BiosafetyNet Training
Introduction For Research Staff

University of South Florida

Research Integrity & Compliance

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USF
UNIVERSITY OF
SOUTH FLORIDA

HELLO
my name is

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BiosafetyNet- Click Safety Module

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

BiosafetyNet- Roles

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.

BiosafetyNet- Roles

Key Actions By Role

Actions and State Transitions			
In this state...	**These roles...**	**Can perform these actions...**	**Changing the submission state to...**
(No State)	Any registered user	Create a new safety protocol	Pre-Submission
Pre-Submission	Principal Investigator or PI Proxy	Submit	Specialist Review
Specialist Review	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

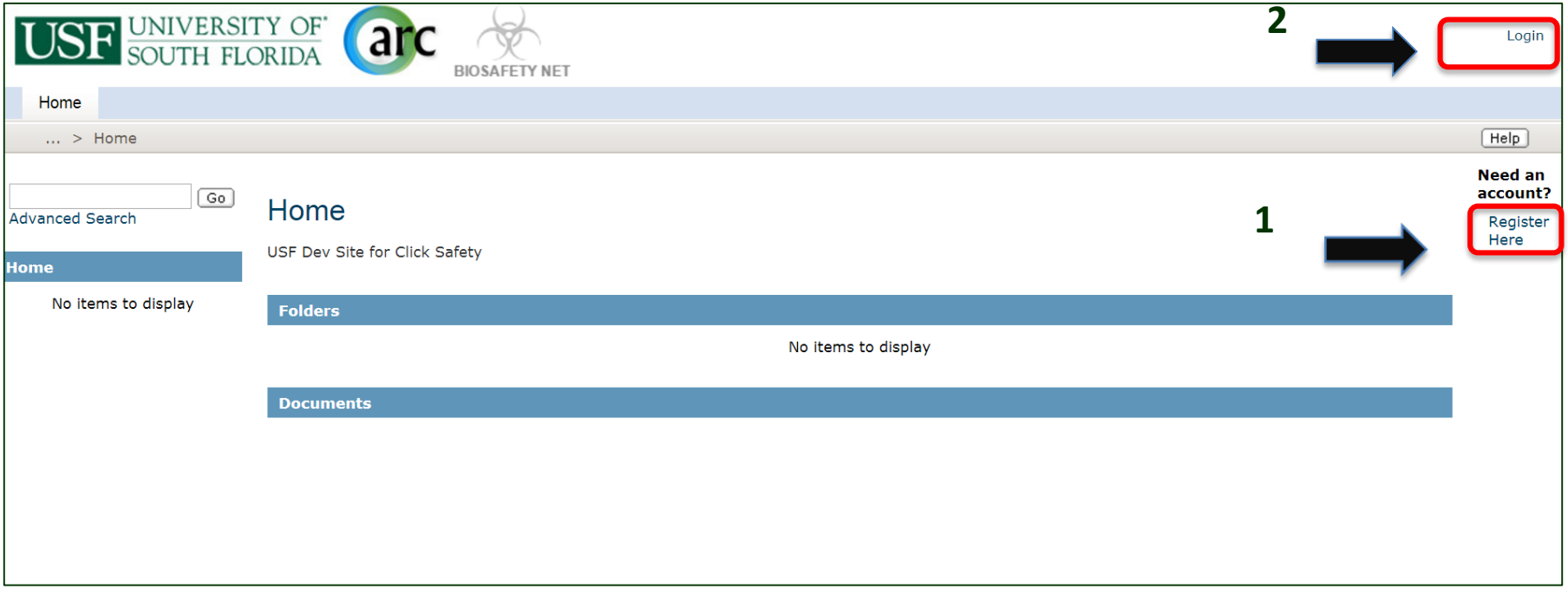
- **Review Complete:** The Safety protocol will reach its final state, Review Complete, after the approval letter is sent

BiosafetyNet- ARC Registration

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

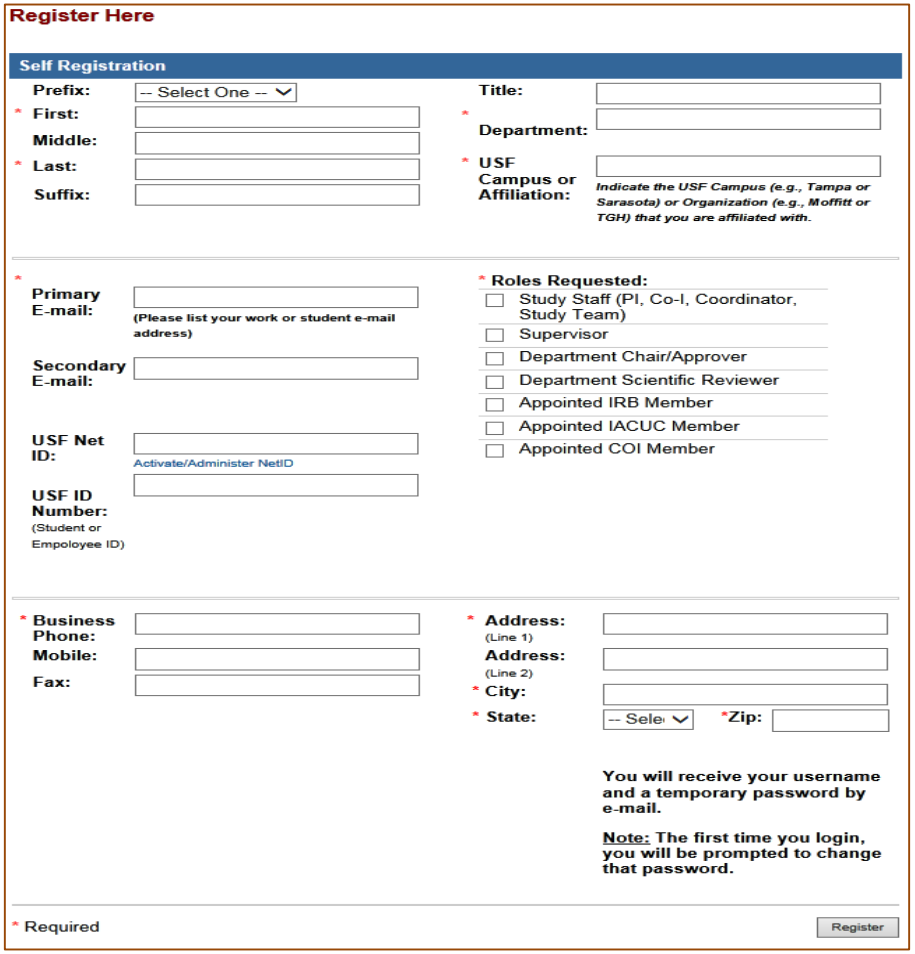
BiosafetyNet- Home Page



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

BiosafetyNet- ARC Registration

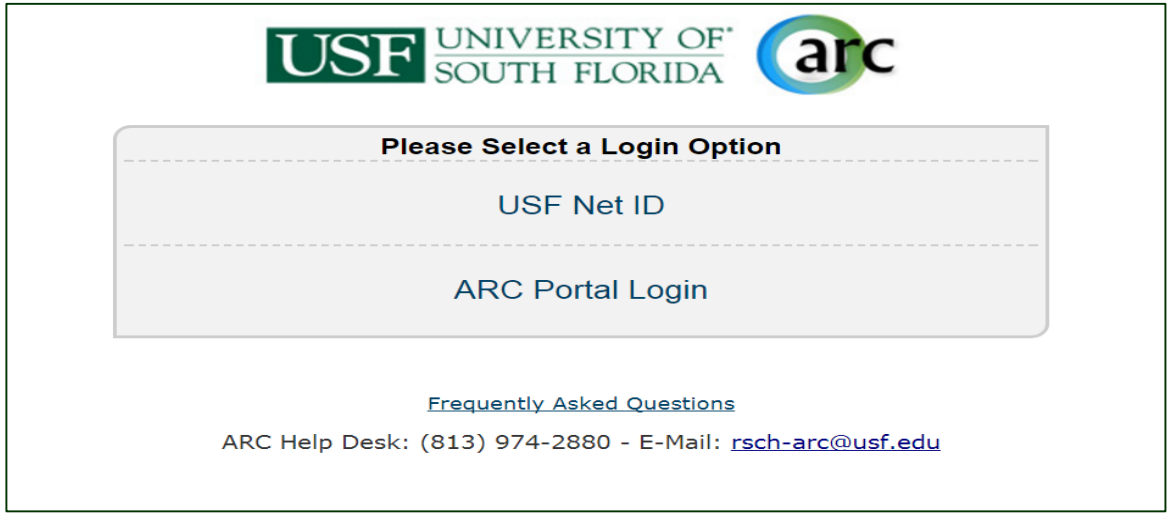


- Required fields are marked with an asterisk *
- PIs/Staff/researchers should select the "Study Staff" role
- You will receive your username and temporary password via email with 2-3 days

BiosafetyNet -Website

Website

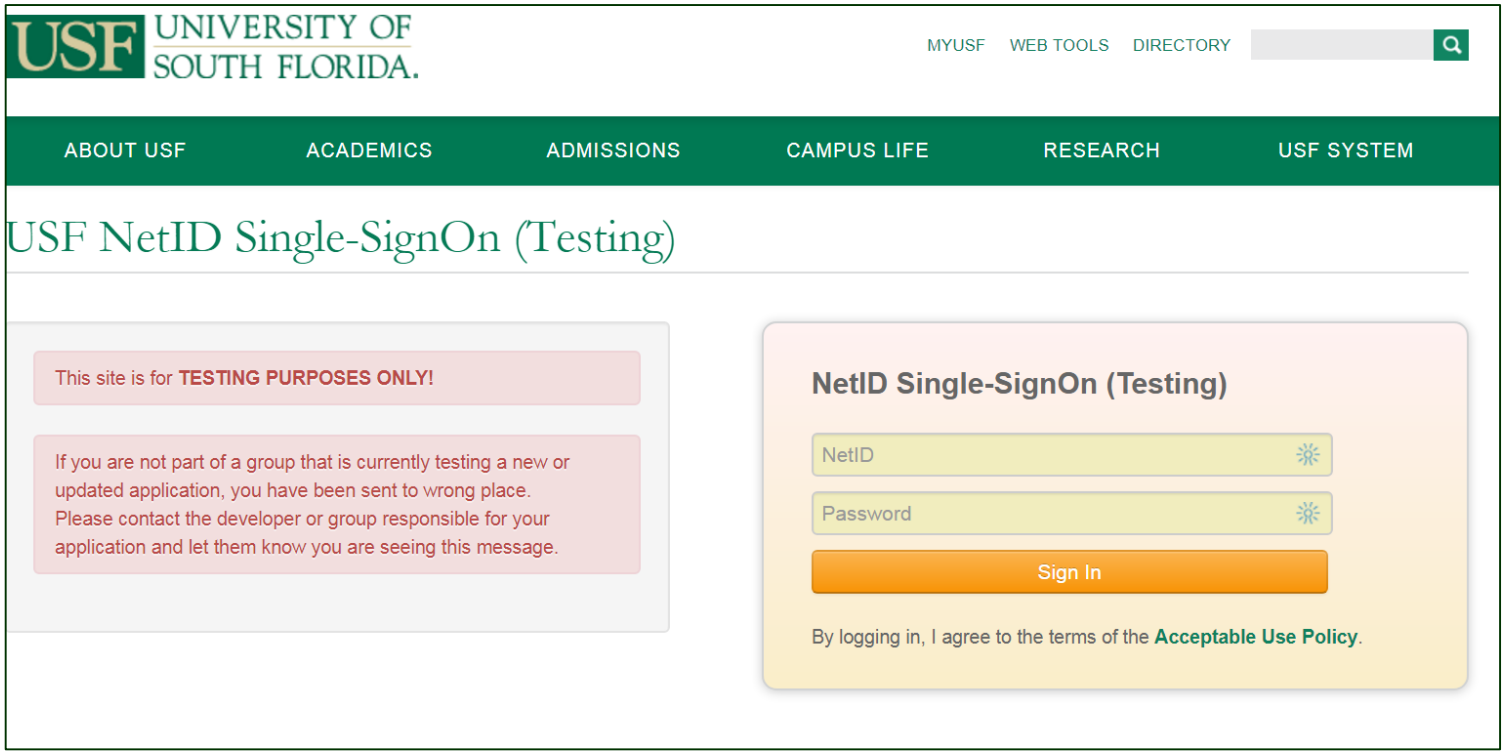
- Navigate to https://arc.research.usf.edu/Safety



- 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.

BiosafetyNet -Log In Net ID

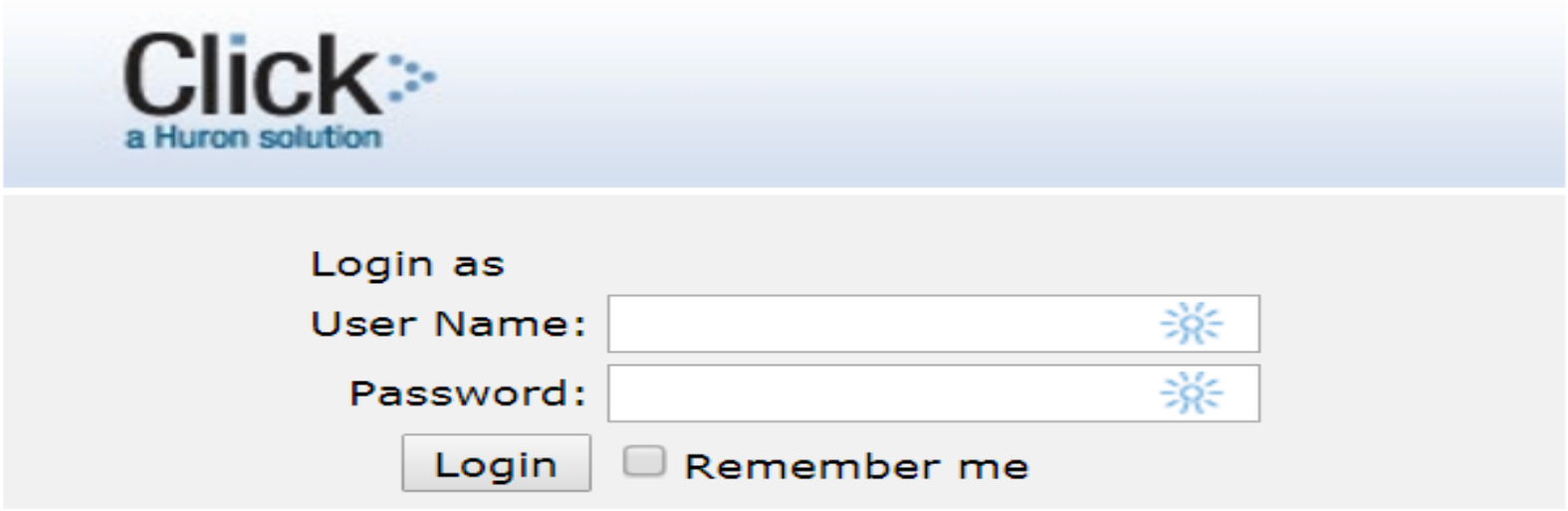
USF Net ID login prompt



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

BiosafetyNet –ARC account Login

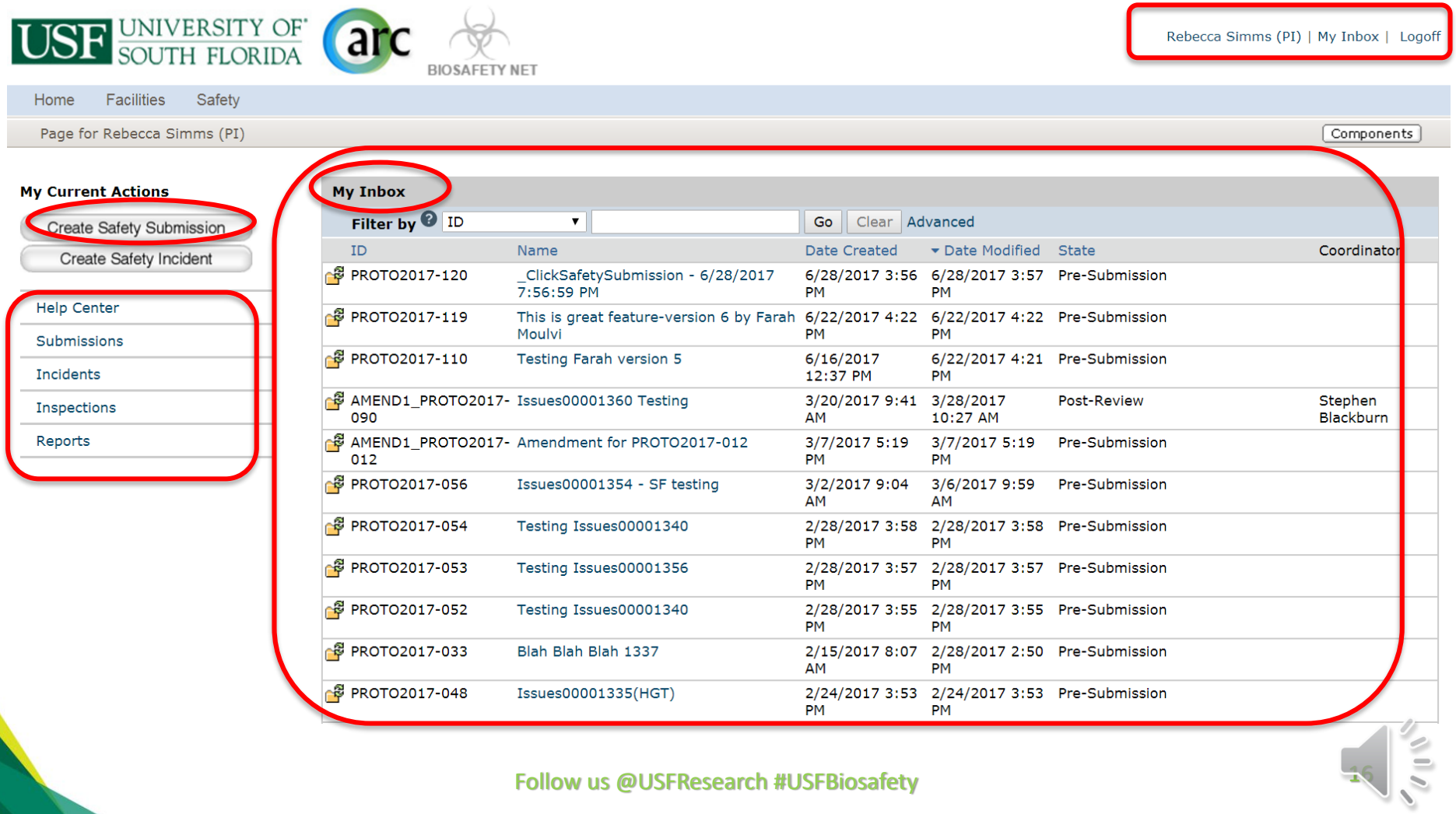
USF ARC account prompt



- 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.

BiosafetyNet- My Inbox

Personal Homepage



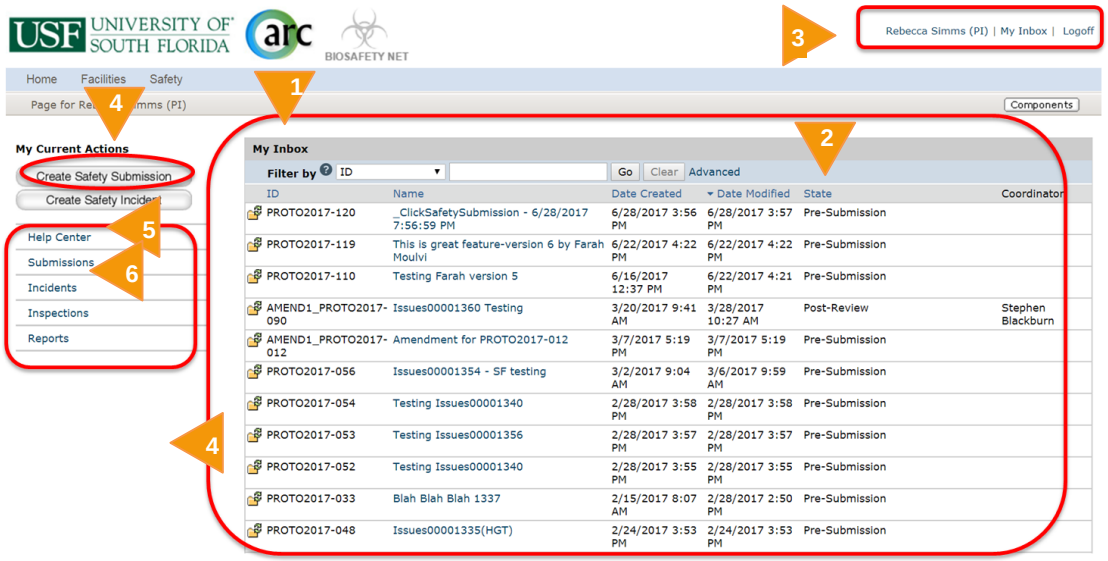
BiosafetyNet- My Inbox

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

BiosafetyNet- My Inbox

My In-Box Features

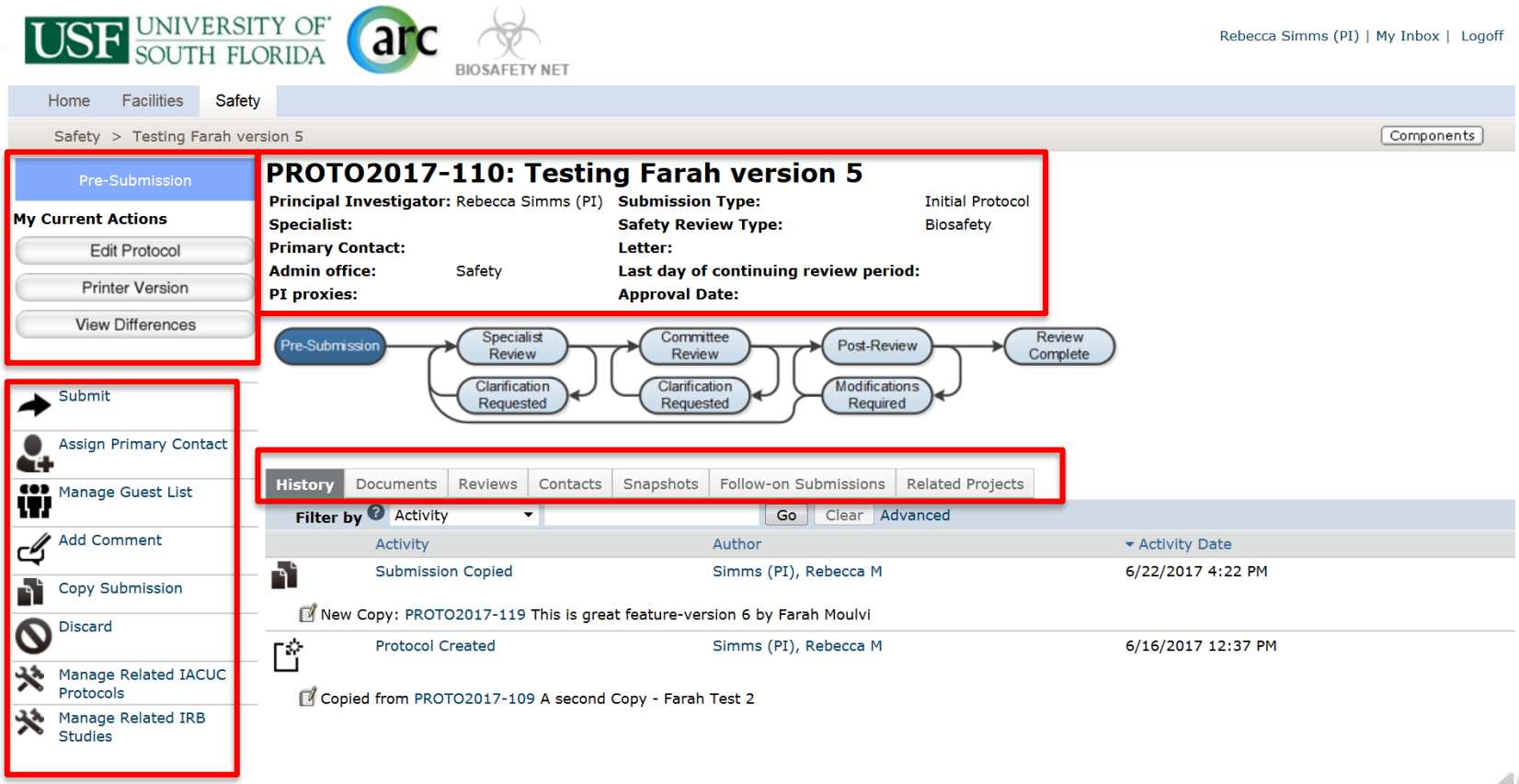


From My Inbox, you will see:

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

BiosafetyNet- My Inbox

Safety Protocol Workspace



BiosafetyNet- Protocol Workspace

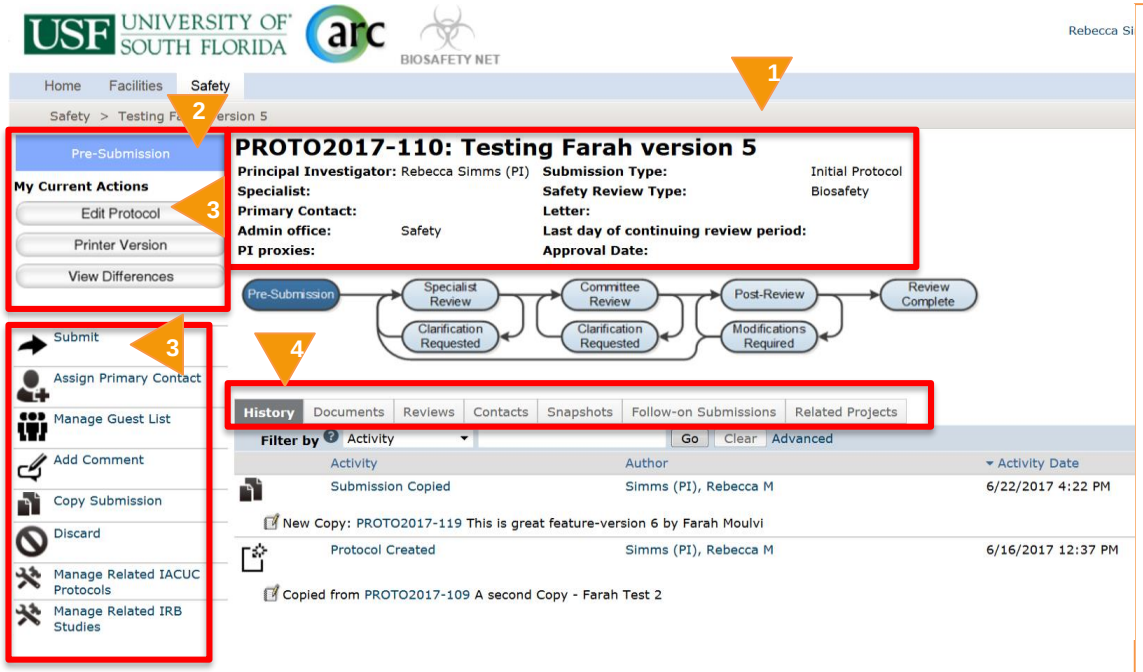
The Workspace is your protocol's homepage

- 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

BiosafetyNet- Protocol Workspace

Safety Protocol Workspace

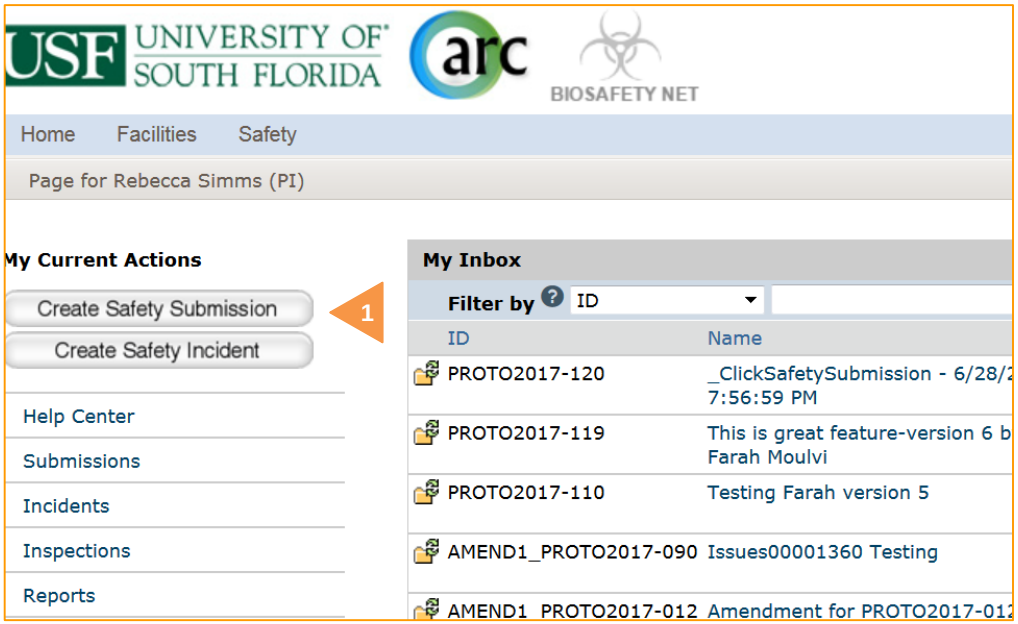


From protocol workspace, you will see:

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

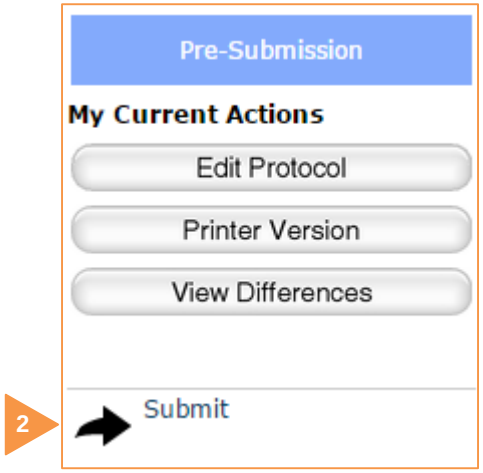
BiosafetyNet – Safety Pre-Submission

Pre-Submission for Safety Protocol



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

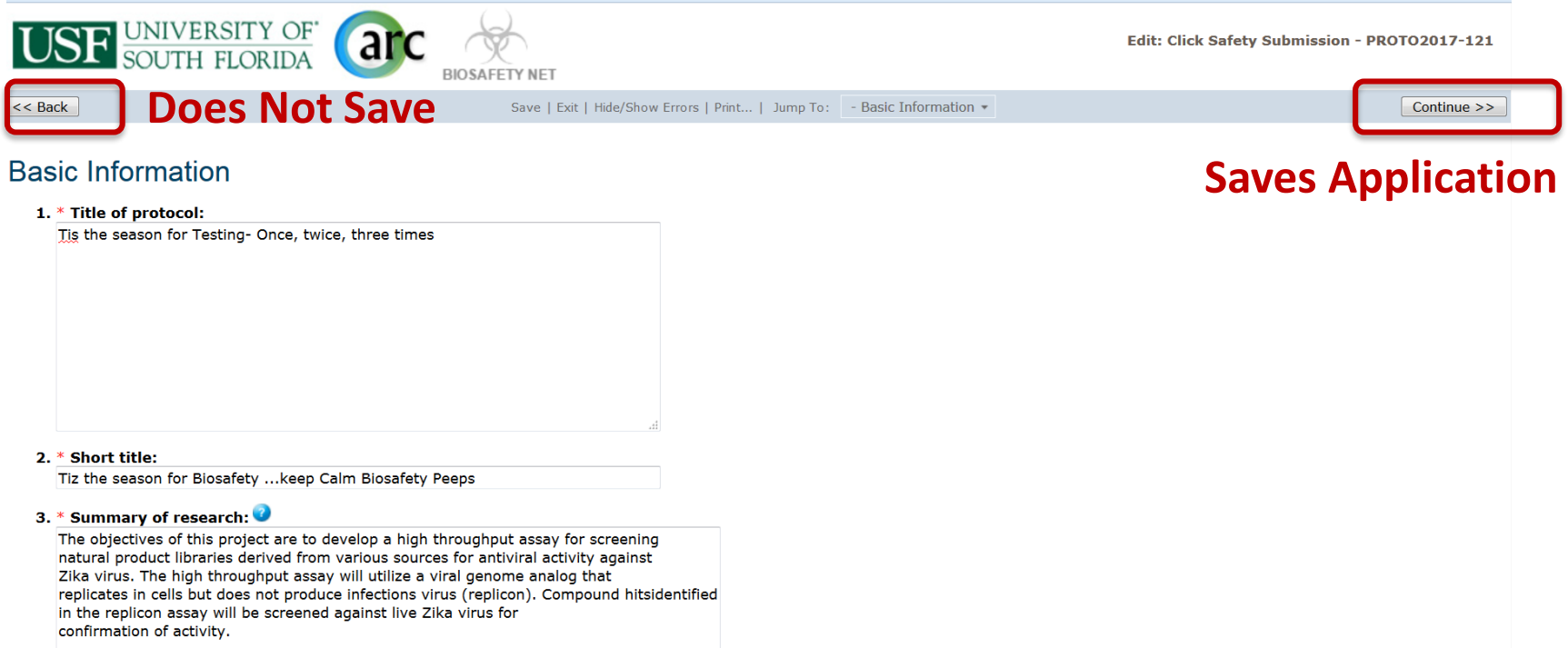


Complete the SmartForm

- 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 *

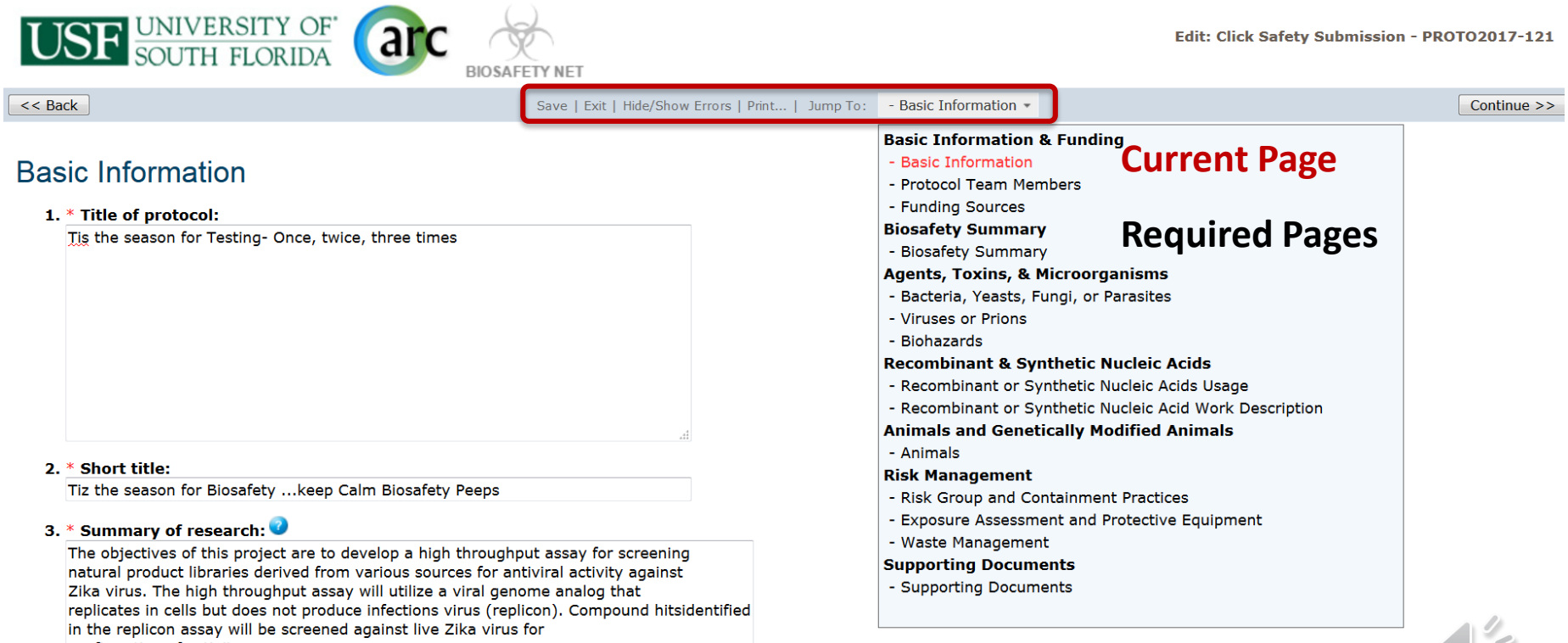
BiosafetyNet -SmartForm

Smart Form Navigation



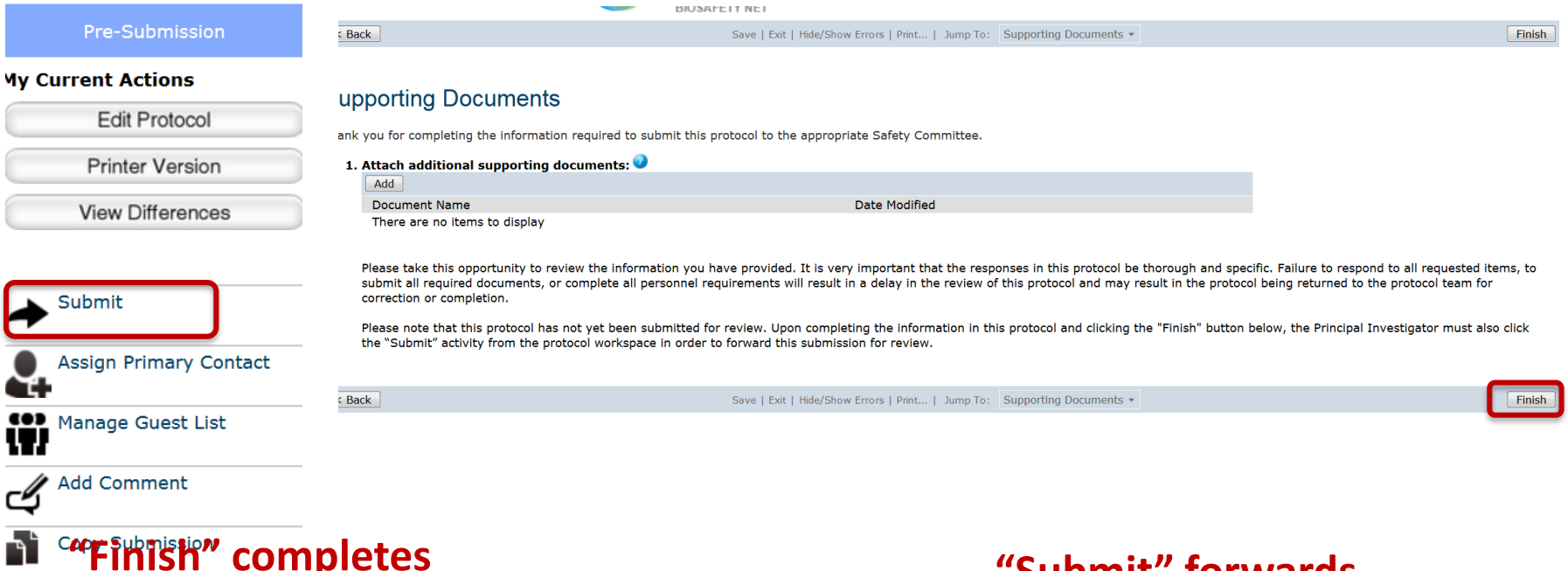
BiosafetyNet -SmartForm

Smart Form Navigation



BiosafetyNet -SmartForm

Smart Form- Finish and Submit



"Finish" completes protocol application

"Submit" forwards the application for review

BiosafetyNet-SmartForm Submission

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

BiosafetyNet- Protocol Submission

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 activites:
  - 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

BiosafetyNet -Requested Clarifications/Revisions

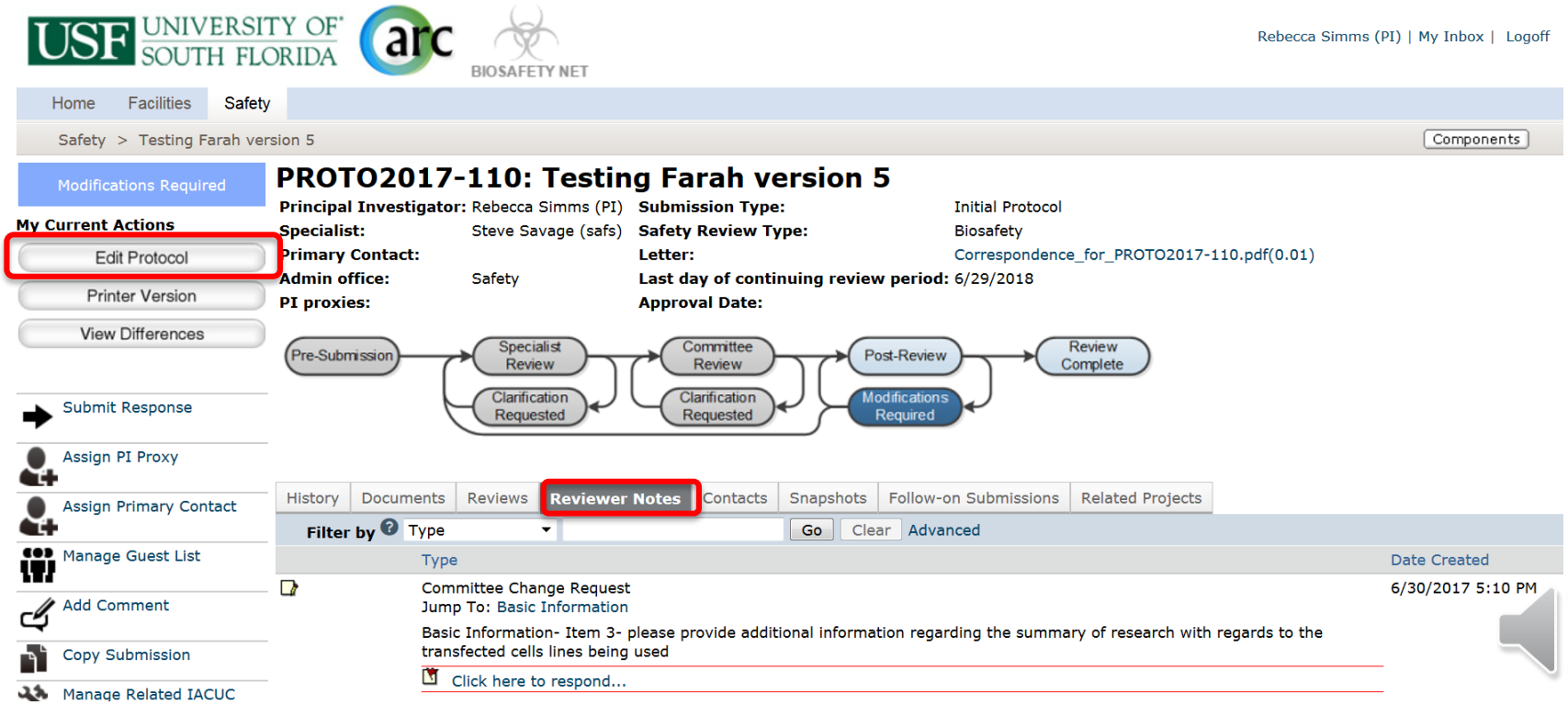
Responding to Reviewers Notes

- 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

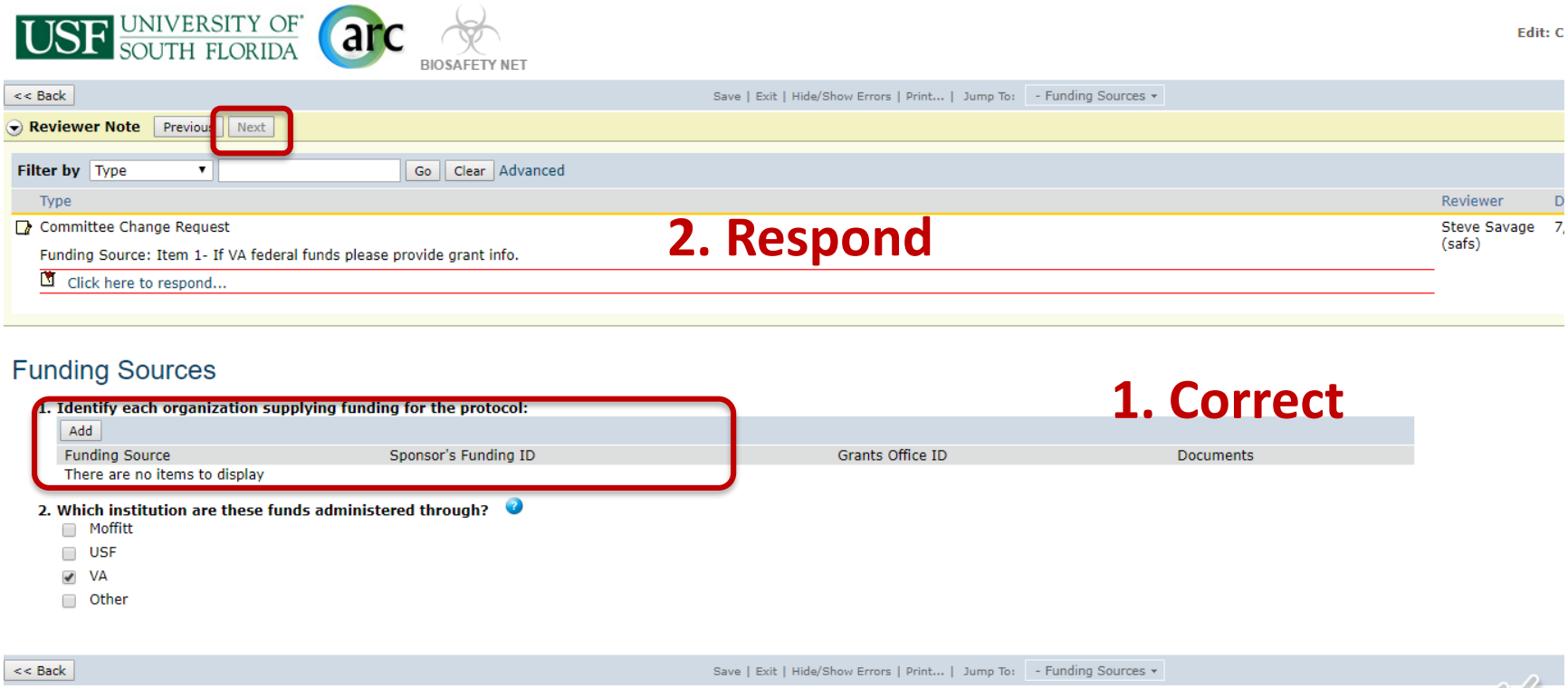
Reviewer Notes are placed on pages in the SmartForm. They can be accessed by selecting:

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



BiosafetyNet -Requested Clarifications/Revisions

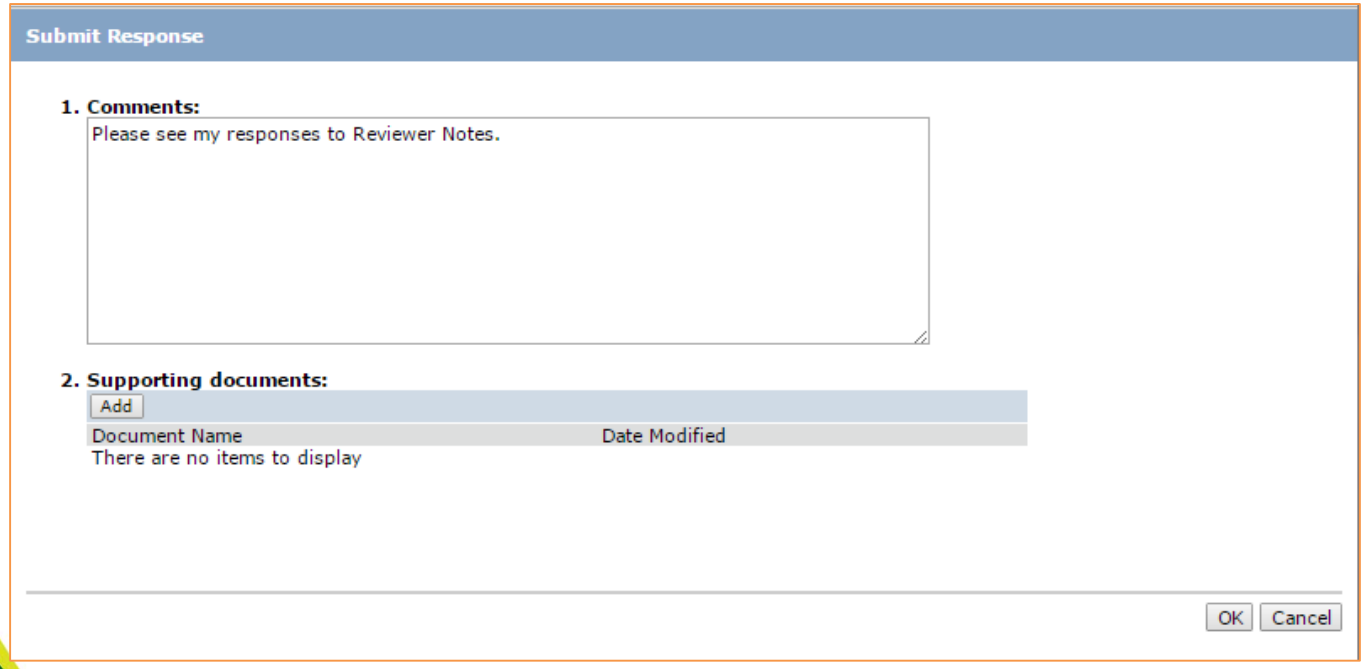
Correct and Respond



BiosafetyNet -Requested Clarifications/Revisions

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

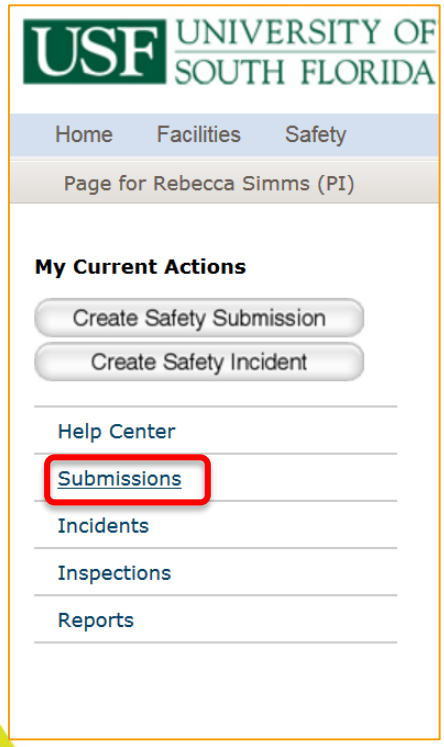


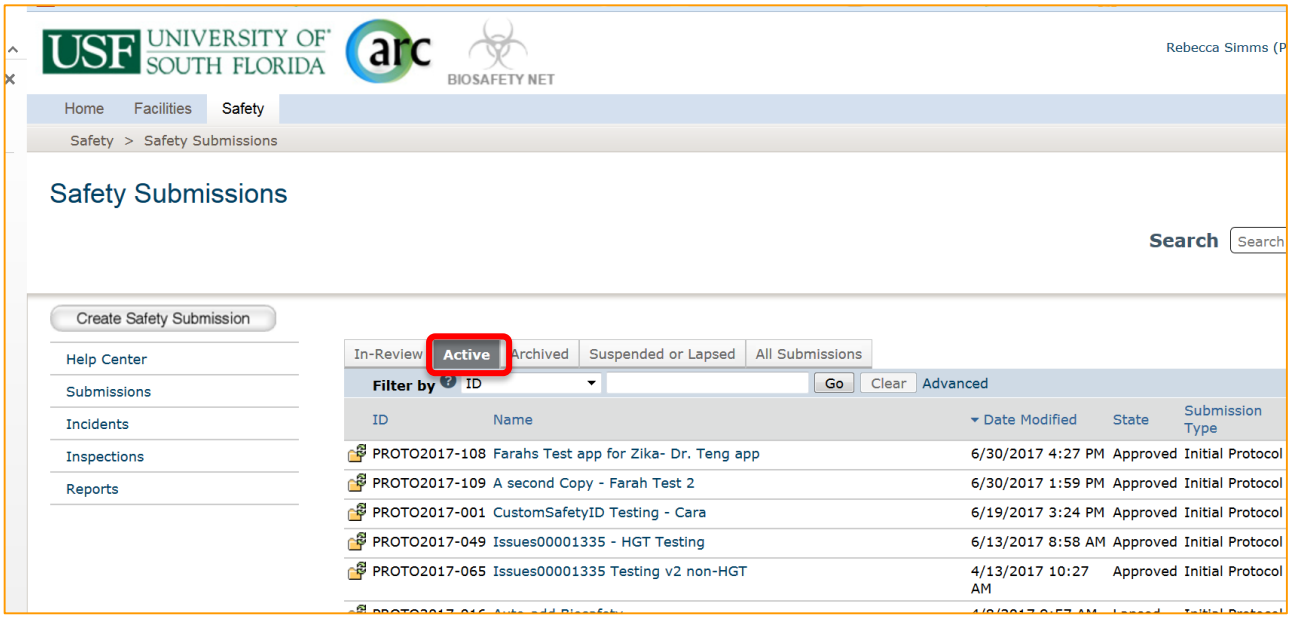
BiosafetyNet-Post Approval

To find your approved Protocol:

Use the link in the email notification OR

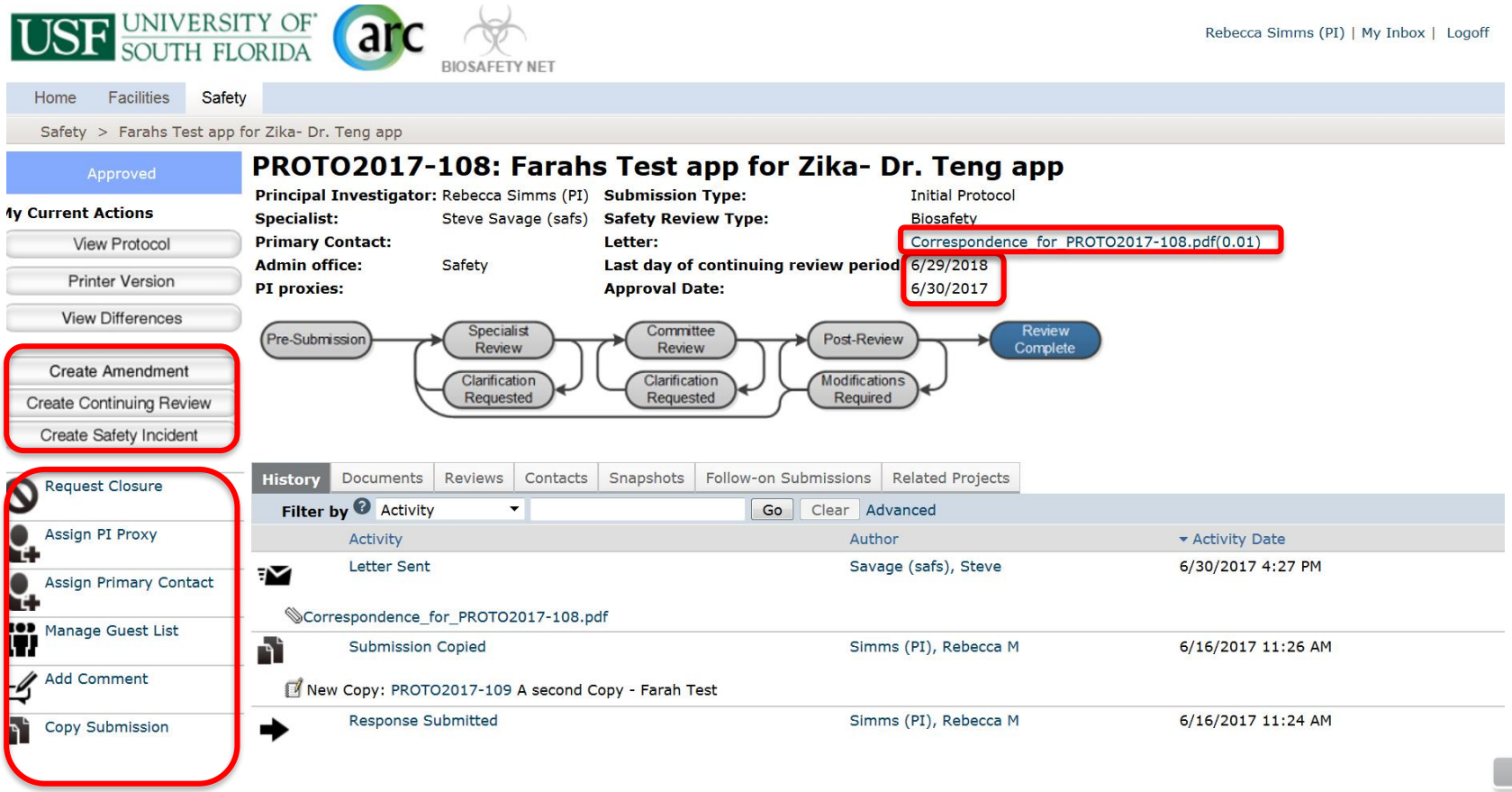
Select Submissions from your homepage and then “Active” tab





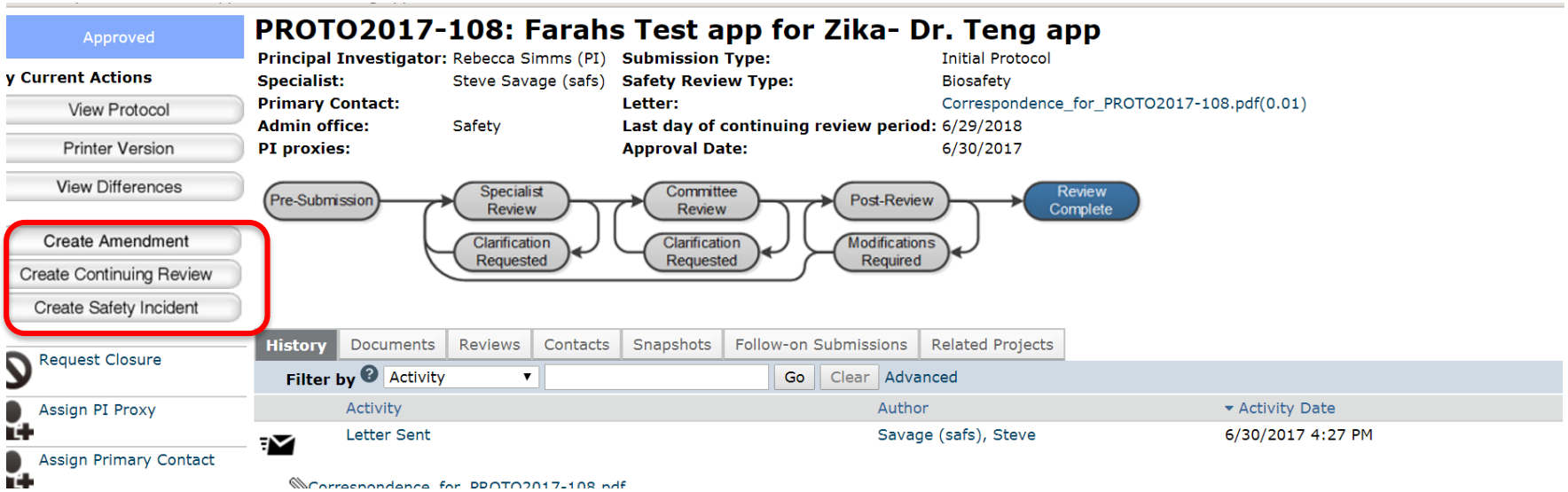
BiosafetyNet -Post Approval

Approved Protocol Workspace



BiosafetyNet- Creating Subprojects

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



BiosafetyNet -Subprojects

- **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

Subprojects Restrictions

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.

BiosafetyNet- Subprojects

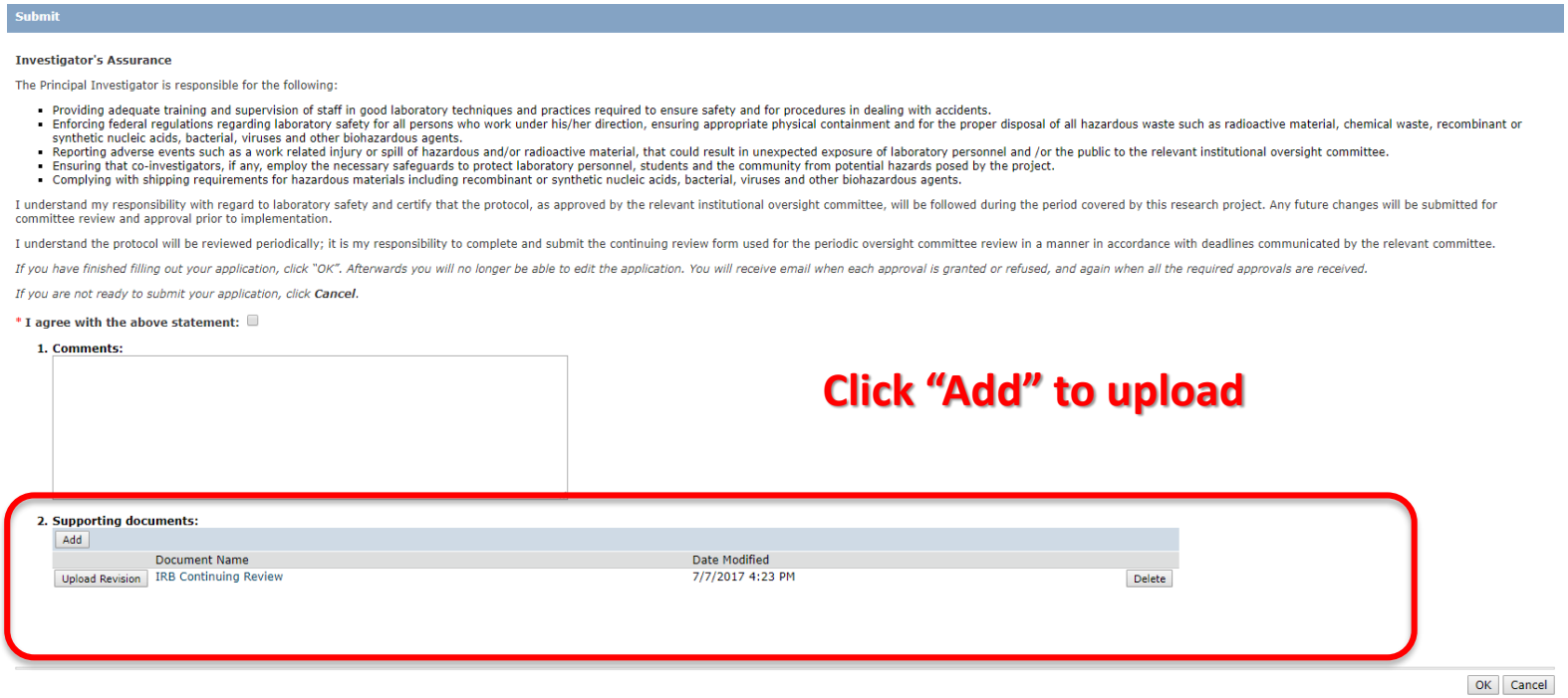
Continuing Review (CR)

- 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

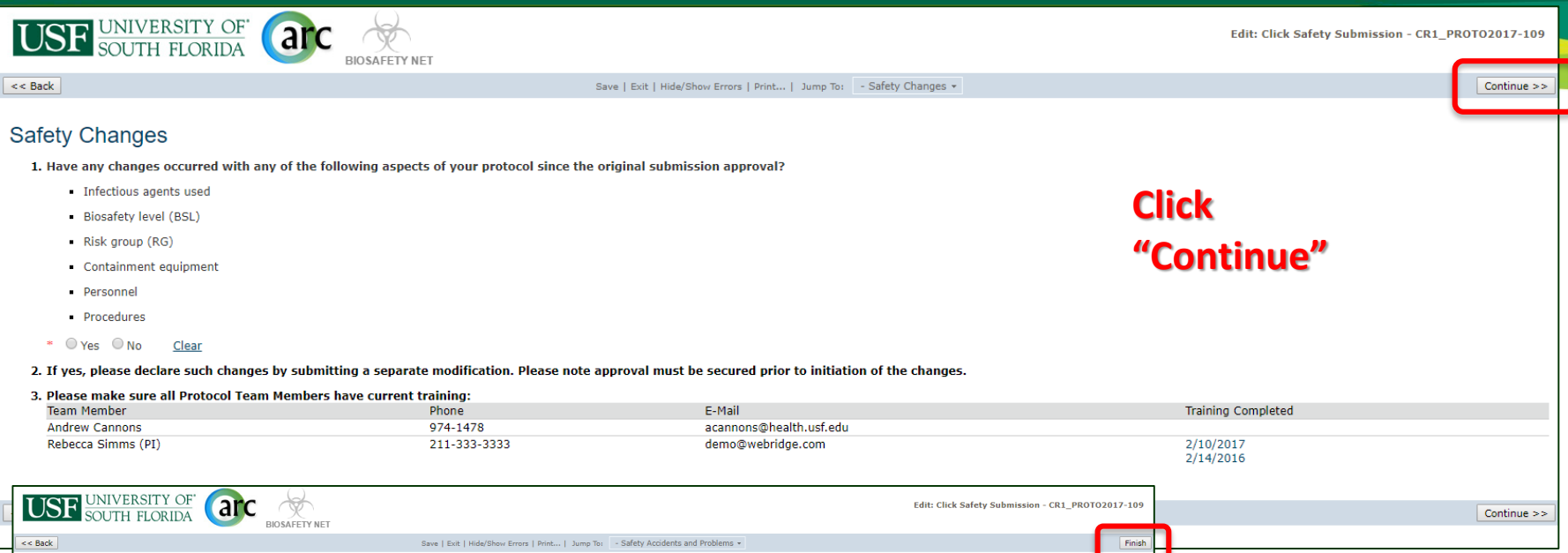
BiosafetyNet- Continuing Review

Continuing review for HGT clinical Protocols

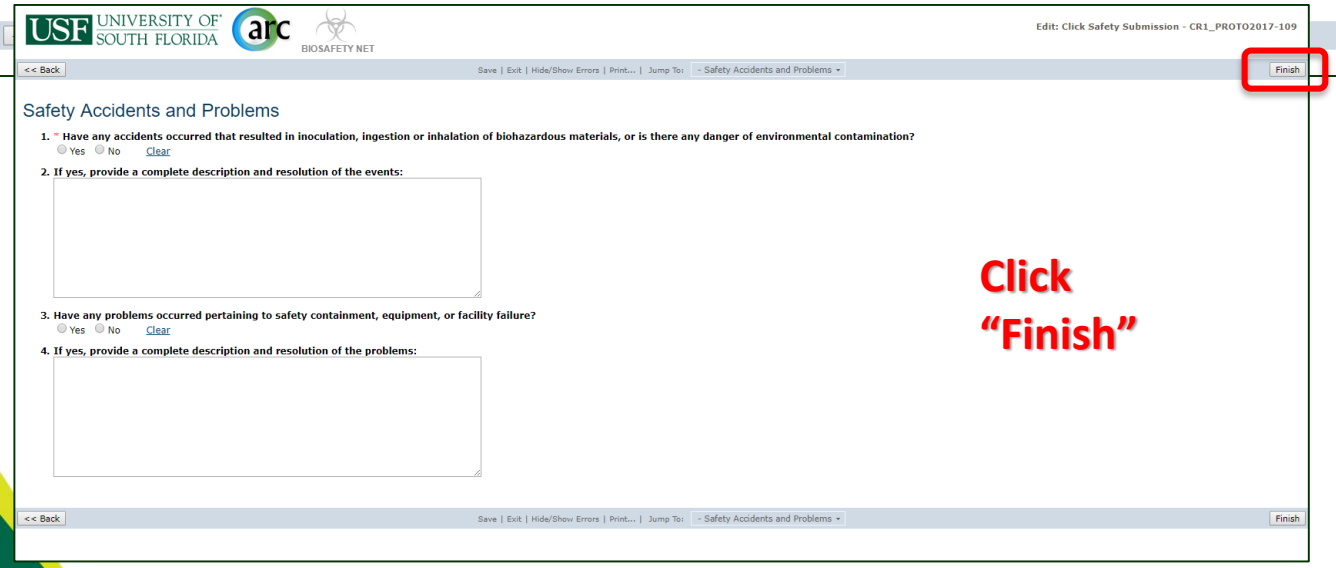
- For HGT clinical protocols Continuing review documents from IRB may be submitted via the “Submit” activity using the supporting document upload feature



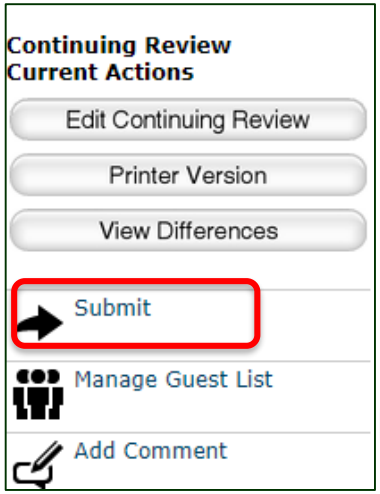
BIOSAFETYNET- SUBMIT CR



Click "Continue"



Click "Finish"



BiosafetyNet- Subprojects

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

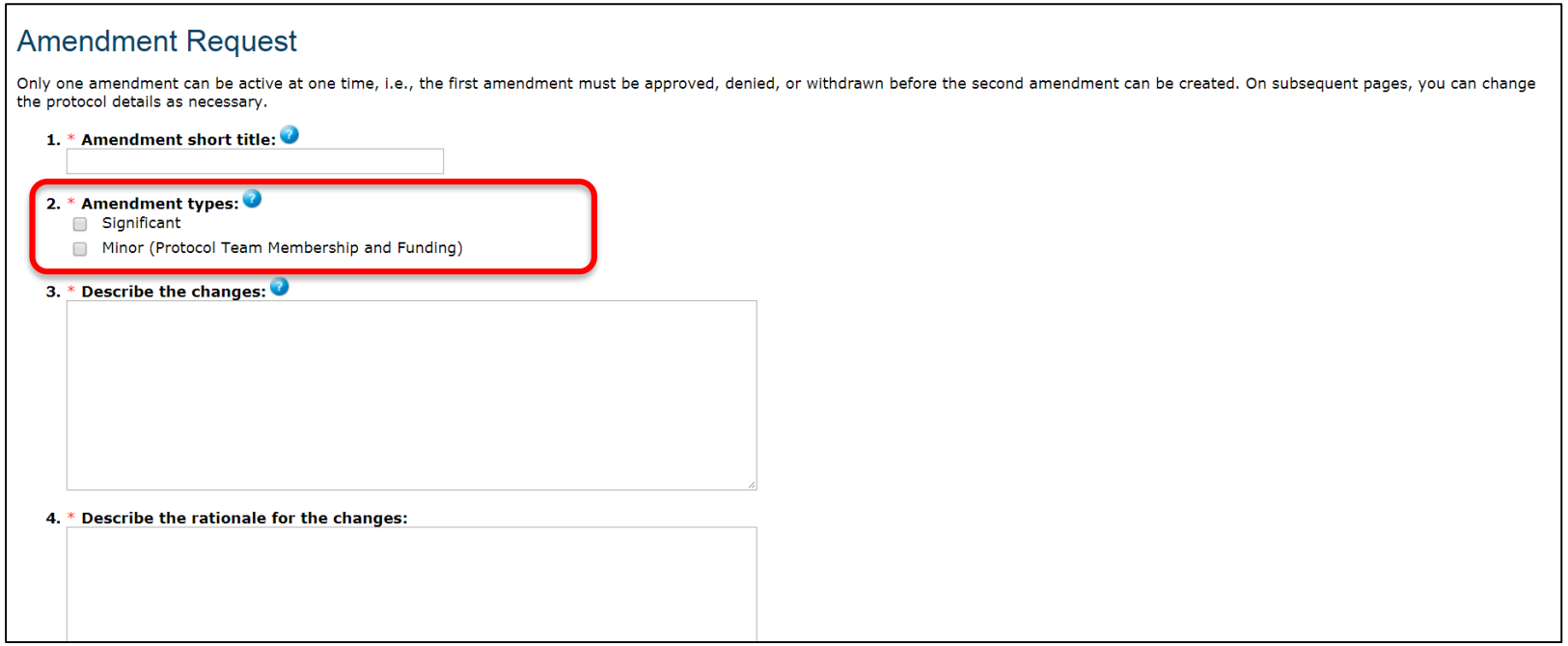
- **Significant:**
  - Changes in biological agent
  - Changes in lab location
  - Changes in protocol title
  - Changes in procedures
  - Human Gene Transfer studies reportable events (e.g. Data safety monitoring reports, non-compliance, SAEs, etc.)
  - Human Gene Transfer studies amendments (e.g. Updates 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

BiosafetyNet- Amendment

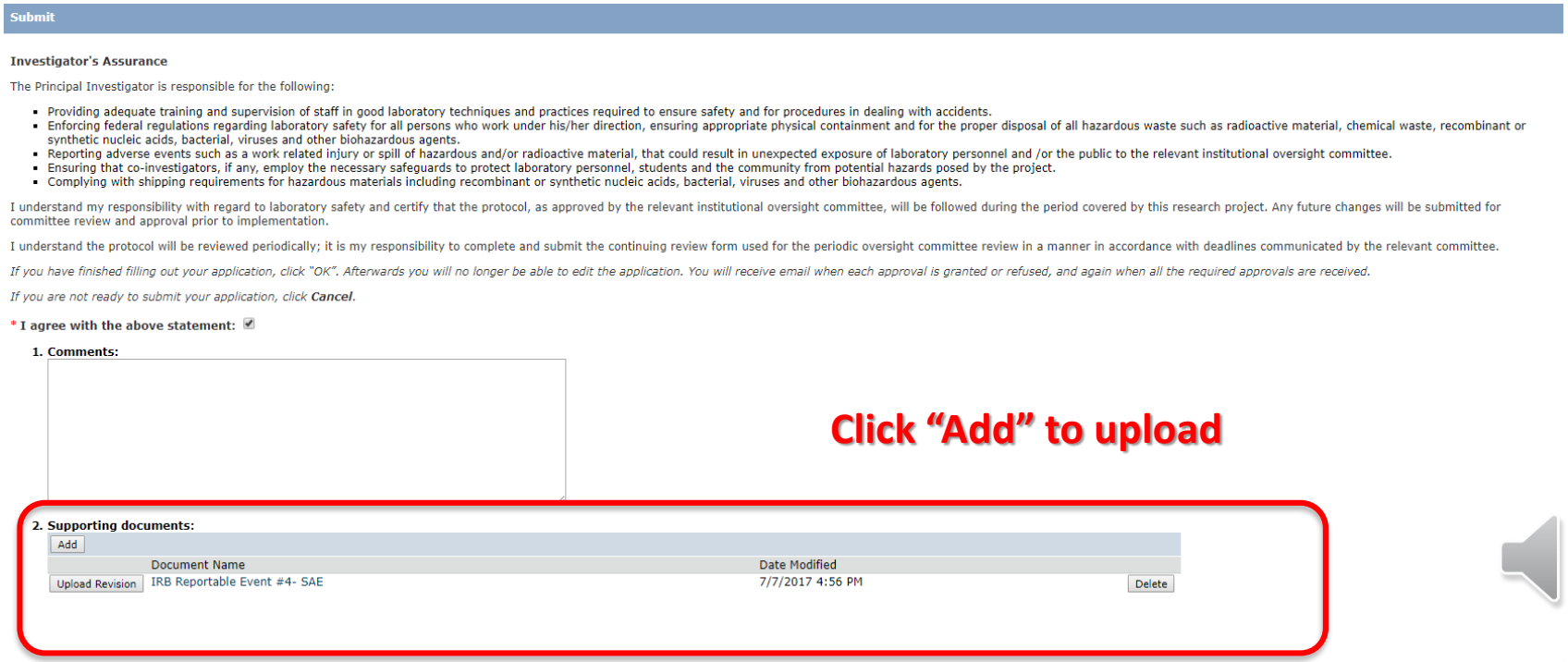
Amendment Types on Smart-Form



BiosafetyNet- Amendment

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



Click “Add” to upload

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
- 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

Credits

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