Potsdam
STATE UNIVERSITY OF NEW YORK

HUMAN SUBJECTS RESEARCH PROTOCOL SUBMISSION WORKSHOP

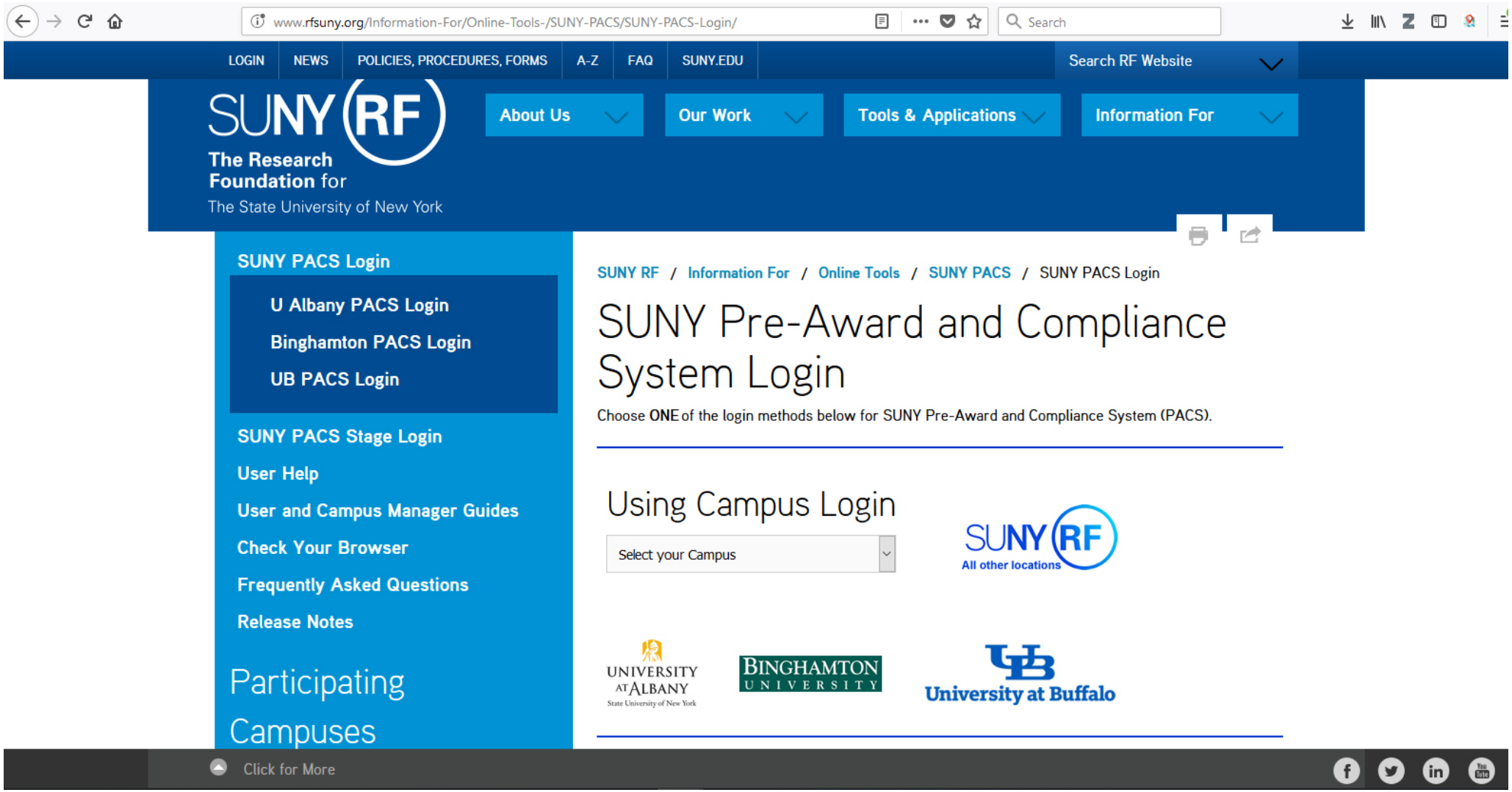
Lydia Rodriguez, Ph.D.

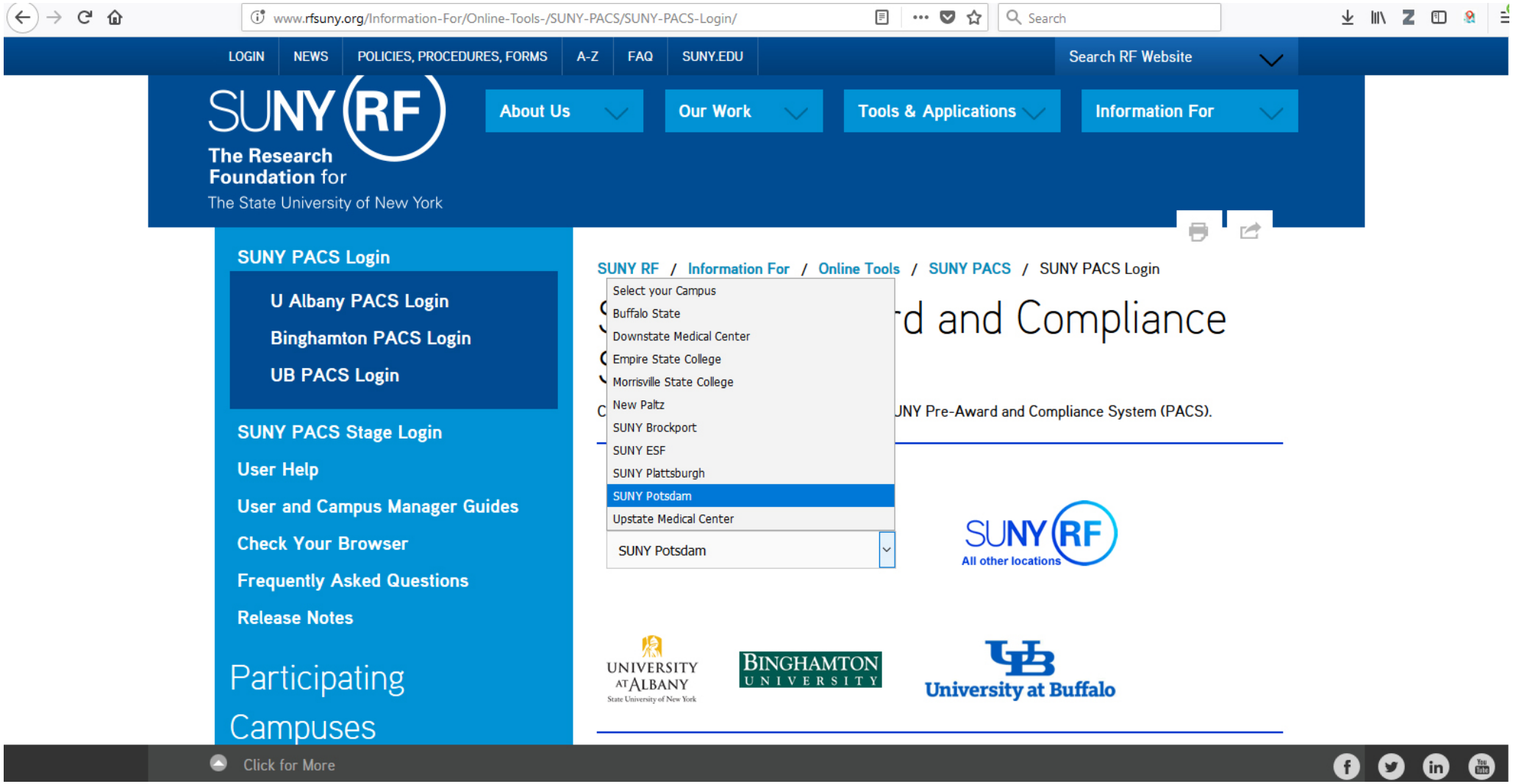
Jack McGuire, Ph.D.

In this workshop you will learn to…

- Sign-on to the system
- Create a study
- Upload your protocol
- Track the process of your submission, and communicate with IRB members.

1. Sign on to the system




www.rfsuny.org/Information-For/Online-Tools-/SUNY-PACS/SUNY-PACS-Login/
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User and Campus Manager Guides
Check Your Browser
Frequently Asked Questions
Release Notes
Participating Campuses
SUNY RF / Information For / Online Tools / SUNY PACS / SUNY PACS Login
Select your Campus
Buffalo State
Downstate Medical Center
Empire State College
Morrisville State College
New Paltz
SUNY Brockport
SUNY ESF
SUNY Plattsburgh
SUNY Potsdam
Upstate Medical Center
SUNY Potsdam
d and Compliance
UNY Pre-Award and Compliance System (PACS).
SUNY RF
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State University of New York
BINGHAMTON UNIVERSITY
University at Buffalo
Click for More

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Search

Potsdam
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Sign in with your SUNY Potsdam username and password

Username

Password

Sign in

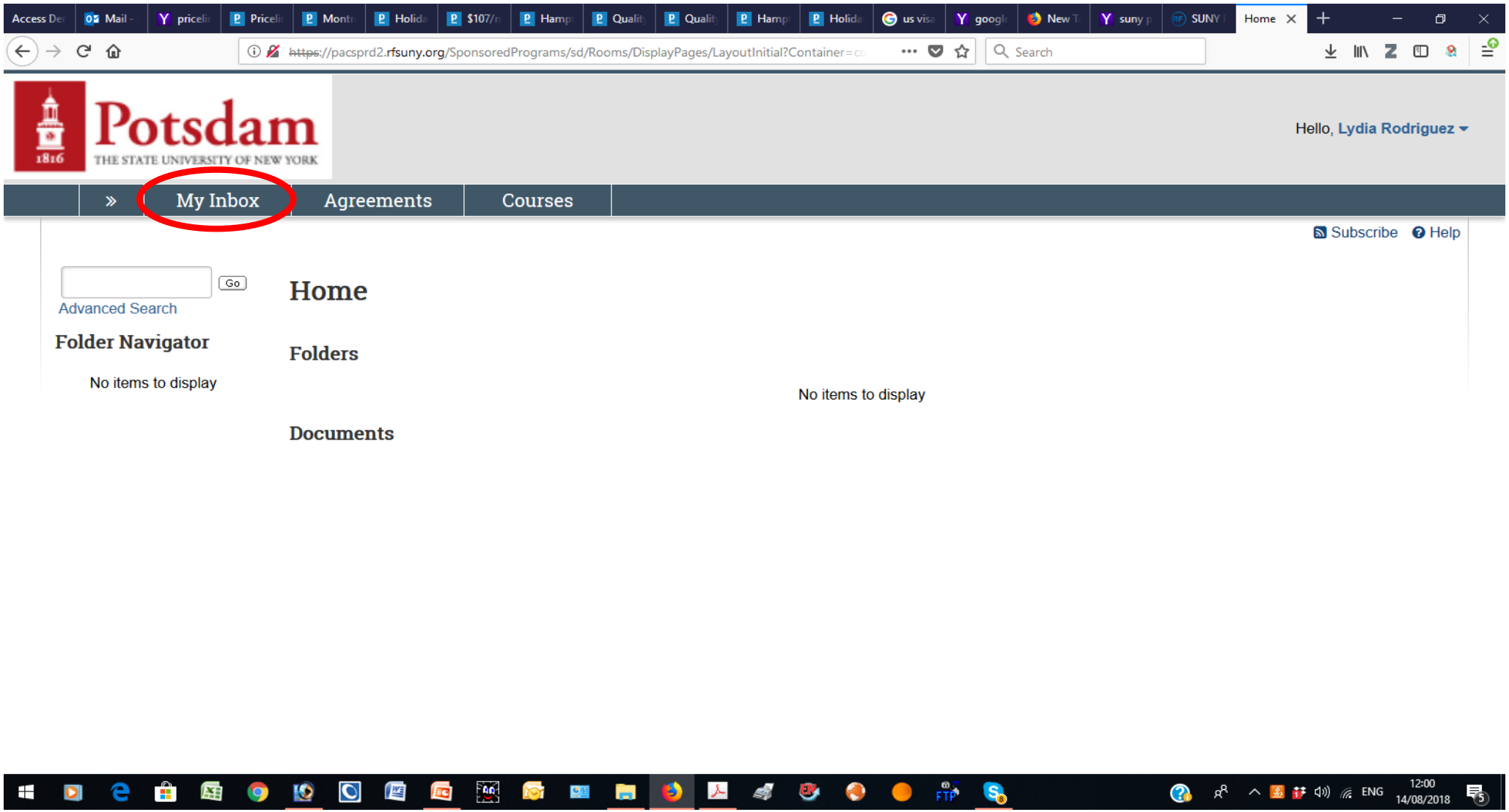
Due to the 2016 server upgrades, your password will not work unless it has been reset at account.potsdam.edu, on or after March 7, 2016. If you have not done this, please do it now before continuing.

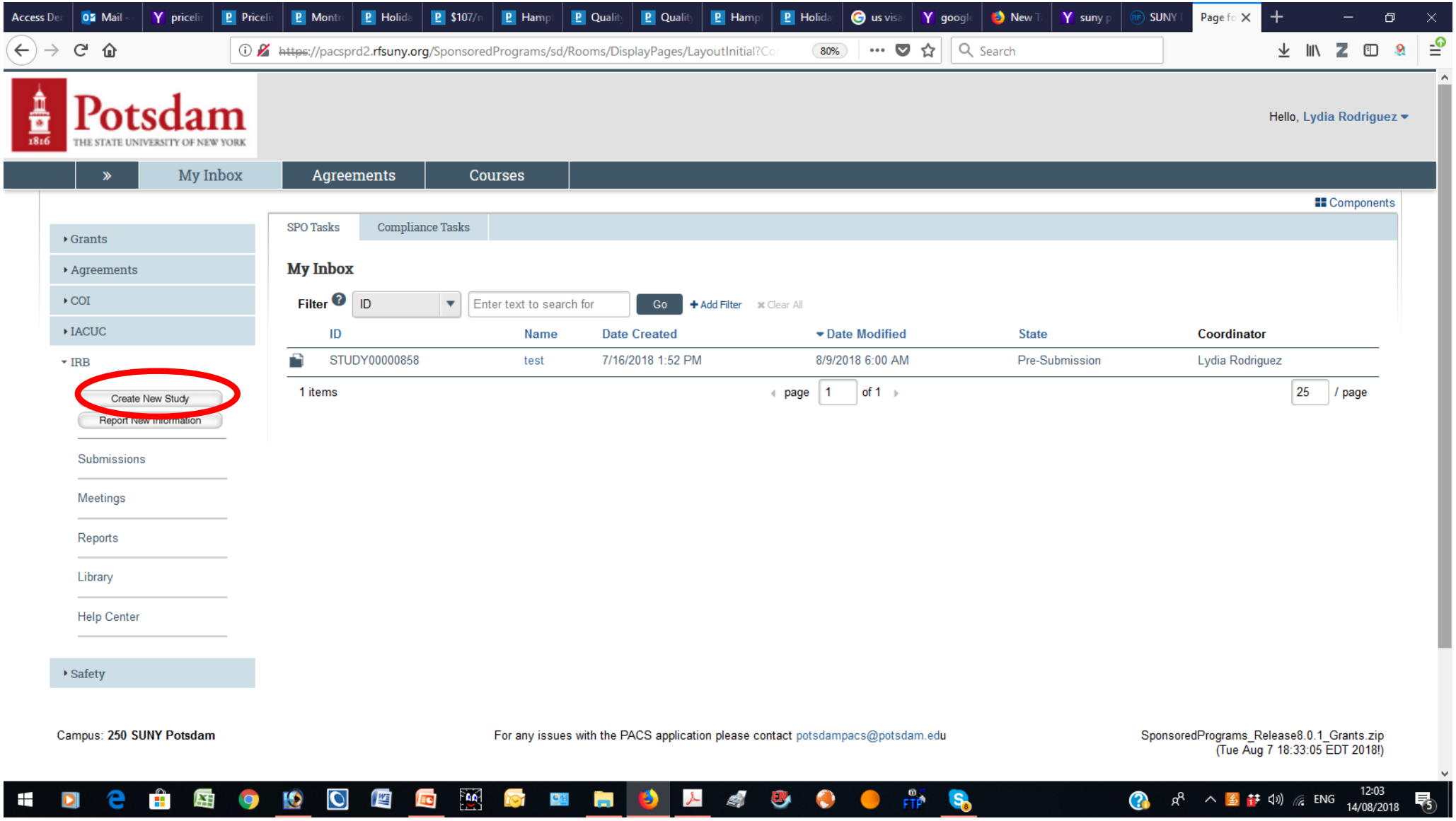
Questions about the Campus Computer Account (CCA) should be directed to the CTS Helpdesk.

Forgot or want to change your password? Visit **https://account.potsdam.edu**

SUNY Federated Login is a service provided by CTS

2. Create a new study




Potsdam
THE STATE UNIVERSITY OF NEW YORK
1816
Hello, Lydia Rodriguez
My Inbox
Agreements
Courses
Components
Grants
Agreements
COI
IACUC
IRB
Create New Study
Report New Information
Submissions
Meetings
Reports
Library
Help Center
Safety
SPO Tasks
Compliance Tasks
My Inbox
Filter
ID
Enter text to search for
Go
Add Filter
Clear All
ID
Name
Date Created
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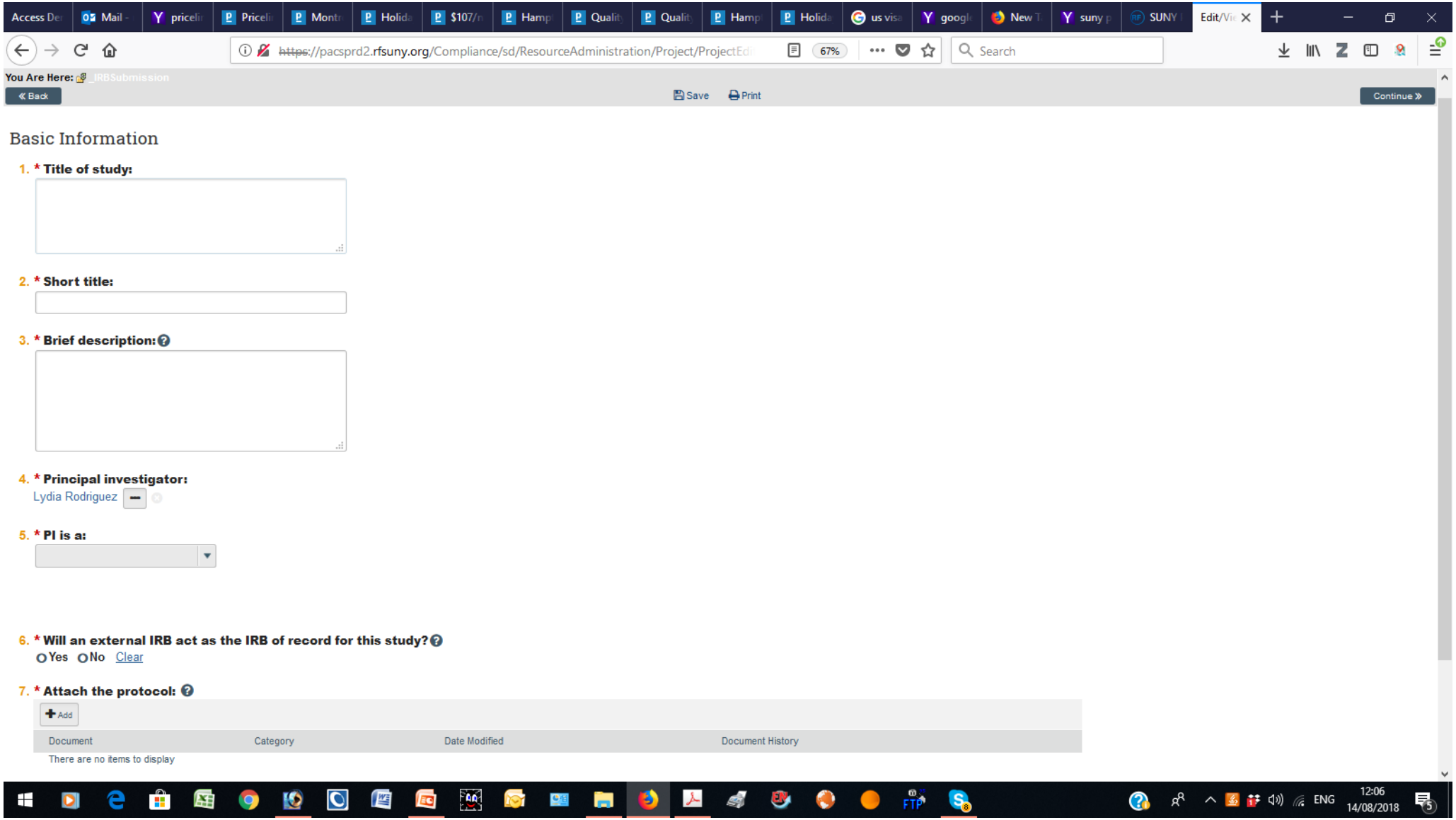
Coordinator
STUDY00000858
test
7/16/2018 1:52 PM
8/9/2018 6:00 AM
Pre-Submission
Lydia Rodriguez
1 items
page 1 of 1
25 / page
Campus: 250 SUNY Potsdam
For any issues with the PACS application please contact potsdampacs@potsdam.edu
SponsoredPrograms_Release8.0.1_Grants.zip
(Tue Aug 7 18:33:05 EDT 2018!)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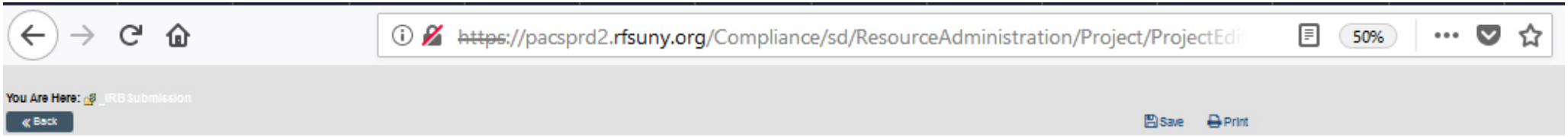
67%
Search
You Are Here: _IRBSubmission
« Back
Save
Print
Continue »
Basic Information
1. * Title of study:
2. * Short title:
3. * Brief description:
4. * Principal investigator:
Lydia Rodriguez
5. * PI is a:
6. * Will an external IRB act as the IRB of record for this study?
Yes No Clear
7. * Attach the protocol:
Add
Document
Category
Date Modified
Document History
There are no items to display
ENG
12:06
14/08/2018



Basic Information

1. * **Title of study:**

   Demo

2. * **Short title:**

   DEMO

3. * **Brief description:**

   This is a < survey, questionnaire, ethnographic study study> that will examine...<x, y, z>
   The central question the research is intended to answer is...
   The primary objectives are...
   The methods used are...

4. * **Principal investigator:**

   Lydia Rodriguez

5. * **PI is a:**

   Faculty

6. * **Will an external IRB act as the IRB of record for this study?**

   ○ Yes ● No Clear

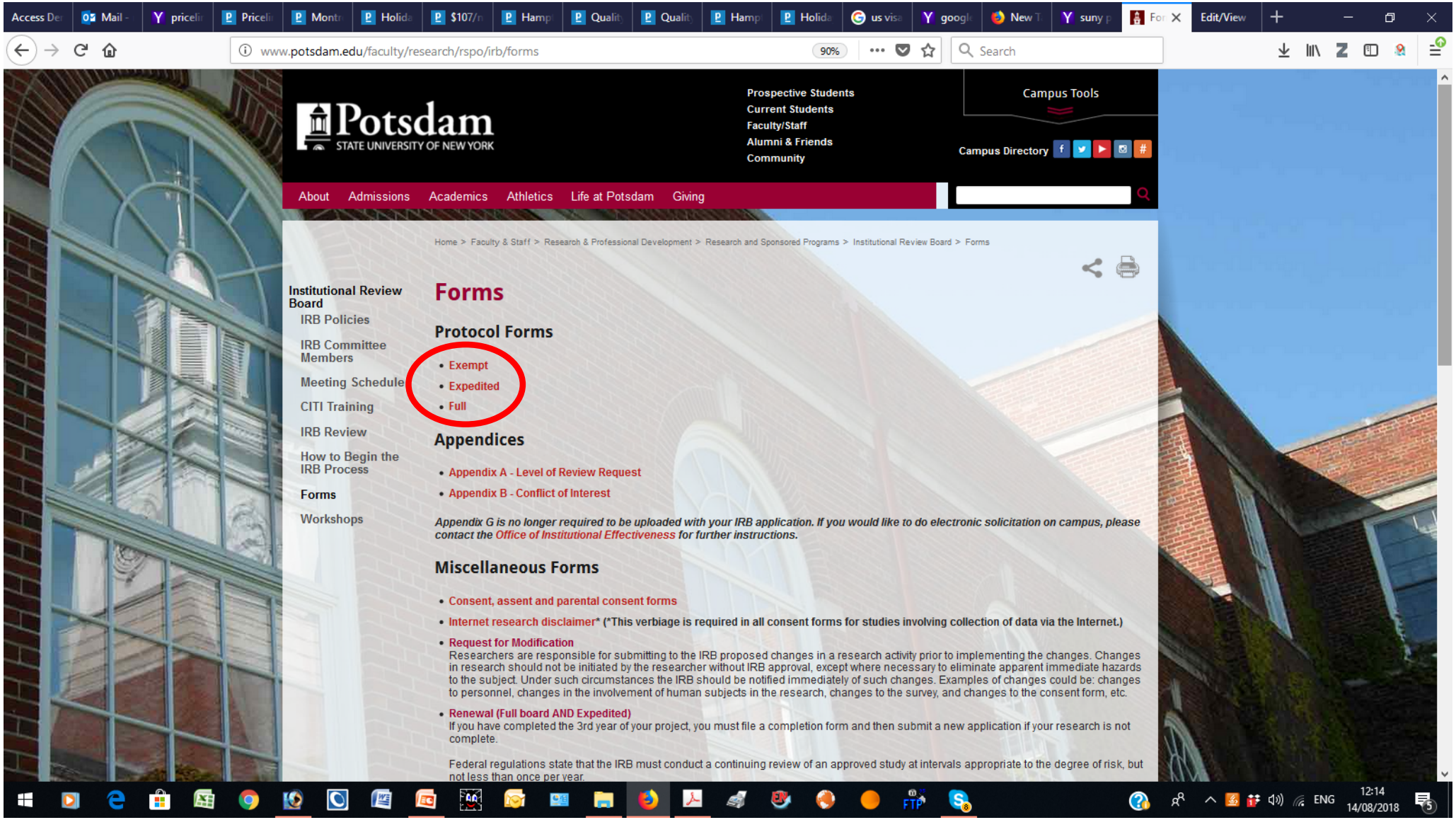
7. * **Attach the protocol:**

   + Add

Document	Category	Date Modified	Document History
There are no items to display			

- **Use one of the templates in the** IRB Library

3. Download and complete forms



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Faculty

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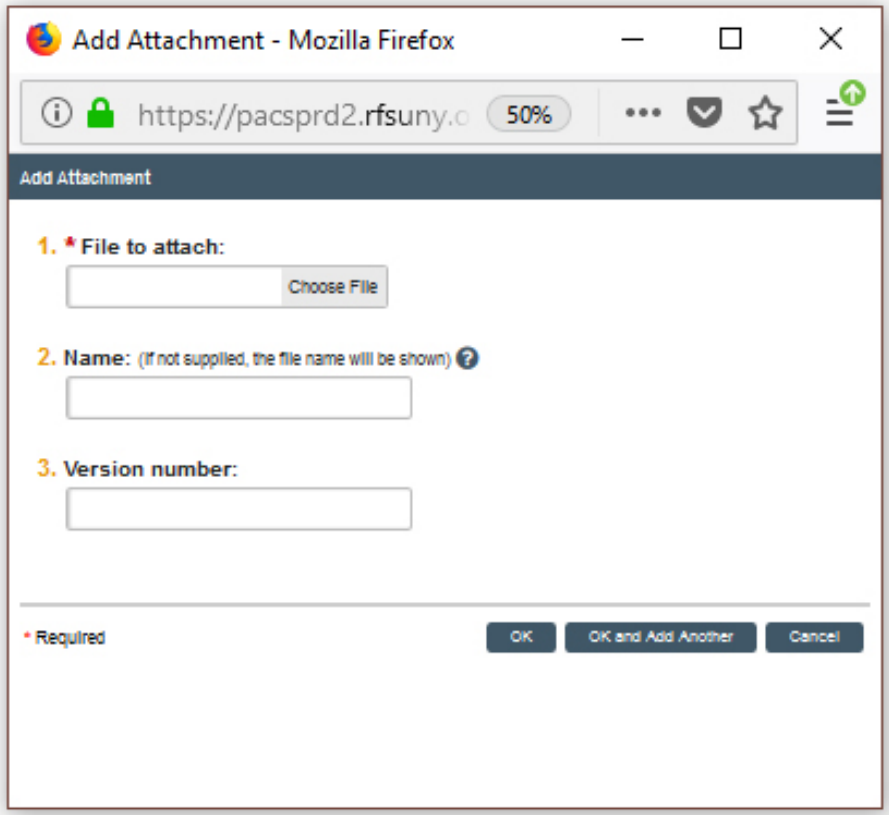
7. * **Attach the protocol:**

Add

Document	Category	Date Modified	Document Histo
There are no items to display			

- **Use one of the templates in the** IRB Library



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You Are Here: IRB Submission

« Back

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The methods used are...

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Lydia Rodriguez

5. * **PI is a:**

Faculty

6. * **Will an external IRB act as the IRB of record for this study?**

Yes No Clear

7. * **Attach the protocol:**

Add

Document	Category	Date Modified	Document Histo
There are no items to display			

- **Use one of the templates in the** IRB Library

Add Attachment - Mozilla Firefox

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Add Attachment

1. * **File to attach:**

Expedited protocol.doc Choose File

2. **Name:** (If not supplied, the file name will be shown)

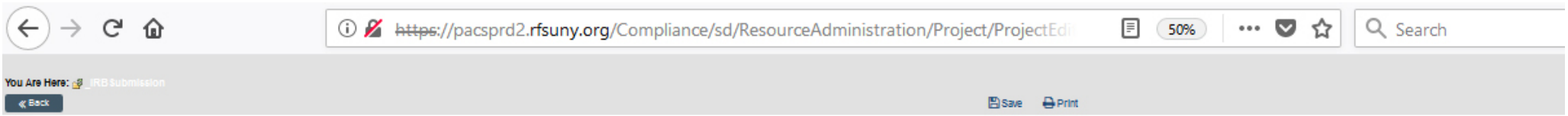
Lydia Rodriguez's Expedited Application

3. **Version number:**

1

* Required

OK OK and Add Another Cancel



Basic Information

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Demo

2. * **Short title:**

DEMO

3. * **Brief description:**

This is a < survey, questionnaire, ethnographic study study> that will examine...<x, y, z>
The central question the research is intended to answer is...
The primary objectives are...
The methods used are...

4. * **Principal investigator:**

Lydia Rodriguez

5. * **PI is a:**

Faculty

6. * **Will an external IRB act as the IRB of record for this study?**

Yes No Clear

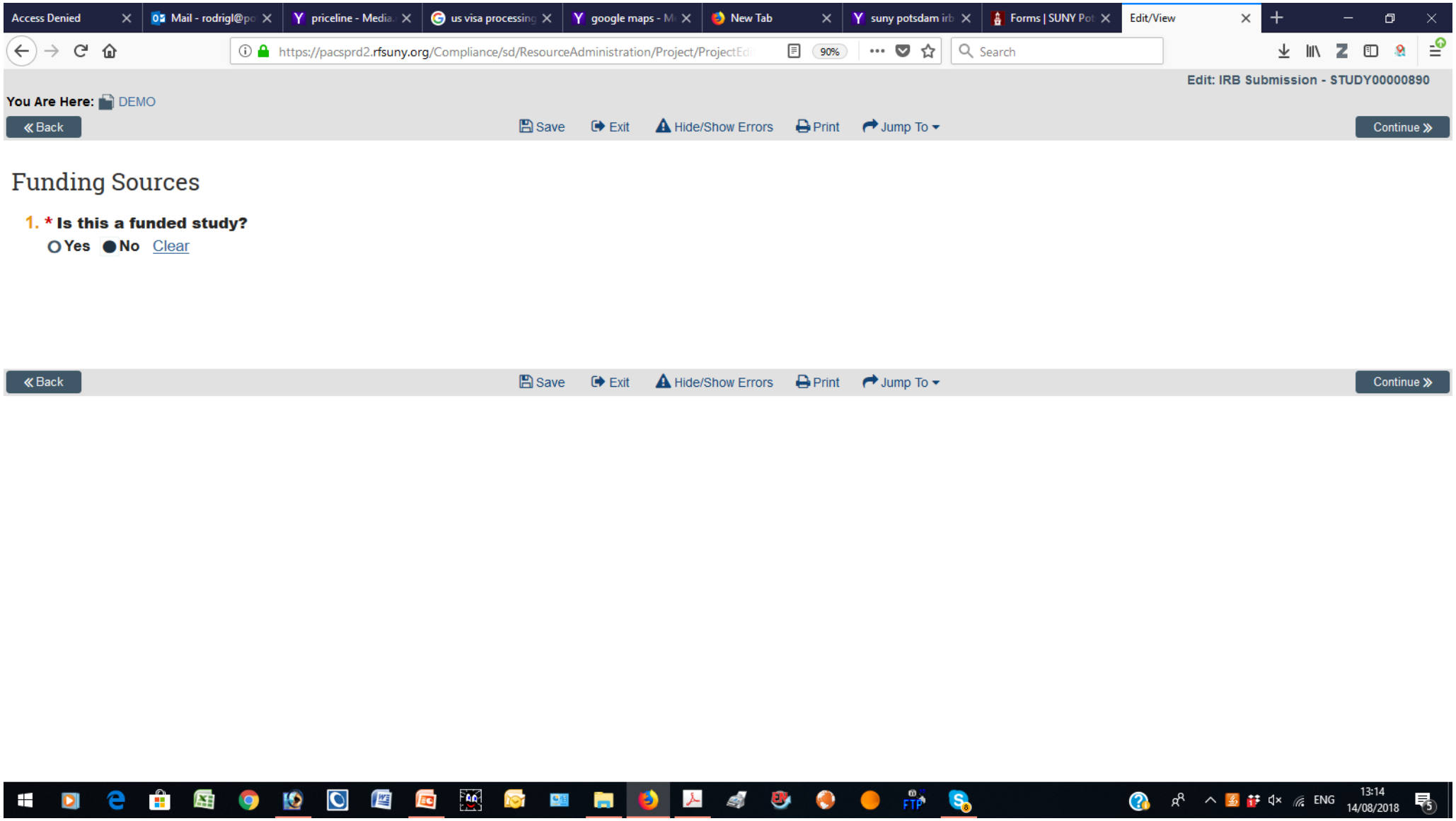
7. * **Attach the protocol:**

Add

	Document	Category	Date Modified	Document History
Update	Lydia Rodriguez's Expedited Application(1)	IRB Protocol	8/14/2018	History

- **Use one of the templates in the** IRB Library

Continue »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Funding Sources
1. * Is this a funded study?
Yes
No
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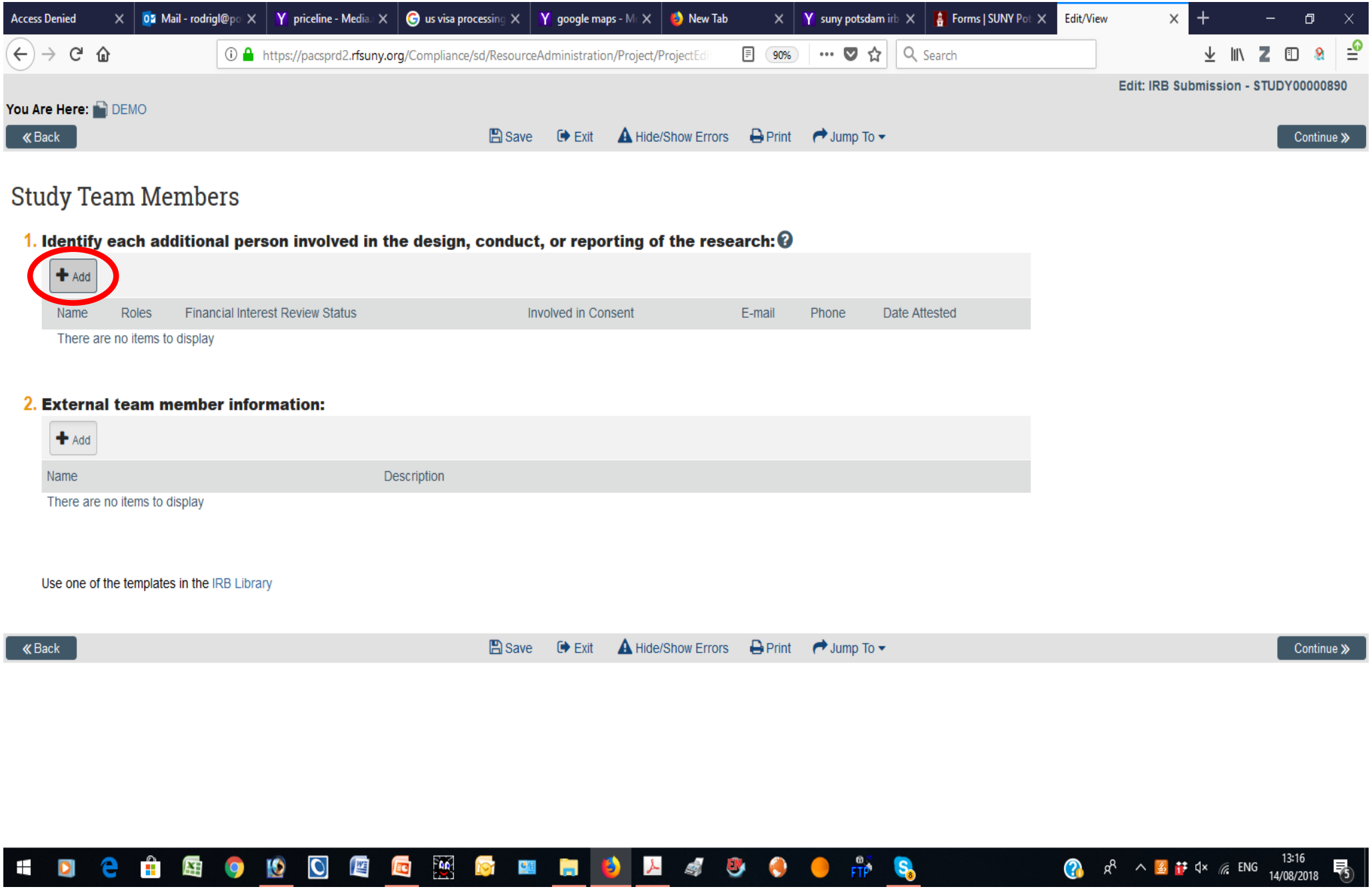
14/08/2018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Study Team Members
1. Identify each additional person involved in the design, conduct, or reporting of the research:
Add
Name
Roles
Financial Interest Review Status
Involved in Consent
E-mail
Phone
Date Attested
There are no items to display
2. External team member information:
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Name
Description
There are no items to display
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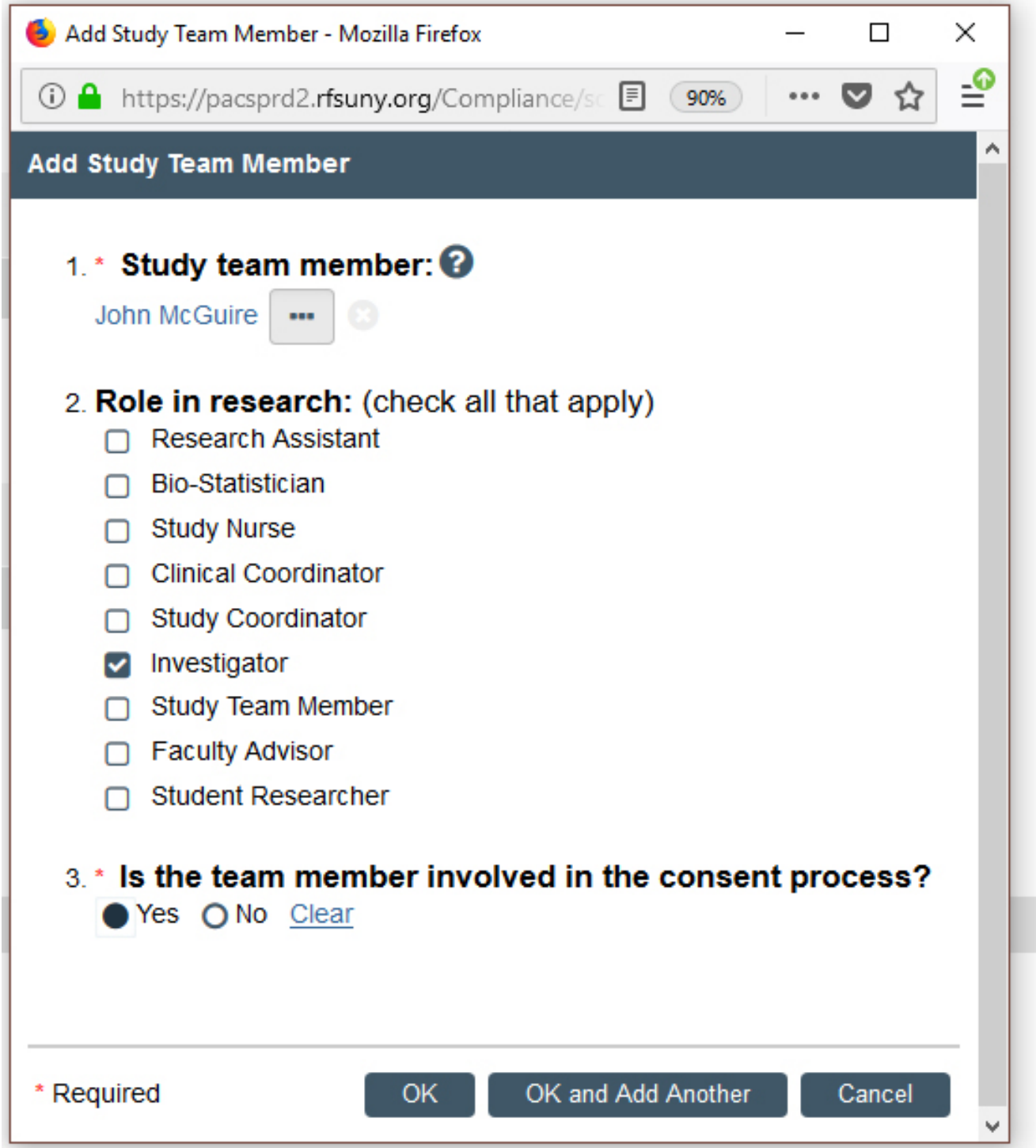
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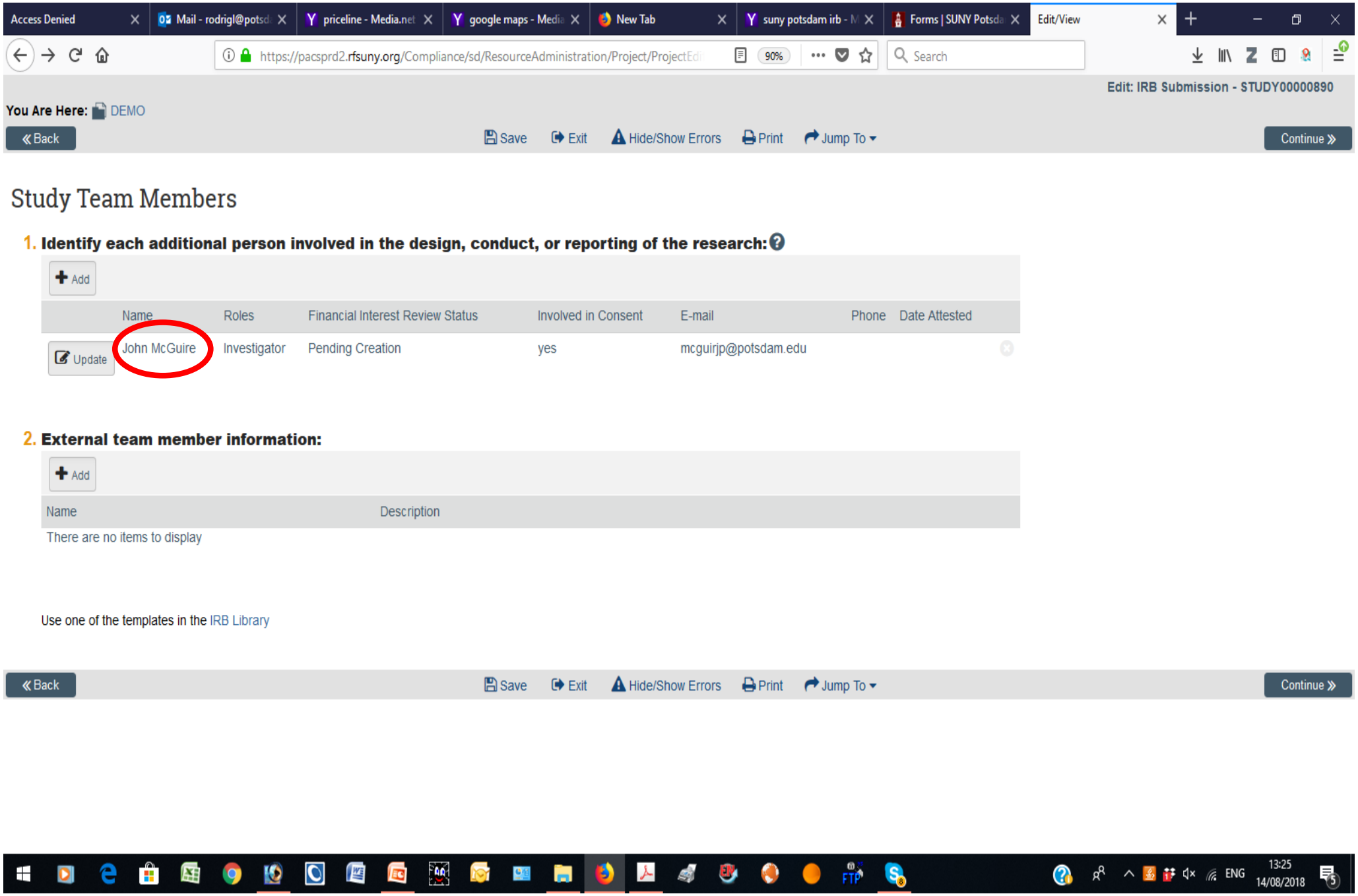
Add Study Team Member
1. * Study team member:
John McGuire
2. Role in research: (check all that apply)
Research Assistant
Bio-Statistician
Study Nurse
Clinical Coordinator
Study Coordinator
Investigator
Study Team Member
Faculty Advisor
Student Researcher
3. * Is the team member involved in the consent process?
Yes
No
Clear
* Required
OK
OK and Add Another
Cancel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Study Team Members
1. Identify each additional person involved in the design, conduct, or reporting of the research:
Add
Name
Roles
Financial Interest Review Status
Involved in Consent
E-mail
Phone
Date Attested
Update
John McGuire
Investigator
Pending Creation
yes
mcguirjp@potsdam.edu
2. External team member information:
Add
Name
Description
There are no items to display
Use one of the templates in the IRB Library
Back
Save
Exit
Hide/Show Errors
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13:25
14/08/2018

Special Note about "Study Team Members"

If your co-investigator is SUNY Potsdam faculty/staff, you will be able to select their name from a drop-down menu.

If your co-investigator is NOT SUNY Potsdam faculty/staff, you will need to download the "External Team Member Information Form" from our website, and upload it to your submission

If you have student-researchers you must include their names in the "Study Team Members" section of the online application. *Please note that students cannot make online submissions, only PIs are able to submit a protocol for review*. However, students need to be registered as users in order for the PIs to be able to list their names in the application.

Before PIs can add students' names, each student must open an account. In the online portal, each student must click on "Don't have a SUNY PACs account" link, and follow instructions to open an account. Once students have registered and have an account, the PI will be able to add them as "student-researcher" in the online application.

Study Scope

1. * **Are there external sites where the investigator will conduct or oversee the research?**
   ● Yes ○ No Clear

2. * **Does the study do any of the following:**
   - Specify the use of an approved drug or biologic?
   - Use an unapproved drug or biologic?
   - Use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?

   ○ Yes ● No Clear

3. * **Does the study do any of the following:**
   - Evaluate the safety or effectiveness of a device?
   - Use a humanitarian use device (HUD)?

   ○ Yes ● No Clear

Continue »

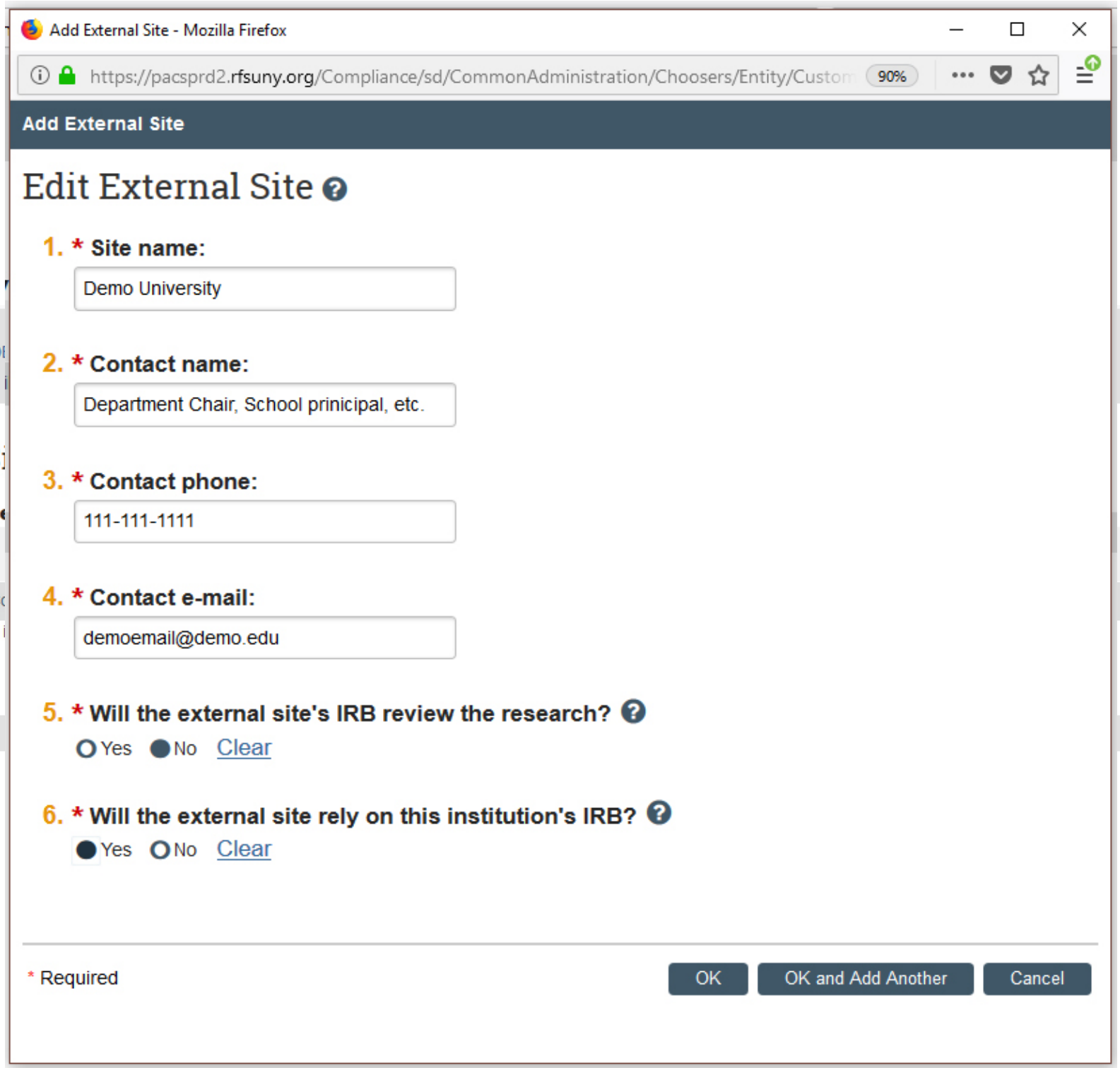
External Sites

1. * **Identify each external site where the investigator will conduct or oversee the research:**

+ Add

Site	Contact	Phone	E-mail	External IRB Review	Rely on This IRB

There are no items to display


Add External Site - Mozilla Firefox
https://pacsprd2.rfsuny.org/Compliance/sd/CommonAdministration/Choosers/Entity/Custom
90%
Add External Site
Edit External Site
1. * Site name:
Demo University
2. * Contact name:
Department Chair, School prinicipal, etc.
3. * Contact phone:
111-111-1111
4. * Contact e-mail:
demoemail@demo.edu
5. * Will the external site's IRB review the research?
Yes
No
Clear
6. * Will the external site rely on this institution's IRB?
Yes
No
Clear
* Required
OK
OK and Add Another
Cancel


https://pacsprd2.rfsuny.org/Compliance/sd/ResourceAdministration/Project/ProjectEdi
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You Are Here: DEMO
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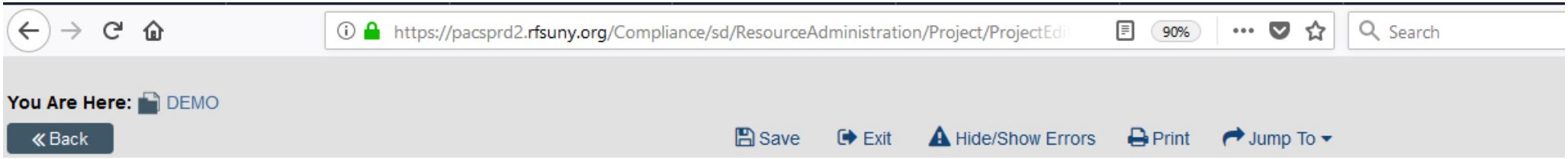
Save
Exit
Hide/Show Errors
Print
Jump To
External Sites
1. * Identify each external site where the investigator will conduct or oversee the research:
Add
Site
Contact
Phone
E-mail
External IRB Review
Rely on This IRB
Demo University
Department Chair, School prinicipal, etc.
111-111-1111
demoemail@demo.edu
no
yes
Back
Save
Exit
Hide/Show Errors
Print
Jump To
Continue



Consent Forms and Recruitment Materials

1. **Consent forms:** (include an HHS-approved sample consent document, if applicable)

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

Refer to the templates and instructional documents in the IRB Library

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads)

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

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Exit
Hide/Show Errors
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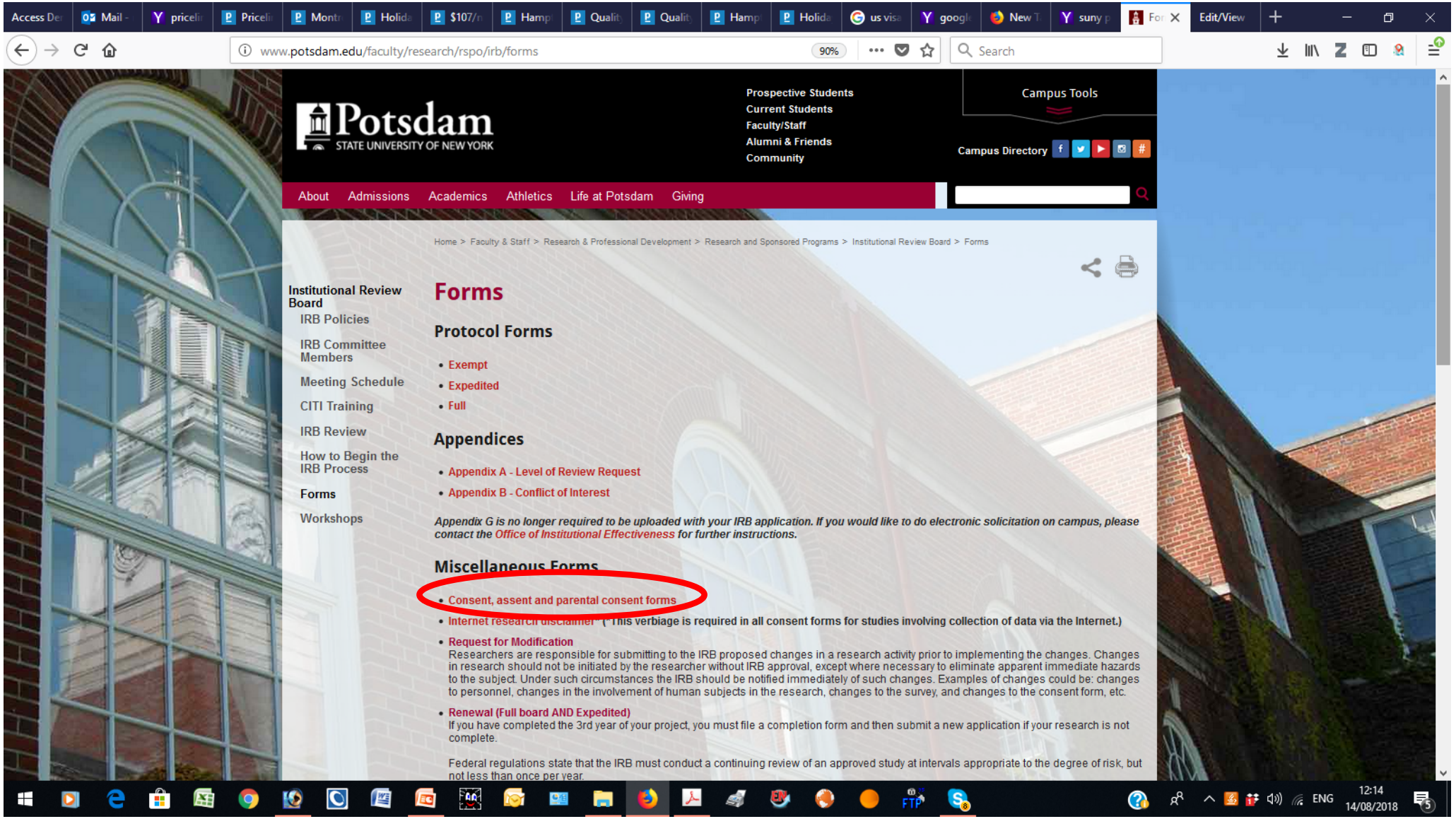
Jump To


Potsdam
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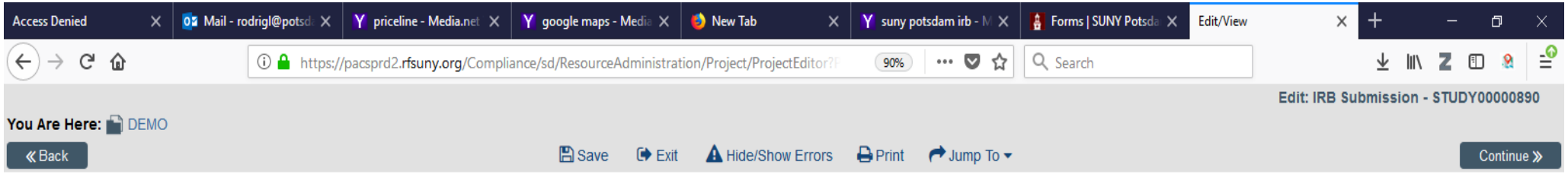
Prospective Students
Current Students
Faculty/Staff
Alumni & Friends
Community
Campus Tools
Campus Directory
About
Admissions
Academics
Athletics
Life at Potsdam
Giving
Home > Faculty & Staff > Research & Professional Development > Research and Sponsored Programs > Institutional Review Board > Forms
Institutional Review Board
IRB Policies
IRB Committee Members
Meeting Schedule
CITI Training
IRB Review
How to Begin the IRB Process
Forms
Workshops
Forms
Protocol Forms
Exempt
Expedited
Full
Appendices
Appendix A - Level of Review Request
Appendix B - Conflict of Interest
Appendix G is no longer required to be uploaded with your IRB application. If you would like to do electronic solicitation on campus, please contact the Office of Institutional Effectiveness for further instructions.
Miscellaneous Forms
Consent, assent and parental consent forms
Internet research disclaimer (* This verbiage is required in all consent forms for studies involving collection of data via the Internet.)
Request for Modification
Researchers are responsible for submitting to the IRB proposed changes in a research activity prior to implementing the changes. Changes in research should not be initiated by the researcher without IRB approval, except where necessary to eliminate apparent immediate hazards to the subject. Under such circumstances the IRB should be notified immediately of such changes. Examples of changes could be: changes to personnel, changes in the involvement of human subjects in the research, changes to the survey, and changes to the consent form, etc.
Renewal (Full board AND Expedited)
If you have completed the 3rd year of your project, you must file a completion form and then submit a new application if your research is not complete.
Federal regulations state that the IRB must conduct a continuing review of an approved study at intervals appropriate to the degree of risk, but not less than once per year.



CITI Training

*Note: For **NIH training**, please scan and attach the completion certificate as a "supporting document" on the last page of this submission. **All researchers must complete either the CITI or NIH training program.**

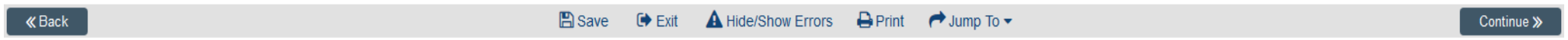
1. PI Completed CITI Coursework:

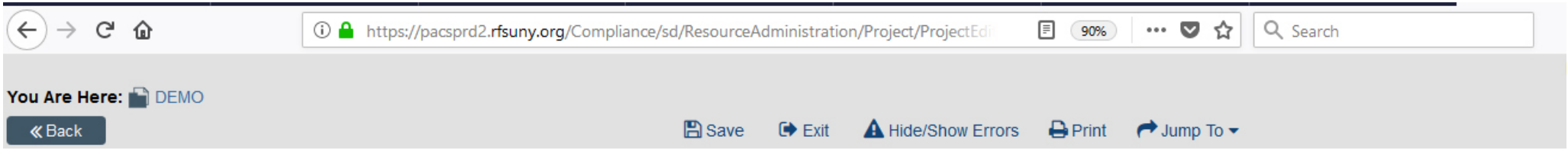
Lydia Rodriguez

Curriculum	Training Course	Group	Training Stage	External Report Identification	Learner's Score	Passing Score	Date Report Completed	Date Report Expired
There are no items to display								

2. Study Team Members Completed CITI Coursework:

Name	Training Details
John McGuire	





Supporting Documents

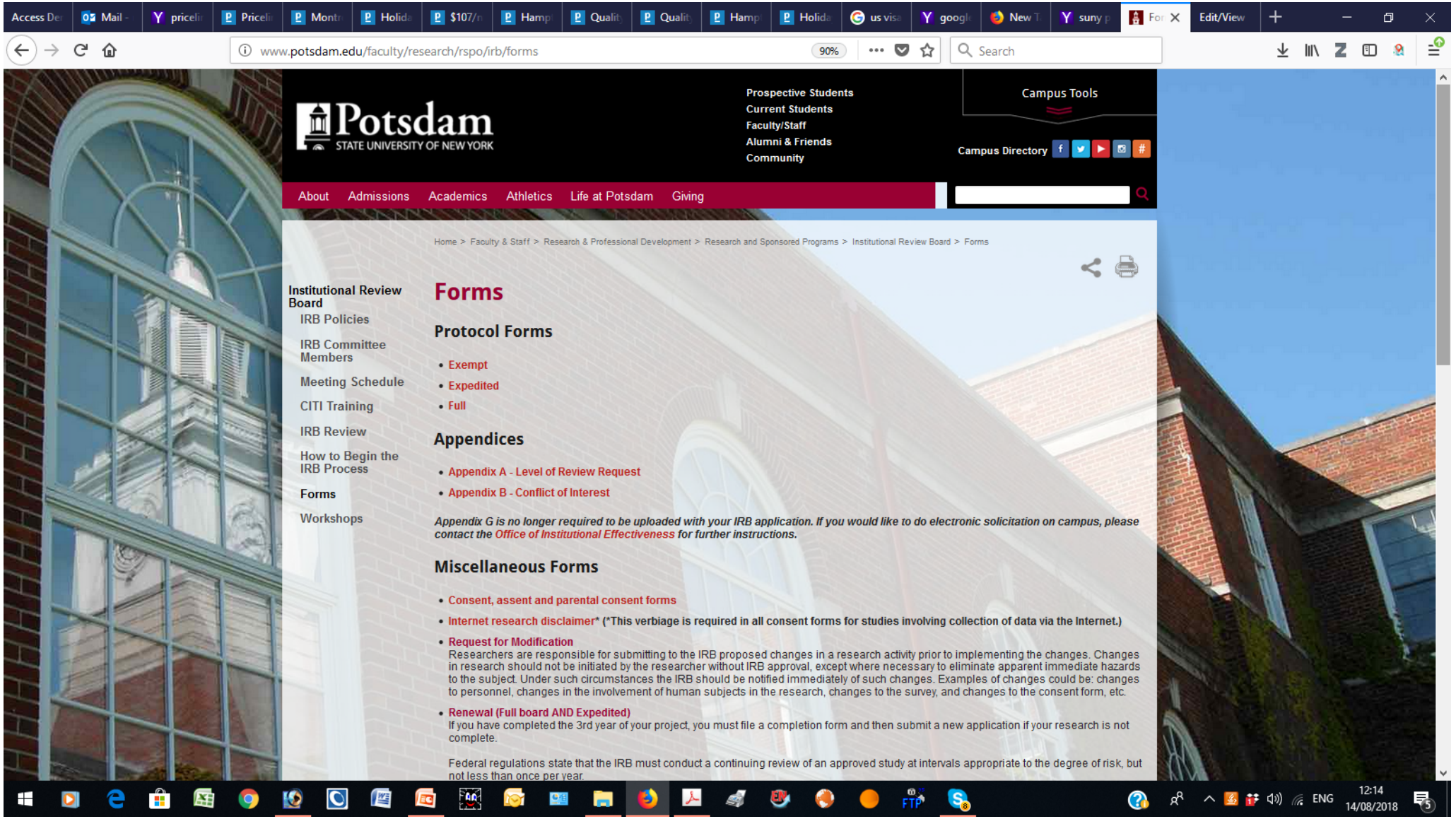
Attach supporting files, naming them as you want them to appear in the approval letter:

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other study-related documents not attached on previous forms
- **NIH training completion certificate**


www.potsdam.edu/faculty/research/rspo/irb/forms
Search
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Prospective Students
Current Students
Faculty/Staff
Alumni & Friends
Community
Campus Tools
Campus Directory
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Admissions
Academics
Athletics
Life at Potsdam
Giving
Home > Faculty & Staff > Research & Professional Development > Research and Sponsored Programs > Institutional Review Board > Forms
Institutional Review Board
IRB Policies
IRB Committee Members
Meeting Schedule
CITI Training
IRB Review
How to Begin the IRB Process
Forms
Workshops
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Protocol Forms
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ENG
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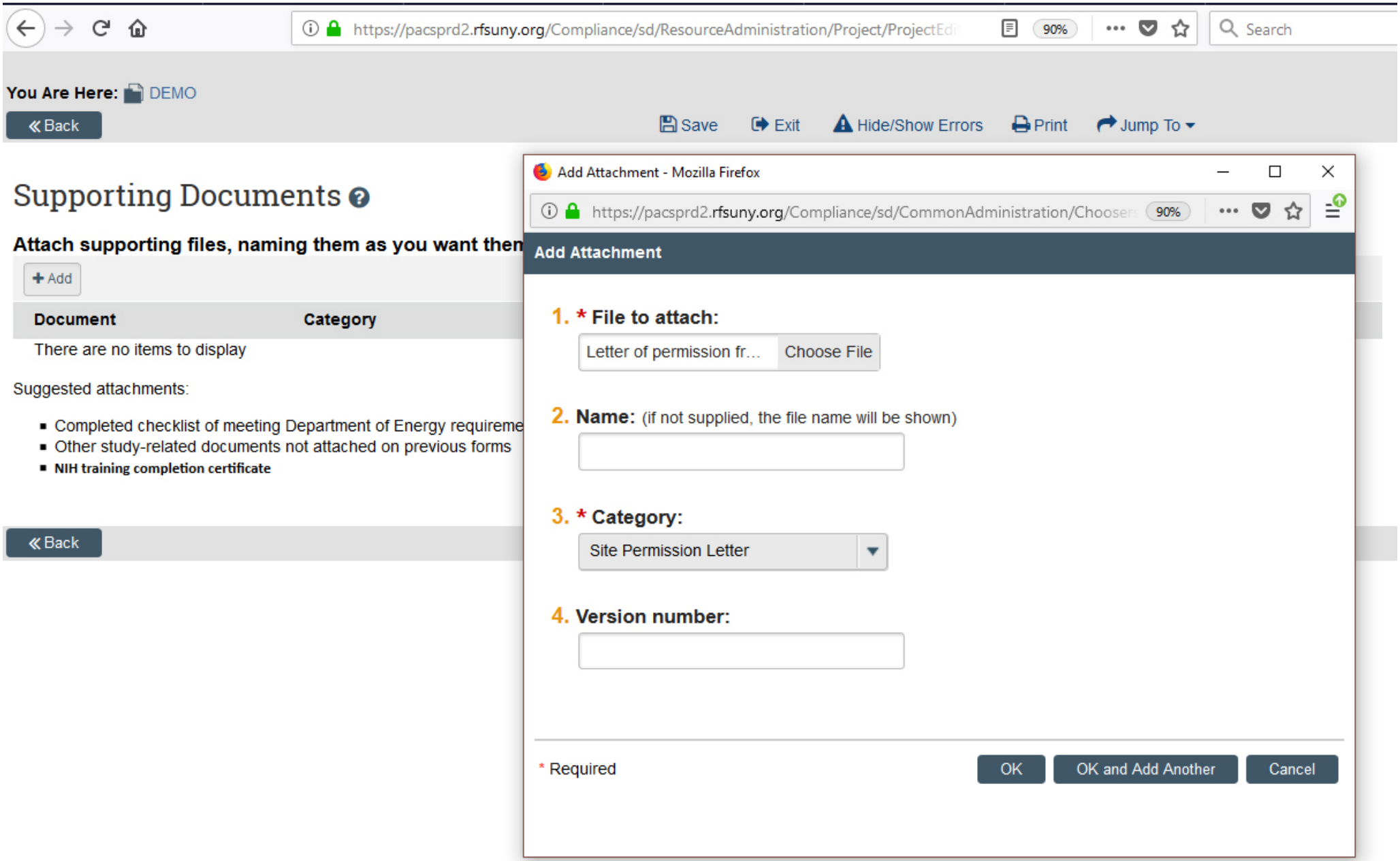
https://pacsprd2.rfsuny.org/Compliance/sd/ResourceAdministration/Project/ProjectEdi
90%
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You Are Here: DEMO
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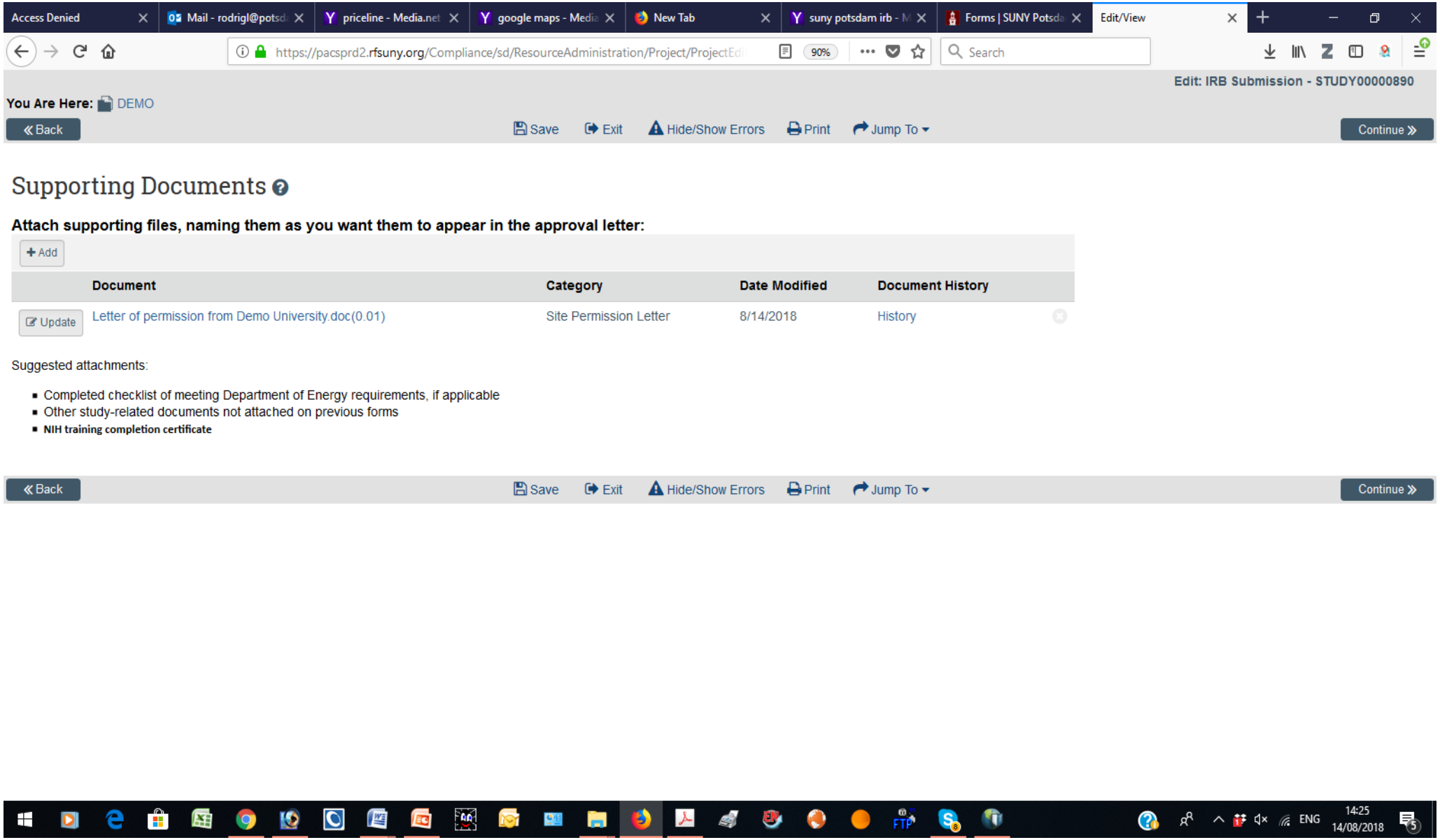
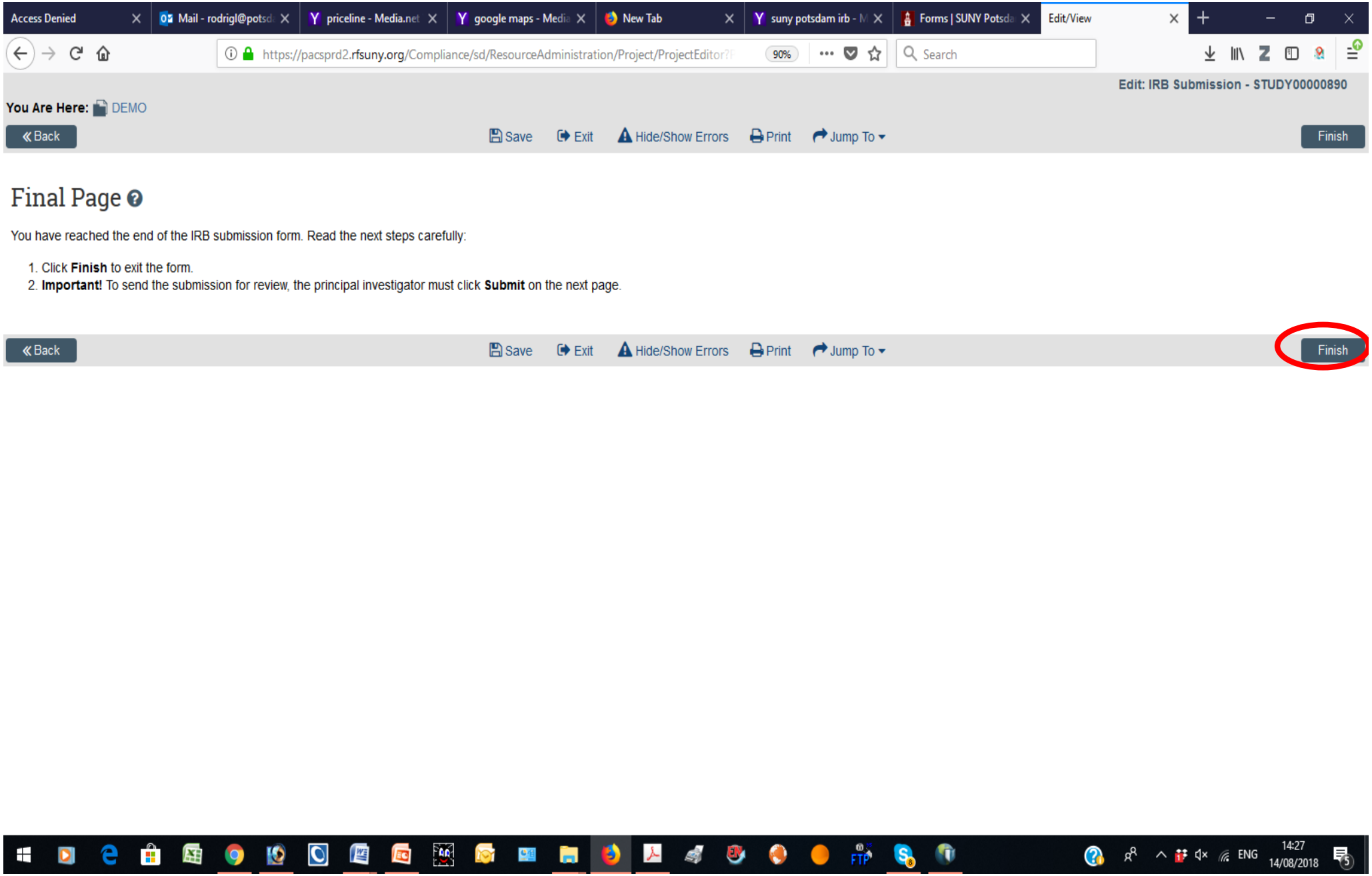
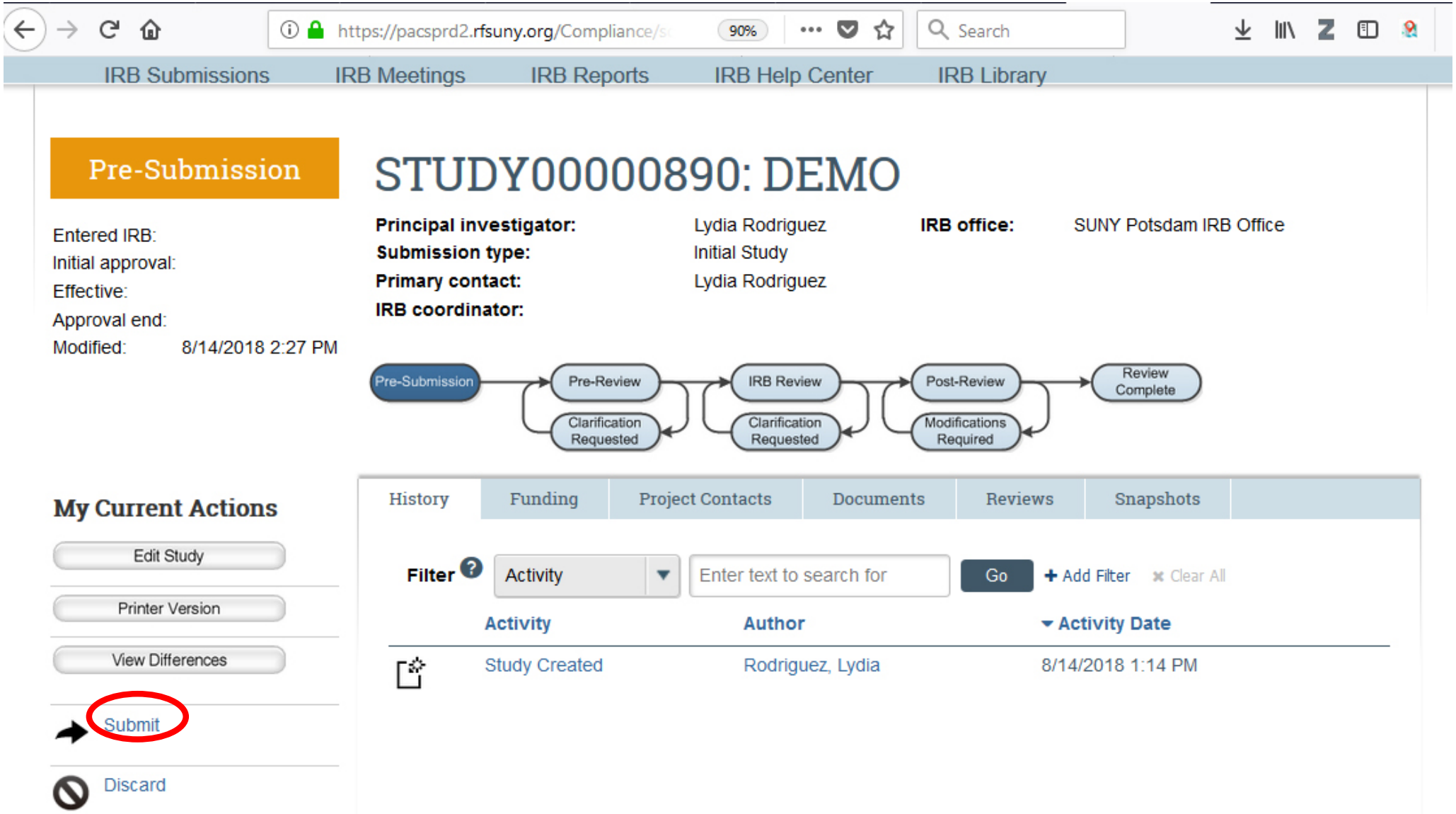
Print
Jump To
Supporting Documents
Attach supporting files, naming them as you want then
Add
Document
Category
There are no items to display
Suggested attachments:
Completed checklist of meeting Department of Energy requireme
Other study-related documents not attached on previous forms
NIH training completion certificate
Back
Add Attachment - Mozilla Firefox
https://pacsprd2.rfsuny.org/Compliance/sd/CommonAdministration/Chooser
90%
Add Attachment
1. * File to attach:
Letter of permission fr...
Choose File
2. Name: (if not supplied, the file name will be shown)
3. * Category:
Site Permission Letter
4. Version number:
* Required
OK
OK and Add Another
Cancel

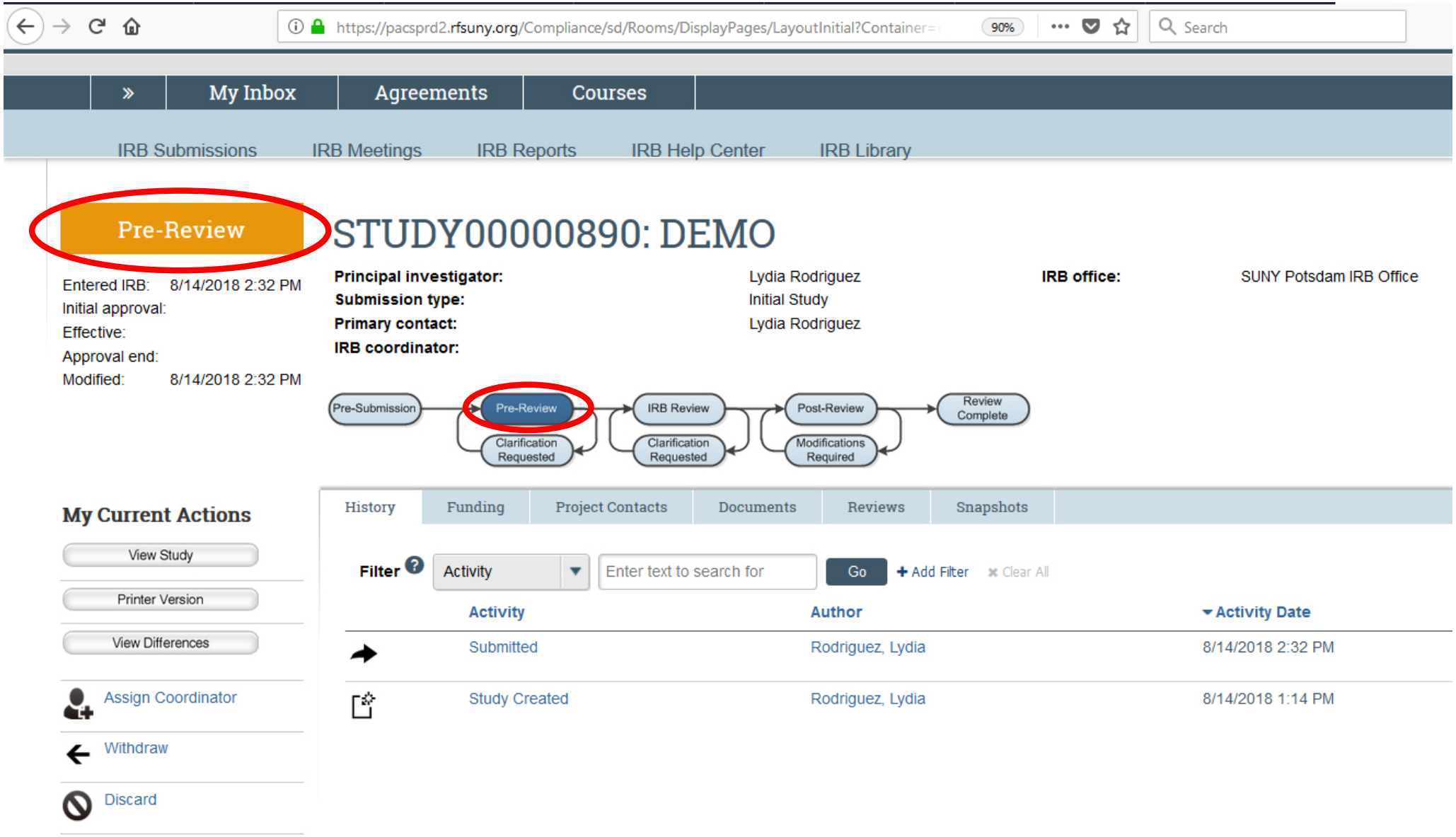

Access Denied
Mail - rodrigl@potsd
priceline - Media.net
google maps - Media
New Tab
suny potsdam irb - M
Forms | SUNY Potsda
Edit/View
https://pacsprd2.rfsuny.org/Compliance/sd/ResourceAdministration/Project/ProjectEdi
90%
Search
Edit: IRB Submission - STUDY00000890
You Are Here: DEMO
Back
Save
Exit
Hide/Show Errors
Print
Jump To
Continue
Supporting Documents
Attach supporting files, naming them as you want them to appear in the approval letter:
+ Add
Document
Category
Date Modified
Document History
Update
Letter of permission from Demo University.doc(0.01)
Site Permission Letter
8/14/2018
History
Suggested attachments:
Completed checklist of meeting Department of Energy requirements, if applicable
Other study-related documents not attached on previous forms
NIH training completion certificate
Back
Save
Exit
Hide/Show Errors
Print
Jump To
Continue
ENG
14:25
14/08/2018


Access Denied
Mail - rodrigl@potsd
priceline - Media.net
google maps - Media
New Tab
suny potsdam irb - M
Forms | SUNY Potsda
Edit/View
https://pacsprd2.rfsuny.org/Compliance/sd/ResourceAdministration/Project/ProjectEditor?
90%
Search
Edit: IRB Submission - STUDY00000890
You Are Here: DEMO
Back
Save
Exit
Hide/Show Errors
Print
Jump To
Finish
Final Page
You have reached the end of the IRB submission form. Read the next steps carefully:
1. Click Finish to exit the form.
2. Important! To send the submission for review, the principal investigator must click Submit on the next page.
Back
Save
Exit
Hide/Show Errors
Print
Jump To
Finish
ENG
14:27
14/08/2018

4. Submit your study



5. Tracking your submission and communicating with IRB members



What are the next steps?

- You will receive an email notification with either a “pre-review clarification request” or the study will be moved to “pre-review”

STUDY00000890 clarification was requested

S SUNYPotsdamIRB@potsdam.edu
Today, 3:24 PM
Lydia Rodriguez

Reply all

Template:IRB_T_Several States_ClarificationRequested

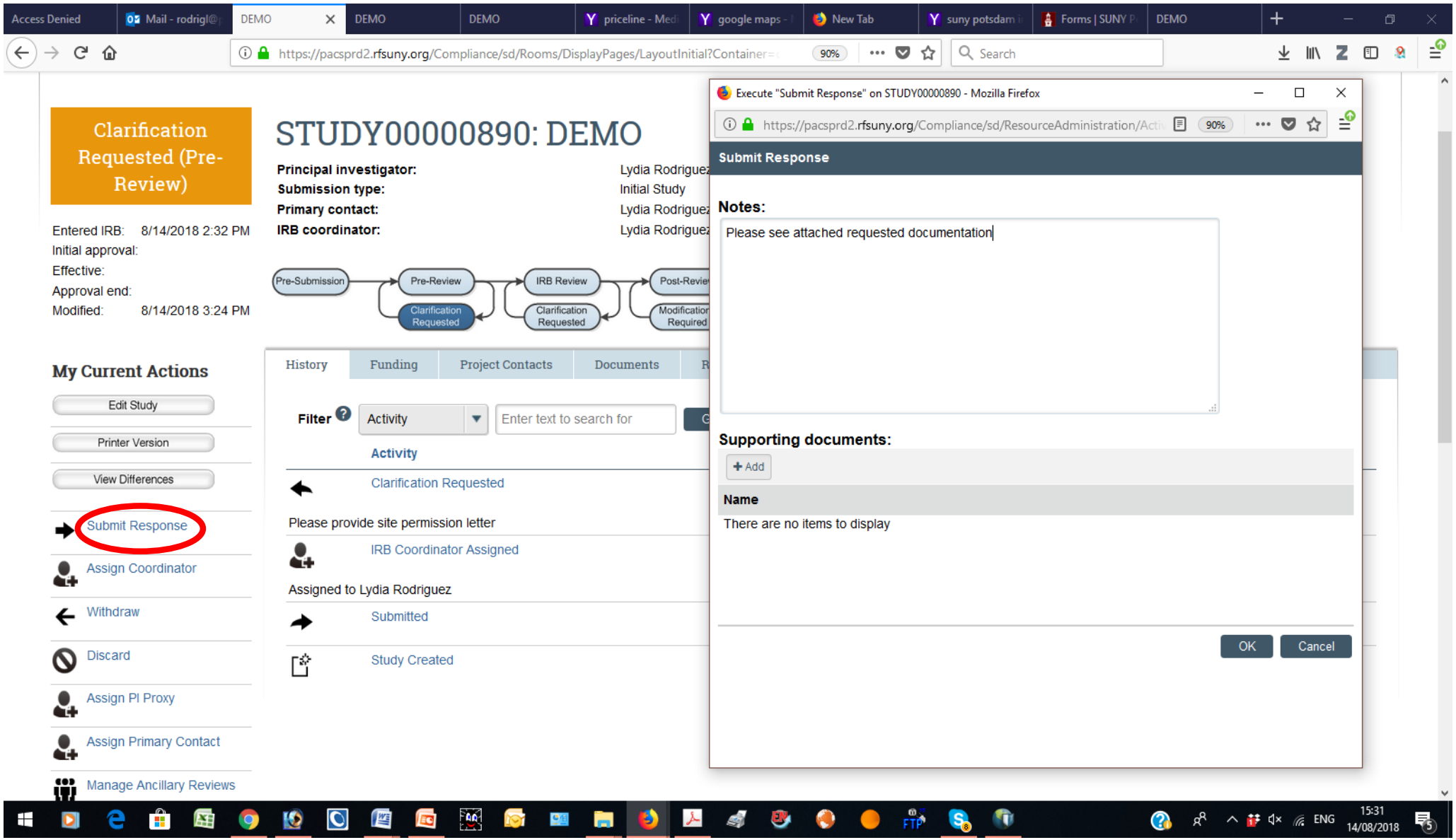
Notification of Requested Clarifications

To:	Lydia Rodriguez
Link:	STUDY00000890
P.I.:	Lydia Rodriguez
Title:	DEMO
Description:	Clarifications have been requested on this submission. This requires a response from you. For additional details, click on the link above to review and provide clarification.

Confidentiality Notice
The information contained in and/or attached to this email message may be confidential. If you are not the intended or authorized recipient, you are hereby notified that any unauthorized distribution, dissemination, or copying of this transmission is prohibited. If you have received this transmission in error, please contact the sender immediately and destroy all copies.

What are the next steps?

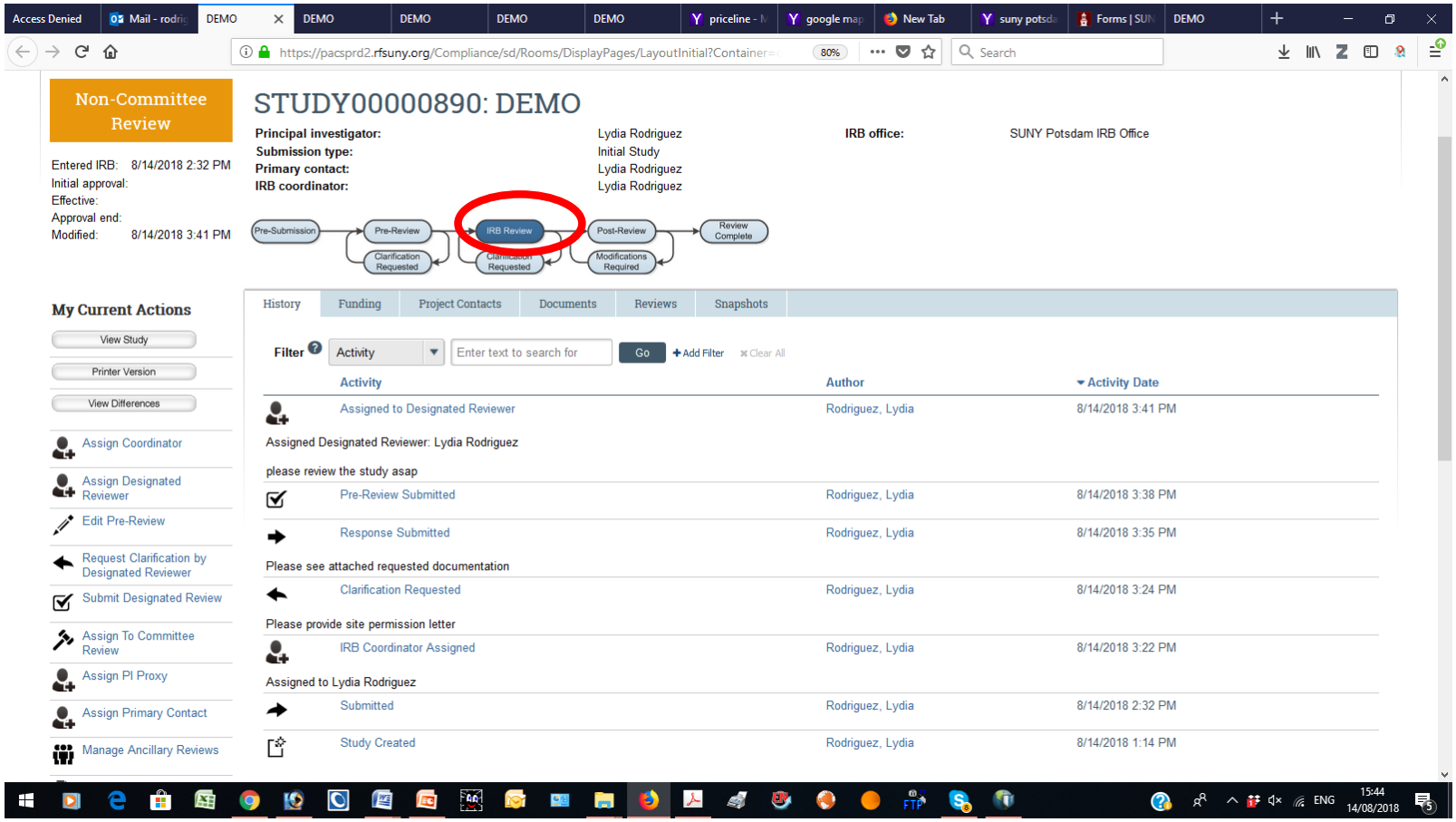
- You will receive an email notification with either a “pre-review clarification request” or the study will be moved to “pre-review”
- If clarifications have been requested, follow the link and use “submit response” to respond to requested clarifications


Clarification Requested (Pre-Review)
STUDY00000890: DEMO
Principal investigator: Lydia Rodriguez
Submission type: Initial Study
Primary contact: Lydia Rodriguez
IRB coordinator: Lydia Rodriguez
Entered IRB: 8/14/2018 2:32 PM
Initial approval:
Effective:
Approval end:
Modified: 8/14/2018 3:24 PM
Pre-Submission
Pre-Review
Clarification Requested
IRB Review
Clarification Requested
Post-Review
Modification Required
My Current Actions
Edit Study
Printer Version
View Differences
Submit Response
Assign Coordinator
Withdraw
Discard
Assign PI Proxy
Assign Primary Contact
Manage Ancillary Reviews
History
Funding
Project Contacts
Documents
Filter
Activity
Enter text to search for
Activity
Clarification Requested
Please provide site permission letter
IRB Coordinator Assigned
Assigned to Lydia Rodriguez
Submitted
Study Created
Execute "Submit Response" on STUDY00000890 - Mozilla Firefox
https://pacsprd2.rfsuny.org/Compliance/sd/ResourceAdministration/Activ
Submit Response
Notes:
Please see attached requested documentation
Supporting documents:
+ Add
Name
There are no items to display
OK
Cancel

What are the next steps?

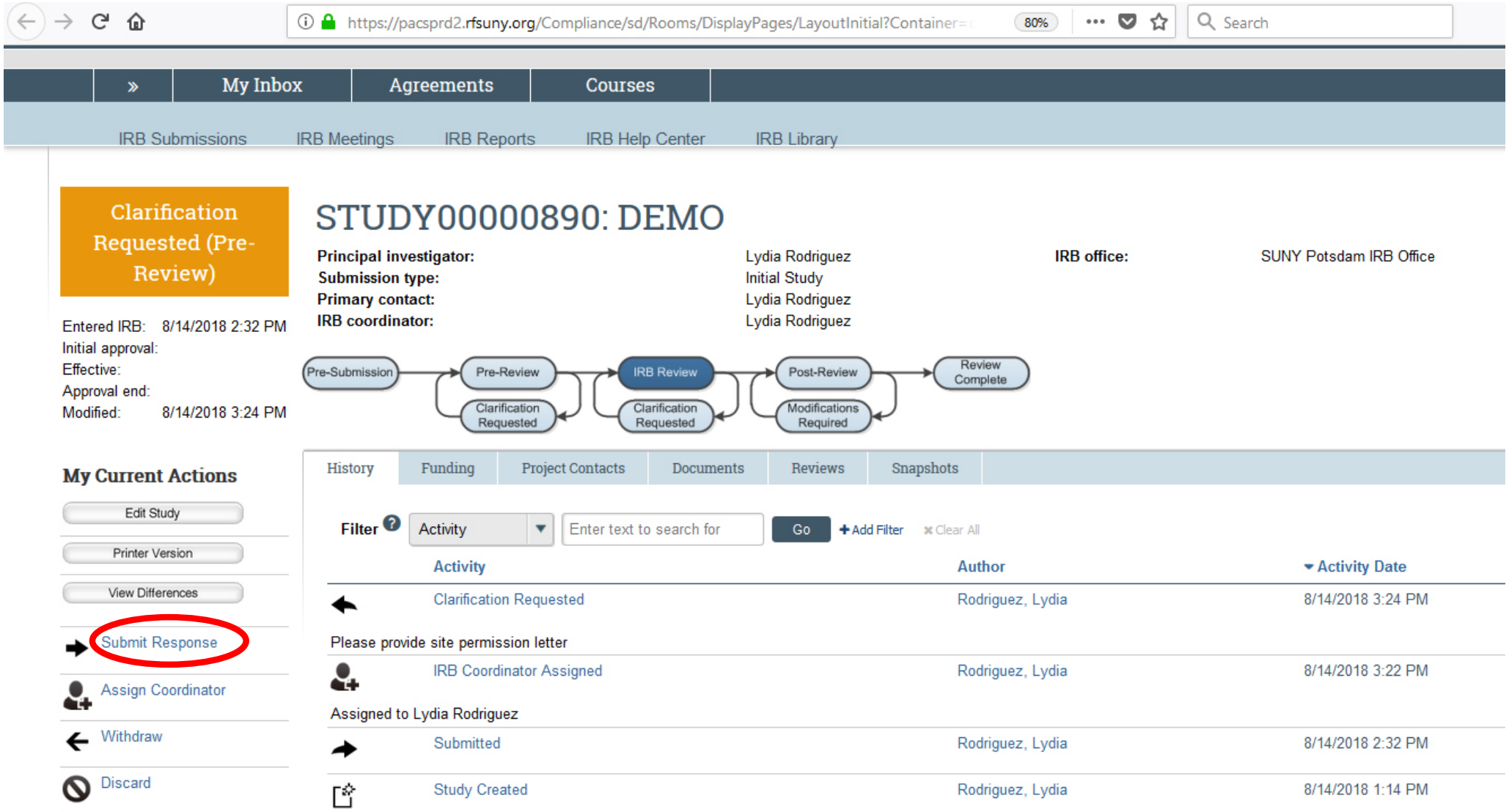
- You will receive an email notification with either a “pre-review clarification request” or the study will be moved to “pre-review”

  (If clarifications have been requested, follow the link and use “submit response” to respond to requested clarifications)
- After submitting initial clarifications the study moves to “IRB review”. When you log in, your inbox should look something like this:



What are the next steps?

- You will receive an email notification with either a “pre-review clarification request” or the study will be moved to “pre-review”
- After submitting initial clarifications the study moves to “IRB review”.
- You will receive another email with clarifications requested by a reviewer.
- To submit requested clarifications, use “submit response” button in your inbox


https://pacsprd2.rfsuny.org/Compliance/sd/Rooms/DisplayPages/LayoutInitial?Container=
80%
Search
»
My Inbox
Agreements
Courses
IRB Submissions
IRB Meetings
IRB Reports
IRB Help Center
IRB Library
Clarification Requested (Pre-Review)
Entered IRB: 8/14/2018 2:32 PM
Initial approval:
Effective:
Approval end:
Modified: 8/14/2018 3:24 PM
STUDY00000890: DEMO
Principal investigator: Lydia Rodriguez
Submission type: Initial Study
Primary contact: Lydia Rodriguez
IRB coordinator: Lydia Rodriguez
IRB office: SUNY Potsdam IRB Office
Pre-Submission
Pre-Review
Clarification Requested
IRB Review
Clarification Requested
Post-Review
Modifications Required
Review Complete
My Current Actions
Edit Study
Printer Version
View Differences
Submit Response
Assign Coordinator
Withdraw
Discard
History
Funding
Project Contacts
Documents
Reviews
Snapshots
Filter
Activity
Enter text to search for
Go
+ Add Filter
Clear All
Activity
Author
Activity Date
Clarification Requested
Rodriguez, Lydia
8/14/2018 3:24 PM
Please provide site permission letter
IRB Coordinator Assigned
Rodriguez, Lydia
8/14/2018 3:22 PM
Assigned to Lydia Rodriguez
Submitted
Rodriguez, Lydia
8/14/2018 2:32 PM
Study Created
Rodriguez, Lydia
8/14/2018 1:14 PM

What are the next steps?

- You will receive an email notification with either a “pre-review clarification request” or the study will be moved to “pre-review”
- After submitting initial clarifications the study moves to “IRB review”.
- You will receive another email with clarifications requested by a reviewer.
- To submit requested clarifications, use “submit response” button in your inbox
- After your all requested clarifications/modifications have been submitted, the study will be moved to “post-review”
- During the “post-review”, the study is revised again by IRB Chair to ensure that all requested changes have been made and that all necessary supporting documentation has been provided
- Study is approved!