

How to Submit a New Application (as a Student)

My Workspaces

Study Assistant

STEP 1

Featured Study Operations

Create a New Study

View My Studies

Start a Study Submission Form

Track Approvals

Incomplete Forms

14

Tasks

View All Tasks

20

View Study Tasks

20

NOTE: The First three (3) sections of the Application will consist of what is called the “Study Shell.” The information captured in these areas will be integrated into different areas of the system.

My Workspaces Study Assistant Study Application Back

Section view of Application Entire view of the Application Save Section Save and Continue to Next Section

1.0 General Information

STEP 2: Fill out both fields then

Each section as you continue will appear here. DO NOT select “Back” or it will take you out of the Application.

1.0 General Information

Please enter the full title of your study:

New Application

Please enter the Abbreviated Study Title you would like to use to reference the study:

NA-1

This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information

2.0 Setup Department(s) Access

2.0 Please add all departments associated with your study.

2.1 List departments associated with this study:

Is Primary?	Department Name
<input type="checkbox"/>	HU - Speech-Language Pathology

Add Remove

STEP 3: Add department(s) associated to the study. By default, the department associated to the individual filling out the Application will appear in the department table.

Adding Department - Search Window

Select the Department(s) that you would like to filter by, then click Save.
You may also filter these results by searching for Institution Name, Department name, Department Code or School Code on the inputs below.
Any Departments already added will not appear here.

Institution Name: Department Name:
School Code: Dept Code:

34 result(s) found... 1 - 10

Select	Institution	Department Name	School Code	Department Code
<input type="checkbox"/>	Covenant Presbyterian Church of Stanton	Unaffiliated		
<input type="checkbox"/>	Misericordia University	Administration		ADMIN
<input type="checkbox"/>	Misericordia University	Biology		BIO
<input type="checkbox"/>	Misericordia University	Business		BUS
<input type="checkbox"/>	Misericordia University	Chemistry/Biochemistry		CHEM
<input type="checkbox"/>	Misericordia University	Diagnostic Medical Sonography		DMS
<input type="checkbox"/>	Misericordia University	English		ENG
<input type="checkbox"/>	Misericordia University	Fine Arts		FA
<input type="checkbox"/>	Misericordia University	Graduate Education		OTHER
<input type="checkbox"/>	Misericordia University	History and Government		HISGOV

Annotations:

- You can search for the department(s).
- Select a Dept.
- then
- This window will pop up if you select "Add."

Section view of Application | **Entire view of the Application**

1.0 General Information
2.0 Setup Department(s) Access

2.0 Please add all departments associated with your study.

2.1 List departments associated with this study:

	Is Primary?	Department Name	
<input checked="" type="checkbox"/>		MU - Speech-Language Pathology	<input type="button" value="Add"/> <input type="button" value="Remove"/>

Annotations:

- Select to go to the next section

Section view of Application | **Entire view of the Application**

1.0 General Information
2.0 Setup Department(s) Access
3.0 Grant Key Personnel access to the study

3.0 Assign key study personnel (KSP) access to the study

3.1 * Please add a Principal Investigator for the study:

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

B) Research Support Staff

3.3 * Please add a Study Contact:

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

Annotations:

- STEP 4: Add Study Personnel.

Directory Browse/Find:

Last Name: First Name:
by Department:

Annotations:

- To add the user, select the green checkmark.
- To search for a user, use the filters and select "Find" to search the database.

Check for Multiple	Select User	Training	User Name	Department	Email
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Administrator	Speech-Language Pathology (primary)	

[Print Friendly](#)
[Save Section](#)
[Save and Continue to Next Section](#)

Section view of Application

1.0 General Information

2.0 Setup Department(s) Access

3.0 **Grant Key Personnel access to the study**

Entire view of the Application

3.0 Assign key study personnel (KSP) access to the study

3.1 * Please add a Principal Investigator for the study:

Administrator	+ Add User
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3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators	+ Add User
B) Research Support Staff	+ Add User

3.3 * Please add a Study Contact:

<input type="checkbox"/> Administrator	+ Add User	✖ Remove
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The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

NOTE: Now that the “Study Shell” is complete, the next section (Section 4) will begin the IRB Application.

[Print Friendly](#)
[Save Section](#)
[Save and Continue to Next Section](#)

Section view of Application

1.0 General Information

2.0 Setup Department(s) Access

3.0 Grant Key Personnel access to the study

4.0 Study Locations

5.0 **IRB Application**

6.0 Study Summary

7.0 Study Subjects

8.0 Risks and Benefits

9.0 Informed Consent & Assent

10.0 HIPAA and Privacy

11.0 FERPA

12.0 Specimens/Data Banking

13.0 Imaging/Radiology Procedures

14.0 Data Management Plan

15.0 Conflict of Interest

16.0 **PI Certification Statements**

Entire view of the Application

16.0 PI Certification Statements

16.1 By selecting below, the Principal Investigator agrees to the following terms:

PART 1 (Study Shell)

I certify that the information provided in this application and attachments is accurate and complete.

I certify I have disclosed any potential Conflict of Interest and am unaware of any other fact or circumstance that would constitute a Conflict of Interest with me or the Investigators listed in this application.

I will fulfill my responsibilities as Principal Investigator as defined by the applicable Code of Federal Regulations, OHRP, and the FDA if applicable. In addition, I will comply with the Privacy rule and policies specifically regarding the use and disclosure of Protected Health Information for research, with the IRB reporting requirements as well as any additional responsibilities that may be imposed by the University.

I certify my commitment to protect the human subjects enrolled in this research. I will be ultimately responsible for the conduct of this protocol, including the actions of my entire research team as listed in this application. In addition, I will assure my research team listed in this application and I will conduct this research consistent with policy and with the common rule found at 45 CFR 46.

PART 2: IRB Application

16.2 For Student Research

☐ Not Applicable

☐ I have approved the procedures of the research project described in the attached application. I agree to assist the student with application of the policies and procedures involving human subject's protection.

Faculty research advisor name and Department/Program

Date

01/10/2019

PART 3: Submission Packet (see next screen shot)

NOTE: Now that the “Application” is complete, the next part is the Submission Packet. This is equivalent to the Manila envelope that gathers all the components of the Study into one submission to the Board for Review.

Section view of the Form Entire view of the Form

1.0 Submission Packet to the Review Board

1.0 Submission Packet to the Review Board

1.1 Please enter the full title of your study

New Application

1.2 Principal Investigator:

Administrator

1.3 Lay Summary/Abstract

STEP 6: Begin completing the Submission Packet. This area will allow the PI to add the Lay Summary, access to the Application (if they need to go back and review), upload Informed Consent and upload Study Documents.

Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 Submission Packet to the Review Board

2.0 Application

3.0 Informed Consent

4.0 Study Document

Form has been Completed!

Instruction of Form has Been Completed Screen

If at any point you want to go back into certain sections of the Submission Packet, simply click on the Section.

Exit Form Notify PI to Signoff Create PDF Packet

Students must select this so the Notification goes out to the PI.

Print Friendly Notify PI to Signoff

Does this submission require additional routing for approval?

Select Then Save and Continue

YES - Click YES to select additional personnel for routing.

NO - Click NO to bypass selecting additional personnel for routing.

Status	View Details	Date Received / Date Completed	Event Description
		01/18/2019 01:44 PM PST	[Redacted] as Principal Investigator review and apply signoff
		01/18/2019 01:44 PM PST	Assign Department Personnel for Signoff
	Routing Assignment List	01/18/2019 01:18 PM PST 01/18/2019 01:18 PM PST	Initial Review Submission Packet has been retracted by Administrator
		01/18/2019 12:01 PM PST 01/18/2019 12:01 PM PST	Initial Review Submission Packet has been retracted by Administrator
		01/18/2019 11:45 AM PST 01/18/2019 11:45 AM PST	Initial Review Submission Packet has been retracted by Administrator
		01/18/2019 11:39 AM PST 01/18/2019 11:39 AM PST	Initial Review Submission Packet has been retracted by Administrator
		01/18/2019 11:33 AM PST 01/18/2019 11:33 AM PST	Initial Review Submission Packet has been retracted by Administrator
		01/17/2019 01:22 PM PST 01/18/2019 01:44 PM PST	Initial Review Submission Packet is waiting to be submitted

After the Student has completed the Application, the system will route the Application to the PI for Review and Signoff.

THE IRB APPLICATION IS NOW SENT TO THE PI TO REVIEW AND SUBMIT
 (see the end of the "How to submit a New Application (as a PI)" User Guide)