

## Create and Submit a Follow-On Submission in PACS



### WORK INSTRUCTIONS: THESE DIRECTIONS ARE FOR THE PI TO SUBMIT AN ANNUAL REVIEW OR MODIFICATION TO AN APPROVED PROTOCOL

1. As the PI of a previously approved protocol, Log into PACS via (Link) click on the **Safety** tab on the top navigation bar, which will then display only Safety, protocols.
2. Find the protocol you submitted in the Approved state that you would like to submit a continuing review for.
  - Users click on the **Active** tab to find the protocols that are in the **Approved** state and can click on the name of the protocol to begin their submission.
  - Users can also navigate directly to the protocol by clicking on the link provided in the Continuing Review Reminder email notification that are sent to the PI and Primary Contact 90, 60, 30, and 15 days prior to the protocol's expiration and then logging into the system.

Abigail McConnell | My Inbox | Projects | Logout

Home Courses Agreements COI Facilities Grants IACUC IRB **Safety**

Safety > Safety Submissions

Safety Submissions

Create Safety Submission

My Inbox  
Help Center  
Submissions  
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Reports

In-Review Active Archived Suspended or Lapsed All Submissions

Filter by ID Go Clear Advanced

ID	Name	Date Modified	State	PI First Name	PI Last Name	Submission Type	Safety Review Type
0208000000047	Biosafety Training Video - Clarifications	5/12/2017 1:36 PM	Clarification Requested (Specialist Review)	Rebecca	Simms (j) 020	Initial Protocol	Biosafety

- From the protocol workspace, Under **My Current Actions**, select the **Create Continuing Review** button to create and submit a **Follow-On Submission**.

The screenshot shows the 'Safety > Test' workspace for protocol '020RAD0000004:Test'. The 'My Current Actions' sidebar includes buttons for 'View Protocol', 'Printer Version', 'View Differences', 'Create Continuing Review', 'Request Closure', 'Assign PI Proxy', and 'Assign Primary Contact'. The 'Create Continuing Review' button is highlighted with a red arrow and a box labeled '3.'. The workflow diagram shows stages: Pre-Submission, Specialist Review (with a 'Clarification Requested' loop), Committee Review (with a 'Clarification Requested' loop), Post-Review (with a 'Modifications Required' loop), and Review Complete. Metadata includes: Principal Investigator: Rebecca Simms (pi)(020), Specialist: Abigail McConnell, Submission Type: Initial Protocol, Safety Review Type: Radiation Safety, Letter: Correspondence\_for\_020RAD00000004.pdf(0.01), Admin office: Binghamton University Radiation Safety Admin Office, Last day of continuing review period: 6/20/2018, and Approval Date: 6/21/2017.

- Entering the required information on the first page of the SmartForm and clicking **Continue** in the top or bottom of the page will create the record.
  - Note that an approved protocol can have only one outstanding amendment or continuing review open at a time.
- Prior to submission to the Safety Specialist, all required fields will need to be completed.
  - Click the **Hide/Show Errors** link in the header of the SmartForm page to display any unanswered questions throughout the SmartForm at the bottom of the page.
    - Use the **Jump To** link to navigate directly to SmartForm pages that are missing information.
  - Submissions with any incomplete information will be redirected to the research team for updates.

The screenshot shows the 'Protocol Team Members' SmartForm page. The header includes navigation links: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: - Protocol Team Members -', and 'Continue >>'. The main content area has two sections: '1. Identify each additional person involved in the design, conduct, or reporting of the research:' and '2. External team member information:'. Each section has an 'Add' button and a table with columns for Name, Roles, Additional Roles, Involved With Procedures, E-Mail, and Phone. The first table is empty, showing 'There are no items to display'. Red arrows point to the 'Save | Exit | Hide/Show Errors | Print...' link (labeled '5.'), the 'Jump To' link (labeled '5.'), and the 'Continue >>' button (labeled '4.').

6. When all of the required fields have been completed, click **Exit** in the header or **Finish** in the footer of the last SmartForm page to be redirected to the protocol workspace.

Supporting Documents

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

1. Attach additional supporting documents:

Add

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 for submission for review.

<< Back Save | Exit | Hide/Show Errors | Print... Jump To: - Supporting Documents + Finish

*Your protocol has not yet been submitted for review.*

7. Once all of the above steps have been completed, the PI (or PI Proxy, if identified) must log into the protocol and click the **Submit** activity. This activity will remind the PI of their responsibilities and the system will check the submission for any missing fields. The PI will need to check that they agree with the statement and then click the **OK** button to submit the protocol.

Home Courses Agreements CCI Facilities Grants IACUC IRB Safety

Safety > TEST

0208100000025:TEST

Principal Investigator: Abigail McConnell

Submission Type: Safety Review Type: Letter: Initial Protocol Biosafety: None

Admin office: Binghamton University Biosafety Admin Office Last day of continuing review period: Approval Date:

PI proxies:

Special Review Committee Review Post Review Review Complete

Clarification Requested Clarification Requested Modifications Requested

Submit

Assign PI Proxy

Assign Primary Contact

Manage Guest List

Manage Ancillary Reviews

Add Comment

Copy Submission

Withdraw

Discard

Assign Admin Office

Manage Related IACUC

History Documents Reviews Contacts Snapshots Follow-on Submissions Related Projects

Activity	Author	Activity Date
Protocol Created	McConnell, Abigail	5/23/2017 2:50 PM

**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, state and campus 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.
- You have obtained the agreement of each research staff to his/her role in the research.

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. I 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 statements:

1. Comments:

2. Supporting documents:

Add	Document Name	Date Modified
There are no items to display		

8. If the submission is successful, the page will refresh and the protocol will transition from the **Pre-Submission** state to the **Specialist Review** state.

