

# How to Submit a New Application (as the PI)

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 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.

Save Section Save and Continue to Next Section

Section view of Application

Entire view of the Application

1.0 General Information

### 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.

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.

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"/>	<input checked="" type="radio"/> MU - 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)." points to the search inputs.  
 - "This window will pop up if you select 'Add.'" points to the Add button.  
 - "Select a Dept." points to a checkbox in the table.  
 - "then" points to the Save button.

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

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"/>

**Annotation:** "Select to go to the next section" points to the "Save and Continue to Next Section" button.

**Section view of Application** | 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:

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).

**Annotation:** "STEP 4: Add Study Personnel." points to the "Add User" buttons.

Directory Browse/Find:

Last Name:  First Name:    
 by Department:

**Annotations:**  
 - "To search for a user, use the filters and select 'Find' to search the database." points to the search inputs and Find button.  
 - "To add the user, select the green checkmark." points to the green checkmark in the table below.

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 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:

Administrator	<input type="checkbox"/>	<input type="button" value="+ Add User"/>	
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The PI is now added. Proceed to do the same for the rest of the Study Personnel.

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators	<input type="checkbox"/>	<input type="button" value="+ Add User"/>	
B) Research Support Staff	<input type="checkbox"/>	<input type="button" value="+ Add User"/>	

3.3 \* Please add a Study Contact:

<input type="checkbox"/> Administrator	<input type="checkbox"/>	<input type="button" value="+ Add User"/>	<input type="button" value="X 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 Entire view of the 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

### 16.0 PI Certification Statements

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

**PART 1 (Study Shell)**

to conduct this protocol.

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

01/18/2019

**PART 3: Submission Packet (see next screen shot)**

STEP 5: Fill out the IRB Application. There is logic applied that includes show/hide, validations, help tips, help links and other resources to help guide you through the process.

This is the last section of the IRB Application

Fill out this section then...

**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.

[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

## 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

Format   Font   Size

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](#)   [Signoff and Submit](#)

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.

Once the Submission Packet is complete you may Signoff and Submit your Study.

If you Exit Form, your work will be saved and you may return and submit your Application at a later time.

Or...

 

[Save and Continue](#)

Does this submission require additional routing for approval?

Select   Then

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

Study Title: New Application  
Submission Reference Number: 000067

**STEP 7**

Printable Version

Include in PDF Packet  
Submission Component Name - Version  
Submission Form(s)  
Initial Review Submission Packet - (Version 1.0)  
Application  
IRB Application - (Version 1.1)

**Misericordia University: Researcher Assurance Statement**  
I understand Misericordia University's IRB Policies and procedures concerning research involving human subjects and I agree to:

Please select all that apply.

- Accept responsibility for the ethical conduct of this research
- Obtain approval from Misericordia University's IRB prior to instituting any changes in this project
- Report to Misericordia University's IRB serious adverse reactions or unexpected effects on subjects
- Complete all required reports in a timely manner
- Disclose any financial or personal conflict of interest

Please type all Researcher's name and Department/Program.

Lauren Adamchak as Principal Investigator?  Approve  Deny  
do you Approve or Deny this submission?  
User ID:   
This form requires your electronic signature. Password:   
Please enter your User ID & Password:

PI is required to select/fill these out.

PI must approve and apply their credentials in order to submit to the Board.

Save Signoff

Status	View Details	Date Received / Date Completed	Event Description
		01/18/2019 11:36 AM PST	IRB received the submission
		01/18/2019 11:36 AM PST 01/18/2019 11:36 AM PST	Send Email with Merge Code
		01/18/2019 11:36 AM PST 01/18/2019 11:36 AM PST	The following Study Personnel are not registered with up to date training records:
		01/18/2019 11:36 AM PST 01/18/2019 11:36 AM PST	Administrator as Principal Investigator review and apply signoff
		01/18/2019 11:33 AM PST 01/18/2019 11:36 AM PST	Assign Department Personnel for Signoff
	Routing Assignment List	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 11:33 AM PST	Initial Review Submission Packet is waiting to be submitted

After the PI signs off, the submission has now been sent to the Board for Review.

## THE IRB APPLICATION IS NOW COMPLETE

IF A STUDENT IS FILLING OUT THE APPLICATION, PLEASE SEE BELOW TO COMPLETE YOUR TASK AS THE PI.

**Featured Study Operations**

- Create a New Study
- View My Studies
- Start a Study Submission Form
- Track Approvals

**Tasks**

- View All Tasks 2
- View Study Tasks 2

All Tasks Outstanding Completed

All Tasks Study Tasks

2 result(s) found...

Task List: [All]

From the home screen, the Tasks table will display all your tasks. Select the "Waiting Submission" task to Review and Signoff on the IRB Application.

Click to open	Task Type	Received	Description
	Waiting Submission	01/18/2019 01:55 PM PST	Unanticipated and/or Adverse Event Form is waiting to be submitted
	Submission Routing Signoff	01/18/2019 01:44 PM PST	as Principal Investigator review and apply signoff

Select

Study Title: New Application  
Submission Reference Number: 000067

Printable Version

Include in PDF Packet

Submission Form(s):

- Initial Review Submission Packet - (Version 1.0)
- Application
  - IRB Application - (Version 1.1)

The PI has the ability to open, view/edit the IRB Application.

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**Misericordia University: Researcher Assurance Statement**

I understand Misericordia University's IRB Policies and procedures concerning research involving human subjects and I agree to:

Please select all that apply.

- Accept responsibility for the ethical conduct of this research
- Obtain approval from Misericordia University's IRB prior to instituting any changes in this project
- Report to Misericordia University's IRB serious adverse reactions or unexpected effects on subjects
- Complete all required reports in a timely manner
- Disclose any financial or personal conflict of interest

Once the PI is ready to submit, they must select/fill out these fields.

Please type all Researcher's name and Department/Program.

The PI must complete in order to submit to the Board for Review.

Lauren Adamchak as Principal Investigator do you Approve or Deny this submission?  Approve  Deny

User ID:  Password:

This form requires your electronic signature. Please enter your User ID & Password.

Save Signoff

Status	View Details	Date Received / Date Completed	Event Description
		01/18/2019 11:36 AM PST	IRB received the submission
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After the PI signs off, the submission has now been sent to the Board for Review.

**THE IRB APPLICATION IS NOW COMPLETE**