MSSU IRBNet and CITI Training

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Abstract

This is the training document to be used by MSSU faculty and student researchers to become familiarized with the IRBNet Human Subjects Application Training system and the CITI Human Subjects Training system. The article contains basic and intermediate functions within IRBNet needed to submit IRB applications. It also shows the user how to register for both IRBNet and CITI. Finally, it shows how to upload CITI training documents to IRBNet. The text is accompanied by example screen shots.

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1 Introduction

IRBNet is a cloud-based suite of electronic tools that will facilitate MSSU's Institutional Review Board (IRB) human subjects research applications. It will also be used to file IACUC applications. It will bring a new level of efficiency to the IRB process and replace paper copies, scanned documents, cumbersome email threads, and manual signatures. This powerful suite of tools allows for the submission of IRB Packages for review, as well the sharing and signing of these packages with groups of colleagues, faculty mentors/advisers, colleagues at external institutions, and the IRB Administrators/Reviewers. IRBNet is easy to use and this document will get users started with the basic platform and some intermediate and advanced functions.

2 New User Registration and Login

New and existing users can get started with IRBNet by navigating to the following URL: https://www.irbnet.org/release/index.html. Figure 1 presents you with a screen shot for the login page. If you are a New User, simply click on *New User Registration* and provide the necessary information. Figure 2 shows the *Registration* page. Enter your first and last name, create a user name and password, confirm your password, and create a password hint. Once you select "Continue," you will be prompted to select your organization. You can search for Missouri Southern State University using the search box or scroll down and select MSSU from the organization list. Figure 3 shows the page where you will select your organization. When you click "Continue" again, you will be prompted for your contact information. You should use your MSSU email address. Figure 4 shows the Contact Information page. When logged into the system you will be brought to the *My Projects* page, which is the default display page on login. Once you have completed the new user registration you will be ready to begin submitting packages to IRBNet.

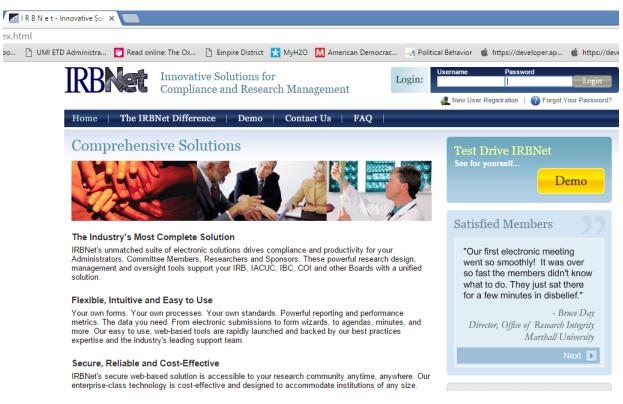


Figure 1: User Registration and Login Page



Figure 2: New User Registration

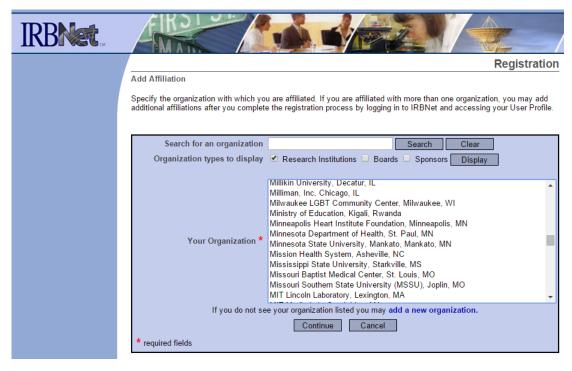


Figure 3: Select Your Institution

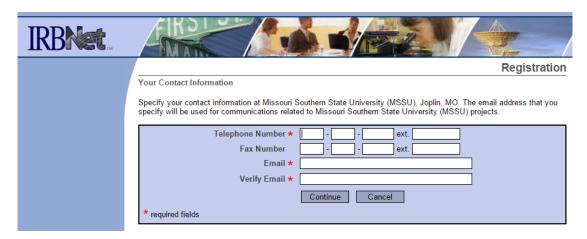


Figure 4: Contact Information

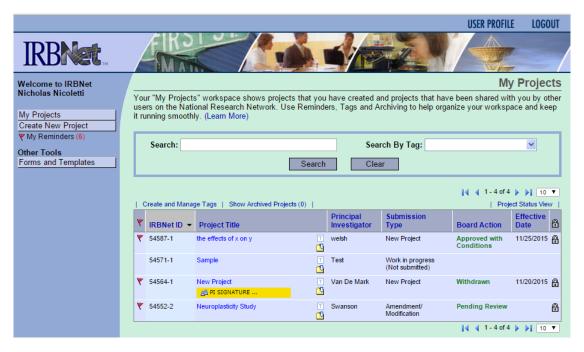


Figure 5: My Projects

3 Basic Package Creation and Design

Once you are logged into the system you can complete a variety of tasks, with the most important being package submission. Faculty and student researchers will generally use the same process, but students will be required to secure the digital signature of their faculty mentor/adviser. This means they will need to share the package with their mentor via IRBNet and that the faculty mentor will provide a digital signature after reviewing the necessary items. Both the faculty member and the student must be a registered MSSU IRBNet user for packages to be properly shared.¹ Of course, it is also possible to share packages with members of external institutions. Figure 5 shows what the *My Projects* page looks like once logged into IRBNet.

User's will use the tabs at the left-hand side of the screen navigate to the system. The firs tab, labeled *My Projects*, is the default page. As you can see in Figure 5, a list of your projects appears in the window with an IRBNet ID number, the project title, the principal investigator, the submission type, the board action, and the effective date. Notice that three of the four projects have a lock symbol (1) next to the effective date. Once a project has been

¹See the Sharing a Project and Package Signature sections for more information on this process.

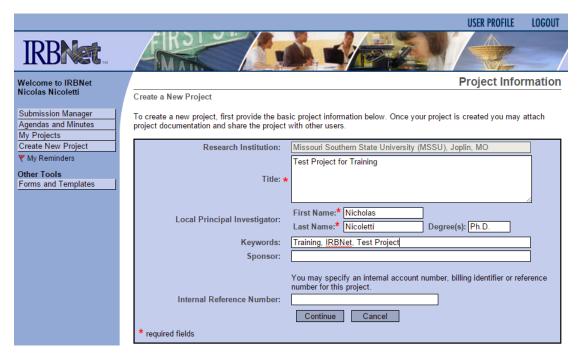


Figure 6: Creating a New Project

submitted to the IRB it is locked and cannot be unlocked until an IRB administrator unlocks the package. Moreover, each time a package is submitted, that package permanently resides in the system. Projects and packages can be updated; however, updating a package will create new versions of your documents in the package time-line, so that all documents are conserved and a digital paper trail permanently exists. You may also add new documents to a package once it is unlocked.

To submit a new project click on the *Create New Project* tab on the left-hand side of the screen. As you can see in Figure 6, you will be taken to the *Project Information* page where you will need to fill in the necessary information - inputs with an * are required fields. You will need to provide the Title of your project, your first and last name, any keywords you want to assign for quick lookup, and your sponsor if applicable. Student researchers should indicate their faculty mentor/adviser in the *Sponsor* section.

The next page will be the *Project Designer* page. There are several options here. First, it will ask you to select a Library from the drop-down menu, as shown in Figure 7. The default Library is the MSSU IRB. Eventually, the system will also add the IACUC Library. Most researchers will need the MSSU IRB Library. The next drop-down menu contains the important documents you will need to download in order to complete your IRB application.

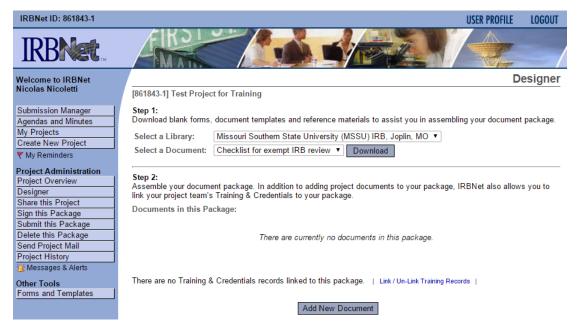


Figure 7: Downloading Documents

Figure 8 shows the various documents for download. There are currently 3 documents: (1) The Checklist for exempt IRB, (2) Informed Consent Checklist, and (3) IRB Application. The primary document you will need to submit is the *IRB Application*. This is a fillable PDF document that contains all the necessary questions and information the IRB needs to process your application. Download this form, fill it out in-full, and then upload the completed document to IRBNet. When you upload documents you are creating a *Package*, that reside under your new *Project* within the system. *Projects* can contain multiple packages, especially if the IRB asks for amendments to the original package. If you look at Figure 7, you will see the "Add New Document" button. Once you have completed the IRB application, you will use this section to upload your documents. In addition to the IRB Application, you should upload your *Informed Consent Checklist*. The *Checklist for exempt IRB review* only needs to be submitted if you are submitting your package for exempt review.

The next step is to attach your documents. Figure 9 shows the *Attach Document* screen. The Document type is a drop-down menu. When you click on the menu, a list of documents will appear. Choose the proper document type, give that document a description, and then choose the document you want to upload by clicking "Choose File." Once you see the name of the file next to the "Choose File" button, click "Attach" to submit the file. Notice in Figure

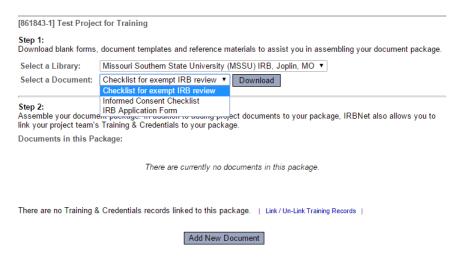


Figure 8: MSSU Documents for Download

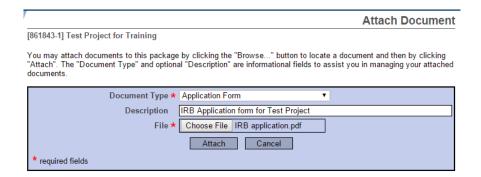


Figure 9: Attaching a Document

9, that I have chosen the "Application" form from the drop-down menu. I have also given the submission a description stating, "IRB Application form for Test Project." Finally, you can see that I have uploaded a PDF file named "IRB Application" to the system. The only thing left to do is click "Attach" and the document will be uploaded.

As you can see in Figure 10, my document is now attached to the package. Continue to attach documents until your package contains all the necessary files for review. If you submit a package without the necessary files, the IRB Administrator will notify you via email that your package is incomplete and you will need to edit the package. Once a document has been submitted, there a few options in the system. You may view the document by clicking on the button. This button will download the file to your computer and you will be able to open it in the folder in which your computer places downloads. You may also edit what files you have uploaded to the system by clicking on the button. This button will take

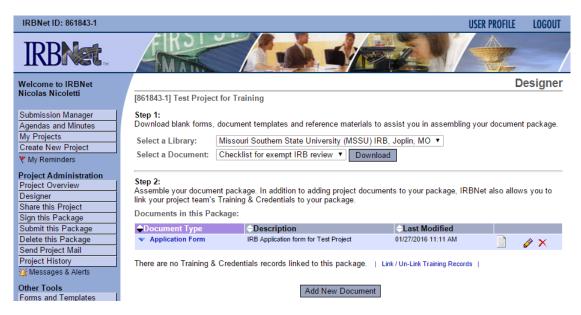


Figure 10: Designer Page Post-Document Attachment

you back to the screen in Figure 9, where you can upload a new document in place of the previous one. Finally, you can delete a document by clicking on the button.

There is one more step to complete before you can submit the package. You need to link your Human Subjects training report to the package so that the MSSU IRB can verify that you have completed the necessary requirement. Refer to Figure 10. At the bottom of the screenshot you will see that it states, "There are no Training and Credentials records linked to this package." Next to that sentence there is a link that reads, "Link/Unlink Training Records." To link your training to your package click on this link. If you have properly uploaded your Training Report to your IRBNet profile² you will see the list of training documents you have already placed in the system. Click on the one you want to link to your package and click Save. This will allow the IRB to see your training credentials within your new package.

When you are finished uploading all your documents it is time to submit the package for your project. Notice in Figure 7, that the left-hand tab options have changed once you start a new project. The page now displays the *Project Administration* menu. There are several things you can do with the newly created package before its submission. The next few sections will explain each of these options. Let's start with a commonly needed tool for student research, the *Share this Project* tool.

²See Section 8: Uploading CITI Report to IRBNet for more information.



Figure 11: Sharing a Project

4 Sharing a Project

To share a project with a colleague, faculty mentor/adviser, or even a student group, click on the *Share this Project* tool. Figure 11 shows the *Share Project* page. As you can see there are three options: (1) Share, (2) Multi-Site, and (3) Transfer. The option that you will most likely need is the *Share* option. This option is used to "share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution." The *Multi-Site* option is only used if "your project is a multi-site project and you wish to send a complete and independent copy of this project to a Principal Investigator at another site." The *Transfer* option is only used to "transfer your ownership of this project to another user. In doing so you will relinquish all access to this project and the designated user will be granted Full access." The *Share* option is the one you want for sharing research with other members of IRBNet at MSSU. Remember, in order to share a project the other researchers/sponsors/advisers/mentors will also need to be a registered IRBNet user. This option can also be used if students plan to work on the project as a group.

Once you have clicked on the *Share* option you will brought to the page in Figure 12, where you will need to select an organization/institution. Select MSSU and click "Select Organization" to continue.³ Next the system will present you with a list of names in the

³You may also search for any other institution if you are planning collaborative work with colleagues at other

MSSU IRBNet system; this is shown in Figure 13. Notice that there are four levels of "Access Type" in the system: (1) Full, (2) Write, (3) Ready, and (4) No Access. These levels are defined as follows:

- Signature Only (Read): Users whose only role is to sign off on project documentation should be granted "Read" access. Users with Read access can view project documentation, communicate with the project team and add their signature. This would typically include advisors, department heads, and other individuals who are required to sign off on the project documentation prior to submission but do not otherwise have a day-to-day role on the project.
- Read: Users that are granted "Read" access can view project documentation, collaborate with other users and add their signature, but may not edit project documents or perform any other administrative functions.
- Write: Users that are granted "Write" access can view and edit project documents, collaborate with other users and add their signature, but may not grant access to other users, submit packages for review or perform any other administrative functions.
- Full: Users that are granted "Full" access can perform all functions without restriction.

 This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages. Only Project Owners with day-to-day responsibility for the project should be granted Full access.

 Users with Full access will receive automatic email copies of all project notifications and alerts that are sent to the Project Owners.

You may also choose to give comments to those who you are sharing the project with. This is also where students will choose to give access to their faculty mentors/advisers. The decision on which access type is left up to the professor/student. However, in order for a faculty member to sign the package, they must have "Read" Access at the very least. Most faculty mentors/advisers will probably desire "Full" access to assist with IRB Applications. Once you select the people to share with, they will always appear within the *Share Project* page as seen in Figure 14. These individuals will receive an email notifying them that they now have access to your project. Figure 15 is an example of what the recipient will receive.

universities. This is great for co-authored research projects.

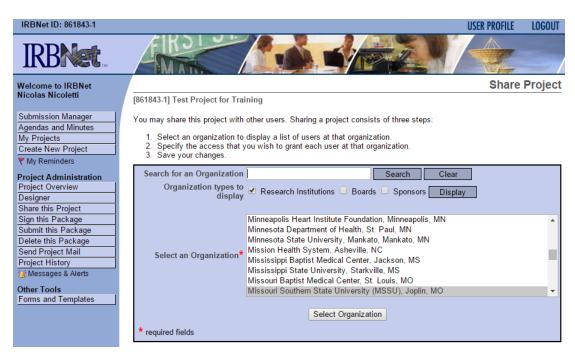


Figure 12: Choose Your Institution



Figure 13: Choose Your Collaborators



Figure 14: The Share Page with Shared Projects

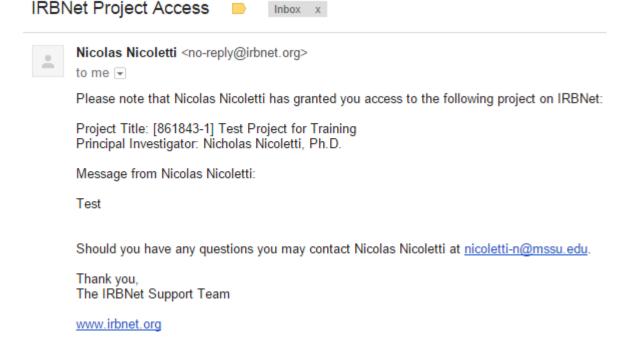


Figure 15: Share Email

Once the project is shared, users can collaborate and sign packages. Package signatures are very important for the MSSU campus as faculty mentors/advisers must sign a package for a student prior to submission. It is important to note that, once shared, signing a package works the same way for both the principal investigator and whoever else need to sign it. In the case of student research, both the faculty member and the student must sign the package. The next section explains package signatures.

5 Package Signature

In order to sign the package click on *Sign this Package* in the *Project Administration* menu. Figure 16 shows the *Sign Package* page. Notice there is a drop-down menu after where it states, "I Your Name, as..." This is where you choose your role in the project. In the example I have chosen "Principal Investor," but you can also choose "Sponsor," "Team Member," or "Advisor." Faculty mentors/advisers will choose "Advisor" when they sign the package. The student would choose "Principal Investigator." There is also a *Signature Designee Mode* where someone may sign on behalf of another person. To use this feature click on "switch to Designee Signature Mode" shown below the "Sign" button in Figure 16. This feature may be needed in rare circumstances, but the traditional signature mode will be adequate for most needs on the MSSU campus. In order for your signature to be processed you will be required to submit your login credentials to IRBNet again in a pop-up window. Your digital signature is equivalent to your traditional signature.

Once the package is signed, the *Sign Package* page will list everyone who has signed the package, as can be seen in Figure 17. The system will also send an email to all users who share that package letting them know it has been signed. Once the project has been signed by everyone required to do so, it is time to submit the package to MSSU's IRB. The next section shows how to submit the package.

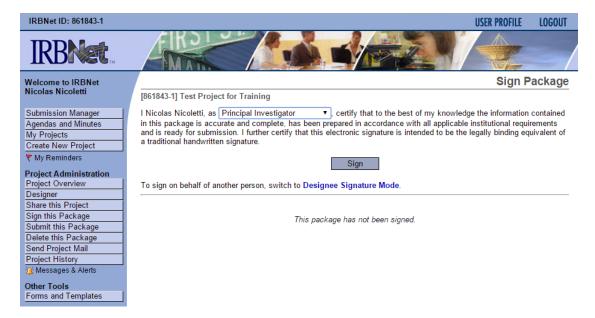


Figure 16: Sign the Package

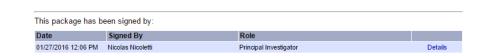


Figure 17: List of Signatories

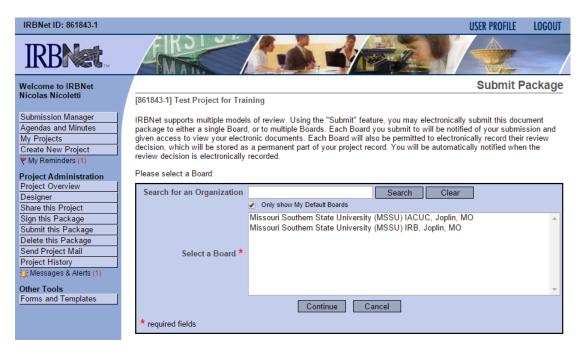


Figure 18: Submitting the Package

6 Submitting a Package

To submit a package click on the *Submit this Package* tool within the *Project Administration* menu. Figure 18 shows the *Submit Package* page. notice you need to select a board for submission. Both the MSSU IRB and IACUC boards are listed. Choose the proper board and click continue. Figure 19 shows the final screen before submission. You are required to choose a submission type from the drop-down menu. I have chosen new project, but there are other submission types such as, Amendment/Modification, Closure/Final Report, Publication, and many more. Choose the proper type and then click "Submit." You may also give the IRB some comments on the package before submission. Once you click "Submit," your project will then appear in the *My Projects* page (see Figure 5) and it will say "Pending Review." The Board Action will be updated as the project progresses through the system. Figure 20 shows the Submission Confirmation page once complete.

Once submitted the package will be locked and the submitted documents will remain in the system permanently. You will also not be able to make any changes to the package until it is unlocked by the system Administrator. When you click on an existing project in the system it will display the *Project Overview* page, as seen in Figure 21. This page will show

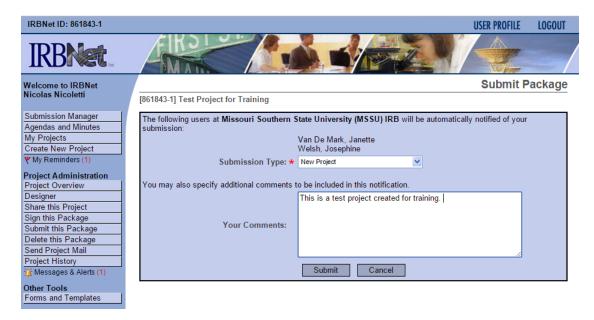


Figure 19: Final Submission Screen



Figure 20: Confirmation Screen

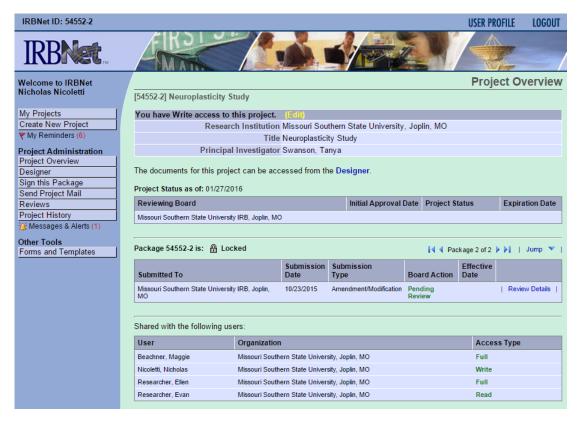


Figure 21: Project Overview

the status of the project, who it is shared with and their access type, the Board Action, and other details. Notice in Figure 21 the package is locked and displays the symbol. To edit this package you will have to wait until the package is unlocked. You will not be able to add additional documents or update your package until it is unlocked. You will also not be able to delete any packages that have submitted to the system. If you have not submitted the package and you choose to delete it, use the *Delete this Package* tool under the *Project Administration* menu. The system will present you with a warning: "WARNING: Deleted packages cannot be recovered." If you click "Delete" the package will be completely deleted from the system and you will lose all changes.

It is also important to note that if changes are required, IRBNet keeps a version history. If you are asked to revise and resubmit a new document - for example a new Application Form - you will make the changes and then submit the new form to the system as a new version, which will then be reviewed by the IRB. Notice in Figure 21, on the project overview page, there is a link that reads, "Review Details." Clicking on that link will bring you to the *Review Details* page, which will include a list of IRB actions on your application. Figure 22 shows



Figure 22: Review Details

this page. This page will provide you details such as the review type, a history of the the Board's Action, the status of the project, and the expiration date. This is a the place you will navigate to to see updates on the project with more detail than on the *My Projects* page.

There are several other tools in the *Project Administration* menu. You can *Send Project Mail*, which allows you to send a message to everyone that you have shared the project with within the IRBNet system. You may also look at your *Reviews*. The *Reviews* page will list the Board Action and also give you access to reviewer comments. These comments are important, especially when the application needs to be amended. You will also receive these comments in an email from the MSSU IRB via IRBNet. The last tab is the *Project History* tool which will present the user with a history of the project since its creation in the system. This concludes the basic introduction to the IRBNet system. This document includes all of the most important uses for MSSU faculty and student researchers that will be using the system. The final section will discuss the CITI Training suite and its integration with IRBNet.

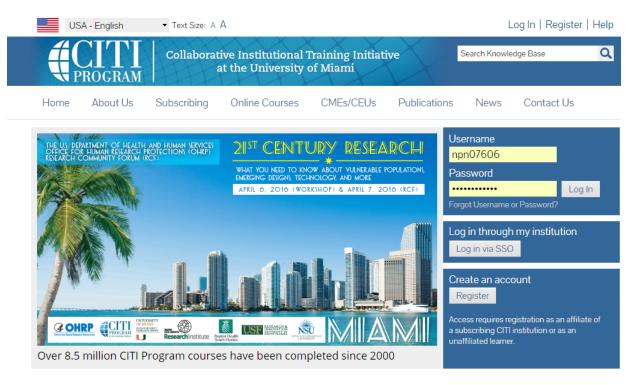


Figure 23: CITI Home Page

7 Human Subjects Training with CITI and IRBNet

Researchers dealing with human subjects are required to complete the Collaborative Institutional Training Initiative (CITI) training program. The program is provided by the University of Miami and is widely considered the best human subjects research training in academia. New and existing users can get started with CITI by navigating to the following URL: https://www.citiprogram.org/. Figure 23 shows the CITI home page. New users will click on the *Register* link in the upper right-hand corner of the screen. The next step shown in Figure 24 is to choose your affiliation. Just start typing the name of our university and it will appear in the list to be selected. You will then be prompted to fill in your personal information as shown in Figure 25. Once you setup your account you will need to choose what type of training you need to complete. You will be asked a series of questions and based on these answers CITI will present you will the necessary modules. Figure 26 through 30 shows the various questions asked.

Once you have chosen the proper modules for training you will need to complete them in order to achieve the required certificate. Once completed, you will be given a report/certificate

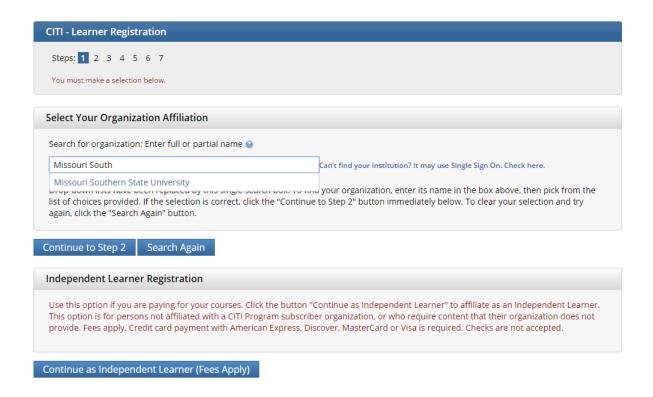


Figure 24: Choose you Affiliation

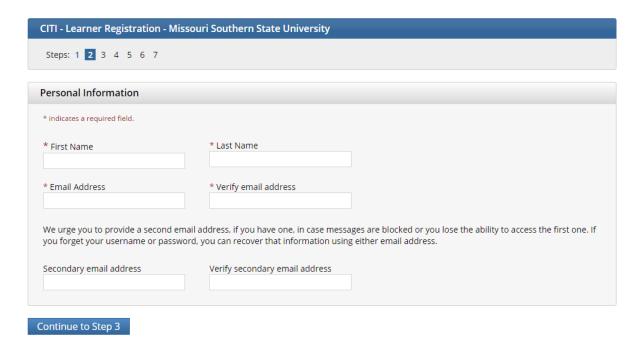


Figure 25: Fill in your Information

Human Subjects Research Please choose one learner group below based on your role and the type of human subjects activities you will conduct. You will be enrolled in the Basic Course for that group. Choose one answer Biomedical Research Investigators: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Biomedical research with human subjects. Social & Behavioral Research Investigators: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social and Behavioral research with human subjects. Research with data or laboratory specimens- ONLY: No direct contact with human subjects.

Figure 26: Human Subject Research

Not at this time.

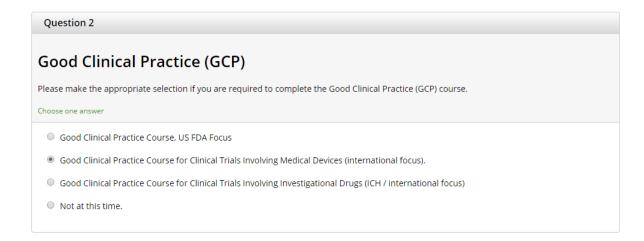


Figure 27: Clinical Research

Information Privacy Security Please make the appropriate selection if you are required to complete the Information Privacy Security (IPS) course. Choose one answer IPS for Clinicians IPS for Researchers IPS for Students and Instructors IPS for Fundraisers IPS for Marketers I am not required to complete the IPS course at this time.

Figure 28: Information Privacy Security

Question 4		
Laboratory Animal Research		
Do you conduct studies that use Lab animals?		
1. If YES, then you must complete the Basic course and the appropriate species specific modules.		
2. If you are an IACUC Member you should complete the "Essentials for IACUC Members".		
3. Choose the appropriate species specific electives according to your research interests.		
Choose all that apply		
□ "Working with the IACUC Course" is required if you plan to use lab animals in your work. □ If you are an IACUC Member you are required to complete the "Essentials for IACUC Members" course now. □ IACUC Community Member □ Institutional Officials □ Post-Approval Monitoring (PAM) □ Antibody Production		
If you are planning to do aseptic surgery on animals, you may want to complete the "Aseptic Surgery" course now. Your Institution may require this.		
If you plan to conduct studies that have the potential to cause "more than momentary pain and distress" in Mice or Rats you should complete the module on "Minimizing Pain and Distress".		
Choose the appropriate species specific electives depending on your work or interests.		
I work with Frogs, Toads or other Amphibians I work with Mice. Family: Muridae Cricetidae I work with Rats. Genus: Rattus I work with Hamsters. Family: Muridae		

Figure 29: Laboratory Animal Research

Question 5		
Responsible Conduct of Research Please make your selection below to receive the courses in the Responsible Conduct of Research. Choose one answer		
 Biomedical Responsible Conduct of Research Course Social and Behavioral Responsible Conduct of Research Course Physical Science Responsible Conduct of Research Course Humanities Responsible Conduct of Research Course Responsible Conduct of Research for Engineers Responsible Conduct of Research for Administrators Not at this time. 		
Question 6 Conflicts of Interest (COI)		
Would you like to take the Conflicts of Interest course? Choose one answer		
Yes No		

Figure 30: Responsible Code of Conduct and Conflicts of Interest

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM) COURSEWORK REQUIREMENTS REPORT* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements. Nicholas Nicoletti (ID: 2757664) Institution Affiliation: SUNY - Buffalo (University at Buffalo) (ID: 479) · Phone: (585) 752-5167 · Curriculum Group: Responsible Conduct of Research Course Learner Group: Social and Behavioral Responsible Conduct of Research Course Stage 1 - Basic Course This course is for investigators, staff and students with an interest or focus in Social and Behavioral research. This course contains text, embedded case studies AND quizzes. Report ID: 7636815 Completion Date: 03/13/2012 • Expiration Date: Minimum Passing REQUIRED AND ELECTIVE MODULES ONLY DATE COMPLETED SCORE Responsible Conduct of Research (RCR) Course Introduction (ID: 1522) Introduction to the Responsible Conduct of Research Archived 1248 (ID: 1248) 03/13/12 No Quiz Introduction to Research Misconduct Archived 1343 (ID: 1343) Research Misconduct (RCR-SBE) (ID: 1495) 03/13/12 5/5 (100%) Data Management (RCR-SBE) (ID: 1523) Authorship (RCR-SBE) (ID: 1518) 03/13/12 5/5 (100%) Peer Review (RCR-SBE) (ID: 1521) 5/5 (100%) Responsible Mentoring 01-1625 Archived 1625 (ID: 1625) 03/13/12 6/6 (100%) Conflicts of Interest (RCR-SBE) (ID: 1462) Collaborative Research (RCR-SBE) (ID: 1484) 03/13/12 6/6 (100%) Responsible Conduct of Research (RCR) Course Conclusion (ID: 1043) SUNY at Buffalo (ID: 756) 03/13/12 No Quiz For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner. Email: citisupport@mian Phone: 305-243-7970 Web: https://www.citipro

Figure 31: Example CITI Report

that proves you have completed the necessary training. Figure 31 gives an example of what the report will look like. Once you have completed the training you will need to upload the report to IRBNet. IRBNet and CITI do not automatically communicate with each other. This next section will discuss how to upload the CITI report to your IRBNet Profile.

8 Uploading CITI Report to IRBNet

Once you have completed your training in CITI log into IRBNet. At the very top of the screen in the right-hand corner you will see a link that says *User Profile*. Clicking on that brings you to the *User Profile* page, which contains all of your personal information. Figure 32 shows an example *User Profile* page. If you scroll all the way to the bottom of the page you will see a section that says, "Training and Credentials." There will be a link that reads, "Add a New Training & Credentials Record." Click that link to add your CITI report.

Figure 33 shows the *Training and Credentials Record* page. You will need to input the

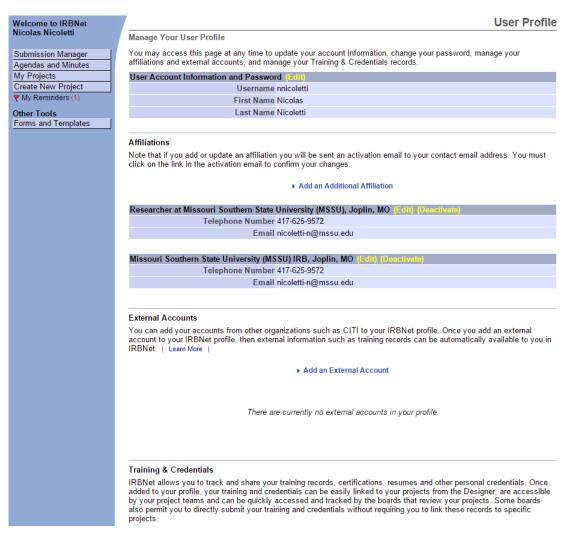


Figure 32: User Profile

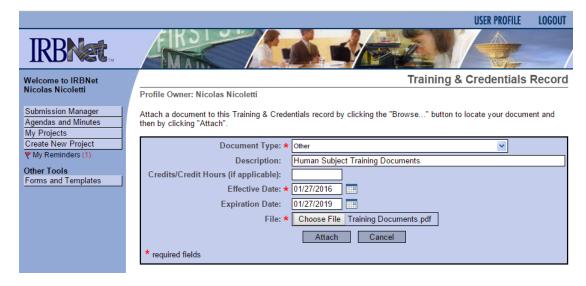


Figure 33: Add Training Document



Figure 34: Listed Training Documents

document type using the drop-down menu. Choose the "Other" option when submitting training. Then give your training a description; for example I have called mine, "Human Subjects Training Documents." The effective date is the date you completed the training and the expiration date is 3 years from the effective date. Then choose the report saved on your computer and click "Attach." Your training documents will then appear under the Training and Credential headings as shown in Figure 34. This training can then be linked to your IRBNet packages so that the MSSU IRB can confirm you are in compliance with MSSU's training requirements.⁴

This concludes the document and you now have the skills necessary to navigate both IRBNet and CITI. I have left very few operations out of this training document, but if you have questions please contact the chair of the MSSU IRB. Contact information can be found at the following URL: http://www.mssu.edu/offices/academic-affairs/institutional-review-board/contact-us.php

⁴See Section 3: Basic Package Creation and Design for more information on linking Training Records to your IRBNet packages.