



OneAegis

Instruction Manual

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1.0 OneAegis

1.1 What Is OneAegis?

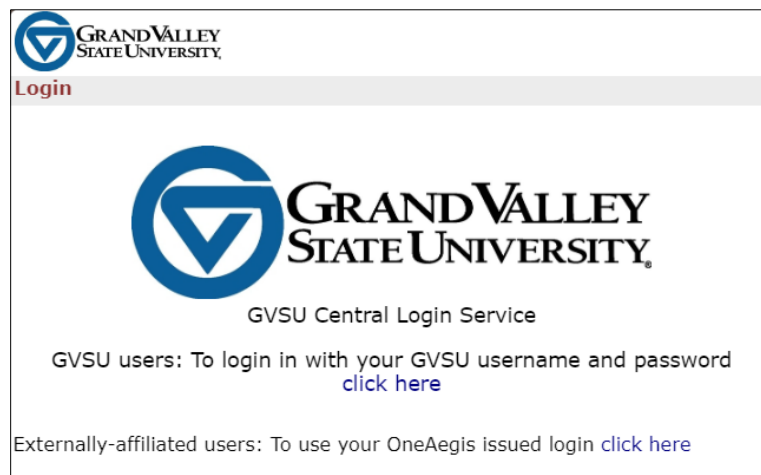
OneAegis is an electronic management system that serves as the “front door” for the submission, tracking, and retention of research protocols and research compliance documents. This includes Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) application forms, as well as the GVSU Investigator Conflict of Interest (COI) Declaration and Certification Form. Users can fill out and submit forms directly in OneAegis, and all forms, attachments, and documents submitted with a participating study will be accessible via OneAegis.

OneAegis is a fully web-based system that is accessible both on- and off-campus.

1.2 How Do I Access OneAegis?

OneAegis can be accessed here: <https://gvsu.oneaegis.com>.

The following login page will appear:



1.2.1 GVSU-Affiliated Users

Click on either the “To login using your GVSU username and password click here” link, or simply click the large GVSU logo in the middle of the page.

GRAND VALLEY STATE UNIVERSITY

Login

GRAND VALLEY STATE UNIVERSITY

GVSU Central Login Service

GVSU users: To login in with your GVSU username and password [click here](#)

Externally-affiliated users: To use your OneAegis issued log [click here](#)

You will then be prompted to enter your GVSU network ID and password in a separate pop-up window.

GRAND VALLEY STATE UNIVERSITY

GVSU Central Authentication Service

Username

This field cannot be left blank

Password

This field cannot be left blank

☐ Keep me signed in

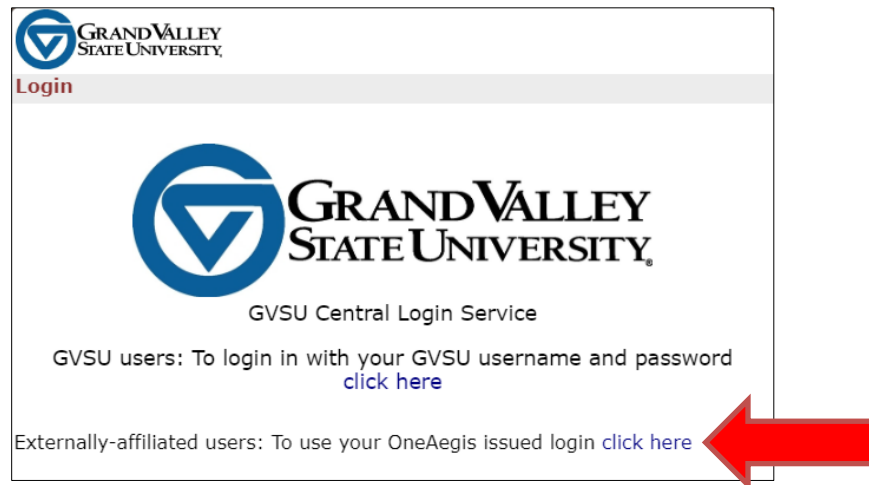
Sign in

Upon entering your credentials, you will automatically be redirected to the OneAegis Dashboard screen (homepage).

1.2.2 Externally Affiliated Users

Non-GVSU users (i.e., co-investigators at another institution, etc.) must be issued a OneAegis username and password to access the system. This can be done one of two ways: 1) any existing OneAegis user can add a new user into the system using the “Contact Look-Up/Add New Contact” xForm, or 2) users can be added manually by the Office of Research Compliance and Integrity (contact rci@gvsu.edu for access).

Upon being added to the system, the new user will receive an email with their username and temporary password. Once non-GVSU users receive their initial OneAegis credentials, they can login via the “Externally-affiliated users: To use your OneAegis issued login, click here” link.



Enter the username and password. If they have forgotten their password, please click the “Forgot Password?” link.

A screenshot of the Grand Valley State University (GVSU) login page. At the top left is the GVSU logo. Below it, the word "Login" is written in red. In the center, there is a large GVSU logo followed by the text "GRAND VALLEY STATE UNIVERSITY". Below this, it says "GVSU Central Login Service". Then, "GVSU users: To login in with your GVSU username and password" followed by a blue "click here" link. At the bottom, it says "Externally-affiliated users: To use your OneAegis issued login" followed by a blue "click here" link. A large red arrow points to the "click here" link for externally-affiliated users.

2.0 Passwords

2.1 GVSU-Affiliated Users

GVSU users are prompted for their email address and current network password upon login to OneAegis. You will never need to change your password in OneAegis.

2.2 Externally-Affiliated Users

For those unaffiliated with GVSU, on your first log-in, you will be prompted to change your password.

Your Password Has Expired	
Your password has expired. You must now select a new password. A valid password must be at least 15 characters long and contain characters from at least 3 of these groups: uppercase letters, lowercase letters, numbers, special characters (!,@,#, etc.).	
User:	Dummy, Test
Username:	testdummy
Current Password:	<input type="password"/>
New Password:	<input type="password"/>
New Password Confirm:	<input type="password"/>
<input type="button" value="Update"/>	

Your new password must be at least 15 characters long and contain characters, from at least 3 of these groups: uppercase letters, lowercase letters, numbers, and special characters (!,@,#, etc.).

To change your password and proceed:

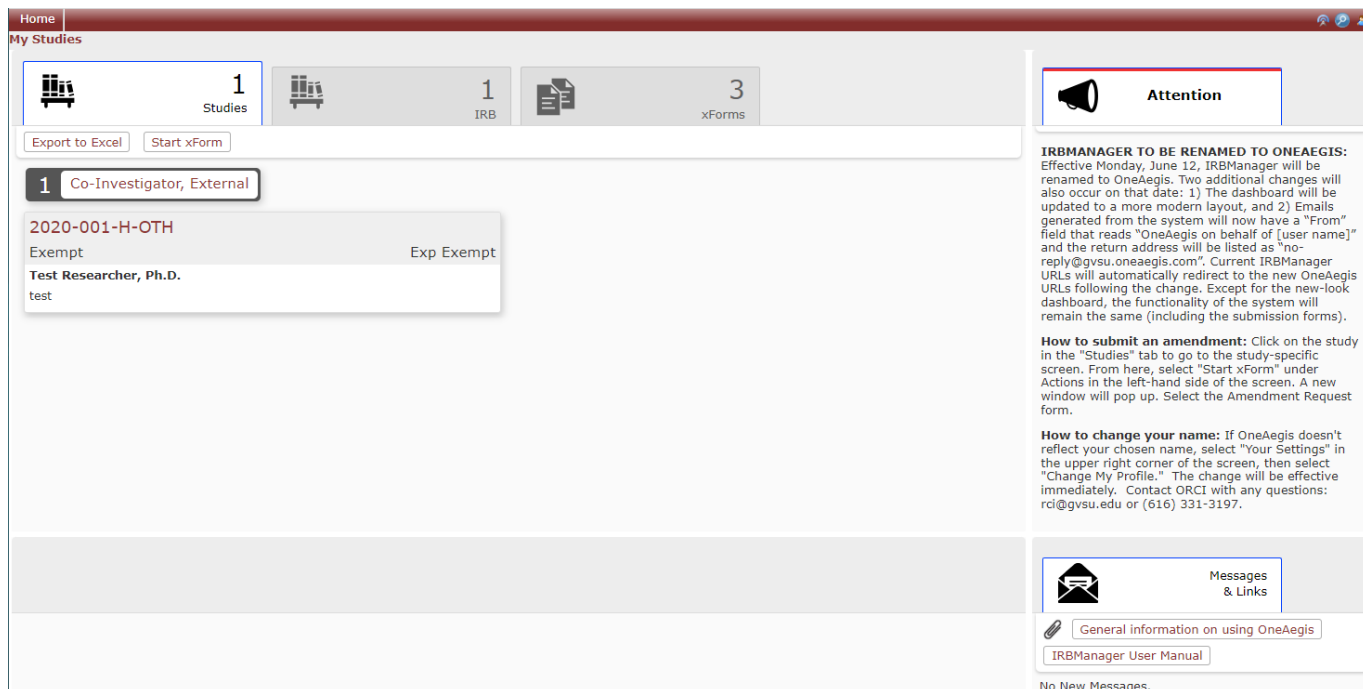
1. Enter current password
2. Enter new password (see requirements above) and then enter new password again to confirm
3. Click “Update”

If on any future log-ins you enter the wrong username/password three times, OneAegis locks your account as a security precaution. If that happens, you can click the “Forgot Password” link from the login screen. After filling in the information requested, a new password will be emailed to you and your account will be unlocked.

Once you log in with your username and password, you’ll be able to provide an electronic signature on any xForm by entering your password.

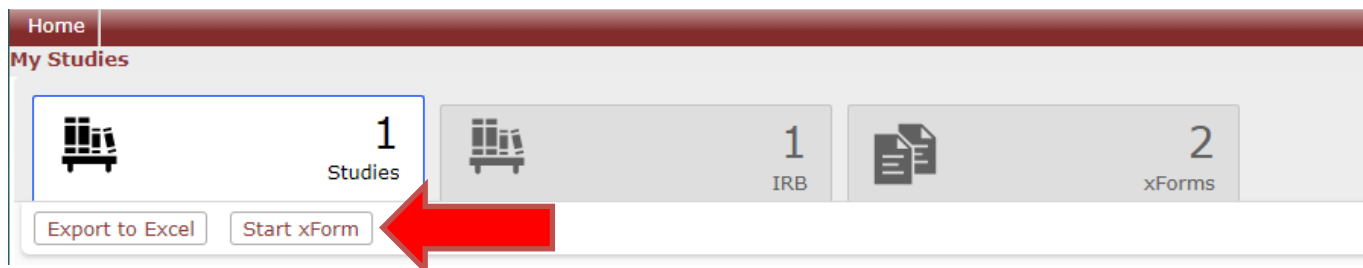
3.0 Navigating the Home Page – Dashboard

The dashboard has several useful features:



1. Start xForm button
2. All studies associated with the researcher
3. A listing of xForms associated with the researcher

3.1 Start xForm button



Click the "Start xForm" button to see a full list and description of available forms, such as initial protocol applications for the various research compliance committees. Please note that certain xForms (e.g., Continuing Review) can only be completed for active protocols. These forms are not available from the Dashboard and must be accessed directly from the study. Refer to section 6.1.2 for information on how to access these study-specific xForms.

3.2 All studies associated with the researcher

The "Studies" tab puts all studies associated with the researcher in a single place. This will include studies being overseen by the IRB, IACUC, IBC, etc. To view studies only under one research committee, select the relevant tab for that committee. Only the applicable tabs will be visible; if a researcher does not have an IBC protocol, then the "IBC" tab is not viewable.

3.3 xForms

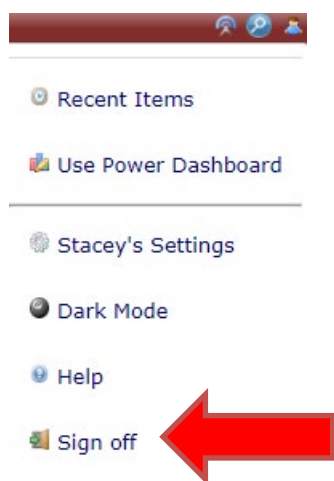
This tab shows the individual xForms to which the researcher has access. Click on the button of the xForm to access it.

3.4 Buttons in the Top Header



In the upper right corner of the screen, click on the magnifying glass to open the Search bar to find existing studies. Studies can be searched by protocol number, site, PI name, title, expiration date, or status.

Use the person icon to access the researcher's settings. This allows the user to edit their profile settings. To log off from OneAegis, select the person icon and select the last option of the menu that pops up.



"My Settings" has the following options:



3.4.1 Change Password

This is applicable only for users without a GVSU email. Click on the "Change My Password" link. You will then see this view:

Change Password	
User	ORCI, Test
Username	ORCI Test Email
Old Password	<input type="password"/>
New Password	<input type="password"/>
New Password Confirm	<input type="password"/>
<input type="button" value="Update"/>	

1. Enter old password.
2. Enter new password. Your new password must be at least 15 characters long and contain characters, from at least 3 of these groups: uppercase letters, lowercase letters, numbers, and special characters (!,@,#, etc.).
3. Click "Update."

3.4.2 Change Your Profile



1. Click on "Change My Profile" link.
You will then see this view:

My Profile			
User Information			
Prefix (Mr, Dr, etc):	<input type="text" value="Ms."/>	First Name:	<input type="text" value="Test"/>
Middle Name:	<input type="text"/>	Last Name:	<input type="text" value="ORCI"/>
Suffix (Jr, III, etc):	<input type="text"/>	Degree:	<input type="text"/>
Specialty:	<input type="text"/>	Email Address:	<input type="text"/>
		From Address for Outbound Email:	<input type="text"/>
<input type="button" value="Update"/>			

2. Update your name, phone number or email address.
3. Click "Update."

3.4.3 My Phone Numbers

1. Click on "My Phone Number" link.
You will then see this view:

My Phone Numbers			
Phone Book (1)			
Action	Primary	Type	Number
 	✓	Home	1-3197

2. Click the "hand holding a piece of paper" icon.
You will then see this view:

Phone Book Edit - ORCI, Test (banashu@mail.gvsu.edu)

Contact Name

Full Name: ORCI, Test

Phone Book

Phone Type: Home

Primary Number: ☒

Update Phone Cancel

3. Update your name, phone number or email address.
4. Click "Update Phone."

3.4.4 My Address

1. Click on "My Address(es)" link.

You will then see this view:

My Addresses								Help	Test's Settings	Sign off
Address Book (1)										
Action	Primary	Type	Street	City	State	Zip	Country			
	<input checked="" type="checkbox"/>	Business	049 JHZ 1 North Campus Drive	Allendale	Michigan	49401	United States			

2. Click the "hand holding a piece of paper" icon

You will then see this view:

Contact Name

Full Name: ORCI, Test

Address Book

Address Type: Business

Street: 049 JHZ

Line 2: 1 North Campus Drive

Line 3:

City: Allendale

State/Province: MI - Michigan

Primary Address: ☒

Update Address Reset Cancel

3. Update your name, phone number or email address.
4. Click "Update Address."

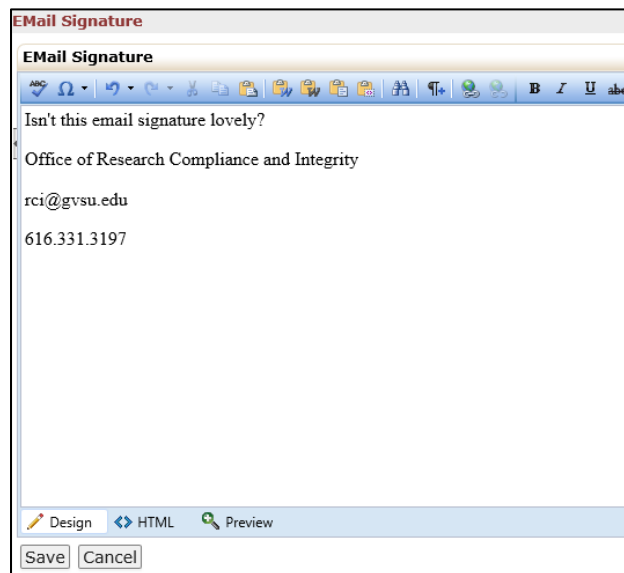
3.4.5 Log-In Information

Lists the time and date of the last 25 times the user logged into OneAegis.

3.4.6 Email Signatures

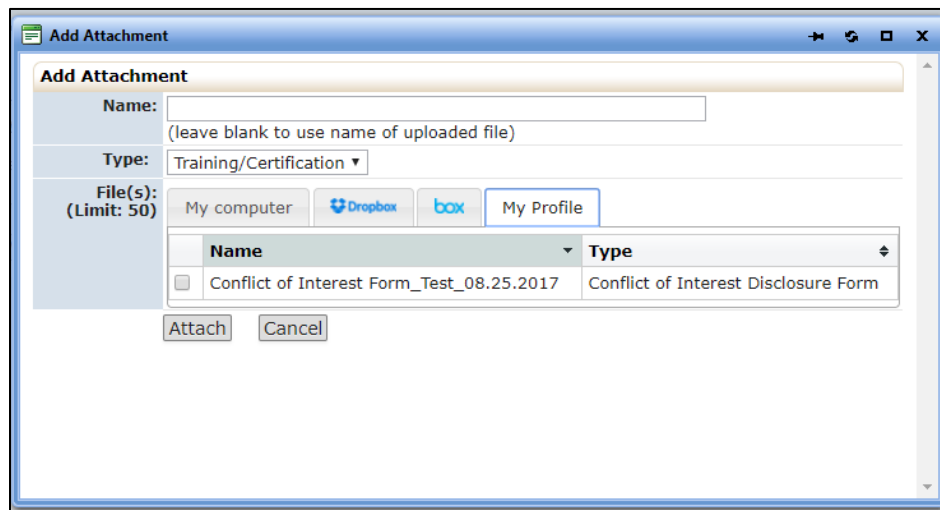
Allows you to enter an email signature when sending email(s) through OneAegis.

1. Click on "Email Signature" link.
2. Enter your signature (see below)
3. Click "Save."



3.5 User Attachments

This function allows the user to attach documents (certificates, forms, etc.) to their OneAegis Contact. These documents will be available on any “Add Attachment” question. They can be accessed by clicking on the “My Profile” tab in the pop-up window that appears when clicking “Add Attachment.”



4.0 Navigating the Study Protocol Page

From the dashboard, you can access the study details for each of your studies. Click on the dark red Study Number link to access the specific study.

4.1 Study

This section notes all of the basic information about the protocol, such as:

- Study number
- Sponsor
- Committee (IRB, IACUC, etc.)


- Sponsor ID or Acronym of the study
- College
- Grants (if applicable)
- Agent Type (methodologies used in the study)
- Study Title
- Year of first review
- Number of Approved Subjects
- Applicable Regulations and Regulatory Determinations

Study: 18-116-S	Sponsor(s): National Institutes of Health (NIH) (DHHS) (Primary)
Committee: IRB	Sponsor Id:
College: Other (Non-Academic Unit)	Grants: R01-235897325
Department: CSCE #1 (Test)	Next Review: Expedited
Last Review: Expedited	CRO:
Agent Types: Survey	Year: 2017
Title: A new IRB study.	COI Disclosure No
Approved Sample Size: 50	Affecting Project:
Compensation: Cash/gift cards less than \$50	COVID-19 Alert Level No research-only in-person interactions
Data Protection Level: Level 1: De-identified data and non-confidential information	Approval:
External Sites/Collaborators: External US collaborator(s)	Exempt Categories: Exempt Category 2
Initial review type: Expedited	Faculty/Student Project: Faculty
Project Team Includes Students: Yes	Other GVSU Involvement: Office of Sponsored Programs
Regulatory Oversight: Revised Common Rule	Regulatory Determinations: Waiver of documentation of consent
Secure Data Storage: External hard drive	Risk Classification: Minimal risk
	Vulnerable Target Populations: GVSU students

You can click on any blue link; in this section, you can click to view more information on the sponsor. The fields available in this section vary depending upon type of project. The study screen is different for each project type, such as IRB and IACUC.

4.2 Study-Site



This section notes information about the study and the study site, such as:

Study-Site 	
Site(s): GVSU - Grand Valley State University	PI: Test Researcher, Ph.D.
Status: Active and Open	Additional: N
Approval: August 24, 2017	Expiration: N/A
Initial Approval: August 24, 2017	Other Expirations: Annual Check-In - 08/24/2023

- Status (active, data analysis, closed, etc.)
- PI name
- Initial approval date
- Expiration date, when applicable
- Other comments, when they exist

4.3 Contacts

This section lists the contacts associated with the study.



▼ Contacts (1)		
Action	Name	Role
 	Researcher, Test Ph.D.	Co-Investigator, Faculty/Staff

4.4 Events

This section lists all the IRB “events” or submissions that have been or are being conducted for this protocol. The event line contains the following sections:

- Type of Event (Initial, Modification, Closure, etc.)
- Att – number of attachments associated with that event or review.
- Instance/UDF – the material being reviewed for the submission.
- Start – the date the event was started or loaded into OneAegis
- Complete – the date the event was completed and reported to the researcher.
- Last Mtg – shows the last meeting this event or review was submitted to. Even if a submission does not require reviewed by the convened board, it will be reported to the board.

You can click on any blue event link in this section to view information specific to the event. After clicking on the blue link, it will take you to the event details (See Section 5.0).

▼ Events (1)		
Action	Event	Att
 	IRB Initial Submission (#19)	3

5.0 Event Details

Event Details are specific to the event or submission.

Home					Create Study	Reports	Contacts	Administration	Find Study (Ctrl+Q)			
Event Details: IRB Initial Submission on 2017-028-GVSU										Help	Shukri's Settings	Sign off
Study-Site												
		Study: 2017-028-GVSU					Site: GVSU - Grand Valley State University					
		Title: BLONDE					Committee: HRRC					
		PI: ORCI, Test										
Event												
		Type: IRB Initial Submission (#19)					Started: 08/16/2017					
		Instance:					Completed:					
		Committee: Inherited from Study										
		Primary Reviewer:					Secondary Reviewer:					
		Action Date:					Date Project Completed:					
Steps (12) <input checked="" type="checkbox"/> Hide Skipped												
Step		Planned		Actual		Complete		Minutes		Micro Note		
Receive Application		08/16/2017		08/16/2017		Yes						
Initial Office Review				08/16/2017		Yes						
Notify Board of Exempt Determination		08/22/2017				No						
Assign to Full Board Review						No						
Notify PI of Results		08/18/2017		08/18/2017		Yes						

5.1 Study Site

The Study Site section shows basic study information, including protocol number, name of principal investigator, etc.

5.2 Event

The Event section shows specific details about the submission you are viewing.

Event	
Type:	IRB Initial Submission (#19)
Instance:	
Committee:	Inherited from Study
Primary Reviewer:	
Action Date:	

These include:

- Type (New Submission, Renewal Request, Revision Request Form, etc.)
- Instance (documents or information related to the event)
- Start and end dates of the review
- Action date (the date the event was completed)

5.3 Notes

Lists the summary of communication on the study, including any notes from ORCI to the research team and emails between ORCI and the research team that were sent within the OneAegis system. (This section may be empty, and therefore not displayed, for many studies.)

▼ Notes (1)
Note
Look at this note!

5.4 Steps

This shows the steps of the submission with the dates. Each event will have the steps listed with a planned date, actual date and when it will go to the full board for either review or notification.

Steps (12)		
Step	Planned	Actual
Receive Application	08/16/2017	08/16/2017
Initial Office Review		08/16/2017
Notify Board of Exempt Determination	08/22/2017	
Assign to Full Board Review		
Notify PI of Results	08/18/2017	08/18/2017

5.5 Actions in the Event Details

Actions in the event details screen are as follows:

- Attachments – shows the attachments related to the event detail
 - Generated Docs – shows documents generated by ORCI for the study (e.g., approval documents associated with the study)
- Send Email – Allows user to email ORCI directly from OneAegis
- xForms – shows the form used to submit the event.

Actions
Attachments (3)
Send EMail
Start xForm
xForms (1)
Done

5.5.1 Attachments

“Attachments” Button: These are the attachments uploaded by the PI. This may also include approval letters from other institutions, consent forms, survey instruments and all other documents provided for this submission.

Attachments on Event IRB Initial Submission Started 08/16/2017 on 2017-028-GVSU			
Attachments (2)	Name	Attached	Type
Generated Docs (1)	Training/Certification	8/16/2017	Training/Certification
	Conflict of Interest Disclosure Form	8/16/2017	Conflict of Interest Disclosure Form

“Generated Docs” Button: Shows all of the documents that have been generated by ORCI for this study.

Attachments on Event IRB Initial Submission Started 08/16/2017 on 2017-028-GVSU			
Attachments (2)	Name	Attached	Type
Generated Docs (1)	Approval Letter	8/18/2017	Generated Document

5.5.2 xForms

Shows the application associated with the event. This is the application completed by the researcher.

Home		Find Study (Ctrl+Q)			
Forms on Event Details: IRB Initial Submission on 2020-001-H-OTH					Help Stace
Filter: <input type="text"/>					
Action	Form	Identifier	Stage/Status	Started	Submitted
	IRB New Protocol Submission Form [Human Subjects Research]	Stacey Gardner (test)	Complete	03/03/2020	03/03/2020

6.0 xForms (Application Forms)








6.1 How to Open an xForm

6.1.1 Opening a New xForm for a New Study (Initial Protocol Submission Form)

On the Dashboard, click the “Start xForm” button in the bar under the navigation tabs.



This will open a new screen with a list of all of the application forms available and a description of each form. Click on the name of the form you wish to complete. Note that only certain forms are available from the Dashboard (including new IRB/IACUC protocol forms, conflict of interest forms, etc.). Forms that can only be completed once a study is already approved (such as a Continuing Review form) are not available from the Dashboard; these must be opened within a study (Section 6.1.2 below).

Select xForm to start		
Action	Form (Click to start)	Description
	Conflicts of Interest and Commitment Disclosure Form	Use this form to disclose conflicts of interest/commitment or to indicate no conflicts exist.
	Contact Look-Up/Add Contact Form	Use this form to check if a Contact exists in the GVSU OneAegis system (e.g., a student researcher you are planning to add to a protocol, etc.). If the Contact does not yet exist, you can use this form to add them into the system. Contacts must be in the system before they can be added to a protocol form.
	IACUC Contingency Plan Training Log	Use this form to document IACUC contingency plan training.
	IACUC New Protocol Submission Form [Animal Research]	The New Project submission process is used for new animal research projects or projects being transferred to GVSU for the first time. This form is also used for a renewal request on a previously approved Institutional Animal Care and Use Committee protocol.
	IRB New Protocol Submission Form [Human Subjects Research]	This form should be completed when proposing a new human subjects research protocol or when requesting that GVSU rely on another IRB's decision. This form is used for exempt determinations and expedited/full committee reviews. If you are unsure if your project falls under the federal regulations for human subjects research (and therefore requires review by ORCI/IRB), please submit the Human Subject Research Determination Form before completing the New Protocol Submission Form.
	IRB Research Determination Form [Human Subjects Research]	This form can be used to determine if your activity requires review by the Institutional Review Board (IRB). You may choose to either self-determine or receive an official determination from the Office of Research Compliance and Integrity (ORCI).
	Training Certificate Upload Form	Use this form to upload training certificate(s) (Responsible Contact of Research, Human Subjects Protections, etc.). ORCI will attach these to your IRBManager "Contact", which will then allow you to more easily attach them to application forms and will trigger automatic expiration reminder emails when your training needs to be renewed.

Note: As described in more detail in Section 6.4 below, these forms use smart logic to guide the user through a series of questions. Depending upon the responses provided, additional questions may or may not appear. If you wish to see the entire form (i.e., all questions, regardless of the user's responses), this can be done by clicking the Print icon to the left of the form name. This will generate a PDF of all questions contained in the form.

6.1.2 Opening a New xForm for an Existing Study (Modification Request, Continuing Review, etc.)

In order to start an event (submission) for an active study, such as a Continuing Review, Change in Approved Protocol or Closure Report, you must first go to the study. Active studies can be found in the “Studies” tab of the Dashboard (see Section 3.2 above).

Once you are in the study, you click the Start xForm button under the “Study-Site” menu on the left. This will open a new screen with a list of all of the application forms available and a description of each form. Click on the name of the form you wish to complete.

6.1.3 Opening an Existing Unsubmitted Form

To return to a form you previously began, but did not yet submit, you can access the form via the “xForms” tab on the dashboard. Click on the form name to open the form and continue work on it.

6.2 Filling out an xForm

6.2.1 General Instructions

xForms use smart logic to guide the user through a series of questions. Depending upon the responses provided, additional questions may appear. For example, if you answer that your study is funded, subsequent questions will prompt you to describe the funding source. If you indicate that you do not have funding related to the study, those subsequent questions asking about funding details will be hidden.

The majority of questions in the xForms require a response; however, some may be optional. OneAegis will not allow the user to submit the form until all required responses have been completed.

Note that some information in the form may be automatically generated. For example, when completing a Continuing Review form, the system will automatically populate the study details (such as project title, name of PI, etc.) on the top of the form.

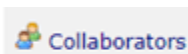
Please carefully read all instructions provided on the form and answer all required questions.

6.2.2 Navigation Buttons at the Top of Each Page

The top of each xForm page will contain a header that looks as follows:

6.2.2.1 Collaborators

The person originally opening a form is initially the only individual who initially will have access to the form. In order to allow others access to the form, these other users must be added via the “Collaborators” function located in the upper left of the header.



*Note that collaborators on a **study** (e.g., co-Investigators, Project Coordinators, Research Assistants, etc.) are added by responding to the study personnel questions in the application xForm; adding a collaborator to your study does not automatically give them access to the **form** itself.*

Upon clicking the “Collaborators” button, a pop-up window will appear.

A screenshot of a web application window titled "Collaborators". The window has a blue header bar with standard window controls. The main content area is divided into two sections. The top section, titled "Add", contains three fields: "E-Mail" with a text input and a dropdown arrow, "Access" with a dropdown menu showing "Edit", and "Note for Collaborator" with a large text area. Below these fields is an "Add" button. The bottom section, titled "Current Collaborators", contains a table with two columns: "Collaborator" and "Permission". The table has one row with the text "Researcher, Test Ph.D." under "Collaborator" and "Author" under "Permission".

Collaborator	Permission
Researcher, Test Ph.D.	Author

- Enter the email address of the user you would like to grant access to the form. Note the user must already have a Contact established within OneAegis to be added as a Collaborator. If you need to add a Contact, you can do this by completing the “Contact Look-Up/Add New Contact” xForm
- Select the access rights you wish to grant
 - “View only” will give the user view only access.
 - “Edit” will allow the user to make edits only.
 - “Edit and manage” will allow the user to make edits and add other collaborators.
 - “Edit, manage and submit” will allow the user to make edits, add other collaborators, and submit.

- Add a note for the collaborator (optional). Text entered in this box will be included in the email sent to the collaborator.
- Click Add. This will automatically send an email to the collaborator with instructions to access the form.

6.2.2.2 Page Titles Drop-down Menu

Allows you to “jump” between pages of a form before completing all required questions on a page. Note that depending on the responses to the questions in a form, entire pages of questions may not be required. Therefore, there may be some pages that are not listed in the drop-down menu.

6.2.2.3 Page Numbers

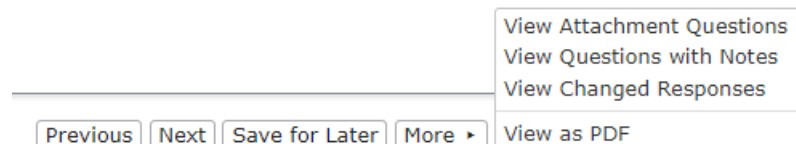
Shows “Page x of y” on each page of the form. Allows you to “jump” between pages of a form before completing all required questions on a page.

6.2.2.4 Next Button

Saves your progress on the current page and takes you to the next page in the form.

6.2.3 Navigation Buttons at the Bottom of Each Page

The bottom of each xForm page will contain a footer that looks as follows:



- Previous – Saves your progress on the current page and takes you to the previous page in the form
- Next – Saves your progress on the current page and takes you to the next page in the form
- Save for Later – Saves your current progress
- More – Opens a vertical menu with the following options
 - View Attachment Questions – Shows only the questions in the form that have “Add Attachment” buttons
 - View Questions with Notes – Shows only those questions where a Note has been added via the “Add Note” feature (Section 6.2.4 Below)
 - View Changed Responses – Shows only those questions that have been revised
 - View as PDF – Allows you to save the form as a PDF file. If you plan to close the form following selecting this PDF button, ensure you Save for Later.

6.2.4 “Add Note” function

Each section of the xForm includes an “Add Note” button on the right-side of the section title.

8b. Description of Intervention/Data Collection/Data Analysis

[Add Note](#) [View Audit](#)

This function allows the user to enter reminders to themselves and/or comments/questions to an individual farther down the review chain (e.g., Authorizing Official, the ORCI, etc.).

Clicking on this button brings up the following note box:



Once entered, the note will be highlighted in blue. You have the option of deleting notes when you no longer need them by pressing the red “X” delete button in the upper right-hand corner of the note.

6.2.5 “View Audit” function

This function allows the user to view the history of that response. It will show entered a response, and when that response was entered. It will also show which changes were made, when and by whom. This is a useful function when multiple people have access to the xForm.

6.2.6 Attaching Documents

Attachments can be added to xForms wherever an “Add Attachment” button is found.

Add Attachment

Documents to be attached will depend on the xForm being submitted. For example, these may include consent forms, recruitment materials, licensing permits, etc.

To attach a document:

1. Click “Add Attachment”.
2. Enter the name for your attachment. (Optional. If left blank, the system will use the filename.)
3. Select the type of attachment in the drop-down list. (On some questions only a certain type of document is intended to be attached, and the type is pre-set.)
4. Click the “Browse” button to locate the file on your computer or drag-and-drop file(s) into the box.
5. Click “Attach” to finish the process.

6.2.7 Signatures

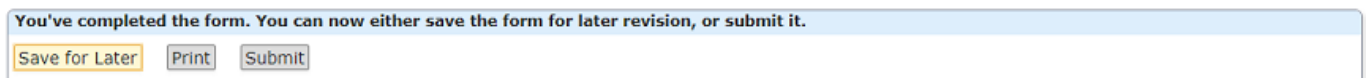
Most xForms require the submitter to electronically sign the form and attest to the accuracy of the information provided within the form, as well as other compliance stipulations. This electronic signature is equivalent to a paper signature.

GVSU-affiliated users: Click the “Sign” box. This may bring up a pop-up window for you to enter your GVSU email and network password. If the researcher has recently signed into OneAegis using multifactor authentication, it may bypass this screen to enter their GVSU network ID and password.

Externally-affiliated users: Enter your OneAegis password in the signature box.

6.3 Submitting an xForm

Once all of the required questions have been answered and the form has been signed, OneAegis will allow you to advance to the submission screen.



You may either save the form for later, print the form, submit the form, or press the browser’s back button to return to the previous page in the form.

You must click the “Submit” button to advance the form to the next person/office in the review chain. If you choose any other action than “Submit,” the form will remain in your list of unsubmitted xForms and will not reach the ORCI. The form will automatically route to the next person in the chain—you do not need to specifically add your Authorizing Official to the form or study.

Note: Clicking “Submit” is equivalent to mailing a paper version of the form to the next person/office in the chain. Once Submit is pressed, you will not have the opportunity to make any changes to the form unless it gets returned to you by someone further down the approval chain (e.g., Authorizing Official, ORCI, etc.).

If an xForm is submitted by someone other than the PI (for example, a student researcher who was added as a collaborator on the form), the xForm will be routed to the PI. Only the PI can submit the form forward to their Authorizing Official/ORCI.

When a form is submitted, an email will be sent to the submitter indicating the form was successfully submitted. The next individual/office in the routing chain will also receive an email indicating a new form has been received and requires attention. Once the form has been submitted to ORCI (after PI submission and Authorizing Official approval, if necessary), OneAegis will automatically create a study event on the protocol page (see Section 4.0). You can then click on the event name (blue link) to track the event progress.

7.0 Authorizing Official Review

The following forms require Authorizing Official (AO) signature before being routed to the ORCI:

- Institutional Review Board (IRB) New Protocol Submission Form
- Institutional Review Board (IRB) Change in Approved Protocol Form
- Institutional Animal Care and Use Committee (IACUC) New Protocol Submission Form

Note: Institutional Review Board (IRB) Reportable Event Forms do not require AO signature due to the time sensitivity of the form, but AOs will be notified upon submission of the form.

Certain Departments/Units may have additional review requirements for other forms. If these exist, they are automatically built into OneAegis and do not require additional action by the PI. All routing to AOs occurs automatically in OneAegis when the PI clicks "Submit."

AOs are automatically notified by the system via email when a PI has submitted a protocol for approval.

7.1 AO Review of Protocol

AOs can access the protocol via one of two methods.

7.1.1 Via Email

The AO will receive an email similar to the one below:

An Amendment Request Form on the following Institutional Review Board (IRB) protocol has been completed by a researcher in your unit and requires Authorizing Official (AO) approval before it can be submitted to the Office of Research Compliance and Integrity (ORCI) for processing.

Principal Investigator: Test Researcher
Project Title: test
Protocol Number: 2020-001-H

To go directly to the form, please click here: [IRB Amendment Request Form \[Human Subjects Research\]](#).

If you approve the submission, please review the AO certification statements and electronically sign the document, click "Next", and then click "Submit." Please note the form is not received by ORCI until the AO has clicked "Submit."

If you require changes/clarifications, please enter those in the box provided on the form and click "Submit." This will route the application back to the PI, informing them of the changes needed.

If you have any questions, please contact ORCI at rci@gvsu.edu or 616-331-3197

Thank you,

GVSU Office of Research Compliance & Integrity
049 James H. Zumberge Hall, 1 Campus Drive
Allendale, MI 49401
(616) 331-3197 | rci@gvsu.edu

The link in the email will take the AO directly to the form. (The AO will be prompted for their GVSU email address and network password upon clicking the link.)

7.1.2 Via Dashboard

Alternatively, the AO can access the xForm from the "xForms" tab of their Dashboard, under the "Awaiting Your Attention" button. To open the form, click on the form name.

7.2 Protocol Review

7.2.1 Reading the PI's protocol

Upon clicking open the form, the AO will see the entire application form as submitted by the PI.

The screenshot shows the top of the 'View xForm - HRRC New Protocol Submission Form [Human Subjects Research]' page. At the top left is the Grand Valley State University logo. To its right is a 'Collaborators' input field and an 'Instructions' dropdown menu. Further right is a 'Next' button. Below these is a header bar with the text: 'This form should be completed when proposing a new human subjects protocol. This form is used for exempt determinations and expedited/full committee reviews. If you are unsure if your project falls under the federal regulations for human subjects research (and therefore requires review by ORCI/HRRC), please submit the Human Subject Research Determination Form before completing the New Project Submission Form.' To the right of this text is a 'Hide Help Text' link. Below the header is a section titled 'Data Entry-HRRC New Protocol' with a timestamp 'Submitted 9/17/2017 10:33:51 AM ET by Researcher, Test Ph.D.'. This section contains two expandable panels. The first is 'Instructions', which is expanded to show 'New Protocol Form Instructions'. This panel contains text about the 'Human Subjects Research Protocol' and a link to 'Add Note'. The second panel is 'IRBManager Instructions', which is also expanded to show instructions on how to use the form's logic and a link to 'Add Note'. At the bottom of the form, there is a blue bar with the text: 'You've completed the form. You can now either save the form for later revision, or submit it.' Below this bar are three buttons: 'Save for Later', 'Print', and 'Submit'.

To review the protocol, simply scroll through the page.

Additional features to aid in the review process:

- “Hide Help Text” – this hides the form instructions the PI viewed when filling out the form. When this is checked, all responses from the PI will still be visible.
- Page Name Drop-Down menu at top of page – Use this to jump to a particular section of the form.
- “Add Note” button – This feature allows you to enter a note that will be viewable by the PI (if the form is returned for changes) and/or by the ORCI when the form is submitted.

7.2.2 Completing the AO Review

Once you have finished reading the protocol, click “Next” either at the top of the page or at the very bottom of the page. This will take you to the AO review page.

If you approve the protocol:

1. Answer “yes” to the question asking if the protocol is ready for submission to ORCI.
2. Read the AO attestation and electronically sign the form by clicking the “Sign” box and entering your GVSU email address and network password.
3. Click “Next” to take you to the submission page.
4. Click “Submit”. **Note: You must click “Submit” for the form to be routed to ORCI for processing.**

This screenshot shows a blue bar at the bottom of the form with the text: 'You've completed the form. You can now either save the form for later revision, or submit it.' Below this text are three buttons: 'Save for Later', 'Print', and 'Submit'.

If changes to the protocol are required:

1. Answer “no” to the question asking if the protocol is ready for submission to ORCI.

2. Enter the changes you want the PI to make in the text box. All text entered in this text box will be sent to the PI via email. Note: If you made your comments via the “Add Note” feature, inform the PI of this in the text box, so they know to look for the notes when they open the protocol again to make the changes.
3. Click “Next” to take you to the submission page.
4. Click “Submit”. **Note: You must click “Submit” for the form to be routed back to the PI.**
5. The PI will receive an email indicating you require changes. Once the PI has made the changes, the form will be routed back to the AO again for approval.

You've completed the form. You can now either save the form for later revision, or submit it.

7.3 Post-AO Approval

For all forms requiring AO approval, the AO will be copied on all emails from ORCI to the PI, including final decision notifications.

Note: If the ORCI needs to return the form to the PI for any reason, the AO approval process will need to be repeated upon re-submission of the form by the PI, unless the AO has specifically indicated in the xForm that they do not need to see future revisions of the xForm.

8.0 Help and Support

If you have any questions or problems using OneAegis, please contact the Office of Research Compliance and Integrity at 616-331-3197 or rci@gvsu.edu.