

Unanticipated and/or Adverse Event Form

MISERICORDIA UNIVERSITY your last login was 01/18/2019 09:31 AM PST
My Workspaces Study Assistant Help My Profile Log out

to start a new Unanticipated and/or Adverse Event Form select Start a Study Submission Form

Featured Study Operations

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

Tasks

- View All Tasks
- View Study Tasks

Select your study and the type of form

All Studies Recently Used Study Status Search for RB Number, Title, Alias Search

All Draft IRB

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

Click to open	Study Status	Review Board	RB Number	RB Expiration	Study Title Study Number	Principal Investigator	Actions
	Pending - Submitted for Initial Review						History Items Forms Hide Copy Delete
	Draft						History Items Forms Hide Copy Delete
	Open	IRB	IRB-2019-0010	01/16/2020			History Items Forms Hide Copy Delete

1-select the study you want to attach the Unanticipated and/or Adverse Event Form

Submission Form List

Initial

Initial	Version List	Start a new Submission	Edit Incomplete Submissions
Initial Review Submission Packet			

IRB

Submission forms select the your form and click start a new submission

Submission forms	Version List	Start a new Submission	Edit Incomplete Submissions
End of Project Form			
Personnel Change Request Form			
Unanticipated and/or Adverse Event Form			
Modification Form			
Continuation or Annual Review Submission Form			

Section 1.Study Information

My Workspaces IRB Number: **IRB-2019-0011** PI: Administrator Study Assistant **Unanticipated and/or Adverse Event Form - (Version 1.0)** Back

Section view of the Form Entire view of the Form

1.0 **Study Information**

1.1 Investigators

1.2 Project Title

New Application

1.3 Faculty Advisor(s)

☐ Yes ☐ No

1.4 Department name

MU - Speech-Language Pathology

1.5 Will this be an Unanticipated Event Form or an Adverse Event Form?

☐ Unanticipated Event Form

☐ Adverse Event Form

1.7 Date PI became aware

after you are done with your questions click on save and continue

all these questions get auto filled by the system

the rest of the questions need to be answer by you

help button offers more information

Notice how questions jump from 1.5 to 1.7, this is because there is a show hide and depending on your answer it will trigger different questions

Section 2: Investigator's Acknowledgment

MISERICORDIA UNIVERSITY Department: MU - Speech-Language Pathology Path: Home Help My Profile Log out

My Workspaces IRB Number: **IRB-2019-0011** PI: Administrator Study Assistant **Unanticipated and/or Adverse Event Form -** Back

Section view of the Form Entire view of the Form

1.0 Study Information

2.0 **Investigator's Acknowledgment**

2.1 I agree to conduct this Human Research in accordance with applicable regulations and the Misericordia University policies and procedures. I certify that the information in this application is complete and correct. I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB. The project will not continue until written approval has been received.

Principal Investigator

Lauren Adamchak

☐ Agree ☐ Disagree

select your answer

once you are done answering all questions click save and continue

Form has been completed

My Workspaces IRB Number: **IRB-2019-0011** PI: Administrator Study Assistant **Unanticipated and/or Adverse Event Form - (Version 1.0)** Back

Section view of the Form Entire view of the Form

1.0 Study Information

2.0 Investigator's Acknowledgment

Form has been Completed!

Instruction of Form has Been Completed Screen

when you select signoff you will be prompted into a new window

Exit Form

Signoff and Submit

once you have clicked save and continue the Form has been Completed! window will show

Submission Routing Signoff

Department: MU - Speech-Language Pathology
 Path: Home > track submission

Help
 My Profile
 Log out

My Workspaces
 Study Assistant
 Submission Routing Signoff
 Back
 Save Signoff

Study Title: New Application
 Submission Reference Number: 000070

Submission Form(s)
 Include in PDF Packet
 Submission Component Name - Version
 Submission Form(s)
 Unanticipated and/or Adverse Event Form - (Version 1.0)
 if you want to create a PDF printable version select what form you want to print and then click printable version icon
 Printable Version

Administrator as Submitter do you Approve or Deny this submission?
 Approve Deny
 to finish with your submission select your answer and type your user ID and Password then click save signoff
 User ID:
 Password:
 Save Signoff

Workflow - Submission

My Workspaces
 IRB Number: IRB-2019-0011
 PI: Administrator

Study Assistant
 Workflow - Submission Tracking
 Back
 Print Friendly

Status	View Details	Date Received / Date Completed	Event Description
		01/18/2019 02:39 PM PST	IRB received the submission
		01/18/2019 02:39 PM PST 01/18/2019 02:39 PM PST	Send Email with Merge Code
		01/18/2019 02:18 PM PST 01/18/2019 02:39 PM PST	Administrator as Submitter review and apply signoff
		01/18/2019 01:55 PM PST 01/18/2019 02:18 PM PST	Unanticipated and/or Adverse Event Form is waiting to be submitted

Workflow - Submission Tracking window will show when you click the save signoff button

when you are done viewing your form's submission workflow select back button to get back to view all your studies