



Center for Research

Electronic IRB Review System Researchers Manual

To be used by **Students** to create a
Research proposal for review
Application A, B, or D

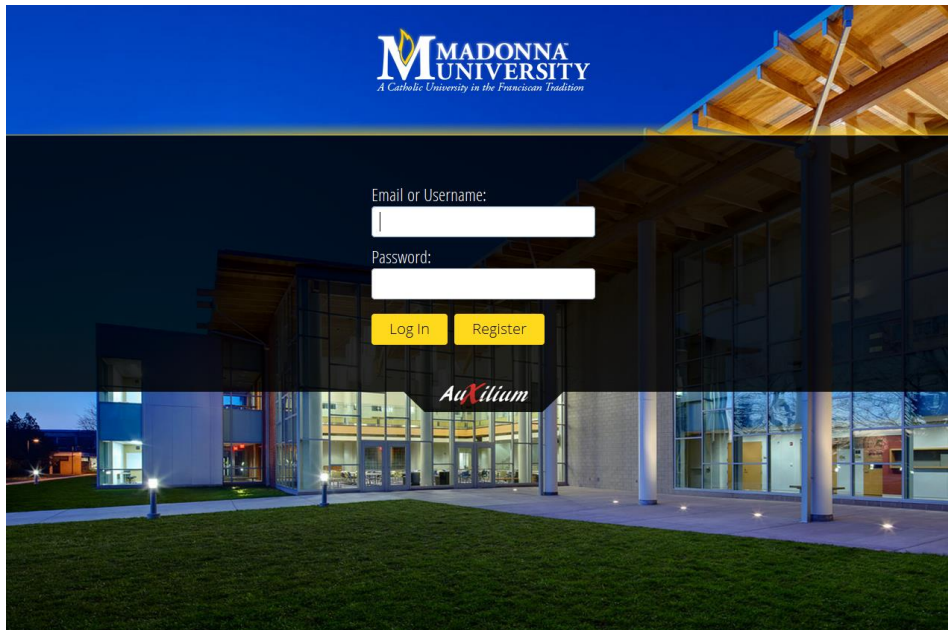
Getting started with the online Human Subject Review Application

Getting Registered

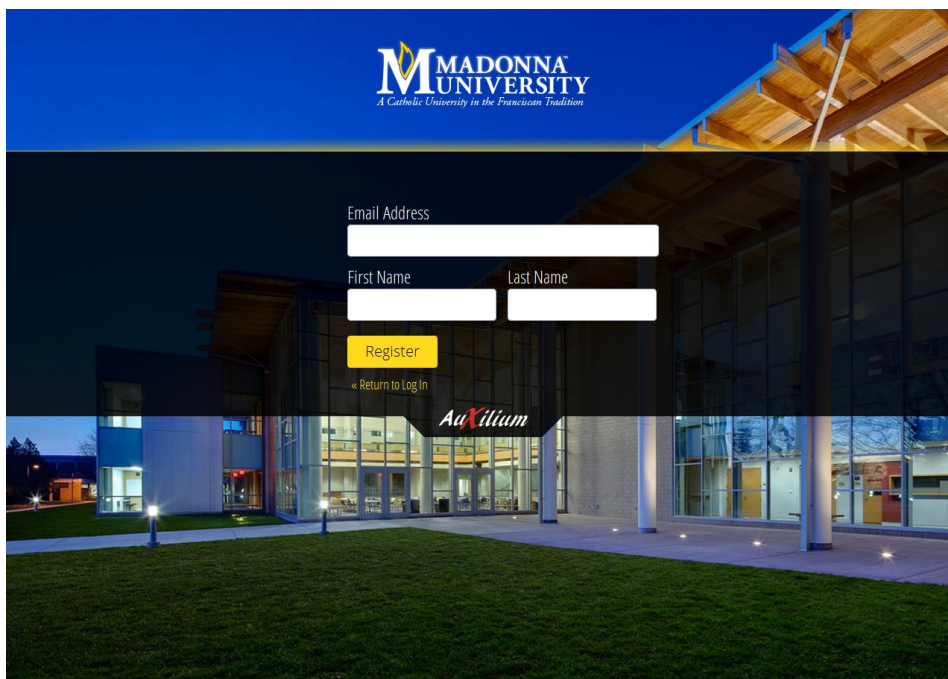
Step 1: **YOU MUST USE FIREFOX OR GOOGLE CHROME TO ACCESS THIS WEBSITE. DO NOT USE INTERNET EXPLORER.**

Type in <https://madonnau.auxiliumgroup.com>

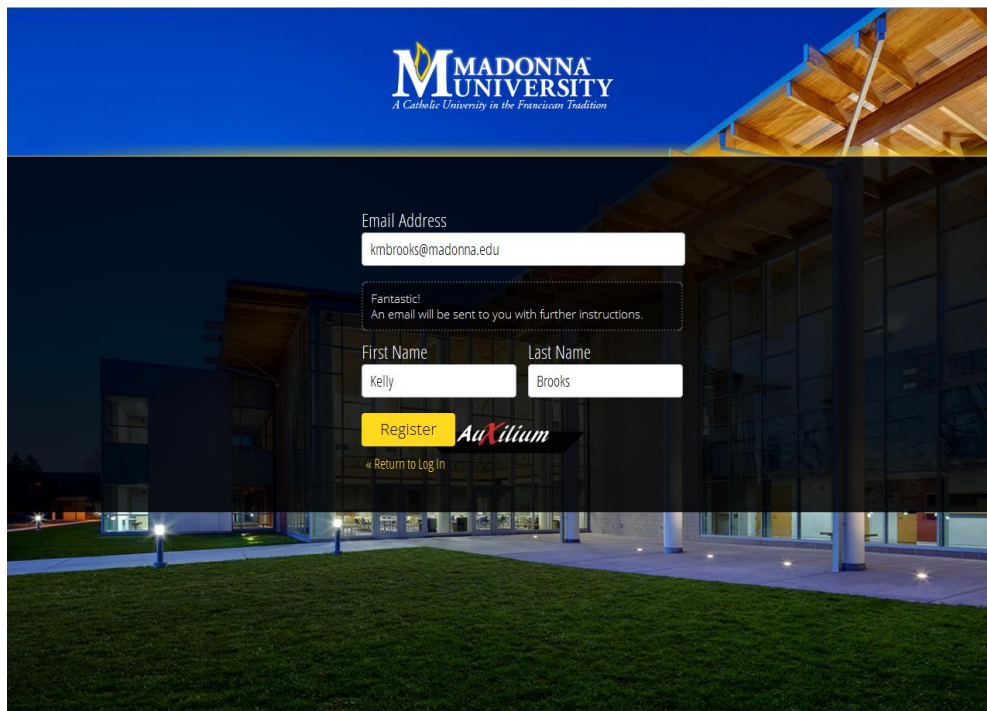
You will see the following screen:



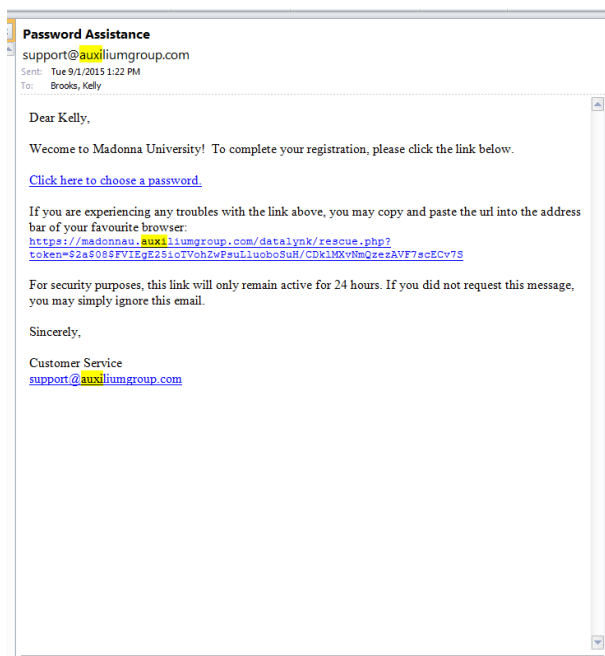
Step 2: Click on the “Register” button. The following screen will appear:



Step 3: Enter your email address, first name, and last name. Click on the “Register” button. You will receive the following message: “Fantastic! An e-mail will be sent to you with further instructions.”



Step 4: Follow the instructions in your email to set your password. Please note that for security purposes, the link in your email will only remain active for 24 hours. Once you have set your password, you can log in by either clicking on “Return to Log in” or by clicking on the “Log in” button on the original screen.




Step 5: Once you have completed your Login, this is the screen you will see. First, you will need to complete your Checklist.

Click "Add Checklist"


1. REQUEST CHECKLIST
APPLICATION - A
APPLICATION - B
APPLICATION - D
APPLICATION - E

STUDENT APPLICATIONS FOR RESEARCH


Please select the most appropriate application from the list below




[MY PROFILE](#)
STEP #1
(Update your profile)




[ADD CHECKLIST](#)
STEP #2
(Complete your checklist)



[Click here to start new Application for Exempt Review](#)



[Click here to start new Application for Expedited or Full Review](#)



[Click here to start new Application for Single Semester Project](#)

STEP #3 (Select your application)

APPLICATION - D
» MY STUDENT APPLICATION

DATE	PROJECT NAME	APPLICATION STATUS	ALL INVESTIGATORS
No records were found.			

Save Add Record Export Print

It looks like you haven't started Firefox in a while. Do you want to clean it up for a fresh, like-new experience? And by the way, welcome back! Refresh Firefox...

Step 6: Click “Request Checklist,” then click “Add Checklist” and this screen will appear. Enter all requested information on each page, then click “Save.”

The screenshot shows a web browser window with the URL <https://madonnau.auxiliumgroup.com/#addFormRecord=46473-0>. The page header includes the Auxilium logo and Madonna University branding. A navigation menu on the left lists '1. REQUEST CHECKLIST' and 'Add Check List'. The main content area displays the 'Checklist to Determine Type of Request' form for the Madonna University Center for Research. The form includes a header with the university logo and title, followed by instructions: 'DIRECTIONS: Use this form to determine the type of application form you need to complete. CAREFULLY read each item and indicate if it applies to your research project.' Below the instructions are two input fields: 'Application Date' with the value 'October 4, 2017' and 'Investigator's' with the value 'CHRISTIE, STACEY'. The form also features a section titled 'REQUIRED APPLICATIONS' and 'Section I.' at the bottom. A toolbar at the top right of the form area contains buttons for 'Comments', 'Save', 'Save & Next', 'Save & Back', and 'Clear'. A blue arrow points from the text above to the 'Save' button. The Windows taskbar at the bottom shows the system tray with the date and time '1:01 PM 10/4/2017'.

Step 7: After you have completed your Checklist it will appear under “Request Checklist.” Click “My Checklist,” and it will be displayed.

This may take a few moments.

Then, click “Home.”

The screenshot shows a web browser window displaying the Auxilium web application. The browser's address bar shows the URL <https://madonnau.auxiliumgroup.com/#openReport=46497>. The application header includes the Auxilium logo and "MADONNA UNIVERSITY" on the left, and "Support" and "Stacey Christie" on the right. A navigation menu on the left contains "Home" (circled in red), "REQUEST CHECKLIST", "My Checklist", "Shared Reports", and "My Checklist". The main content area displays a report titled "1. REQUEST CHECKLIST" with a sub-header "My Checklist 1 Check List". Below this is a table with the following data:

Application Date	Investigator's	REQUIRED APPLICATIONS
September 13, 2017	Christie, Stacey	

At the bottom of the browser window, a message reads: "It looks like you haven't started Firefox in a while. Do you want to clean it up for a fresh, like-new experience? And by the way, welcome back!" with a "Refresh Firefox..." button.

Step 8: Next, you will complete Application A, B, or D based on the research checklist you created earlier. Your professor will tell you which application to complete.

The screenshot shows a web browser window displaying the Auxilium web application. The browser's address bar shows the URL <https://madonnauxiliumgroup.com/#homes=11>. The application header includes the Auxilium logo and 'MADONNA UNIVERSITY'. A navigation menu on the left lists: 1. REQUEST CHECKLIST, APPLICATION - A, APPLICATION - B, APPLICATION - D, and APPLICATION - E. The main content area is titled 'STUDENT APPLICATIONS FOR RESEARCH' and contains the instruction: 'Please select the most appropriate application from the list below'. Below this instruction are three main steps:
1. **STEP #1 (Update your profile)**: Includes an icon of two people and a link 'MY PROFILE'.
2. **STEP #2 (Complete your checklist)**: Includes an icon of a checklist and a link 'ADD CHECKLIST'.
3. **STEP #3 (Select your application)**: Includes three application options:
- **APPLICATION A**: A red box with a white 'A' and a downward arrow. Below it is a link: 'Click here to start new Application for Exempt Review'.
- **APPLICATION B**: A blue box with a white 'B' and a downward arrow. Below it is a link: 'Click here to start new Application for Expedited or Full Review'.
- **APPLICATION D**: A purple box with a white 'D' and a downward arrow. Below it is a link: 'Click here to start new Application for Single Semester Project'.
At the bottom of the application area, there is a breadcrumb trail: 'APPLICATION - D > MY STUDENT APPLICATION'. To the right of this trail are icons for 'Save', 'Add Record', 'Export', and 'Print'. Below the breadcrumb trail is a table with the following headers: 'DATE', 'PROJECT NAME', 'APPLICATION STATUS', and 'ALL INVESTIGATORS'. The table body is empty and contains the text 'No records were found.' At the very bottom of the browser window, a message reads: 'It looks like you haven't started Firefox in a while. Do you want to clean it up for a fresh, like-new experience? And by the way, welcome back!' with a 'Refresh Firefox...' button.

Step 9: Once you have chosen your Application, this is the screen you will see. Enter all requested information, and continue to scroll down to complete entire application. After you have completed your application, click “Save.”

The screenshot shows a web browser window displaying the 'APPLICATION FOR EXEMPTION' form on the Auxilium website of Madonna University. The browser's address bar shows the URL: <https://madonna.auxiliumgroup.com/#addFormRecord=46477-0>. The page header includes the Auxilium logo and 'MADONNA UNIVERSITY'. A navigation menu on the left lists '1. REQUEST CHECKLIST' and 'APPLICATION - A' through 'E'. The main content area is titled 'APPLICATION - A' and 'Record New'. It features a 'Save' button and navigation icons. The form itself is green and contains the following fields:

- DATE:** 2017/09/15
- APPLICATION TYPE:** EXEMPT
- PROJECT TITLE:** (empty text box)
- 1. PRINCIPAL INVESTIGATOR (OR STUDENT INVESTIGATOR)**
 - INVESTIGATOR:** Christie, Stacey
 - PROGRAM:** (empty dropdown)
 - ADDRESS:** (empty text box)
 - CITY:** (empty text box)
 - STATE:** (empty dropdown)
 - ZIP:** (empty text box)
 - MU EMAIL:** staceyachristie@gmail.com
 - ALTERNATE EMAIL:** (empty text box)
 - PRIMARY:** YES
 - PRIMARY EMAIL:** staceyachristie@gmail.com
 - TEL: WORK:** (empty text box)
 - TEL: HOME:** (empty text box)
- 2. FACULTY ADVISOR**
 - FACULTY:** (empty dropdown)
 - Faculty Program:** (empty text box)
 - Email:** (empty text box)

At the bottom of the browser window, a message reads: "It looks like you haven't started Firefox in a while. Do you want to clean it up for a fresh, like-new experience? And by the way, welcome back!"

You will then receive an on-screen message stating that your application has been received.

Step 10: After you have completed and submitted your application, it will appear under Application A, B, or D. Click on your Application, and it will be listed. You can then logout by clicking your name and choosing "Logout."

The screenshot shows a web browser window with the Auxilium application interface. The browser tabs include 'Mail - schristie@my.mado...', 'Datalynk - Dashboard', and 'Inbox (1,555) - staceyachris...'. The address bar shows the URL 'https://madonnau.auxiliumgroup.com/#viewDashboard=33'. The page header features the 'Auxilium' logo and 'MADONNA UNIVERSITY'. A user profile dropdown menu is visible in the top right corner, showing the name 'Stacey Christie' and a red circle around it. The main content area displays a table of applications under the heading 'APPLICATION - A' and 'ALL APPLICATIONS 1 Exemption'. The table has columns for 'DATE', 'PROJECT TITLE', 'FACULTY NAME', and 'APPLICATION STATUS'. A single application is listed with the date 'September 15, 2017', project title 'Sepsis Screening', faculty name 'Christie, Stacey', and status 'SUBMITTED'. The left sidebar contains a 'REQUEST CHECKLIST' with options for 'APPLICATION - A', 'APPLICATION - B', 'APPLICATION - D', and 'APPLICATION - E'. At the bottom of the browser window, a message reads: 'It looks like you haven't started Firefox in a while. Do you want to clean it up for a fresh, like-new experience? And by the way, welcome back!' with a 'Refresh Firefox...' button.

DATE	PROJECT TITLE	FACULTY NAME	APPLICATION STATUS
September 15, 2017	Sepsis Screening	Christie, Stacey	SUBMITTED

Section 2: Steps for making Corrections/Changes once you have submitted your Application

Once you have submitted your application, you cannot go back into it to make changes. However, once it has been reviewed, the Reviewer may request that you make changes or corrections before your application can be approved. If a change is requested, you will be notified by e-mail and it will look like this:



Center for Research

36600 Schoolcraft Road
Livonia, Michigan 48150-1176
734-432-5666 Fax: 734-432-5862
Center for Research@madonna.edu

INSTITUTIONAL REVIEW BOARD CHANGE REQUEST

«Current Date»

Title: «Title of Project»
Author: «Name of Investigator»
Advisor: «Name of Faculty Advisor»

Dear «GreetingLine»:

The Madonna University Institutional Review Board has reviewed your research project.

Please review your application and make the necessary revisions as noted in the reviewer's comments. The changes are considered necessary for compliance with full human subject protection as provided by the Code of Regulations Title 45 and must be documented in the procedures and re-submitted electronically to the Center for Research for approval.

Please contact our office if you have any questions or concerns. [\[insert link to application if possible\]](#)

Sincerely,

Madonna University
Institutional Review Board

You will then need to Log back in to: <https://madonnau.auxiliumgroup.com>. You will Log in as you did before. Click on the type of Application you submitted (A, B, or D), then click "View Dashboard" to gain access to your completed application(s).

The screenshot shows the Auxilium Group web application interface. The browser address bar displays <https://madonnau.auxiliumgroup.com>. The page header includes the Auxilium Group logo and "MADONNA UNIVERSITY". A navigation menu on the left is circled in red, listing "APPLICATION - A", "APPLICATION - B", "APPLICATION - C", "APPLICATION - D", "APPLICATION - E", and "FILE MANAGER". The main content area shows "APPLICATION - A" with a sub-menu "» ALL APPLICATIONS" and "2 Exemptions". A table displays application details:

DATE	PROJECT TITLE	FACULTY NAME	APPLICATION STATUS
September 15, 2017	Sepsis Screening	Christie, Stacey	CHANGE REQUEST
September 15, 2017	Sepsis Screening	Christie, Stacey	INCOMPLETE

Below this, there is a section for "APPLICATION - B" with a sub-menu "» OPEN APPLICATIONS". A table header is visible, but no records are found:

id	DATE	PROJECT TITLE	LEAD INVESTIGATOR	APPLICATION STATUS
No records were found.				

You will see Change Request in red under Application Status next to your application.

Click on the pencil to view the Change Request

DATE	PROJECT TITLE	FACULTY NAME	APPLICATION STATUS
September 15, 2017	Sepsis Screening	Christie, Stacey	CHANGE REQUEST
September 15, 2017	Sepsis Screening	Christie, Stacey	INCOMPLETE

Then, scroll to the bottom of the application and you will be able to see the Reviewer's comments.

Once you have completed your application select "I AGREE TO AFOREMENTIONED ASSURANCE" from the dropdown below. PLEASE NOTE: the moment you select I AGREE, you will not be able to edit any form information. HOWEVER, you will be able to add supplement information as your application makes it through the approval process. You can also continue to add supporting documents to your application as needed. Once you have selected yes, go to the top of the form and select SAVE. Good Luck.

SIGNATURE
I AGREE TO AFOREMENTIONED ASSURANCE

WARNING: You will not be able to modify this document once its SUBMITTED

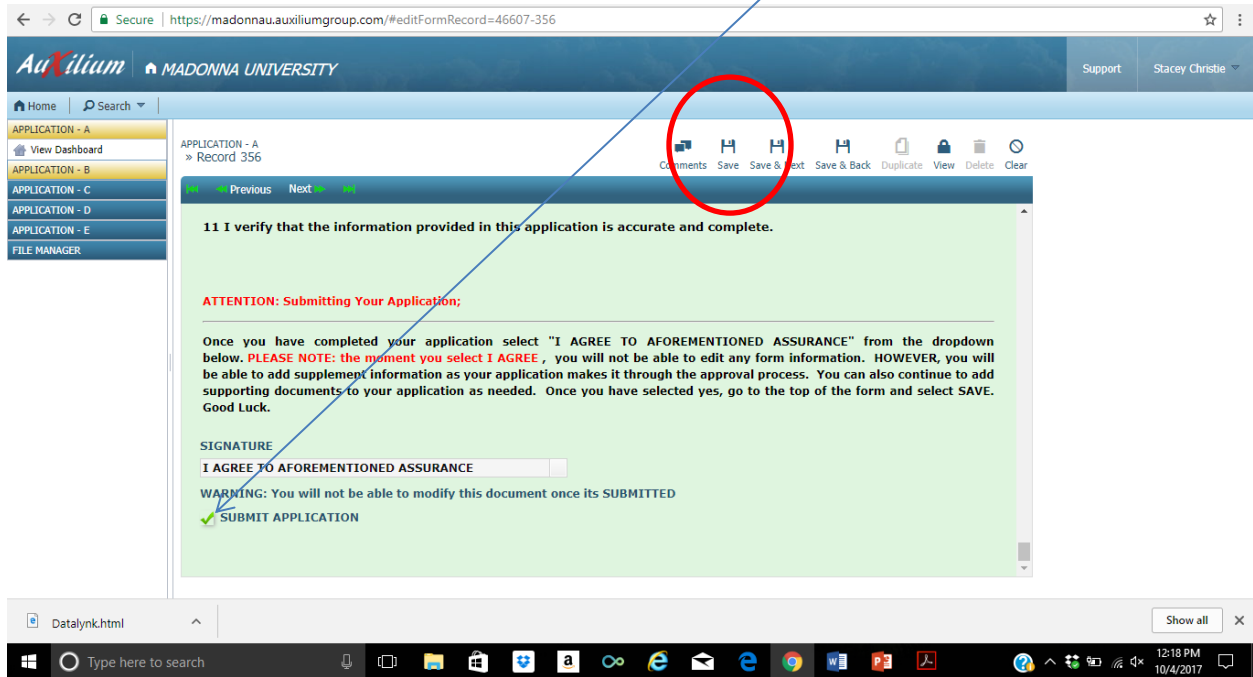
SUBMIT APPLICATION

COMMENTS HISTORY

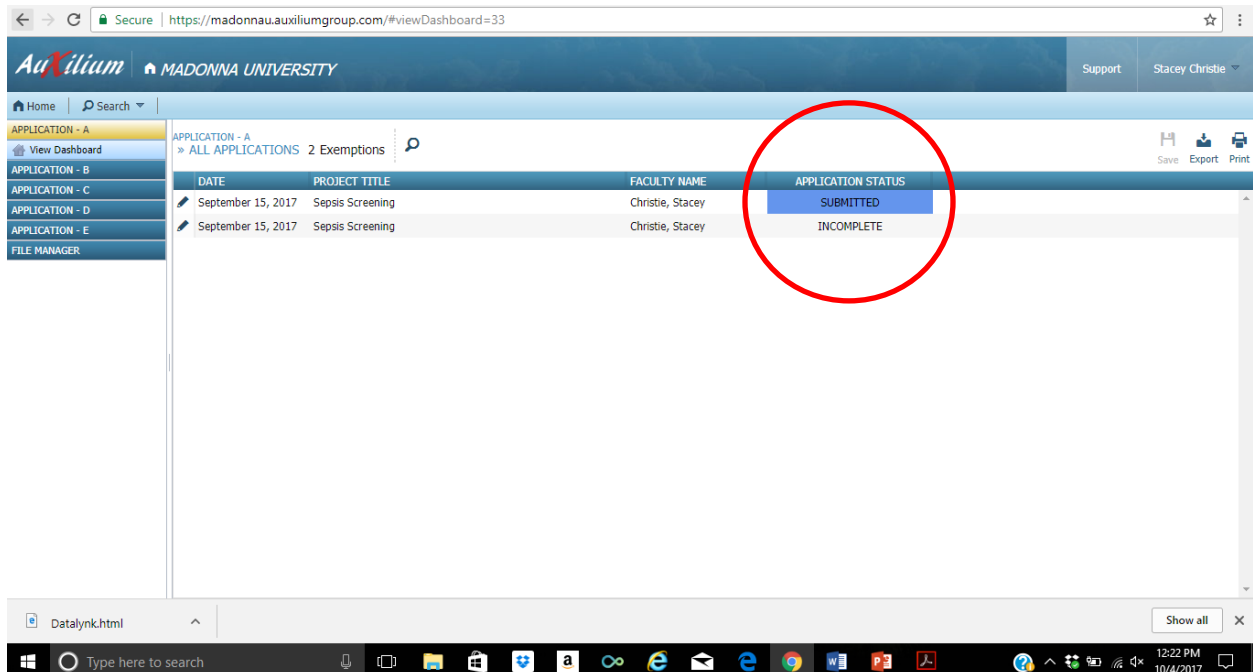
- [2017/10/04, 11:51] Please expound upon the goal of your research.
- [2017/09/22, 12:02] Please attach your certificate regarding completion of the Human Research modules.

COMMENTS / NOTES

Once you have scrolled through your entire application, and addressed all the Reviewer's comments, submit your corrected application by clicking the box next to "Submit Application" and save.



Once you have re-submitted your Application, you will see Completed in Blue under Application Status next to your application.



You will be notified via e-mail when your application has been approved. It will look like this:



Center for Research

36600 Schoolcraft Road
Livonia, Michigan 48150-1176
734-432-5666 Fax: 734-432-5862
Center for Research@madonna.edu

NOTICE OF APPROVAL OF EXEMPT RESEARCH PROJECT

Title: «Title of Project»
Author: «Name of Investigator»
Advisor: «Name of Faculty Advisor»

Dear «GreetingLine»:

Your research study has been reviewed by the Institutional Review Board of Madonna University and has been found to meet all requirements of the **Research Guide for Graduate Studies** of Madonna University. Based upon this review, your study has been determined to be exempt from the **Federal Policy for the Protection of Human Subjects** of the United States Government. The investigator(s) of the study are hereby authorized to proceed with the study as agreed upon in the application. A copy of your application will be kept in a confidential file at the Center for Research for a period of three years.

APPROVAL DATE: «Current Date»

EXPIRATION DATE: «Current Date plus One Year»

It is the Principal Investigator's responsibility to:

1. Notify promptly the Institutional Review Board at (734) 432-5666 of any untoward incidents or unanticipated adverse reactions that develop in the course of your research on human subjects.
2. Report promptly all changes in key personnel.
3. Report promptly new information affecting the risk/benefit ratio and obtain **prior IRB approval** for any short addendum to the consent/assent documents that may be required to inform participants of new information regarding the study.

Congratulations and good luck with your study. Please feel free to contact the Center for Research with any further questions.

Sincerely,

A handwritten signature in blue ink, appearing to read 'P. Olla'.

Phillip Olla, PhD
Director, Center for Research
Institutional Review Board

YOU ARE ON YOUR WAY!! GOOD LUCK!!