

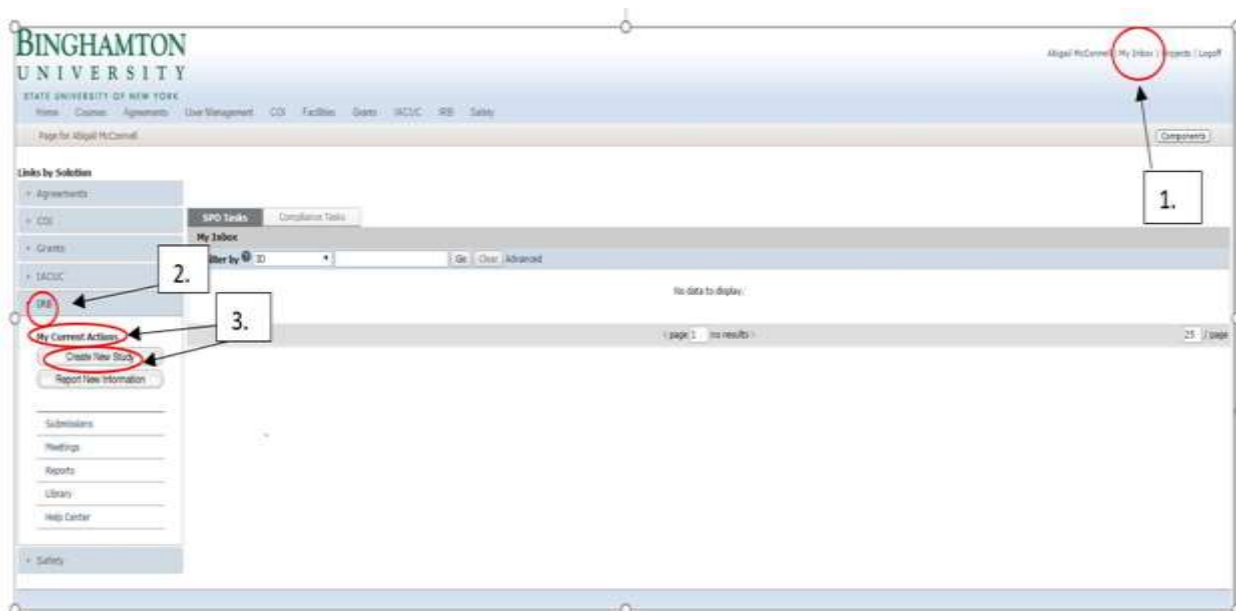
## Create and Submit a New Study



## WORK INSTRUCTIONS: THESE DIRECTIONS ARE FOR THE PI TO SUBMIT A NEW PROTOCOL FOR APPROVAL

**NOTE:** It is best to have all documents ready for upload before beginning the PACS submission (i.e. informed consent, recruitment script, survey tools, narrative, etc.). You may access any necessary forms and/or templates at <https://www.binghamton.edu/research/compliance/humansubjects/irbpacs.html>

1. As the PI, log into the PACS Portal and click on the **My Inbox** next to your name on the top right of the screen.
2. Next click the **IRB** tab on the left side of the navigation screen.
3. Under **My Current Actions**, select the **Create New Study** button to create a new study.



4. Enter the required information on the first page of the Basic Information SmartForm.

- Required information fields are marked with an asterisks (\*).
5. Click **Continue** at either the top or bottom of the form.
  6. **Navigate** through all of the SmartForms and complete all of the required fields
    - Click the help icon ( ? ) for more information about a question or field
  7. Click the **Hide/Show Errors** link near the top of the SmartForm page to display any unanswered questions.
    - Use the **Jump To:** link to navigate directly to SmartForm pages that are missing information
    - Studies with any incomplete information will be redirected to the research team for updates

The screenshot shows the 'Basic Information' section of a SmartForm. It includes fields for title, short title, description, principal investigator, financial interest, and IRB of record. A table at the bottom lists attached protocols. Red arrows and numbered boxes (4, 5, 6, 7) highlight specific UI elements: the 'Continue' button, the 'Jump To' link, the 'Hide/Show Errors' link, and the 'Brief description' field.

8. When all of the required fields have been completed, click **Finish** in the footer of the last SmartForm page. **Your study has not yet been submitted for review.**

The screenshot shows the 'Final Page' of a SmartForm. It contains instructions for the user to click 'Finish' and 'Submit'. Red arrows and a numbered box (8) highlight the 'Finish' button at the top right and the 'Submit' button at the bottom right.

9. You are now in the **“Pre-Submission”** state.

10. You must click the **Submit** icon located under **My Current Actions** on the left side of your workspace. This activity will remind you of your responsibilities and the system will check the submission for any missing fields. You will need to re-authenticate into the system to click the **OK** button to submit the study to the IRB.

The screenshot displays the IRB system interface. The top section shows the 'Pre-Submission' state for study **STUDY00000868: xxx**. A workflow diagram at the top right indicates the process: Pre-Submission (highlighted with a red arrow and '10.'), Pre-Review, IRB Review, Post-Review, and Review Complete. Below the diagram, a 'Submit' button is highlighted with a red arrow and '10.'. The bottom section shows the 'Submit' confirmation dialog with the following text:

By clicking the "OK" button on this page you are verifying that:

- You have obtained the financial interest status ("yes" or "no") of each research staff.
- You have obtained the agreement of each research staff to his/her role in the research.
- All faculty, staff, and students conducting human subjects research need to complete ethics training, as specified by the federal regulations. although researchers may complete other federally-approved training programs to satisfy this requirement, researchers are encouraged to complete the CITI program.
- Consult your campus Click Campus Library for SOPs, checklists, forms, worksheets, templates, and instructions.

An 'OK' button is highlighted with a red arrow and '10.'.

11. If the submission is successful, the page will refresh and the study will transition from the "Pre-Submission" state to the "Pre-Review" state as identified by the workflow diagram at the top of the workspace.

**STUDY00000868: xxx**

Principal investigator: Nancy Lewis  
 Submission type: Initial Study  
 Primary contact: Nancy Lewis  
 IRB coordinator:

Created IRB: 5/4/2017 4:18 PM  
 Initial approval:  
 Effective:  
 Approval end:  
 Modified: 5/4/2017 4:18 PM

IRB office: Binghamton University IRB Office

Workflow: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete  
 (Clarification Requested and Modifications Requested are sub-steps within Pre-Review, IRB Review, and Post-Review)

**11.**

My Current Actions: View Study, Print Version, View Differences, Add Related Grant, Discard, Add Comment

Activity	Author	Activity Date
Submitted	Lewis, Nancy	5/4/2017 4:18 PM
Study Created	Lewis, Nancy	5/4/2017 3:57 PM

Your submission will now be routed to the HSRR office for Pre-Review. The HSRR office may ask for Clarifications which is now done through PACS. You will be notified via email that you have a **Clarification Requested**.

See the **Clarification Requested and/or Modifications Requested** worksheet for instruction.