

Physical Address: 1415 Woodland Avenue, Health Sciences Library Mailing Address: 1200 Pleasant Street Des Moines, IA 50309 515-241-8598 IRBSubmissions@unitypoint.org

UnityPoint Health Des Moines IRB Researcher User Manual for IRBManager



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Adding Study Team Members for an Amendment3	3
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If you need to update study team members at the time of continuing review, this can be completed within the continuing review submission. However, please note that new study team members cannot participate on the study until approval of the continuing review. Please see the Continuing Review/Administrative Update Application section on how to navigate and start the xform for this type of submission	ł
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Getting Started with IRBManager

Open your web browser and go to <u>https://up.my.irbmanager.com/</u>. It is recommended to use Google Chrome or Microsoft Edge.

This should take you to the initial log in screen:

Login	
	The following issue(s) must be addressed:You have attempted to access a page that requires a login. If you are already a user of the system, please login below.
	UnityPoint Health
	To login using your organizational account <u>click here</u>
	tyPoint Users: our IRBManager issued login click here
	Copyright ©2000-2022 Tech Software. All Rights Reserved.

Logging in to IRBManager

- <u>New Users</u>: Email the IRB office at <u>IRBSubmissions@unitypoint.org</u> to find out your log in information (username and password). Please note that you will be prompted to change your password the first time you log in to the system.
- 2) <u>Existing Users</u>: Use the email address affiliated with your account and your chosen password.
- 3) If your username is an UPH email address, you can use the single sign on feature by selecting this login option:



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4) If your username is a non-UnityPoint Health email address, you will select this login option:



 If you have issues logging into your IRBManager account, please email <u>irbsubmissions@unitypoint.org</u> explaining the issue. Please allow 24-48 business hours for a response.

IRBManager Dashboard

After logging into IRBManager, you will be taken to your IRBManager Dashboard. Your dashboard will provide you a snapshot of active studies in which you are either the primary investigator or a study team member.

The dashboard provides the status of current submissions, is the starting point for any new submissions, and returns you to a previously started xform. Hyperlinks can be used to quickly access active studies, xforms, and events.

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Institutional Review Board Human Research Protection Program

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	My Studies					Help Nice	ole's <mark>S</mark> ettings	Sign	0
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Reviewer Open Events Completed Reviews Agendas & Minutes Search Studies	 You are the Committee 	sociated with <u>3 active</u> Stud PI for <u>3 active</u> and <u>4 tota</u> IRB has <u>385 active</u> and <u>5</u> test committee has <u>0 acti</u>	al Studies. 192 total Studies.						
Forms	xForms (6 A	ctive)							
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se Bubble Dashboard	Events (29 C	(pen)							
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ecent Items y Docs & xForms Attachments	You have 6 You have 2 You have 2 You have 25 My Studies (Study 2020-001-	Closure events. 3 External IRB CR/Modifi Total Open events 3 Active) Site Iowa Methodist Medical	PI Sample, Nicole MPA	Title	10/03/2022 Ope				

Studies- This section outlines approved studies, both active and closed. Click on the hyperlinks to view the studies. These studies will also be listed individually at the bottom of the dashboard page under "My Studies". Here you can click on the study number link to take you directly to the study information, forms and events pertaining to that study.

xForms- This section outlines studies that have not yet been completed. There are two sections, unsubmitted xForms and being processed at a later stage.

- Unsubmitted xForms are applications that have been started but have yet to be submitted to the IRB for review. Select the link in this section to open what forms have not been submitted.
- XForms that have been submitted but are still being processed or reviewed can be found in "being processed at a later stage". Click on the link in this section to find out what stage your application is in with the IRB.

Events- This section outlines all open events. Events such as new submissions, continuing reviews, amendments, closures, etc. are considered open until the full board is notified of the event at the next IRB meeting after approval.



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Selecting the Home button on any page will return you to your dashboard.

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\leftarrow \rightarrow C \bigcirc	The s://up.my.irbmanager.com/Dashboard/PortalHome.aspx
UnityPoint Health	Home leetings Create Study Reports Contacts Administration
Actions Reviewer	Studies (3 Active)
Reviewer Open Events Completed Reviews Agendas & Minutes Search Studies	 You are associated with <u>3 active</u> Studies and <u>4 total</u> Studies. You are the PI for <u>3 active</u> and <u>4 total</u> Studies. Committee IRB has <u>385 active</u> and <u>592 total</u> Studies. Committee test committee has <u>0 active</u> and <u>0 total</u> Studies.
xForms	xForms (6 Active)
Start xForm Show Sponsor Ids Use Bubble	 You have <u>0 unsubmitted</u> xForms. You have <u>6 xForms</u> being processed at a later stage.
Dashboard	Events (29 Open)
View as Another User	Only show events where I am:
Recent Items	You have <u>6 Closure</u> events. You have <u>23 External IRB CR/Modification</u> events. You have <u>29 Total Open</u> events

Dashboard & Profile Settings

There are different setting options for your dashboard such as bubble dashboard and dark mode, as well as the ability to change your profile information and view your researcher document expiration information.

Bubble Dashboard

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https://up.my.irbmanager.com/Dashboard/PortalHome.aspx	
Home Meetings Create Study Reports Contacts Administrati My Studies <td< th=""><th>on</th></td<>	on
Studies (3 Active)	
 You are associated with <u>3 active</u> Studies and <u>4 total</u> Studies. You are the PI for <u>3 active</u> and <u>4 total</u> Studies. Committee IRB has <u>385 active</u> and <u>592 total</u> Studies. Committee test committee has <u>0 active</u> and <u>0 total</u> Studies. 	
xForms (6 Active)	
 You have <u>0 unsubmitted</u> xForms. You have <u>6 xForms</u> being processed at a later stage. n) 	
Only show events where I am:	
You have <u>6 Closure</u> events. You have <u>23 External IRB CR/Modification</u> events. You have <u>29 Total Open</u> events	
	My Studies Studies (3 Active) • You are associated with <u>3 active</u> Studies and <u>4 total</u> Studies. • You are the PI for <u>3 active</u> and <u>4 total</u> Studies. • Committee IRB has <u>385 active</u> and <u>592 total</u> Studies. • Committee test committee has <u>0 active</u> and <u>0 total</u> Studies. xForms (6 Active) • You have <u>0 unsubmitted</u> xForms. • You have <u>6 xForms</u> being processed at a later stage. n) Only show events where I am: You have <u>6 Closure</u> events. You have <u>23 External IRB CR/Modification</u> events.



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Ші і 3 Ігв	xForms	Events	Notices
earch Studies Export to Excel	Start xForm		
020-001-IMMC	2020-003-IMMC	2022-026-IMMC	
pen Enrolling New Participants Exp 10/03/2022	Open Not Enrolling New Participants	Open Enrolling New Participants Exp 03/28/2023	
esting IRB forms	Exp 03/28/2023 Expedited Test Study	testing expedited checklist	
Inactive Studies			
PI 1			
k 2	ete 0		
IRB Meetings	test committee Meetings		
InityPoint Health Des Moines Institutio	nal Review Board Study Search		
Future Meetings			

Click on "Use Bubble Dashboard", and it will revert to this:

To revert to the original dashboard, click on the person in the upper right-hand corner and go to your settings:





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Select "Reset Dashboard" and it will return to the original dashboard view:

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UnityPoint Health	Home	Meetings	Create Study	Reports	Contacts	Administration	
	My Setting	gs					
Actions	Edit Sett	ings					
Recent Items	Change M	y Profile					
	My Phone	Number(s	;)				
	My Address(es)						
	My Expirations						
	My Attachments						
	Last 25 Lo	ogins					
My Docs & xForms 2 Attachments	EMail Signature						
155 xForms	Turn on Dark Mode						
	Reset Das	hboard					
	Switch Da	shboard					

To access your settings from the original dashboard, select "(Your Name) Settings" in the upper right-hand corner:

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$\leftrightarrow \rightarrow$ C A	https://up.m	y.irbmanager.com/Dashboard/Portal	Home.aspx			Aª 5	6 12 G		
UnityPoint Health	Home Meeti My Studies	ngs Create Study Report	ts Contacts Adm	ninistration		🔗 🥯 🏶 😑 Find Study (Ctrl+ Help Nico	Q) le's Setting s	: Sign	off
Actions Reviewer Reviewer Open Events Completed Reviews Agendas & Minutes Search Studies	 You are the Committee Committee 	ociated with <u>3 active</u> Studies PI for <u>3 active</u> and <u>4 total</u> S IRB has <u>385 active</u> and <u>592</u> test committee has <u>0 active</u>	Studies. total Studies.			Notices			Ī
xForms	xForms (6 Ac					_			
Start xForm Show Sponsor Ids Use Bubble		unsubmitted xForms. xForms being processed at a	a later stage.						
Dashboard	Events (29 O	pen)							
View as Another User		nts where I am: 🗸 🗸							
Recent Items	You have 23	<u>Closure</u> events. <u>External IRB CR/Modifica</u> Total Open events	<mark>tion</mark> events.						
	My Studies (3	Active)							31
My Docs & xForms 2 Attachments	Study	Site	° PI	* Title	* Expires * St	tatus	 Reference Doc(s) 		٠
155 xForms	2020-001- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	Testing IRB forms	10/03/2022 O	pen Enrolling New Participants			
	2020-003- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	Expedited Test Study		pen Not Enrolling New articipants			
	2022-026- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	testing expedited checklist	03/28/2023 O	pen Enrolling New Participants			Ŧ
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Dark Mode

Within the settings, you can change your dashboard to Dark Mode:

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\leftarrow \rightarrow C \bigcirc	https://up.my.irbmanager.com/Setting	igs/MySettings.aspx				
UnityPoint Health	Home Meetings Create Study	Reports Contacts Administration				
	My Settings					
Actions	Edit Settings					
Recent Items	Change My Profile					
	My Phone Number(s)					
	My Address(es)					
	My Expirations					
	My Attachments					
	Last 25 Logins					
My Docs & xForms 2 Attachments	EMail Signature					
155 xForms	Turn on Dark Mode					
	Reset Dashboard					
	Switch Dashboard					

Your IRBManager screens will now look like this:

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\leftrightarrow \rightarrow C \Leftrightarrow	ttps://up.my.irbmanager.com/Settings/MySettings.aspx					
UnityPoint Health	Home Meetings Create Study Reports Contacts Administration					
	My Settings					
Actions	Edit Settings					
Recent Items	Change My Profile					
	My Phone Number(s)					
	My Address(es)					
	My Expirations					
	My Attachments					
Mar D 0 5	Last 25 Logins					
My Docs & xForms 2 Attachments	EMail Signature					
155 xForms	Turn off Dark Mode					
	Reset Dashboard					
	Switch Dashboard					



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Profile Settings

To update your profile settings, go to settings and select the option you would like to update or view:

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\leftarrow \rightarrow C \Leftrightarrow	https://up.my.irbmanager.com/Settings/MySettings.aspx
UnityPoint Health	Home Meetings Create Study Reports Contacts Administration My Settings
Actions	Edit Settings
Recent Items	Change My Profile My Phone Number(s) My Address(es) My Expirations My Attachments
My Docs & xForms 2 Attachments 155 xForms	Last 25 Logins EMail Signature Turn on Dark Mode Reset Dashboard Switch Dashboard

Starting a New Application

From your IRBManager Dashboard, select "Start xform" on the left side under Actions:

🔲 📔 🔤 UPH Intranet	× 📎	My Studies	× +		
\leftarrow \rightarrow C \bigcirc	https://up.my	.irbmanager.com/Dashbo	ard/PortalHon	ne.aspx	
UnityPoint Health	Home Meetir My Studies	ngs Create Study	Reports	Contacts	Administration
Actions Reviewer	Studies (3 Act	ive)			
Reviewer Open Events Completed Reviews Agendas & Minutes Search Studies	 You are the I Committee I 	ciated with <u>3 active</u> PI for <u>3 active</u> and <u>4</u> RB has <u>385 active</u> a est committee has <u>0</u>	total Stud and <u>592 to</u>	dies. <mark>tal</mark> Studies.	
xForms	xFerms (6 Act	ive)			
Start xForm Show Sponsor Ids Use Bubble Dashboard View as Another User	Events (29 Op Only show even			iter stage.	
Recent Items	You have 23	i <u>losure</u> events. External IRB CR/M Fotal Open events	odificatio	n events.	
	My Studies (3	Active)			
My Docs & xForms	Study	Site	¢	PI	[‡] Title
155 xForms	2020-001-	Iowa Methodist Me	dical	Sample, Ni	cole Testing IRB f



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The following menu options will appear:

	UPH Intranet	🗙 🛛 🔊 My Studies	× 📎	Start xForm	×	+
\leftarrow	C Q	+ https://up.my.irbmanager.com/xFor	ms/StartForm.as	spx?Dashboard=1		
Unit	yPoint Health					
Start Fo	rm on User					
Select x	Form to start					
Action	Form (Click to	start)	 Descr 	ription		
	Application for	New Protocol	Applic	ation for New Researc	h Pr	otocol or Request to Review PHI Submission
۵	Emergency Use	Authorization	-	an subject in a life-th		his form must be used to notify the Institutional Review Board (IRB) of the em ening situation in which no standard acceptable treatment is available, and in v
۵	External IRB- N	ew Submission (CIRB/WIRB/O	her) Submi	it this report when sub	omitt	ting a NEW external IRB application for local review.
						Convrint @2000.2022 Tark Software All Dinkte Decenied

Definitions

Initial submission definitions are as follows, please contact the IRB office if you have questions about which application to use for your study:

Application for New Protocol

This application is used for all new studies (full board, expedited, exempt and requests to review PHI) in which UnityPoint Health Des Moines IRB will be the IRB overseeing the study. Within the application, the "type" of study you select will guide the questions required for that application type. <u>Please note, if you are applying for an exempt</u> <u>study, you must select exempt as the study type.</u>

External IRB- New Submission

This application is used for all new studies in which another IRB (for example CIRB, WIRB, Advarra, etc.) is overseeing the study and UnityPoint Health Des Moines IRB is relying on that institutional IRB for oversight.

<u>Emergency Use Authorization-</u> The FDA defines this as, "the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)]. The emergency use provision in the FDA regulations [21 CFR 56.104(c)] is an <u>exemption</u> from prior review and approval by the IRB." (Retrieved May 5, 2022 from <u>Emergency Use of an Investigational Drug or Biologic |</u> FDA)

Navigating pages

For new applications, the first page of the application is the administrative information page. This page must be completed before gaining access to the remaining application pages.



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Amendments and continuing reviews may have required questions on the initial pages; however, they can be navigated similarly as described throughout this section.

& Collaborators	Administrative Information Pag	e 1 of 11
ormation		
Submitting User	Add Note	View Audit
Sample, Nicole MPA		
Email: nicole.samp	ple@unitypoint.org Phone:	
Which type of application is	s being requested? (Required) Add Note	View Audit
The Dequest to Deview Dec	tected Health Information (PHI) should <u>ONLY</u> be selected if you are con	
	e.g. chart review) to determine adequate sample size to develop a prote n for a research study.	ocol prior
preliminary data analysis (ocol prior

Once this page is complete, the remaining application pages will become available. There are several pages to the application, and additional pages may be added based on your answers to individual questions. To skip to different application pages, use the drop-down box at the top of the page and select the page you want to skip to. Your changes will be automatically saved when you jump to a new page:

🍰 Collaborators	Administrative Information	Page 1 of 11
ormation	Administrative Information	
Submitting User	Conflict of Interest	And Note View Audit
Sample, Nicole MPA	Study Summary	
Email: nicole.sample@u	Resources	
	Study Participants	
Which type of application is bein	Vulnerable Populations	Add Note View Audit
The Request to Review Protecter preliminary data analysis (e.g. of to submitting an application for	Financial Considerations	lected if you are conducting a e to develop a protocol prior
Initial study submission	Data Safety & Monitoring Plan	
○ Request to Review PHI	Privacy/Confidentiality & Informed Consent	
Study Title (Required)	PI Signature	Add Note View Audit
User Manual Screenshot Test Subm	Check & Submit Form	ASC



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Additional Navigation Options

Next: After you complete a page, you can select the "Next" button located at the bottom of each page; additionally, there is a "Next" button located in the upper right-hand corner of each page.

Previous: You can utilize the "Previous" button located at the bottom of each page to go back to earlier pages of the application.

Save for Later: If you need to leave the application, but are not finished, select the "Save for Later" button located at the bottom of each page. This will save the information you have entered so you can return to the application later.

DO NOT use your browser back button as you may lose your application information.

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UnityPoint Health	Collaborators Conflict of Interest Page 2 of 11		Next		^
Application for Nev					
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Notes

Each of the IRB forms have questions that have the "Add Note" feature which allows you to add a note for the IRB office and reviewers should you need to provide further explanation on a particular question. Click on the "Add Note" text within the question box:

Participant Procedures: Please check all procedures which the participant must undergo in the research project: (Required)	Add Note	View Audit
Study Visits		
Lab Testing		
Cardiac Testing		
Drug Treatments		
Radiology Testing		
Other		
Not Applicable		



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Type in the text box and click "Save" when you are done:



After entering a note, you can edit or delete the note. You can also include additional attachments if needed.

Participant Procedures: Please check all procedures which the participant must undergo in the research project: (<i>Required</i>)	Add Note	View Audit
Lab tests will only be run if patients meet criteria based on survey responses. 05/10/2022 • Sample, Nicole MPA • Internal	✓ 🖻 € I 🔍 🗙	
Study Visits		
Lab Testing		
Cardiac Testing		
Drug Treatments		
Radiology Testing		
Other		
Not Applicable		

Adding Collaborators

Adding collaborators to a new submission allows other individuals the ability to view & edit the application during the data entry process. To add collaborators, have the researcher who is completing the application click on "Collaborators" at the top of the submission screen:

Collaborators	Administrative Inform	ation 🔹	Page 1 of 10	
ocol Administrative Information				
Submitting User			Add Note	View Audit
Sample, Nicole MPA Email: nicole.sample@uni	typoint.org	Phone:		
Which type of application is being			Add Note	View Audit
The Request to Review Protected	Health Information (PHI) s	hould <u>ONLY</u> be sel	ected if you are con	ducting a



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In the pop-up window, begin typing the name or email address of the person you would like to add as a collaborator (note the individual must already be a user in IRBManager). Next, select the access to be given (view only, edit, edit & manage, or edit, manage & submit). Finally, click add at the bottom of the screen. Continuing adding collaborators as needed, then click the X to close out the window when you are finished.

Collaborat	cors		Ċ		×
Add					
EI	Mail Karpowicz, Kathryn RN, MA (kat	ny.karpowicz@unitypoint.org)))	
Acc	ess Edit 🗸 🔮				
Note Collabora	for View Only ator Edit				
	Edit and manage Edit, manage and submit		1.		
	CC Me				
	Add				
Current	Collaborators				
Action	Collaborator	 Permission 	* BGR	4	+
۹,	Sample, Nicole MPA	Author			

The individuals added to the application as collaborators will receive an email with a link to the application so they can begin utilizing the application based on the access permissions given.

Adding attachments

Throughout the various IRB forms, you may be asked to attach documents such as consents, protocols, study team member documents, other miscellaneous study documents, etc. To add an attachment, click on the "Add Attachment" button:

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	💣 Collaborators		Page 10 of 11	
I Privac	y/Confidentiality & Info	rmed Consent		
🛛 Compl	lete protocol (required-a de	escription of who, what, why, when, where of the study)		
🖾 Inform	ned Consent/Assent Docum	ents or Waiver of Consent form		
Invest	igator Brochure or Instruct	ions for Use (if one exists)		
	Contract with Sponsor (if no ved, version of the contract	ot available at time of submission, please submit an "all l t)	but signed", verb	ally
🖾 All rec	ruitment materials, includi	ng advertisements intended to be seen or heard by poter	ntial participants	
Appro	ved DHHS sample informed	d consent documents (if one exists)		
Compl	leted DHHS approved proto	ocol (if one exists)		
 Docun (requi 		t's Protection (NIH or CITI) & COI training, if not already	on file in the IRI	B office
Docum	nentation of Conflict of Inte	erest form, if not already on file in the IRB office (require	d)	
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Once you have clicked the button, a window will pop-up allowing you to select the file type and choose your file destination for upload.

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Use the drop-down box to select the type of attachment, noting the options available are dependent upon the type of attachment. For example, below shows the attachment types for consent documents.



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After clicking "Attach", you will see a link to the attachment populate within the question.



You can delete an attachment by clicking on the **X** or replace an attachment by clicking on the **double green arrows**.



During revisions, please replace the previous file with the updated version so that only the updated version is attached to the application.

Signing & Submitting Forms

Once the form is completed, the PI must electronically sign the form before submitting. <u>Please</u> <u>make sure to read and understand the entire section of Investigator responsibilities before</u> <u>signing. Researchers and research personnel will be held accountable for these items</u>.

UnityPoint Health Des Moines

Institutional Review Board Human Research Protection Program

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	🖨 Collaborators	PI Signature	-	Page 11 of 11
ire				
	As principal investigator of the s responsibility for:	study being submitted for review, I a	accept	Add Note View Audit
	 Committing to upholding the F with every application of research 	Principles stated in the Belmont Repo ch.	ort and to follow the	e HRPP Procedures
E F		are of human research participants a Assurance between UnityPoint Health		
t		proved and signed informed consen has specifically waived this requiren		
a		y the IRB, obtaining and documenti \$45CFR46.111; 45CFR46.116; 45CFR R56.111.		
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•	• Reporting to the IRB about the	e progress of the proposed research.		
•	 Reporting to the IRB when all 	study-related activities have ceased	l and the study can	be closed.
(Required)			
(Sign			
P	revious Next Save for Later	More ►		

To sign the form, enter your IRBManager password (same as your login credentials) in the provided box.

As principal investigator of the study being submitted for review, I accept responsibility for:	Add Note	View Audit
 Committing to upholding the Principles stated in the Belmont Report and to follow with every application of research. Protecting the rights and welfare of human research participants and for complying provisions of the Federal Wide Assurance between UnityPoint Health-Des Moines and Human Research Protection. Providing a copy of the IRB approved and signed informed consent document to eat time of consent, unless the IRB has specifically waived this requirement or the study IRB to be exempt. Unless otherwise authorized by the IRB, obtaining and documenting informed consapplicable federal regulations at 45CFR46.111; 45CFR46.116; 45CFR46.117; 21CFR50.25; 21CFR50.27; 21CFR56.111. Promptly reporting proposed changes in previously approved research activities to changes may not be initiated without IRB require prompt reporting to the IRB within first discovering it. Serious Adverse Events require reporting to the IRB within 24 ho discovering it. Reporting to the IRB about the progress of the proposed research. Reporting to the IRB about the progress of the proposed research. (<i>Required</i>) 	y with all appli I the Federal C ch participant is determined ent in accord 1 0.20; 21CFR50 the IRB. My p ary to eliminal 7 calendar da urs of my first	icable office of at the I by the with 23: roposed te ys of my
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Previous Next Save for Later More		

After entering your password, select Next to get to the submission page. From this screen, you can go back into the form to make changes, save it for later if you are not ready to submit the



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form, print, or submit the form. Once you select submit, the IRB office will be notified of your completed submission, and you will be able to track the status of the form within IRBManager from your dashboard.

xForms		×	Form Complet	te	× +
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	Go Back	Save	for Later	Print	Submit
					Copyright ©2000-2022 Tech Software, All Rights Reserved.
					/2022.5.6618.0/Release/0b3af4f GCWAWS1 2022-05-24 14:57:57Z 0.102s

Non-PI Submissions

If the submitter is not the PI or CO-PI, they will click "Submit" on the final page of the form. There is no signature page for form submitters who are not the PI or CO-PI. Once the application has been submitted, it will be sent to the PI for approval and signature. The PI will receive an email from IRBManager with a link to the submitted form:

Dear PI Testing,
Nicole Sample, MPA has completed an application for study title irbmanager user manual test study. Your review and electronic signature are now required for submission to the IRB for processing. Please use the following link to access the submission materials <u>Application for New Protocol</u> .
Thank you,
Office of the IRB

The PI will then be able to review the submitted form. Click next on the last form of the application, the PI will then be asked if the form is ready for submission.

all Collaborators	PI Review & Signature	•	Page 1 of 1
Signature			
Is this form ready for submi	ssion to the IRB? (Required)		Add Note View Audit
○ Yes			
○ No			



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Select Yes if it is ready for submission, the prompts will be the same as outlined above in the PI submission information. If revisions need to be made to the application, select No then explain what revisions are needed.

Is t	this forn	n ready for submission	to the IRB?	(Required)		Add Note	View Audit
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		il what changes are ne the individual who com			oonse will be	Add Note	View Audit
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Choose Next, then click submit to return the form back to the submitting user to make the requested revisions.

Revisions to Applications

There may be occasions where the application is returned for revisions by the IRB office, a reviewer, or the PI (if PI was not the original submitter of the xForm). If you are asked to make revisions, you will receive an email like the one below. (This email will go to the individual who submitted the form and the PI if the original submitter is not the PI.)

Notification of incomplete non-compliance report
IRBManager on behalf of IRB Office <no-reply@up.my.irbmanager.com> To Nicole Sample, MPA; Nicole Sample, MPA</no-reply@up.my.irbmanager.com>
Dear Nicole Sample, MPA,
The Non-compliance Report form for study title Expedited Test Study is being returned to you for the following reasons:
Update sponsor notification date.
Please click here to go directly to the form to make the necessary corrections and resubmit the form Non-compliance Report form.

Click on the link in the email and you will be taken directly to your application (after logging in) to make the requested changes. You can edit and navigate the application just as you did on the initial submission. Navigate through the pages and make the necessary revisions.



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If you are attaching new versions of files, please use the replace feature (**double green arrows**). This will make it easier for your reviewer, so they do not have to figure out which file is the new file to be reviewed.



Once all revisions are complete, resubmit the form. If you are the PI, you will be asked to sign the form again. If you are a non-PI submitter, you will simply click "Submit". The application will then be routed as it was previously for signatures and review (see <u>Signing & Submitting Forms</u>)

Approvals

Once a submission is approved, you will receive an email notification from IRBManager, and if applicable, an approval letter and/or stamped documents will be included. (Please note some submissions only require an acknowledgement rather than an approval letter.)

Notification of new protocol for final approval for 2022-026
IRBManager on behalf of IRB Office <no-reply@up.my.irbmanager.com> To Nicole Sample, MPA; Nicole Sample, MPA</no-reply@up.my.irbmanager.com>
Image: New Study Expedited Approval Letter.docx.pdfPor241 KB
Dear Nicole Sample, MPA,
Your recent submission for IRB # 2022-026, testing expedited checklist has received final approval. The approval documents for this event are attached.
Please contact the IRB Office at IRBSubmissions@unitypoint.org if you need further assistance or have questions.

You can also access approved studies, their accompanying documents, and any email correspondence through your dashboard (see <u>IRBManager Dashboard</u>).

Continuing Review/Administrative Update Application

A continuing review or an administrative update is a required annual review for all non-exempt studies approved by the IRB. The PI and study coordinator (if applicable) will receive a 60-day and a 30-day email reminder notification that the continuing review/administrative update is coming due.



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Dear Dr. Research,
Study Title: Research Study Principal Investigator: Dr. Research, MD Protocol IRB #: 2022-001 Expiration Date: 6/30/2022
Except for studies determined to be exempt from IRB oversight, all human subject's studies are required to undergo continuing review based on the level of risk as assessed by the IRB. This review takes place no less than annually and may require more frequent review or reports as determined by the IRB.
On 7/1/2021 the IRB approved the protocol referenced above.
Options:
1. Submit the Continuing Review of Research Form to continue your research, collecting data, and analyzing data, click the link <u>Continuing Review</u>
 Submit the Study Closure Final report to close your protocol (subject recruitment, subject visits, data collection and analysis are complete), click the link <u>Final Closure</u>
Note: To ensure adequate time for the UnityPoint Health Des Moines IRB to process the Continuing Review and to avoid study expiration, the information should be submitted as soon as possible.
If continuing review approval is not granted before the approval expires, all research activities must stop. This includes recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Advertisements must be pulled.
If you have any questions or concerns, please contact the IRB office at <u>irbsubmission@unitypoint.org</u> .
Sincerely,
Office of the IRB

Starting a continuing review submission- There are several ways to navigate to the continuing review form within IRBManager.

1) Use the link provided in the email reminder notifications labeled "Continuing Review":

Options:
1. Submit the Continuing Review of Research Form to continue your research, collecting data, and analyzing data, click the link <u>Continuing Review</u>

2) OR Log into IRBManager, type in the study number into the "Find a Study" field in the upper right of the screen:



Institutional Review Board

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l Study-Site	Category:		Grants	
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Attachment	Title:	Testing IRB forms	Year:	2020
l Contact l Event l Note l Animal irations irations irations tr XForm rms (1) : : : : : : : : : : : : :		Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement); survey procedures, Interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria are met: (1) the information obtained is recorded by the readity accentianed, directly or through identifiers linked to the subjects (1) any disclosure of the human subjects' responses outside the research would reasonably place the subjects of risk or criminal or civil liability or be damaging to the subjects' rinsonation and in elevational data of the subjects' information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascentianed, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination by 45CFR46.11(a)(7).	Expedited Categories:	(2) Collection of blood samples by finger stick, heel stick, are stick, o venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn m not exceed 530 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure; the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amound drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
port	Informed Consent Documents:	Waiver of documentation of informed consent	Initial Submission Review Type:	
dy Audit dy Sub Screen		(45CFR46.404) Research not involving greater than minimal risk	Vulnerable Populations:	

3) OR from your dashboard, go the "My Studies" located at the bottom of your screen and select the study you would like to begin the continuing review on:

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Once you are in the study, navigate to the "Actions" panel on the left of the screen and select "Start xForm".

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Next, select "Continuing Review" from the menu options:

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		Filter:
Select x	Form to start	
Action	Form (Click to start) -	Description +
	24 Hour SAE Notification Form	24 Hour SAE Notification Form
	Amendment	Amendment
	Continuing Review	This is the annual continuing review form to be used for all study types.
	Enrollment Closure	Submit this report when all subjects have been enrolled and there is continued follow up. Enrollment closure means that no additional subjects will be enrolled.
	External IRB- CR/Amendment/Events (CIRB/WIRB/Other)	External IRB Continuing Reviews, Amendments, Adverse Events/Unanticipated Problems and other documentation
	Final Closure	Submit this report when the study is going to be completed and no further study activities will occur.
	Non-compliance Report form	Non-compliance/Adverse Event formal submission report to the IRB: Reports should be submitted to the IRB within 7 days of event notification/discovery of the event.

Finally, complete the continuing review xform using the same navigation processes outlined previously (see <u>Navigating pages</u>). For additional instructions on adding or removing study team members, see <u>Adding/Removing Study Team Personnel</u>.

*Continuing Reviews for external IRB/CIRB/WIRB studies have a different submission process, please see the separate instructions for these studies below (Continuing Reviews/Amendments for External IRB Studies).

Amendment Application

If you need to make a revision to your approved study, please submit an amendment request. Starting an amendment request is like that of starting a continuing review, you have similar options to navigate to the amendment form:



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1) Log into IRBManager, type the study number into the "Find a Study" field in the upper right of the screen:

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UnityPoint Health	•	udy Reports Contacts Administration		🔊 🍳 🕱 🙂 Find Study (Ctrl+Q)
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Update Add Contact	Committee:	IRB	Sponsor Id:	
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itudy-Site	Department:			
Update	Agent Types:	Drug	CRO:	
Add Attachment	Title:	Testing IRB forms	Year:	2020
Add Contact Add Event Add Note Add Animal Expirations Generate Doc Send EMail Start xForm Aforms (1) <i>lisc</i> Contact History Doc Templates Notifications Run Study-Report Run Study-Site		Category 2: Research that only includes interactions involving educational tests (cognitive, diapostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria are met: (1) the information obtained is recorded by the investigator in such a manner that the identify of human subjects cannot be readily accertained, directly or through identifiers linked to the subjects (ii) are directly or through identifiers linked to the subjects (ii) are directly or through identifiers linked to the subjects (ii) are directly or through identifiers linked to the subjects (ii) are domaging to the subjects at risk of criminal or civil liability or be damaging to the subjects at risk of aritimation obtained is recorded by the investigator in such a manner that the identify of the human subjects (an endally be accentained, directly or through identifiers linked to the subjects and an IRB conducts a limited IRB review to make the determination 45 CFR46.11(a)(7).		(2) Collection of blood samples by finger stick, heel stick, ear stick, or venjourcture as follows: (a) from healthy, non-regregant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not excered 550 mill in a ns week protiod and collection may not occur more frequently than 2 times per week; or (b) from other adults and childran, considering the age, weight, and health of the subjects, the collection procedure; the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the subjects, the mount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
Report Study Audit	Informed Consent Documents:	Waiver of documentation of informed consent	Initial Submission Review Type:	
Study Sub Screen	Risk Category:	(45CFR46.404) Research not involving greater than minimal risk	Vulnerable Populations:	Elderly (65+)

2) OR from your dashboard, go to the "My Studies" located at the bottom of your screen and select the study you would like to begin the amendment on:

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	2020-003- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	Expedited Test Stud		Open Not Enrolling New Participants			
	2022-026- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	testing expedited checklist	03/28/2023	Open Enrolling New Participants			
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Once you are in the study, navigate to the "Actions" panel on the left of the screen and select "Start xForm".

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Next, select "Amendment" from the menu options:

Start Form on Study IM2020-005-test-IMMC (IRB) Filter: Select xForm to start Action Form (Click to start) Description 24 Hour SAE Notification Form 24 Hour SAE Notification Form Amendment Amendment This is the annual continuing review form to be used for all study types. Continuing Review Enrollment Closure Submit this report when all subjects have been enrolled and there is continued follow up. Enrollment closure means that no additional subjects will be enrolled. External IRB- CR/Amendment/Events (CIRB/WIRB/Other) External IRB Continuing Reviews, Amendments, Adverse Events/Unanticipated Problems and other documentation Submit this report when the study is going to be completed and no further study activities will Final Closure occur. Non-compliance Report form Non-compliance/Adverse Event formal submission report to the IRB: Reports should be submitted to the IRB within 7 days of event notification/discovery of the event.

Finally, complete the amendment xform using the same navigation processes outlined previously (see <u>Navigating pages</u>). For additional instructions on adding or removing study team members, see <u>Adding/Removing Study Team Personnel</u>.

*Amendments for external IRB/CIRB/WIRB studies have a different submission process, please see the separate instructions for these studies below (Adding/Removing Study Team Personnel).



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Continuing Reviews/Amendments for External IRB Studies

Navigating to the External IRB- CR/Amendment xForm is like that of the regular continuing review and amendment:

1) Log into IRBManager, type the study number into the "Find a Study" field in the upper right of the screen:



2) OR from your dashboard, go the "My Studies" located at the bottom of your screen and select the study you would like to begin the xform on:

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UnityPoint Health	Home Meeti	ngs Create Study Reports	Contacts Ac	Iministration		🔗 🥝 🎘 🙂 Find Study (Ctrl-	⊦Q)	2 1
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155 xForms	2020-001- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	 Testing IRB form 	ns 10/03/2022	Open Enrolling New Participants		
	2020-003- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	Expedited Test	Study 03/28/2023	Open Not Enrolling New Participants		
	2022-026- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	testing expedite checklist	ed 03/28/2023	Open Enrolling New Participants		
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Once you are in the study, navigate to the "Actions" panel on the left of the screen and select "Start xForm".

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Next, select "External IRB-CR/Amendment/Events" from the menu options:

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		Filter:
Select x	Form to start	
Action	Form (Click to start) -	Description +
	24 Hour SAE Notification Form	24 Hour SAE Notification Form
	Amendment	Amendment
	Continuing Review	This is the annual continuing review form to be used for all study types.
	Enrollment Closure	Submit this report when all subjects have been enrolled and there is continued follow up. Enrollment closure means that no additional subjects will be enrolled.
	External IRB- CR/Amendment/Events (CIRB/WIRB/Other)	Example and tinuing Reviews, Amendments, Adverse Events/Unanticipated Problems and other occumentation
	Final Closure	Submit this report when the study is going to be completed and no further study activities will occur.
	Non-compliance Report form	Non-compliance/Adverse Event formal submission report to the IRB: Reports should be submitted to the IRB within 7 days of event notification/discovery of the event.

Finally, complete the External IRB CR/Amendment xform using the same navigation processes outline previously (see <u>Navigating pages</u>). External IRB CR and Amendment submissions do not receive approval letters, but rather you will receive an email notification of review and the stamped external IRB letter for your records.

Adding/Removing Study Team Personnel

New Applications

Please see the <u>Starting a New Application</u> section on how to navigate and start the xform for this type of submission. Begin typing the last name of the individual you would like to add as a



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study team member until their name comes up, then click on their name. Next, select their role on the study team. Finally, select "Save" after each entry or the information will not be added to the application:

A Collaborators	Administrative Information	 Page 1 of 11
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lease click "save" when addir	g each study member.	
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	Sa	ive
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Once it is saved, it will appear like this which gives you the ability to edit, duplicate, or delete the information if needed:

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	Karpowicz, Kathryn RN, MA		
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	Role on Study Team Sub-Inve	stigator	

Continue adding additional study team members as needed. If an individual is not currently listed in IRBManager you will need to create a new contact first (see red circle in picture below).



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Once this is done, you can go back into your amendment, refresh the page, and add the individual as explained above.

udy Personnel Table	Add Note View
ease click "save" when adding each study member.	
Save	
Study Member Name	
(If COI or any CITI training column is Missing or Expired, attach current document/certificate at the end of the application.)	
Type Name here	
Role on Study Team	
Role on Study Team	
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the study member's name does not appear, they are not yet in the system. Ple	

Amendments

If you need to change the primary investigator on a study or add/remove study team personnel, this can be done through an amendment. Please see the <u>Amendment Application</u> section on how to navigate and start the xform for this type of submission. Once in the amendment form, go to the "Revision Description" section and select the option(s) you would like to do:

A Collaborators	Amendment Information 🔹	Pag	ge 2 of 3
Is this study currently enrolling subje	cts? (Required)	Add Note	View Audit
 Yes No Study does not enroll subjects 			
Type of Review Requested (Required)		Add Note	View Audit
Expedited ReviewFull Board Review			
Revision Description (Required)		Add Note	View Audit
Revision to currently approved protoco Revision to an amendment Revision to currently approved informed			
 Revision to principal investigator Add study team personnel Remove study team personnel 			
	cripts, investigator brochure, survey/data collec		
Please summarize what revisions are	being made and explain the reason for the	erevisions. (Required	1)

Amendment Change to Principal Investigator

Select "Revision to principal investigator", explain the change the in PI then go to the drop-down box and type in the name of the PI. The researcher documents they have on file will auto populate. If there are any missing or are listed in red, you can attach them



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here. Any outdated or missing documents must be attached to make the amendment request.

	scription (Required)						Add Note	View Audi
Revision	to currently approved pr	rotocol						
Revision	to an amendment							
Revision	to currently approved in	formed cons	ent/waiver o	of informed co	onsent			
Revision	to principal investigator							
Add stud	y team personnel							
	study team personnel							
Other (e.	.g. recruitment, advertis	ing, scripts, i	nvestigator	brochure, su	·vey/data c	ollection tools	s, etc.)	
								<i>i</i>
New Princi	pal Investigator (Requi	ired)						li
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Please atta	ch conflict of interest	(if one is n						4
Please atta	t conflict of interest	(if one is n			int.org/desi	noines/irb		Å

Adding Study Team Members for an Amendment

Select "Add study team personnel", explain the addition of the study team member then go to the drop-down box and add the new study team member. The researcher documents they have on file will auto populate. If there are any missing or are listed in red, you can attach them here. Any outdated or missing documents must be attached to make the amendment request. Finally, select "Save" after each entry or the information will not be added to the amendment form.

If an individual is not currently listed in IRBManager you will need to create a new contact first (see red circle in picture below). Once this is done, you can go back into your amendment, refresh the page, and add the individual as explained above.

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Institutional Review Board Human Research Protection Program

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Informat	tion				Page 2 of 3	
	study team personnel					
	ove study team personnel					
Othe	er (e.g. recruitment, advertisin	g, scripts, inves	tigator brochure, sur	vey/data o	collection tools, etc.)	
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Removing Study Team Members for an Amendment

Select "Remove study team personnel", explain the removal of the study team member then go to the drop-down box and type in the study team member you would like to remove along with their role. Finally, select "Save" after each entry or the information will not be added to the amendment form.

	💣 Collaborators	Amendment Information 🔹	Page 2 of 3
nformat	tion		
🗆 Revi	sion to currently approved proto	col	
Revi	sion to an amendment		
Revi	sion to currently approved inform	ned consent/waiver of informed consent	
Revi	sion to principal investigator		
Add	study team personnel		
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Flease	summarize what revisions ar	e being made and explain the reason for	the revisions. (kequired)
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Continuing Reviews

If you need to update study team members at the time of continuing review, this can be completed within the continuing review submission. However, please note that new study team members cannot participate on the study until approval of the continuing review. Please see the <u>Continuing Review/Administrative Update Application</u> section on how to navigate and start the xform for this type of submission.

If you need to make changes to the study team, answer "No" to the question whether the current list of study team members is correct, then select add or remove (or both) study team personnel.

	Collaborators	Report of Activity 🔹	Page 2 of 5
of Activity		(orpri)	
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Current Stu	dy Team Members	Dic	Add Note View Audi
Name		✓ Role	¢
Sample, Nic	ole MPA	Principal Investigator	
Is the list o ○ Yes ● No	of study team members	s above accurate? (Required)	
Please selec	ct the changes to the s	tudy team that need to occur. (Requirea) Add Note View Audi
Add study	y team members study team members	(Select all that app	ly)

Adding Study Team Members during Continuing Review

Select "Add study team members", then go to the drop-down box and add the new study team member. The researcher documents they have on file will auto populate. If there are any missing or are listed in red, you can attach them here. Any outdated or missing documents must be attached to add them to the study. Finally, select "Save" after each entry or the information will not be added to the continuing review form.



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	⁴ Collaborators		Report	of Activity	•		Page 2 of	5		
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	earcher Training Certi	ficate Add	Attachment							
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	of Interest Form Ad	d Attachme	nt							

Removing Study Team Members during Continuing Review

Select "Remove study team personnel", then go to the drop-down box and type in the study team member you would like to remove along with their role. Finally, select "Save" after each entry or the information will not be added to the continuing review form.

	all Collaborators	Report of Activity 🔹	Page 2 of 5	
of Activity		FORM		
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	dy team members	(Select all that apply)	Add Note	view Audi
Remove	study team members			
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		Save		
Study T	Feam Member Name			
Study T	Feam Member Role	~		



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Enrollment/Final Closures

If your study is closing its enrollment or if you need to close the study entirely, please complete the appropriate form. Navigating to the forms are like that of the continuing review and amendments; however, when you get to the select xForm to start screen, select the "Enrollment Closure" if you are only closing enrollment to your study but keeping it active for follow up and data analysis. Select "Final Closure" if you are closing out the study to make it inactive.

		Filter:
Select x	Form to start	
Action	Form (Click to start)	- Description
	24 Hour SAE Notification Form	24 Hour SAE Notification Form
	Amendment	Amendment
	Continuing Review	This is the annual continuing review form to be used for all study types.
	Enrollment Closure	Submit this report when all subjects have been enrolled and there is continued follow up. Enrollment closure means that no additional subjects will be enrolled.
	External IRB- CR/Amendment/Events (CIR OR	External IRB Continuing Reviews, Amendments, Adverse Events/Unanticipated Problems and other documentation
	Final Closure	Submit this report when the study is going to be completed and no further study activities will occur.
	Non-compliance Report form	Non-compliance/Adverse Event formal submission report to the IRB: Reports should be submitted to the IRB within 7 days of event notification/discovery of the event.

Complete the xform using the same navigation processes outline previously (see <u>Navigating</u> <u>pages</u>). Please note that enrollment closures do not receive a formal letter but rather an email acknowledging the enrollment closure. Final Closures must be reported to the full board, so any final closure submissions will be finalized after the next IRB meeting following the submission date. The PI will receive a formal closure letter for the study at that time.

Unanticipated Events and Deviations

24-Hour Serious Adverse Event (SAE) Reporting

The 24-Hour Serious Adverse Event Notification is to be used to notify the IRB of any Serious Adverse Event that occurs that is unexpected, related to research and poses risk to subject or others. This form is also used to report the death of a subject.

Non-compliance Reporting

The Non-Compliance Form is to be used to report all internal unanticipated problems and protocol deviations and violations with the protocol, board requirements or regulations. This form also serves as a follow up report to the 24-Hour SAE Reporting form.

To access these forms:

1) Log into IRBManager, type the study number into the "Find a Study" field in the upper right of the screen:



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> C @	https://up.my.irbmanager.com/P	ojects/b07ceb28-d89a-4db4-a348-622e0b600d2f?retUrl=%2FDashboard%2FPortalHome.aspx		A^ G G G 🐨 🐷
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udy	Study:	2020-001	Sponsor(s):	
date Id Contact	Committee:	IRB	Sponsor Id:	
d Study-Site	Category:		Grants:	
dv-Site	Department:			
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d Attachment	Title:	Testing IRB forms	Year:	2020
d Contact d Event d Note d Animal Jirations nerate Doc nd EMail ntr xForm orms (1) c c c c tact History c Templates tifications n Study Report		Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, gaitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if al least one of the following criteria are met: (1) the information obtained is recorded by the readity accentianed, directly or through identifiers linked to the subjects (ii) any disclosure of the human subjects' responses outside the subjects (ii) any disclosure of the human subjects' responses outside the subjects (ii) any disclosure of the human subjects' responses outside the subjects of the subjects in fixed or criminal or civil liability or be damaging to the subjects 'infancial standing, employability, educational advancement, or regulator(iii) the information obtained is recorded by the investigator in such a manner that the identify of the human subjects can readily be ascentianed, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination by 45CFR64.Int(1a(7)).	Expedited Categories:	(2) Collection of blood samples by finger stick, heel stick, ear stick, o verignucture as follows: (a) from healthy, non-greganat adults who weigh at least 110 pounds. For these subjects, the amounts drawn m not enceed 530 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amound drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 wee period and collection may not occur more frequently than 2 times per week.
n Study-Site eport udy Audit	Informed Consent Documents:	Waiver of documentation of informed consent	Initial Submission Review Type:	
idy Audit idy Sub Screen	Risk Category:	(45CFR46.404) Research not involving greater than minimal risk	Vulnerable Populations:	

2) OR from your dashboard, go the "My Studies" located at the bottom of your screen and select the study you would like to begin the xform on:

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UnityPoint Health	Home Mee My Studies	tings Create Study Report	ts Contacts Admir	nistration		🔊 🤗 🖉 🙂 Find Study (Ctrl- Help Nice	•Q) ole's Settings	Sign off
Actions Reviewer	Studies (3 A	ctive)				Notices		
Reviewer Open Events Completed Reviews Agendas & Minutes Search Studies	 You are the Committee 	sociated with <u>3 active</u> Studies e PI for <u>3 active</u> and <u>4 total</u> S IRB has <u>385 active</u> and <u>592</u> test committee has <u>0 active</u>	itudies. total Studies.					
xForms	xForms (6 A	ctive)						
Start xForm Show Sponsor Ids Use Bubble		unsubmitted xForms. • xForms being processed at a	a later stage.					
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View as Another User Recent Items	You have 6 You have 2 You have 25	ents where I am: V Closure events. 3 External IRB.CR/Modifican D Total Open events						
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My Docs & xForms 2 Attachments	Study	Site	* PI	* Title	* Expires *	Status	 Boc(s) 	•
155 xForms	2020-001- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	Testing IRB forms	10/03/2022	Open Enrolling New Participants		
	2020-003- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	Expedited Test Study	03/28/2023	Open Not Enrolling New Participants		
	2022-026- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	testing expedited checklist	03/28/2023	Open Enrolling New Participants		
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Once you are in the study, navigate to the "Actions" panel on the left of the screen and select "Start xForm".

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	 Study 													collap	ose
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Actions	C	Committee:	IRB					Sponsor Id:							
Study	i i	Category:						Grants:							- 1
Update Add Contact	De	epartment:													
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Study-Site		Title:	FB test t	to CR				Year:							
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Add Contact Add Event Add Note			than mir	46.404) Research not inv nimal risk	<i>i</i> olv	/ing greater		Vulnerable Populations:	N/A						
Expirations Generate Doc	Study-Sit														
Send EMail			ІММС -	Iowa Methodist Medi	ica!	Center		PI:	Samp	ole, Nicole BA					
Start xForm				nrolling New Participants				Additional:							
xForms (0)				2021 for 12 months				Expiration:	July 2	22, 2022					
Misc	Initia	Approval:	July 23	2021		(Oth	ner Expirations:	-						
Contact History		Comments:													
Doc Templates	- Review	ws on Open	a Event	s (1)										collap	ose
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Study Audit	Events		8 👩	w							~		2:(⊲>)2:(collar 00 PM 1/2021	se D

Next, select either "24 Hour SAE Notification" or "Non-compliance Report" from the menu options:



Finally, complete the xform(s) using the same navigation processes outlined previously (see <u>Navigating pages</u>).



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Event Pages

Any time you submit an xform to the IRB (new application, continuing review, amendment, etc.) it creates an event for that submission. It is within the event page(s) that you can obtain more detail for each submission such as attachments to the xform/event, viewing the approved xform, approval letters and emails sent.

To access the events for an approved study:

1) Log into IRBManager, type the study number into the "Find a Study" field in the upper right corner of the screen:



2) OR from your dashboard, go the "My Studies" located at the bottom of your screen and select the study you would like to view:

		My Studies ×						- 0				
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Forms	xForms (6 A	ctive)										
art xForm now Sponsor Ids		<u>o unsubmitted</u> xForms. 5 xForms being processed at	a later stage.									
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ecent Items	You have 6 You have 2 You have 2	i Closure events. 13 External IRB CR/Modifica 9 Total Open events		* Title	* Expires * 5	Status	• Refere Doc(s)					
ecent Items	You have 2 You have 2 You have 2	i Closure events. 13 External IRB CR/Modifica 9 Total Open events 13 Active)	t <mark>ion</mark> events.	* Title Testing IRB forms		Status Open Enrolling New Participants	* Doc(s)					
y Docs & xForms Attachments	You have 6 You have 2 You have 2 You have 2 You have 2 You have 2	s Closure events. 3 External IRB CR/Modifica • Total Open events 3 Active) • Site Iowa Methodist Medical	 tion events. PI Sample, Nicole 		10/03/2022 0 03/28/2023 0		* Doc(s)					



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Once you are in the study, scroll to the bottom of the page to "Events":

Update	v Events (13)									
Add Attachment Add Contact	Action	Event +	Att	Instance/UDF	Start Complete					
Add Event Add Note	i 🔄 🏷 🗙	Continuing Review	2		06/03/2022					
Add Animal	🛃 🖓 🗙	SAE/Non-compliance related to Research	0		05/24/2022					
Expirations Generate Doc	🛃 🖓 🗙	SAE/Non-compliance related to Research	1		05/18/2022 06/09/2022					
Send EMail	🚰 🖓 🗙	Amendment	2		10/28/2021 10/29/2021					
Start xForm xForms (1)	🛃 🖓 🗙	Amendment	2		12/03/2020 12/10/2020					
Misc	🛃 🖓 🗙	Amendment	2		12/03/2020 12/03/2020					
Contact History	🛃 🖓 🗙	Amendment	2		12/03/2020 01/07/2021					
Doc Templates Notifications	🛃 🖓 🗙	Amendment	2		12/01/2020 12/10/2020					
Run Study Report	🛃 🖓 🗙	Amendment	2		11/19/2020 07/16/2021					
Run Study-Site Report	🖻 🏷 🗙	Continuing Review	4		10/22/2020 10/12/2021					
Study Audit	🛃 🖓 🗙	Continuing Review	11		10/13/2020 07/16/2021					
Study Sub Screen Study-Site Audit	🛃 🖓 🗙	Continuing Review	3		09/21/2020 10/12/2021					
Study-Site Sub	🖅 🖓 🗙	Initial Submission	13		06/04/2020 01/18/2022					
Deleted Events	 Study 	-Site Emails (17)								

From here, you can select the event you want:

Update	v Events (13)										
Add Attachment Add Contact	Action	Event +	Att	Instance/UDF	Start Complete						
Add Event Add Note	l 🖂 🏷 🗙	Continuing Review	2		06/03/2022						
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Expirations Generate Doc	🛃 🏷 🗙	SAE/Non-compliance related to Research	1		05/18/2022 06/09/2022						
Send EMail	🛃 🖓 🗙	Amendment	2		10/28/2021 10/29/2021						
Start xForm	🛃 🏷 🗙	Amendment	2		12/03/2020 12/10/2020						
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Contact History	🛃 🖓 🗙	Amendment	2		12/03/2020 01/07/2021						
Doc Templates Notifications	🖻 🏷 🗙	Amendment	2		12/01/2020 12/10/2020						
Run Study Report	🛃 🏷 🗙	Amendment	2		11/19/2020 07/16/2021						
Run Study-Site Report	🛃 🖓 🗙	Continuing Review	4		10/22/2020 10/12/2021						
Study Audit	🛃 🏷 🗙	Continuing Review	11		10/13/2020 07/16/2021						
Study Sub Screen Study-Site Audit	🛃 🖓 🗙	Continuing Review	3		09/21/2020 10/12/2021						
Study-Site Sub	🛃 🖓 🗙	Initial Submission	13		06/04/2020 01/18/2022						
Deleted Events	🔻 Study	-Site Emails (17)									



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Once you have clicked on the event, it will open the event details page:

UnityPoint Health				Administration				🔊 🥝 🏋 😑 Find Study (C		
Ev	ent De	tails: Continuing Rev	view on 2020-001-IMMC					Help N	licole's Settings	s Sign o
	itudy-S									
date Event d Note			2020-001-IMMC				- Iowa	Methodist Medical Center		
w Sub Screen			Testing IRB forms		Committe					
achments (4)		PI:	Sample, Nicole MPA		Sponsor	d				
w Step Audit	vent	Tomas	Continuing Review		Charde	: 10/22	12020			
nerate Doc		Instance:			Complete					
nd EMail art xForm		Committee:			Assigne					
orms (1)		Primary Reviewer:	Sample, Nicole MPA		Secondary Reviewe	samp	le, Nico	ble MPA		
ow Deleted eviews			Administrative Office Revie	2W						
ne		Action Date:			Changes Requeste	I: Updat	e proto	ocol		
cent Items	Origin	al Full Board Meeting Date:								
	Revie	ws (1)								sellap
le. Marv Jane PA-C A	ction	Туре		 Reviewer 	 Review Item 	•	Outc	ome	+ Due + Co	omplete
9	1	FB Reviewer Recomm	nendations	Sample, Nicole MPA	Continuing Review		Recor	mmend Approval®	10	0/22/202
-	Notes	(1)								selles
. A	ction	Note						Entered A By	Type	♦ Int
	ł x	Event Date Complet	ted was set to the latest ac	tual step date by TheSystem when all th	e steps were marked as completed.		(01/18/2022 nicole.sample@unityp	oint.org Automa	ation Yes
-	Email	5 (13)								sellag
xForms A	ction	Subject			* Di	te :	+ Del	To/From		+ Int
-		Notification of final a	pproval for continuing revie	ew for study 2020-001	10	12/202	1 👒	nicole.sample@unitypoint.org		Ye
3	1	Approval documents	for 2020-001 for review		10	22/202	0 👒	nicole.sample@unitypoint.org		Ye
2		Notification of full boa	ard continuing review comp	pleted by IRB reviewer	10	22/202	0 👒	nicole.sample@unitypoint.org		Ye
-	1		ompleted a FB Reviewer Re			22/202		nicole.sample@unitypoint.org		Yes
-			oard Continuing Review			/22/202		nicole.sample@unitypoint.org		Yes
3			ard continuing review			22/202		nicole.sample@unitypoint.org		Yes
-			uing Review Full Board Cor	ditional Review Not Met		22/202		nicole.sample@unitypoint.org		Yes
-	-		ange due to FB Modification			22/202		irbsubmissions@unitypoint.org		Yes
_		Notification of full box				22/202		nicole.sample@unitypoint.org		Ye
			ard continuing review comp	lated by TDD and average		22/202		nicole.sample@unitypoint.org		Yes

To access the approved xform for the event, select "xforms" under Actions on the left side of the page:

UnityPoint Health	Home	Meetings	Create Stud	y Reports	Contacts	Administration					
	Event De	etails: Cont	inuing Revie	ew on 2020 [.]	-001-IMMC						
Actions	Study-9	Study-Site									
Update Event			Study: 2	020-001-IMM	IC						
Add Note			Title: Te	sting IRB for	ms						
View Sub Screen	4			ample, Nicole							
Attachments (4) View Event Audit			• • • •	imple, Meole							
View Step Audit	Event										
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Start xForm		C	ommittee: IF	B							
xForms (1)		Primary	Reviewer: S	Sample, Nicole MPA							
Show Deleted		Review Type: Administrative Office Review									
Reviews		A	tion Date: 10	10/26/2020							
Done	Oriai	nal Full Boa	rd Meeting 10)/23/2020							
Recent Items	-		Date:	, ,							
-IMMC	Reviews (1)										
y Jane PA-C	Action	Туре				• Revi	ewer				
BS 1, Brittani	FB Reviewer Recommendations					Sam	ple, Nicole MP				
ry DO	 Note 	• Notes (1)									



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To access attachments for the event, select "Attachments" under Actions on the left side of the page:

UnityPoint Health	Home	Meetings	Create Stu		orts		Administration					
	Event De	tans: Cont	inuing Rev	new on z	020	-001-IMMC						
Actions	Study-S	tudy-Site										
Update Event	-		Study:	2020-001	-тмм	IC						
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Attachments (4) 🛛 🔫			PI:	Sample, N	licole	e MPA						
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Start xForm		C	ommittee:	IKB								
xForms (1)		Primary	Reviewer:	Sample, Nicole MPA								
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	Reviews (1)											
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The attachments page will open, from here you can select, open, and download attachments.





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To view and/or download the approval letter, within the attachments page, select Generated Docs:

\leftarrow \rightarrow C a	https://up.my.irbn	nanager.com/attach	nment/Attachme	ntList.aspx?Owi	ningGuid=6b3568				
UnityPoint Health	Home Meetings	Create Study	/ Reports	Contacts	Administratio				
	Attachments								
Actions									
Add Attachment	Study-Site								
Tag Attachments	PI Sample, Nicole MPA								
Set as copy/move target	Attachments on Event Continuing Review Started 10/22/2020 o								
Export	····· Attachments (3)		Action	Name	Name				
Show Deleted	 Generated Docs (1) 		ef 🖙 🗎 🗅 🗟	🛛 🗙 test attac	test attachment.docx				
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Any documentations generated by IRBManager for this event can be found here. From within the Generated Docs screen, you can select the document you would like to view or download:

lome	Meetings	Create Study	Reports	Contacts	Administration						
tachm	achments										
tudy-9	Site										
		PI Sam	ple, Nicole	MPA							
ttachr	nents on E	vent Continuin	g Review	Started 10	0/22/2020 on 2020-0	01-IMMC					
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Additional Information & Assistance

To access additional submission guidelines, forms, or the policies and procedures of the IRB/HRPP, please go to our website: <u>Institutional Review Board | UnityPoint Health - Des</u> <u>Moines</u>

Should you have additional questions regarding IRBManager, please contact the IRB office via email (<u>IRBSubmission@unitypoint.org</u>) or call our office at 515-241-8598. Please allow 24-48 business hours for a response.