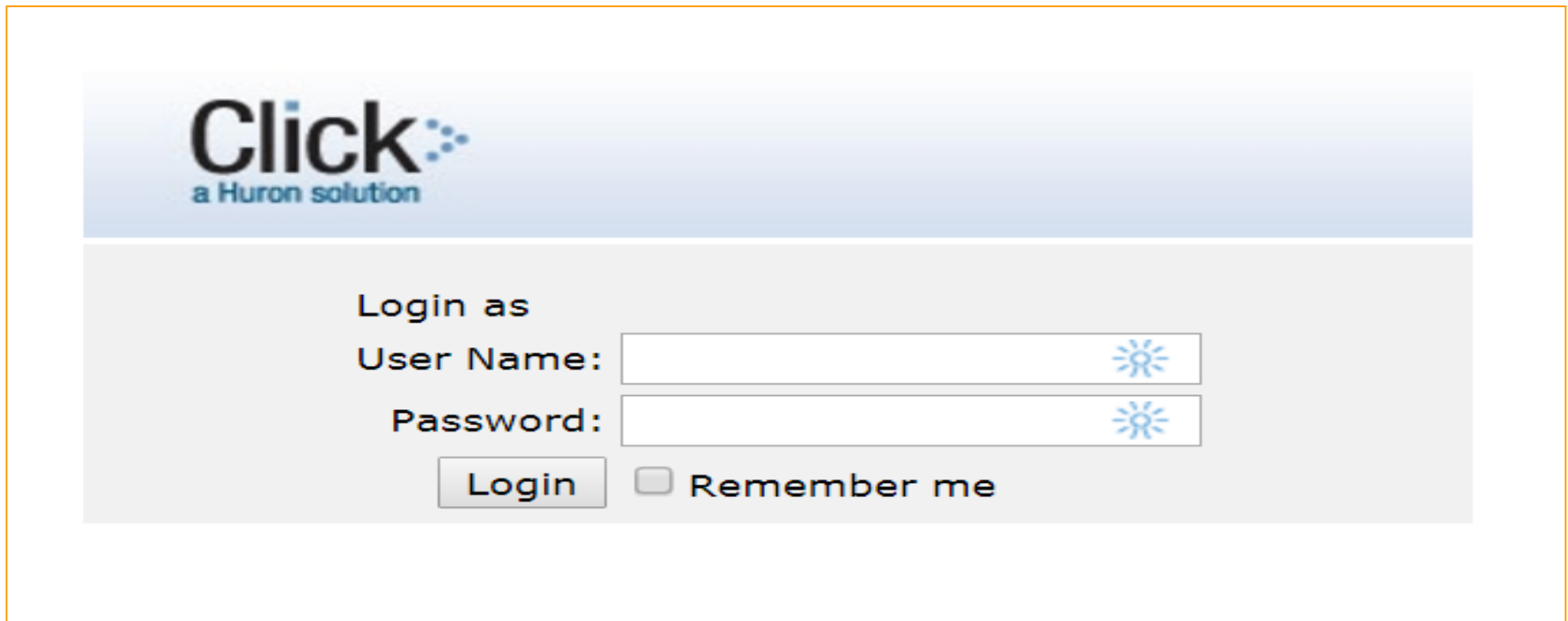
**Sign In**

By logging in, I agree to the terms of the [Acceptable Use Policy](#).

- Enter a User Name and Password, and click the Login button.
- You will be redirected back to BiosafetyNet



## USF ARC account prompt



The screenshot shows a login interface for 'Click', a solution by Huron. The interface is contained within a light gray box with a blue gradient header. The header contains the 'Click' logo and the text 'a Huron solution'. Below the header, the text 'Login as' is displayed. There are two input fields: 'User Name:' and 'Password:'. Each input field has a blue sun icon on the right side. Below the input fields, there is a 'Login' button and a checkbox labeled 'Remember me'.

- If you do not have a USF NetID or prefer this login, enter your login information that was emailed to you
- Enter a User Name and Password, and click the Login button.



## Personal Homepage

### My Current Actions

[Create Safety Submission](#)

[Create Safety Incident](#)

[Help Center](#)

[Submissions](#)

[Incidents](#)

[Inspections](#)

[Reports](#)

### My Inbox

Filter by <sup>?</sup> ID		Go	Clear	Advanced		
ID	Name	Date Created	Date Modified	State	Coordinator	
PROTO2017-120	_ClickSafetySubmission - 6/28/2017 7:56:59 PM	6/28/2017 3:56 PM	6/28/2017 3:57 PM	Pre-Submission		
PROTO2017-119	This is great feature-version 6 by Farah Moulvi	6/22/2017 4:22 PM	6/22/2017 4:22 PM	Pre-Submission		
PROTO2017-110	Testing Farah version 5	6/16/2017 12:37 PM	6/22/2017 4:21 PM	Pre-Submission		
AMEND1_PROTO2017-090	Issues00001360 Testing	3/20/2017 9:41 AM	3/28/2017 10:27 AM	Post-Review	Stephen Blackburn	
AMEND1_PROTO2017-012	Amendment for PROTO2017-012	3/7/2017 5:19 PM	3/7/2017 5:19 PM	Pre-Submission		
PROTO2017-056	Issues00001354 - SF testing	3/2/2017 9:04 AM	3/6/2017 9:59 AM	Pre-Submission		
PROTO2017-054	Testing Issues00001340	2/28/2017 3:58 PM	2/28/2017 3:58 PM	Pre-Submission		
PROTO2017-053	Testing Issues00001356	2/28/2017 3:57 PM	2/28/2017 3:57 PM	Pre-Submission		
PROTO2017-052	Testing Issues00001340	2/28/2017 3:55 PM	2/28/2017 3:55 PM	Pre-Submission		
PROTO2017-033	Blah Blah Blah 1337	2/15/2017 8:07 AM	2/28/2017 2:50 PM	Pre-Submission		
PROTO2017-048	Issues00001335(HGT)	2/24/2017 3:53 PM	2/24/2017 3:53 PM	Pre-Submission		





## Personal Homepage- My Inbox

- Lists all applications that require action by you or your research staff
  - **Protocol ID-** is your unique identifier for submission
    - PROTO2017-123- For new study protocol
    - AMEND1\_PROTO2017-123- For Amendment
  - **Name-** is the short title of your study
  - **State-** is the state that application is in- example “pre-submission”
- Selecting the application’s **Name** will bring you to the safety protocol workspace
- Left side has shortcuts to help center and resources



## My In-Box Features

The screenshot shows the BiosafetyNet My Inbox interface. At the top, there are logos for USF University of South Florida, arc, and Biosafety Net. A user profile box in the top right shows 'Rebecca Simms (PI) | My Inbox | Logout'. Below the navigation bar, there are sections for 'My Current Actions' and 'My Inbox'. The 'My Current Actions' section includes buttons for 'Create Safety Submission', 'Create Safety Incident', 'Help Center', 'Submissions', 'Incidents', 'Inspections', and 'Reports'. The 'My Inbox' section contains a table of submissions with columns for ID, Name, Date Created, Date Modified, State, and Coordinator. Numbered callouts (1-6) point to specific features: 1 points to the 'Create Safety Submission' button; 2 points to the 'My Inbox' table; 3 points to the user profile box; 4 points to the 'Page for Rebecca Simms (PI)' breadcrumb; 5 points to the 'Help Center' link; and 6 points to the 'Submissions' link.

ID	Name	Date Created	Date Modified	State	Coordinator
PROTO2017-120	_ClickSafetySubmission - 6/28/2017 7:56:59 PM	6/28/2017 3:56 PM	6/28/2017 3:57 PM	Pre-Submission	
PROTO2017-119	This is great feature-version 6 by Farah Moulvi	6/22/2017 4:22 PM	6/22/2017 4:22 PM	Pre-Submission	
PROTO2017-110	Testing Farah version 5	6/16/2017 12:37 PM	6/22/2017 4:21 PM	Pre-Submission	
AMEND1_PROTO2017-090	Issues00001360 Testing	3/20/2017 9:41 AM	3/28/2017 10:27 AM	Post-Review	Stephen Blackburn
AMEND1_PROTO2017-012	Amendment for PROTO2017-012	3/7/2017 5:19 PM	3/7/2017 5:19 PM	Pre-Submission	
PROTO2017-056	Issues00001354 - SF testing	3/2/2017 9:04 AM	3/6/2017 9:59 AM	Pre-Submission	
PROTO2017-054	Testing Issues00001340	2/28/2017 3:58 PM	2/28/2017 3:58 PM	Pre-Submission	
PROTO2017-053	Testing Issues00001356	2/28/2017 3:57 PM	2/28/2017 3:57 PM	Pre-Submission	
PROTO2017-052	Testing Issues00001340	2/28/2017 3:55 PM	2/28/2017 3:55 PM	Pre-Submission	
PROTO2017-033	Blah Blah Blah 1337	2/15/2017 8:07 AM	2/28/2017 2:50 PM	Pre-Submission	
PROTO2017-048	Issues00001335(HGT)	2/24/2017 3:53 PM	2/24/2017 3:53 PM	Pre-Submission	

From My Inbox, you will see:

1. Submissions that require action
2. State in the review process
3. Your account name and shortcut to your Inbox
4. Create a new Safety Submission
5. Shortcut to user guides under Help Center
6. Shortcut to view all submissions



## Safety Protocol Workspace

Home Facilities Safety

Safety > Testing Farah version 5 Components

**Pre-Submission**

**My Current Actions**

Edit Protocol

Printer Version

View Differences

**Submit**

Assign Primary Contact

Manage Guest List

Add Comment

Copy Submission

Discard

Manage Related IACUC Protocols

Manage Related IRB Studies

**PROTO2017-110: Testing Farah version 5**

**Principal Investigator:** Rebecca Simms (PI)    **Submission Type:** Initial Protocol

**Specialist:**    **Safety Review Type:** Biosafety

**Primary Contact:**

**Letter:**

**Admin office:** Safety    **Last day of continuing review period:**

**PI proxies:**    **Approval Date:**

**History** Documents   Reviews   Contacts   Snapshots   Follow-on Submissions   Related Projects

Filter by Activity   Go   Clear   Advanced

Activity	Author	Activity Date
Submission Copied	Simms (PI), Rebecca M	6/22/2017 4:22 PM
New Copy: PROTO2017-119 This is great feature-version 6 by Farah Moulvi		
Protocol Created	Simms (PI), Rebecca M	6/16/2017 12:37 PM
Copied from PROTO2017-109 A second Copy - Farah Test 2		



## The Workspace is your protocol's homepage

- The Workspace provides access to:
  - The SmartForm and status information
  - Documents including Approval Letters
  - Activities to move the protocol forward in the review process
  
- Access the Protocol's Workspace by selecting:
  - Exit or Finish in the SmartForm
  - The name of the Protocol from your homepage
  - The link in an ARC BiosafetyNet email notification



## Safety Protocol Workspace

USF UNIVERSITY OF SOUTH FLORIDA arc BIOSAFETY NET

Home Facilities Safety **1**

Safety > Testing Farah version 5 **2**

**Pre-Submission**

**My Current Actions**

- Edit Protocol **3**
- Printer Version
- View Differences

**PROTO2017-110: Testing Farah version 5**

Principal Investigator: Rebecca Simms (PI) Submission Type: Initial Protocol  
Specialist: Biosafety Safety Review Type: Biosafety  
Primary Contact: Letter:  
Admin office: Safety Last day of continuing review period:  
PI proxies: Approval Date:

Pre-Submission → Specialist Review → Committee Review → Post-Review → Review Complete  
Clarification Requested → Clarification Requested → Modifications Required

**History** Documents Reviews Contacts Snapshots Follow-on Submissions Related Projects **4**

Filter by Activity Go Clear Advanced

Activity	Author	Activity Date
Submission Copied	Simms (PI), Rebecca M	6/22/2017 4:22 PM
New Copy: PROTO2017-119 This is great feature-version 6 by Farah Moulvi		
Protocol Created	Simms (PI), Rebecca M	6/16/2017 12:37 PM
Copied from PROTO2017-109 A second Copy - Farah Test 2		

Submit **3**

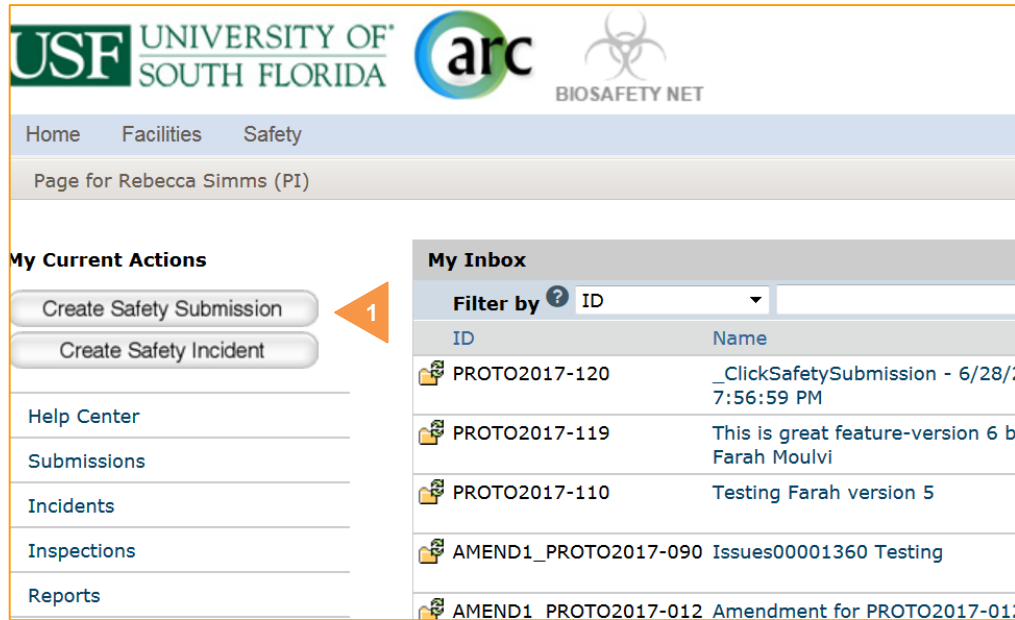
- Assign Primary Contact
- Manage Guest List
- Add Comment
- Copy Submission
- Discard
- Manage Related IACUC Protocols
- Manage Related IRB Studies

From protocol workspace, you will see:

1. Protocol detail header information
2. The State in the review process
3. Actions you can take in the protocol's state
4. Tabs with information about the protocol and review process



## Pre-Submission for Safety Protocol



USF UNIVERSITY OF SOUTH FLORIDA arc BIOSAFETY NET

Home Facilities Safety

Page for Rebecca Simms (PI)

**My Current Actions**

Create Safety Submission **1**

Create Safety Incident

Help Center

Submissions

Incidents

Inspections

Reports

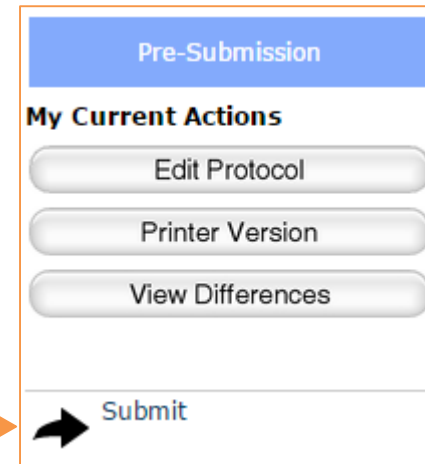
**My Inbox**

Filter by ID

ID	Name
PROTO2017-120	_ClickSafetySubmission - 6/28/2017 7:56:59 PM
PROTO2017-119	This is great feature-version 6 b Farah Moulvi
PROTO2017-110	Testing Farah version 5
AMEND1_PROTO2017-090	Issues00001360 Testing
AMEND1_PROTO2017-012	Amendment for PROTO2017-012

The PI/research will :

1. Create the Safety protocol and complete the protocol SmartForm pages
2. Only the PI only can submit the protocol for review



Pre-Submission

**My Current Actions**

Edit Protocol

Printer Version

View Differences

**2** Submit






## Complete the SmartForm

- The SmartForm is an electronic form where you answer questions about your research project
- It is a SmartForm because it uses your answers to branch only to pages relevant to your research
- Required questions are marked with a red asterisk \*



## Smart Form Navigation

Edit: Click Safety Submission - PROTO2017-121

<< Back **Does Not Save** Save | Exit | Hide/Show Errors | Print... | Jump To: - Basic Information - Continue >>

### Basic Information

1. \* **Title of protocol:**  
Tiz the season for Testing- Once, twice, three times

2. \* **Short title:**  
Tiz the season for Biosafety ...keep Calm Biosafety Peeps

3. \* **Summary of research:**  
The objectives of this project are to develop a high throughput assay for screening natural product libraries derived from various sources for antiviral activity against Zika virus. The high throughput assay will utilize a viral genome analog that replicates in cells but does not produce infections virus (replicon). Compound hits identified in the replicon assay will be screened against live Zika virus for confirmation of activity.  
  
No virus isolation work.

**Saves Application**





## Smart Form Navigation

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: - Basic Information ▾ | Continue >>

### Basic Information

1. \* **Title of protocol:**

Tiz the season for Testing- Once, twice, three times

2. \* **Short title:**

Tiz the season for Biosafety ...keep Calm Biosafety Peeps

3. \* **Summary of research:**

The objectives of this project are to develop a high throughput assay for screening natural product libraries derived from various sources for antiviral activity against Zika virus. The high throughput assay will utilize a viral genome analog that replicates in cells but does not produce infections virus (replicon). Compound hits identified in the replicon assay will be screened against live Zika virus for confirmation of activity.

No virus isolation work.

<b>Basic Information &amp; Funding</b>	<b>Current Page</b>
- Basic Information	
- Protocol Team Members	
- Funding Sources	
<b>Biosafety Summary</b>	<b>Required Pages</b>
- Biosafety Summary	
<b>Agents, Toxins, &amp; Microorganisms</b>	
- Bacteria, Yeasts, Fungi, or Parasites	
- Viruses or Prions	
- Biohazards	
<b>Recombinant &amp; Synthetic Nucleic Acids</b>	
- Recombinant or Synthetic Nucleic Acids Usage	
- Recombinant or Synthetic Nucleic Acid Work Description	
<b>Animals and Genetically Modified Animals</b>	
- Animals	
<b>Risk Management</b>	
- Risk Group and Containment Practices	
- Exposure Assessment and Protective Equipment	
- Waste Management	
<b>Supporting Documents</b>	
- Supporting Documents	



## Smart Form- Finish and Submit

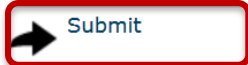
Pre-Submission

### My Current Actions


Edit Protocol

Printer Version

View Differences

 Submit

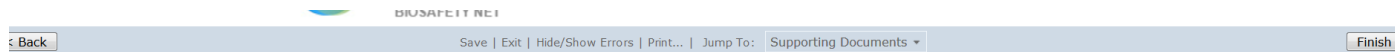
 Assign Primary Contact

 Manage Guest List

 Add Comment

 Copy Submission

**“Finish” completes protocol application**



### Supporting Documents

Thank you for completing the information required to submit this protocol to the appropriate Safety Committee.

#### 1. Attach additional supporting documents:

Document Name	Date Modified
There are no items to display	

Please take this opportunity to review the information you have provided. It is very important that the responses in this protocol be thorough and specific. Failure to respond to all requested items, to submit all required documents, or complete all personnel requirements will result in a delay in the review of this protocol and may result in the protocol being returned to the protocol team for correction or completion.

Please note that this protocol has not yet been submitted for review. Upon completing the information in this protocol and clicking the "Finish" button below, the Principal Investigator must also click the "Submit" activity from the protocol workspace in order to forward this submission for review.



**“Submit” forwards the application for review**



## Create and Submit Biosafety Protocol

- “Create Safety Submission”
- Complete the Smartform
  - Dependent on choices made on form-branching questions
  - “Save’ or “Continue” saves the entry on each page.
  - “Back” or “Exit” does not save changes on page
- Continue through the SmartForm completing all required fields noted by an asterisk \*
- Clicking “Finish” does not submit your protocol
- Use Activities to “Submit” for Review
- All Applications follow the same basic submission process



## Tips

- All applications must be:
  1. Created
  2. Completed (SmartForm)
  3. Submitted (Activity)
  
- If an application is in your Inbox, it still requires your or your research staff attention.
  
- Actions → Look to the left side menu
  
- Remember to Save:
  - Save or Continue saves your changes
  - Back and Exit do not save



## What to expect after Protocol Submission

- ❑ Submitting your protocol initiates the review process which includes the following activities:
  - Review by Safety Specialist
  - Review by a Safety committee
  - Optional ancillary review by individuals, departments, and other organizations
  - Communication of the committee's decision to the investigator
- ❑ Any of these may lead to a request for the study team to take further action, such as providing clarifications regarding the protocol
- ❑ Whenever the study team needs to act, the PI receives an e-mail notification, and the protocol appears in My Inbox for all study team members when they log in to the ARC BiosafetyNet Portal



## Responding to Reviewers Notes

- The PI or the PI proxy will:
  - Receive notification that a clarification request was made
  - Open the protocol, and click the **Edit Protocol** button
  - Makes changes in the body of the application
  - Read and respond to any Reviewer Notes (e.g. Committee Change Request)-select *Click here to respond*
- PI responds to revisions by:
  1. *Correcting* the SmartForm **Edit Protocol**
  2. *Responding* to the Reviewer Note
  3. *Submitting* back for review



# BiosafetyNet -Requested Clarifications/Revisions

Reviewer Notes are placed on pages in the SmartForm. They can be accessed by selecting:

- Edit Protocol to access the SmartForm
- Reviewer Notes tab to view all notes

The screenshot displays the BiosafetyNet interface for protocol **PROTO2017-110: Testing Farah version 5**. The top navigation bar includes 'Home', 'Facilities', and 'Safety'. The breadcrumb trail shows 'Safety > Testing Farah version 5'. The left sidebar contains 'My Current Actions' with 'Edit Protocol' highlighted in a red box. The main content area shows protocol details: Principal Investigator: Rebecca Simms (PI), Submission Type: Initial Protocol, Specialist: Steve Savage (safs), Safety Review Type: Biosafety, Primary Contact, Letter: Correspondence\_for\_PROTO2017-110.pdf(0.01), Admin office: Safety, Last day of continuing review period: 6/29/2018, and PI proxies. A flowchart below the details illustrates the review process: Pre-Submission leads to Specialist Review, which can lead to Clarification Requested, then Committee Review, which can also lead to Clarification Requested, then Post-Review, which can lead to Modifications Required, and finally Review Complete. The 'Reviewer Notes' tab is highlighted in a red box in the navigation bar. Below the tabs, a table shows a 'Committee Change Request' with a 'Jump To: Basic Information' link and a date of '6/30/2017 5:10 PM'. A red line is drawn under the 'Click here to respond...' link in the table.

## Correct and Respond

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - Funding Sources

Reviewer Note Previous **Next**

Filter by Type    Advanced

Type	Reviewer	D
<input type="checkbox"/> Committee Change Request Funding Source: Item 1- If VA federal funds please provide grant info. <input type="checkbox"/> <a href="#">Click here to respond...</a>	Steve Savage	7, (safs)


**2. Respond**

### Funding Sources

**1. Correct**

1. Identify each organization supplying funding for the protocol:

Funding Source	Sponsor's Funding ID	Grants Office ID	Documents
There are no items to display			

2. Which institution are these funds administered through? 

- Moffitt
- USF
- VA
- Other

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - Funding Sources





## Submit Response

- The PI or PI proxy will:
  - Click on Submit Response in the protocol Workspace
  - Add any comments, and/or upload supporting documents if needed

### Submit Response

**1. Comments:**

Please see my responses to Reviewer Notes.

**2. Supporting documents:**

Add

Document Name	Date Modified
There are no items to display	

OK Cancel

Clarification Requested  
(Specialist Review)

**My Current Actions**

Edit Protocol

Printer Version

View Differences

**Submit Response**

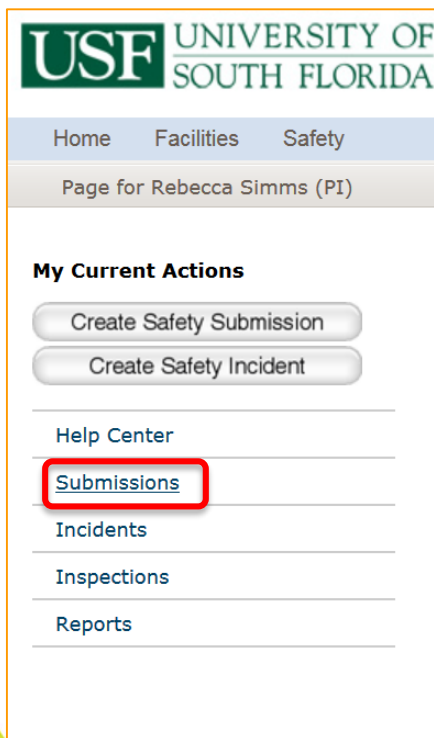


# BiosafetyNet-Post Approval

To find your approved Protocol:

Use the link in the email notification OR

Select Submissions from your homepage and then “Active” tab



USF UNIVERSITY OF SOUTH FLORIDA

Home Facilities Safety

Page for Rebecca Simms (PI)

**My Current Actions**

Create Safety Submission

Create Safety Incident

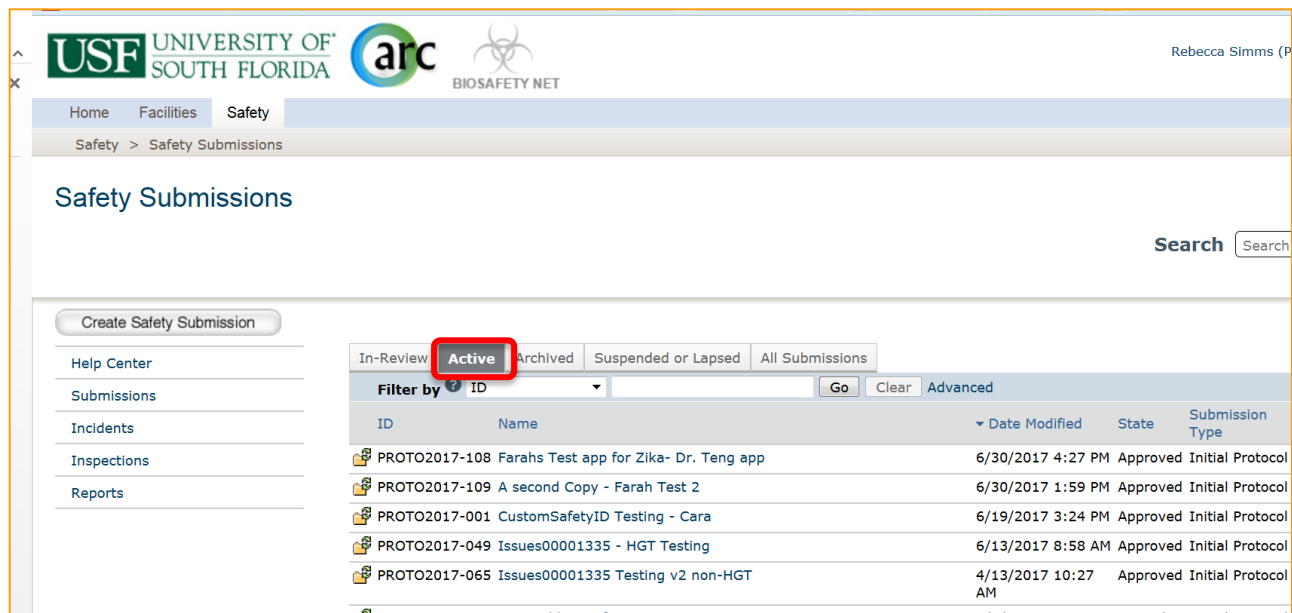
Help Center

**Submissions**

Incidents

Inspections

Reports



USF UNIVERSITY OF SOUTH FLORIDA arc BIOSAFETY NET

Rebecca Simms (P

Home Facilities Safety

Safety > Safety Submissions

**Safety Submissions**

Search Search

Create Safety Submission

Help Center

Submissions

Incidents

Inspections

Reports

In-Review **Active** Archived Suspended or Lapsed All Submissions

Filter by ID Go Clear Advanced

ID	Name	Date Modified	State	Submission Type
PROTO2017-108	Farahs Test app for Zika- Dr. Teng app	6/30/2017 4:27 PM	Approved	Initial Protocol
PROTO2017-109	A second Copy - Farah Test 2	6/30/2017 1:59 PM	Approved	Initial Protocol
PROTO2017-001	CustomSafetyID Testing - Cara	6/19/2017 3:24 PM	Approved	Initial Protocol
PROTO2017-049	Issues00001335 - HGT Testing	6/13/2017 8:58 AM	Approved	Initial Protocol
PROTO2017-065	Issues00001335 Testing v2 non-HGT	4/13/2017 10:27 AM	Approved	Initial Protocol



## Approved Protocol Workspace

Home Facilities Safety

Safety > Farahs Test app for Zika- Dr. Teng app

Approved

### PROTO2017-108: Farahs Test app for Zika- Dr. Teng app

**Current Actions**

- View Protocol
- Printer Version
- View Differences
- Create Amendment
- Create Continuing Review
- Create Safety Incident

**Principal Investigator:** Rebecca Simms (PI)    **Submission Type:** Initial Protocol  
**Specialist:** Steve Savage (safs)    **Safety Review Type:** Biosafety  
**Primary Contact:**    **Letter:** Correspondence for PROTO2017-108.pdf(0.01)  
**Admin office:** Safety    **Last day of continuing review period:** 6/29/2018  
**PI proxies:**    **Approval Date:** 6/30/2017



History	Documents	Reviews	Contacts	Snapshots	Follow-on Submissions	Related Projects
Filter by Activity <input type="text"/> Go Clear Advanced						
	Activity	Author	Activity Date			
✉	Letter Sent	Savage (safs), Steve	6/30/2017 4:27 PM			
📎	Correspondence_for_PROTO2017-108.pdf					
📄	Submission Copied	Simms (PI), Rebecca M	6/16/2017 11:26 AM			
📄	New Copy: PROTO2017-109 A second Copy - Farah Test					
➔	Response Submitted	Simms (PI), Rebecca M	6/16/2017 11:24 AM			

- Request Closure
- Assign PI Proxy
- Assign Primary Contact
- Manage Guest List
- Add Comment
- Copy Submission



# BiosafetyNet- Creating Subprojects

- Go to the associated study's main workspace.
- Look to the left side menu for the subprojects available

**Approved** **PROTO2017-108: Farahs Test app for Zika- Dr. Teng app**

**Principal Investigator:** Rebecca Simms (PI) **Submission Type:** Initial Protocol  
**Specialist:** Steve Savage (safs) **Safety Review Type:** Biosafety  
**Primary Contact:** **Letter:** Correspondence\_for\_PROTO2017-108.pdf(0.01)  
**Admin office:** Safety **Last day of continuing review period:** 6/29/2018  
**PI proxies:** **Approval Date:** 6/30/2017

**Current Actions**

- View Protocol
- Printer Version
- View Differences
- Create Amendment**
- Create Continuing Review
- Create Safety Incident

**Request Closure**

- Assign PI Proxy
- Assign Primary Contact

**History** Documents Reviews Contacts Snapshots Follow-on Submissions Related Projects

**Filter by** Activity

Activity	Author	Activity Date
Letter Sent	Savage (safs), Steve	6/30/2017 4:27 PM

Correspondence\_for\_PROTO2017-108.pdf

```

graph LR
    A[Pre-Submission] --> B[Specialist Review]
    B --> C[Committee 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
  
```





- **AMENDMENTS**

- Significant-allows you to make changes to the approved protocol such as changes to labs rooms, agents, procedures etc.
- Minor-allows you make changes to the approved protocol to add and remove non-PI research team members & funding
- For HGT clinical trials allows you to notify the IBC of reportable events/adverse events/amendments that require review

- **CONTINUING REVIEWS**

- Request an annual extension of your protocol's approval period.
- For Human Gene Transfer (HGT) clinical trials, the CR request may require submission every six months.

- **SAFETY INCIDENT**

- allows you submit reports of lab exposures or spills



## Amendments and Continuing Reviews

- Amendments
  - Only one Amendment can be opened at the same time for a approved protocol. A unique identifier will be issued for each subprojects (i.e. Amendment).
  - However, several changes can be made within the same amendment
  - Reportable events and Serious adverse events must for HGT clinical trials be submitted as Amendments
  
- Continuing Review (CR)
  - Only one Continuing Review can be opened at the same time for a approved protocol.
  - Except HGT clinical protocols, all biosafety protocols are approved for a three year term with annual CR requirement
  - HGT clinical protocols are approved coinciding with the IRB review cycle.

## Continuing Review (CR)

- Subprojects follow the same process as the initial study
  - Create the Continuing Review
  - Complete the SmartForm
  - Submit for Review from workspace
- Each subproject has its own workspace
- Subprojects that require your attention will show up in your inbox
- Reminder notices are sent out automatically at 90, 60, and 30 days from study annual or third expiration
- Tip: Ensure that all protocol team members have current IBC training



## Continuing review for HGT clinical Protocols

- For HGT clinical protocols Continuing review documents from IRB may be submitted via the “Submit” activity using the supporting document upload feature

### 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.

If you are not ready to submit your application, click **Cancel**.

\* I agree with the above statement:

#### 1. Comments:

**Click “Add” to upload**

#### 2. Supporting documents:

Add	Document Name	Date Modified	
Upload Revision	IRB Continuing Review	7/7/2017 4:23 PM	Delete

OK Cancel





USF UNIVERSITY OF SOUTH FLORIDA arc BIOSAFETY NET

Edit: Click Safety Submission - CR1\_PROTO2017-109

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Safety Changes Continue >>

### Safety Changes

- Have any changes occurred with any of the following aspects of your protocol since the original submission approval?
  - Infectious agents used
  - Biosafety level (BSL)
  - Risk group (RG)
  - Containment equipment
  - Personnel
  - Procedures

Yes  No [Clear](#)
- If yes, please declare such changes by submitting a separate modification. Please note approval must be secured prior to initiation of the changes.
- Please make sure all Protocol Team Members have current training:
 

Team Member	Phone	E-Mail	Training Completed
Andrew Cannons	974-1478	acannons@health.usf.edu	2/10/2017
Rebecca Simms (PI)	211-333-3333	demo@webridge.com	2/14/2016

Click  
"Continue"

USF UNIVERSITY OF SOUTH FLORIDA arc BIOSAFETY NET

Edit: Click Safety Submission - CR1\_PROTO2017-109

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Safety Accidents and Problems Finish

### Safety Accidents and Problems

- Have any accidents occurred that resulted in inoculation, ingestion or inhalation of biohazardous materials, or is there any danger of environmental contamination?
 

Yes  No [Clear](#)
- If yes, provide a complete description and resolution of the events:
- Have any problems occurred pertaining to safety containment, equipment, or facility failure?
 

Yes  No [Clear](#)
- If yes, provide a complete description and resolution of the problems:

Click  
"Finish"

**Continuing Review Current Actions**

Edit Continuing Review

Printer Version

View Differences

Submit

Manage Guest List

Add Comment

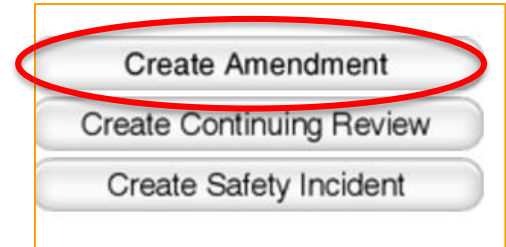
## Amendment (AMEND)

- You can use one Amendment to make all necessary changes.
- **Minor** amendments are **limited to** non-PI personnel change and funding change.
- All changes that are not minor are Significant
- If you choose Significant Changes, in addition to completing the Amendment form, you will need to make the necessary changes in the body of the main application.



## Amendment Type Definition

- **Significant:**
  - Changes in biological agent
  - Changes in lab location
  - Changes in protocol title
  - Changes in procedures
  - Human Gene Transfer studies reportable events (e.g. Data safety monitoring reports, non-compliance, SAEs, etc.)
  - Human Gene Transfer studies amendments (e.g. Updates to informed consent forms, investigator brochures and/or protocols, etc.)
- **Minor:** Changes are limited to changes in protocol team membership (except PI) and funding.



## Amendments for Human Gene Transfer Studies


- For HGT clinical protocols use Amendments for reporting
  - reportable events - e.g. adverse events & protocol deviation
  - Amendments- e.g. change in consent form or investigator brochure
  - can be submitted via the amendments activity using the document upload feature to the Supporting documents page of the form



## Amendment Types on Smart-Form

### Amendment Request

Only one amendment can be active at one time, i.e., the first amendment must be approved, denied, or withdrawn before the second amendment can be created. On subsequent pages, you can change the protocol details as necessary.

1. \* Amendment short title: 

2. \* Amendment types: 

- Significant
- Minor (Protocol Team Membership and Funding)

3. \* Describe the changes: 

4. \* Describe the rationale for the changes:



## Amendment/Reportable Events for HGT clinical Protocols

- For HGT clinical protocols Reportable Events documents from IRB may be submitted via the “Submit” activity using the supporting document upload feature

### 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.

If you are not ready to submit your application, click **Cancel**.

\* I agree with the above statement:

#### 1. Comments:

**Click "Add" to upload**

#### 2. Supporting documents:

Add	
Document Name	Date Modified
<input type="button" value="Upload Revision"/> IRB Reportable Event #4- SAE	7/7/2017 4:56 PM <input type="button" value="Delete"/>



## Contact Information

- Access to *BiosafetyNet*
  - Official regulatory site: <https://arc.research.usf.edu/Safety>
  - Need Help?
    - Contact the ARC Help Desk:
    - 813-974-2880 between 8 AM - 5 PM Monday through Friday
    - Email: [rsch-arc@usf.edu](mailto:rsch-arc@usf.edu)
- Access to training
  - Demo Site for training and practice:  
<https://arcdev.research.usf.edu/SafetySandbox>
    - Login: pi Password:1234.test
- Need to schedule a training?
  - Contact the Biosafety Office at (813) 974-5091

## References/Sources for training Info

- USF ARC help-desk training materials
- Huron- Click Safety training Materials
- University of Buffalo- The State University of New York Training Materials
- Biosafety Team members