

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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Continuing Reviews	5
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	; 5
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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>
Non-Un To use y	ityPoint Users: rour IRBManager issued login click here

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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UnityPoint Health	Home Meet My Studies	ings Create Study Reports	Contacts Admir	histration	ଛ (Find Study (Ctrl+ Help Nico	Q) le's Setting	js Sigr	n off
Actions Reviewer	Studies (3 Ad	ctive)				Notices			
Reviewer Open Events Completed Reviews Agendas & Minutes Search Studies	 You are ass You are the Committee Committee 	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 Ad	ctive)							
Start xForm Show Sponsor Ids	 You have 0 You have 6 	unsubmitted xForms. xForms being processed at a	later stage.						
Dashboard	Events (29 O	pen)							
Recent Items	'iew as Another User Only show events where I am: 'iecent 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								
	My Studies (3	3 Active)							
My Docs & xForms	Study	Site	° PI	* Title	• Expires • Status		Reference Doc(s)	e	٠
155 xForms	2020-001- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	Testing IRB forms	10/03/2022 Open E	nrolling New Participants			
	2020-003- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	Expedited Test Study	03/28/2023 Open N Particip	lot Enrolling New pants			
	2022-026- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	testing expedited checklist	03/28/2023 Open E	nrolling New Participants			
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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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UnityPoint Health	Home leetings Create Study R	eports	Contacts	Administration					
Actions	Studies (3 Active)								
Reviewer 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	 You have <u>0 unsubmitted</u> xForms. You have <u>6 xForms</u> being processed 	l at a la	ater stage.						
Dashboard	Events (29 Open)								
View as Another User Recent Items	Only show events where I am: You have <u>6 Closure</u> events. You have <u>23 External IRB CR/Modi</u> You have <u>29 Total Open</u> events	~ ficatio	<u>n</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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UnityPoint Health	Home Meetings My Studies	Create Study	Reports	Contacts	Administration	
Actions Reviewer Reviewer Open	Studies (3 Active • You are associa	e) ted with <u>3 active</u>	Studies ar	nd <u>4 total</u> S	tudies.	
Events Completed Reviews Agendas & Minutes Search 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. 					
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Start xForm Show Sponsor Ids Use Bubble Dashboard	 You have <u>0 uns</u> You have <u>6 xFo</u> 	ubmitted xForms orms being proces	s. sed at a la	iter stage.		
View as Another User	Only show events	where I am:	~			
Recent Items	You have <u>6 Clos</u> You have <u>23 Ex</u> You have <u>29 Tot</u>	sure events. ternal IRB CR/M cal Open events	odificatio	<u>n</u> events.		



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D UPH intranet X 🔊 My Studies × + - o × https:// 668 C A -/up.my.irbmanager.com/Dashb Meetings Create Study Reports Contacts <u>II</u>11 3 29 6 È Notices IRB Search Studies Export to Excel Start xForm 2020-001-IMMC 2020-003-IMMC 2022-026-IMMC Open Enrolling New Participants Open Enrolling New Participants Exp 03/28/2023 Open Not Enrolling New Exp 10/03/2022 Participants Exp 03/28/2023 testing expedited checklist Testing IRB forms Expedited Test Study Inactive Studies PI 1 2 4 test committee Meetings IRB Meetings UnityPoint Health Des Moines Institutional Review Board Study Search Future Meetings 05/12/2022 MAY 06/09/2022 🛛 🖬 👩 🥫 •

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 N	leetings	Create Study	Reports	Contacts	Administration		
	My Setting	S						
Actions	Edit Setti	ngs						
Recent Items	Change My	Profile						
	My Phone	Number(s	5)					
	My Addres	s(es)						
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	My Attachi	nents						
	Last 25 Lo	gins						
My Docs & xForms 2 Attachments	EMail Sign	ature						
155 xForms	Turn on Dark Mode							
	Reset Dashboard							
	Switch Das	shboard						

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

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UnityPoint Health	Home Meeti My Studies	ngs Create Study Repo	rts Contacts Adm	inistration			Q) Ile's Setting	s Sign	₽ off
Actions Reviewer Reviewer Open Events Completed Reviews Agendas & Minutes Search Studies <i>xForms</i> Start <i>xForm</i> Show Sponsor Ids	Studies (3 Ac • You are asso • You are the • Committee xForms (6 Ac • You have 0 • You have 6	tive) cicited with 3 active Studi PI for 3 active and 4 total RB has 385 active and 59 test committee has 0 active tive) unsubmitted xForms. KForms being processed at	es and <u>4 total</u> Studies Studies. 2 total Studies. a and <u>0 total</u> Studies. a later stage.			Notices			
Use Bubble Dashboard View as Another User Recent Items	ds • You have 6 <u>LForms</u> being processed at a later stage. Events (29 Open) User Only show events where I am: You have 6 <u>Closure</u> events. You have 23 <u>External IRB CR/Modification</u> events. You have 29 <u>Total Open</u> events								
Ay Docs & xForms 2 Attachments 155 xForms	Study 2020-001- IMMC 2020-003- IMMC 2022-026- IMMC	Site Iova Methodist Medical Center Iova Methodist Medical Center Iova Methodist Medical Center	 PI Sample, Nicole MPA Sample, Nicole MPA Sample, Nicole MPA 	 Title Testing IRB forms Expedited Test Study testing expedited checklist 	 Expires Std 10/03/2022 03/28/2023 03/28/2023 03/28/2023 05 	tatus been Enrolling New Participants been Not Enrolling New prticipants been Enrolling New Participants	Reference Doc(s)	e	•
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Dark Mode

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

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UnityPoint Health	Home	Meetings	Create Study	Reports	Contacts	Administration		
	My Settings							
Actions	Edit Set	ttings						
Recent Items	Change	My Profile						
	My Phon	e Number(s	5)					
	My Addr	ess(es)						
	My Expirations							
	My Attachments							
	Last 25	Logins						
My Docs & xForms 2 Attachments	EMail Sig	gnature						
155 xForms	Turn on Dark Mode							
	Reset Dashboard							
	Switch D	ashboard						

Your IRBManager screens will now look like this:

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\leftarrow \rightarrow C \bigcirc	thtps://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							
	Last 25 Logins							
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 a	https://up.my.irbmanager.com/Settings/MySettings.aspx							
UnityPoint Health	Home Meetings Create Study Reports Contacts Administration							
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	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 a	https://up.m	y.irbmanager.com/Dashboa	rd/PortalHon	ne.aspx	
UnityPoint Health	Home Meetin My Studies	ngs Create Study	Reports	Contacts	Administration
Actions Reviewer	Studies (3 Act	tive)			
Reviewer Open Events Completed Reviews Agendas & Minutes Search Studies	 You are asso You are the Committee I Committee t 	ociated with <u>3 active</u> PI for <u>3 active</u> and <u>4</u> IRB has <u>385 active</u> a cest committee has <u>0</u>	Studies ar total Stud nd <u>592 to</u> active an	nd <u>4 total</u> S dies. <u>tal</u> Studies. d <u>0 total</u> St	tudies. udies.
xForms	xFerms (6 Act	tive)			
Start xForm Show Sponsor Ids Use Bubble Dashboard View as Another User	Events (29 Op Only show even	submitted xForms xForms being proces pen) hts where I am:	sed at a la	ater stage.	
Recent Items	You have 23 You have 29	External IRB CR/M Total Open events	odificatio	<u>n</u> events.	
	My Studies (3	Active)			
My Docs & xForms	Study	Site	¢	PI	[‡] Title
155 xForms	2020-001-	Iowa Methodist Med	dical	Sample, Ni	cole Testing IRB fo



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The following menu options will appear:

	UPH Intranet	× 📎 My Studies	×	Start xForm	>	-	+
\leftarrow -) C Q	https://up.my.irbmanager.com/xForms	/StartF	orm.aspx?Dashboard=1			
Unit	y Point Health						
Start Fo	rm on User						
Select >	Form to star	t					
Action	Form (Click	to start)	• D	escription			
	Application f	or New Protocol	A	pplication for New	Research F	Pro	stocol or Request to Review PHI Submission
a	Emergency l	Jse Authorization	E a 5	mergency Use Auth human subject in 6.102(d).	norization: a life-threa	Tŀ te	nis 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
	External IRB	- New Submission (CIRB/WIRB/Oth	er) S	ubmit this report w	hen subm	itti	ing a NEW external IRB application for local review.
							Converselyt @ 2000_2022 Tech Coffware_All Display Deserved

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.

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

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 Protecte preliminary data analysis (e.g. c 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 Subr	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	w Protocol Conflict of Interest ® NO Do any investigators, research personnel, or their immediate family have any financial relationship with the Sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment? (Required) CYae				
	No Is any investigator(s) a member of an advisory board with the Sponsoring company? (Required) Oyes No Do any investigators preside time of from the Sponsoring company? (Security)				l
	Do any investigators receive girl funds from the sponsoring company? (Required) OYes ®No Do any investigators, research, essence, or their immediate family have an ownership or royalty interest in omi intellectual property utilized by us protocol? (Required) OYes ®No				
	Previous Next Save for Later More Constit 02000-2021 Tech Software. All Rights Reserved. 2021.7.554 Heteserved. (027272 02744753 0221-08-23 35:58-482 0.1135 Preverse Treatmagner				
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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: (Required) Add Note Lab tests will only be run if patients meet criteria based on survey responses. 05/10/2022 • Sample, Nicole MPA • Internal Image: Comparison of the comparison of	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 In	nformation	•	Page 1 of 10	
ocol Administ	rative Information					
Submitting	User				Add Note	View Audit
Sample, Nic E	cole MPA : mail: nicole.sample@unitypo	int.org	Phone:			
Which type	of application is being req	uested? (Required)			Add Note	View Audit
The Reques	st to Review Protected Hea	alth Information (Pl	II) should <u>ON</u>	<u>LY</u> be sele	cted 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	hy.karpowicz@unitypoint.org)		0	
Acc	ess Edit 🗸 😣				
Note	for View Only				
Collabora	Edit Edit Edit and manage Edit, manage and submit				
	□CC Me		h		
	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:

UnityPoint Health Des Moines

Institutional Review Board Human Research Protection Program

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

	C Contaborators					
I Privacy	//Confidentiality & Info	rmed Consent				
Comple	ete protocol (required-a de	escription of who, what, why, when, where of the study)				
Inform	ed Consent/Assent Docum	nents or Waiver of Consent form				
🗆 Investi	igator Brochure or Instruct	ions for Use (if one exists)				
Final C approv	Final Contract with Sponsor (if not available at time of submission, please submit an "all but signed", verbally approved, version of the contract)					
All recipient of a second s	ruitment materials, includi	ng advertisements intended to be seen or heard by poter	ntial participants			
Approv	ed DHHS sample informed	d consent documents (if one exists)				
Comple	eted DHHS approved prote	ocol (if one exists)				
Docum (requir	nentation of Human Subjec red)	t's Protection (NIH or CITI) & COI training, if not already	on file in the IRI	B office		
Docum	entation of Conflict of Inte	erest form, if not already on file in the IRB office (require	d)			
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Add Atta	chment					
Please at (Required)	tach all Informed Conse	ent, Assent, and Waiver of Consent Documents:	Add Note	View Audi		
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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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Add Attacl	iment	Ç		×
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10)	Informed Consent Form			
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After selecting the attachment type, go to my computer to browse for your document and select the file you would like to upload and attach.

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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>.

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	a Collaborators	PI Signature	Ŧ	Page 11 of 11		
ire						
/ r	As principal investigator of the s responsibility for:	study being submitted for review, I a	ccept	Add Note View Audit		
•	• Committing to upholding the P with every application of resear	rinciples stated in the Belmont Repo ch.	ort and to follow the	HRPP Procedures		
Ē	• Protecting the rights and welfare of human research participants and for complying with all applicable provisions of the Federal Wide Assurance between UnityPoint Health-Des Moines and the Federal Office of Human Research Protection.					
۹ t I	• Providing a copy of the IRB approved and signed informed consent document to each participant at the time of consent, unless the IRB has specifically waived this requirement or the study is determined by the IRB to be exempt.					
• 2	• Unless otherwise authorized by the IRB, obtaining and documenting informed consent in accord with applicable federal regulations at 45CFR46.111; 45CFR46.116; 45CFR46.117; 21CFR50.20; 21CFR50.23: 21CFR50.25; 21CFR50.27; 21CFR56.111.					
	• Promptly reporting proposed changes in previously approved research activities to the IRB. My proposed changes may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to my participants.					
f	 Reporting to the IRB any prob irst discovering it. Serious Adve liscovering it. 	lems that require prompt reporting t erse Events require reporting to the 1	o the IRB within 7 c IRB within 24 hours	calendar days of my of my first		
•	• Reporting to the IRB about the	e progress of the proposed research.				
•	• Reporting to the IRB when all	study-related activities have ceased	and the study can b	oe 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 t 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 ead 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 consea applicable federal regulations at 45CFR46.111; 45CFR46.116; 45CFR46.117; 21CFR50.27; 21CFR50.27; 21CFR56.111. Promptly reporting proposed changes in previously approved research activities to the changes may not be initiated without IRB review and approval, except where necessa apparent immediate hazards to my participants. Reporting to the IRB any problems that require reporting to the IRB within 24 how discovering it. Reporting to the IRB when all study-related activities have ceased and the study ca (<i>Required</i>) 	the HRPP Procession with all applic the Federal C ch participant is determined ent in accord 10 0.20; 21CFR50 the IRB. My p my to eliminal 7 calendar da urs of my first n be closed.	redures icable office of at the I by the with 0.23: roposed te ys of my
To sign, enter password for jnsampler waboo com		
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	e	x +
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	You've com	pleted t	he form. You	can now	either save the form for later revision, or submit it.
	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.

🖨 Collaborators	PI Review & Signature	•	Page 1 of 1
gnature			
Is this form ready for submi	ssion to the IRB? (Required)		Add Note View Audit
○ Yes			
O 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.

ins form	ready for submission	to the IRB?	(Required)		Add Note	View Audit
Yes						
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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.



IRBSubmissions@unitypoint.org

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:



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UnityPoint Health	Home Meetings Create Sti Study 2020-001-IMMC (IRB)	udy Reports Contacts Administration		
Actions	 Study 			collapse
Study	Study:	2020-001	Sponsor(s):	
Update	Committee	IRB	Sponsor Id	
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Add Study-Site	Category:		Grants:	
Study-Site	Department:		000	
Update	Agent Types:	Drug	CRO:	
Add Attachment	Title:	Testing IRB forms	Year:	2020
Add Contact	Exempt Category(s):	Category 2: Research that only includes interactions involving	Expedited Categories:	(2) Collection of blood samples by finger stick, heel stick, ear stick, or
Add Event Add Note Add Animal Expirations Generate Doc Send EMail Start xForm XForms (1) Misc Contact History Doc Templates Notifications Run Study Report Run Study-Site		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 investigator in such a manner that the identity of human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects (ii) any disclosure of the human subject's exponses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation(iii) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects; an an IR8 conducts a limited IRB review to make the determination by 45CFR46.111(a)(7).		venipurcture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml m 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 k will be collected. For these subjects, the amount 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+)
Study-Site Audit	Ctudu-Cita			

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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UnityPoint Health	Home Meet My Studies	ings Create Study Reports	s Contacts Admi	nistration		🔗 🥝 🎕 🤨 Find Study (Ctrl+ Help Nice	·Q) ole's Settin	gs Sign	off
Actions Reviewer	Studies (3 Ad	ctive)	and distant Chudles			Notices			
Events Completed Reviews Agendas & Minutes Search Studies	 You are the Committee Committee 	PI for <u>3 active</u> and <u>4 total</u> St IRB has <u>385 active</u> and <u>592 1</u> test committee has <u>0 active</u> a	udies. total Studies. and <u>0 total</u> Studies.						
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	My Studies (3 Active)					Peferen		-1
Attachments	Study	Site	* PI	* Title	* Expires *	Status	* Doc(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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UnityPoint Health	Study 2021-028-IM	MC (IRB)					Help	Nicole'	s Sett	ings	Sign	off
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Actions	Committee:	IRB			Sponsor Id:							- 1
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Add Contact	Agent Types:	Biologic			CRO:							
Add Study-Site	Title:	FB test to CR			Year:	2021						
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Add Note Expirations	Comments:											
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xForms (0)	Approval:	July 23, 2021 for 12 mont	hs		Expiration:	July 22, 202	2					
Misc	Initial Approval:	July 23, 2021			Other Expirations:							
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Next, select "Continuing Review" from the menu options:

Start For	m on Study IM2020-005-test-IMMC (IRB)	
		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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$\leftarrow \rightarrow \ {\tt C} \ {\tt \widehat{n}}$	https://up.my.irbmanager.com/Pr	ojects/b07ceb28-d89a-4db4-a348-622e0b600d2f?retUrl=%2FDashboard%2FPortalHome.aspx		A* 😘 🎓 🛈 📚 …
InityPoint Health	Home Meetings Create St	udy Reports Contacts Administration		🔊 🕐 😨 Find Study (Ctrl+Q)
Chityrome neura	Study 2020-001-IMMC (IRB)			Help Nicole's Settings Sign off
Actions	 Study 			collapse
Study	Study:	2020-001	Sponsor(s):	
Add Contact	Committee:	IRB	Sponsor Id:	
Add Study-Site	Category:		Grants:	
Study-Site	Department:			
Update	Agent Types:	Drug	CRO:	
Add Attachment	Title:	Testing IRB forms	Year:	2020
Add Contact Add Event Add Animal Expirations Generate Doc Send EMail Start xForm xForms (1) Misc Contact History Doc Templates Notifications Run Study Report Run Study-Site	Exempt Category(s):	Category 2: Research that only includes interactions involving deucational tests (complitue, 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 ascertained, directly or through identifiers linked to the subjects (ii) any disclosure of the human subjects responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, unman subjects, can readily be accentained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination by 45CR#6.11(a)(7).	Expedited Categories:	(2) Collection of blood samples by finger stick, heel stick, ear stick, or venjourcture as follows: (a) from healthy, non-regenant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 mills and sweeks or (b) from other adults and children, considering the age, weight, and health for 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 amount drawn may not eace the lease of 50 mill of 3 mills weigh 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+)
Study-Site Audit	Ctudu_Cita 🕅			

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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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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Actions Reviewer	Studies (3 Ac	tive)				Notices		
Reviewer Open Events Completed Reviews Agendas & Minutes Search Studies	 You are asso You are the Committee Committee 	ociated with <u>3 active</u> Studies a PI for <u>3 active</u> and <u>4 total</u> Stu IRB has <u>385 active</u> and <u>592 to</u> test committee has <u>0 active</u> ar	nd <u>4 total</u> Stud idies. Ind <u>9 total</u> Studies. Ind <u>9 total</u> Stud	lies. es.				
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	2020-003- IMMC	Iowa Methodist Medical Center	Sample, Nico MPA	e Expedited Tes	t Study 03/28/2023	Open Not 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:

Start For	m on Study IM2020-005-test-IMMC (IRB)	
		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 1 tinuing Reviews, Amendments, Adverse Events/Unanticipated Problems and other accumentation
	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 conaborators	Administrative Information	 Page 1 of 11
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tudy Personnel Table		Add Note View Audit
lease click "save" when addir	g each study member.	
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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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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.

click "save" when adding each study member. Yy Member Name Yo or any CITI training column is Missing or Expired, attach current document/certificate at the end application.) ype Name here e on Study Team study member's name does not appear, they are not yet in the system. Please click mean study team personnel to IRBManager.		
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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	ol ed consent/waiver of informed consent		
 Revision to principal investigator Add study team personnel Remove study team personnel 			
🗆 Other (e.g. recruitment, advertising, s	cripts, investigator brochure, survey/data collec	tion tools, etc.)	
Please summarize what revisions are	being made and explain the reason for the	erevisions. (Required) ASS

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.

Revision Description (R	eauired)			Add Note	View Audi
Revision to currently a	pproved protocol				
Revision to an amenda	nent				
Revision to currently a	pproved informed cons	ent/waiver of informed co	nsent		
Revision to principal in	vestigator				
 Add study team person 	nel				
Remove study team period	rsonnel				
Other (e.g. recruitment	t, advertising, scripts,	investigator brochure, sur	vey/data collec	tion tools, etc.)	
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New Principal Investiga Please attach conflict o The current conflict of int	tor (Required) f interest (if one is n erest form can be four	• ot currently on file). d at http://www.unitypoi	eason for the	es/irb	A

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.

UnityPoint Health Des Moines

Institutional Review Board Human Research Protection Program

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Please	summarize what revisions	are being mad	e and explain the r	eason fo	or the revisions. (Required)	
						~
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Add stu	idy team members (Required					
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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		
🛛 Rem	ove study team personnel		
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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		rn		
IesNo		aft FOI		
Current Stu	dy Team Members	Dic	Add Note	View Audit
Name		✓ Role		\$
Sample, Nic	ole MPA	Principal Investigator		
Is the list o ○ Yes ● No	f study team members	above accurate? (Required)		
Please selec	ct the changes to the s	tudy team that need to occur. (Required	d) Add Note	View Audit
Add study	y team members	(Select all that ap	oly)	

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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Current Stu	dy Team Members		D'				Add Note	View Audit
Name				- Role				۰
Sample, Nic	ole MPA			Principal	Investigato	r		
Is the list o ○ Yes ◎ No	f study team memb	ers abo	ve accurate?	(Required)				
Please selec	t the changes to th	e study	team that n	eed to occu	I r. (Require	ed)	Add Note	View Audit
Add study	team members			(Selec	t all that ap	oply)		
Remove s	tudy team members							
Add study t	eam members (Requ	uired)						
				Sava	After to click	filling in al	I applicable informat	ion make f the row
Study Te	am Member Name*			Save	to chek	SAVE ON	ane right hand side o	r the row.
				•			_	
Study Te	am Member Role*			~				
	Training Certificate	Add Att	achment					
CITI COI								
CITI COI	earcher Training Certi	ficate /	Add Attachm	ent				
CITI COI CITI Res Conflict o	earcher Training Certi	ficate /	ment	ent				

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		
Current St	udy Team Members	aft	Add Note	View Audit
Name		Role		٥
Sample, Ni	icole MPA	Principal Investigator		
No	ect the changes to the st	udy team that need to occur. (Required)	Add Note	View Audi
Add stud	dy team members	(Select all that apply)	Add Note	view Audi
Remove	study team members			
Remove S	tudy Team Members (Req	uired)		
		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.

Start For	m on Study IM2020-005-test-IMMC (IRB)					
		Filter:				
Select x	Form to start					
Action	Form (Click to start)	Description	ф			
	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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🔲 📔 UPH Intranet	× 🛞 Study 2020-001-IMMC	(IR8) x CITI - Collaborative Institutional x +		-
$\leftrightarrow \rightarrow$ C \otimes	https://up.my.irbmanager.com/Pr	ojects/b07ceb28-d89a-4db4-a348-622e0b600d2f?retUrl=%2FDashboard%2FPortalHome.aspx		A G 🖨 🐨
UnityPoint Health	Home Meetings Create Study 2020-001-IMMC (TPB)	udy Reports Contacts Administration		P Find Study (Ctrl+Q) P Help Nicole's Settings Sign off
	Study 2020 001 11111C (1RD)			help medic a settinga olgi on
Actions	 Study 			collapse
Jodato	Study:	2020-001	Sponsor(s):	
Add Contact	Committee:	IRB	Sponsor Id:	
Add Study-Site	Category:		Grants:	
Study-Site	Department:			
Undate	Agent Types:	Drug	CRO:	
Add Attachment	Title:	Testing IRB forms	Year:	2020
Add Contact	Exempt Category(s):	Category 2: Research that only includes interactions involving	Expedited Categories:	(2) Collection of blood samples by finger stick, heel stick, ear stick, or
Add Event		educational tests (cognitive, diagnostic, aptitude, achievement), survey		venipuncture as follows: (a) from healthy, non-pregnant adults who
Add Note		procedures, interview procedures, or observation of public behavior		weigh at least 110 pounds. For these subjects, the amounts drawn may
Add Animal		(including visual or auditory recording) if at least one of the following		not exceed 550 ml in an 8 week period and collection may not occur
Expirations		criteria are met: (i) the information obtained is recorded by the		more frequently than 2 times per week; or (b) from other adults and
Generate Doc		investigator in such a manner that the identify of human subjects cannot		children, considering the age, weight, and health of the subjects, the
Send Email		be readily ascertained, directly or through identifiers linked to the		collection procedure, the amount of blood to be collected, and the
Start XForm		subjects (ii) any disclosure of the numan subjects responses outside the		drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 9 week
Mina (1)		liability or be damaging to the subjects' financial standing, employability.		period and collection may not occur more frequently than 2 times per
Contact History		educational advancement, or reputation(iii) the information obtained is		week.
Dor Templates		recorded by the investigator in such a manner that the identity of the		
Notifications		human subjects can readily be ascertained, directly or through identifiers		
Run Study Report		linked to the subjects, and an IRB conducts a limited IRB review to make		
Run Study-Site		the determination by 45CFR46.111(a)(7).		
Report	Informed Consent	Waiver of documentation of informed consent	Initial Submission Review	
Study Audit	Documents:	(AECED46 404) Received not involving greates than minimal side	Type: Vulnerable Deputationer	Elderly (EE)
Study Sub Screen	Risk Category:	(45CFK46.404) Research not involving greater than minimal risk	vumerable Populations:	Elderly (65+)
Study-Site Audit	Ctudu_Cita			

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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$\leftarrow \rightarrow \ \bigcirc \ \bigcirc \ $	Attps://up.	my.irbmanager.com/Dashboard/Portali	Home.aspx			A ^N	° € @					
UnityPoint Health	Home Meet My Studies	ings Create Study Report	s Contacts Admir	histration		🔊 🤗 🖉 🙂 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 ass You are the Committee Committee 	I are associated with <u>2 active</u> Studies and <u>4 total</u> Studies. I are the PI for <u>2 active</u> and <u>4 total</u> Studies. mmittee IRS has <u>385 active</u> and <u>59 total</u> Studies. mmittee test committee has <u>0 active</u> and <u>0 total</u> Studies.										
xForms	xForms (6 A	ctive)										
Start xForm Show Sponsor Ids	 You have 0 You have 6 											
Dashboard	Events (29 C	(pen)										
View as Another User	Only show eve	ents where I am: 💙										
Recent Items	You have 2 You have 2	3 External IRB CR/Modificat	<mark>lon</mark> events.									
My Docs & xForms	My studies (' Active)	•	•	• •		Reference					
2 Attachments	Study	Site	PI	Title	Expires	Status	Doc(s)					
155 xForms	2020-001- IMMC	Iowa Methodist Medical Center	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".

UPH Intranet	×	Study 2021-02	8-IMMC (II	(B) × +									-	٥	×
$\leftarrow \rightarrow$ C \square	🗇 https:	://up.my.irbman	ager.com	/Projects/0c5daac5-6ecb-4a52-9	91c-	d397f9e086a4?retUrl=	=%2F	Events%2F22dcf67c-0	dbc-42	c8-ace7-df762aeec	16 To	£≡	Ð		
	Home	Meetings	Create	Study Reports Conta	cts	Administration	١	2	2 **	🙂 Find Stud	ly (Ctrl+	Q)			2
UnityPoint Health	Study 20	21-028-IM	MC (IF	RB)						Help	Nicole	's Setti	ings	Sign	off
	▼ Study											colla	ose		
		Study:	2021-	028				Sponsor(s):	PI Init	tiated (Primary	()				_
ttions		Committee:	IRB					Sponsor Id:							- 1
Study	1	Category:						Grants:							
Update Add Contact	D	epartment:													
Add Contact	Ag	Agent Types: Biologic					CRO:								
Aud Study-Site		Title:	FB tes	t to CR				Year:	2021						- 1
Update	Inform E	ed Consent Documents:	Informed Consent will be obtained from all participants and documented with a signed, Review Type			tial Submission Review Type:	on Full Board pe:								
Add Attachment			writter	n consent form											
Add Event	Risk	k Category:	(45CFI	R46.404) Research not inv	/olv	ing greater	Vulnerable N/A								
Add Note		C	than n	ninimal risk				Populations:							
Expirations		Comments:													
Generate Doc	Study-Si	ite 🖾													
Send EMail		Site(s):	ІММС	- Iowa Methodist Medi	cal	Center		PI:	Samp	ole, Nicole BA					
Start XForm		Status:	Open I	Enrolling New Participants				Additional:	N						
Aforms (0)		Approval:	July 23	3, 2021 for 12 months				Expiration:	July 2	22, 2022					
Contact History	Initia	l Approval: Comments:	July 23	3, 2021			Oth	ner Expirations:							
Doc Templates	- Revie	ws on Oper	n Even	ts (1)										colla	ose
Run Study Report	Action	Event	•	Туре	۰	Reviewer +	R	eview Item		Outcome	•	Due -	Con	plete	• •
Run Study-Site Report	_	Initial Submission	n	FB Reviewer Recommendations		Sample, Nicole BA	Aj Pr	pplication for New rotocol	N	Recommend Approval 🕫			07/2	2/202	21
Study Audit	- Event	s (1)												collar	ase
🖷 오 🖽 🧮	<i>e</i> •	2 💽	\$ 🔇									, 99 1	小) 8/1	0 PM 1/2021	

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:

UPH Intranet	×	My Studies ×	+				-	o ×	4		
$\leftarrow \rightarrow \bigcirc \square$	https://up.	my.irbmanager.com/Dashboard/Port	alHome.aspx			An -	6 t G				
UnityPoint Health	Home Mee	tings Create Study Repo	orts Contacts Adm	inistration		🔊 🥝 🖉 🙂 Find Study (Ctrl-	+Q)	2	ľ		
	My Studies					Help Nice	ole's Settings	Sign off	2		
Actions Reviewer	Studies (3 A	ctive)				Notices			1		
Reviewer Open Events Completed Reviews Agendas & Minutes Search Studies	 You are as You are the Committee Committee 	J are associated with <u>2 active</u> Studies and <u>4 total</u> Studies. J are the PI for <u>2 active</u> and <u>4 total</u> Studies. mmittee IRS has <u>285 active</u> and <u>592 total</u> Studies. mmittee test committee has <u>0 active</u> and <u>0 total</u> Studies.									
xForms	xForms (6 A	ctive)									
Start xForm Show Sponsor Ids	 You have You have) unsubmitted xForms. 5 xForms being processed at	t a later stage.								
Dashboard	Events (29 C	Open)									
View as Another User	Only show ev	ents where I am:	~								
Recent Items	Ana Jas Only snow events where I am: o as Vou have 23 External IRB CR/Modification events. You have 29 Total Open events										
	My Studies (3 Active)									
My Docs & xForms	Study	Site	* PI	* Title	* Expires *	Status	Reference Doc(s)	•	1		
155 xForms	2020-001- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	Testing IRB forms	10/03/2022	Open Enrolling New Participants			I		
	2020-003- IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	Expedited Test Study	03/28/2023	Open Not Enrolling New Participants			ł		
	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, scroll to the bottom of the page to "Events":

Update	▼ Events (13)										
Add Attachment Add Contact Add Event	Action	Event +	Att	Instance/UDF	Start	Complete					
	🖅 🖓 🗙	Continuing Review	2		06/03/20	22					
Add Animal	🛃 🖓 🗙	SAE/Non-compliance related to Research	0		05/24/20	22					
Expirations	🛃 🖓 🗙	SAE/Non-compliance related to Research	1		05/18/20	22 06/09/2022					
Send EMail	🛃 🖓 🗙	Amendment	2		10/28/20	21 10/29/2021					
Start xForm	🛃 🖓 🗙	Amendment	2		12/03/20	20 12/10/2020					
Misc	🛃 🖓 🗙	Amendment	2		12/03/20	20 12/03/2020					
Contact History	🛃 🖓 🗙	Amendment	2		12/03/20	20 01/07/2021					
Doc Templates Notifications	🛃 🖓 🗙	Amendment	2		12/01/20	20 12/10/2020					
Run Study Report	ピ 🖓 🗙	Amendment	2		11/19/20	20 07/16/2021					
Run Study-Site Report	ピ 🖓 🗙	Continuing Review	4		10/22/20	20 10/12/2021					
Study Audit Study Sub Screen Study-Site Audit Study-Site Sub	🛃 🖓 🗙	Continuing Review	11		10/13/20	20 07/16/2021					
	ピ 🖓 🗙	Continuing Review	3		09/21/20	20 10/12/2021					
	🖅 🖓 🗙	Initial Submission	13		06/04/20	20 01/18/2022					
Deleted Events	🔻 Study	/-Site Emails (17)									

From here, you can select the event you want:

Update	• Events (13)									
Add Attachment Add Contact Add Event Add Note Add Animal	Action	Event	Att	Instance/UDF	Start	Complete				
	^I 🖓 🔀	Continuing Review	2		06/03/20	22				
	🖻 🏷 🗙	SAE/Non-compliance related to Research	h 0		05/24/20	22				
Expirations	🚰 🏷 🗙	SAE/Non-compliance related to Research	h 1		05/18/20	22 06/09/2022				
Send EMail	🚰 🖓 🗙	Amendment	2		10/28/20	21 10/29/2021				
Start xForm	🖻 🏷 🗙	Amendment	2		12/03/20	20 12/10/2020				
Misc	🚰 🖓 🗙	Amendment	2		12/03/20	20 12/03/2020				
Contact History	🚰 🖓 🗙	Amendment	2		12/03/20	20 01/07/2021				
Doc Templates Notifications	🛃 🖓 🗙	Amendment	2		12/01/20	20 12/10/2020				
Run Study Report Run Study-Site Report Study Audit Study Sub Screen Study-Site Audit Study-Site Sub Scroon	🛃 🖓 🗙	Amendment	2		11/19/20	20 07/16/2021				
	🛃 🖓 🗙	Continuing Review	4		10/22/20	20 10/12/2021				
	🚰 🏷 🗙	Continuing Review	11		10/13/20	20 07/16/2021				
	🛃 🖓 🗙	Continuing Review	3		09/21/20	20 10/12/2021				
	🛃 🖓 🗙	Initial Submission	13		06/04/20	20 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	Home	Meetings Create Study	Reports Contacts Ac	Iministration				🔊 🥝 🏋 🙂 Find Study (C	trl+Q)	2
	Event De	etails: Continuing Review	on 2020-001-IMMC					Help N	licole's Settings	s Sign o
ctions	Study-9	ite								
pdate Event dd Note		Study: 2020	0-001-IMMC		Sit	IMMC	- Iowa	Methodist Medical Center		
/iew Sub Screen	1	Title: Test	ng IRB forms		Committe	IRB				
ttachments (4)		PI: Sam	ple, Nicole MPA		Sponsor	d				
lew Step Audit	Event	Tumas Card	inuine Deview		Charde	h 10/22	(2020			
enerate Doc		Instance:	inuing Review		Complete	1: 10/22	/2020			
Send EMail		Committee: IRB			Assigne	1:	2021			
Forms (1)		Primary Reviewer: Sam	ple, Nicole MPA		Secondary Reviewe	: Sampl	e, Nico	le MPA		
show Deleted		Review Type: Adm	inistrative Office Review							
lana		Action Date: 10/2	6/2020		Changes Requeste	I: Update	e proto	col		
locent Items	Origi	nal Full Board Meeting 10/2 Date:	3/2020							
2020-001-IMMC	💌 Revie	ews (1)								collaps
dills. Marv 1ane P∆-(Action	Туре		 Reviewer 	 Review Item 	Outcome			+ Due + Co	omplete 4
	<u></u>	FB Reviewer Recommenda	ations	Sample, Nicole MPA	Continuing Review		Recor	nmend Approval®	10	0/22/2020
	 Note: 	s (1)								sellers
	Action	Note						intered A By	Type	• Int •
1	e x	Event Date Completed w	as set to the latest actua	I step date by TheSystem when all th	e steps were marked as completed.		0	1/18/2022 nicole.sample@unityp	oint.org Automa	ation Yes
	🔻 Emai	ls (13)								sollaps
.82 xForms	Action	Subject			* Di	te ‡	Del	To/From		+ Int +
	2	Notification of final approv	al for continuing review f	or study 2020-001	10	/12/2021		nicole.sample@unitypoint.org		Yes
		Approval documents for 2	020-001 for review		10	/22/2020) 🙀	nicole.sample@unitypoint.org		Yes
	<u>e</u>	Notification of full board o	ontinuing review complete	ed by IRB reviewer	10	/22/2020) 😼	nicole.sample@unitypoint.org		Yes
	<u>-</u>	Nicole Sample has comple	ted a FB Reviewer Recom	mendations review	10	/22/2020) 😼	nicole.sample@unitypoint.org		Yes
	1	Notification of Full Board (Continuing Review		10	/22/2020		picole sample@upitypoint.org		Yos
	-	Notification of full board of	optiquing review		10	/22/2020	1.12	nicole.sample@unitypoint.org		Voc
	-	Notification of Continuing	10	/22/2020		nicole.sumple@unitypoint.org		Voc		
	<i></i>	Notification of CP Change	10	10/22/2020 incole.sample@unitypoint.org						
	-	Notification of CK Change	aue to PD Plounications R	equested 2020-001	10	/22/2020		nissionissions@unitypoint.org		res
		Nouncation of full board d	etermination		10	22/2020		nicole.sample@unitypoint.org		res
			optiniung review complet				1 14	picole sample/dupitypoint ord		Yes

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

InityPoint Health	Home	Meetings	Create Study	Reports	Contacts	Administration						
	Event Details: Continuing Review on 2020-001-IMMC											
Actions	Study-9	tudy-Site										
Update Event		Study: 2020-001-IMMC										
Add Note			Title: Te	stina IRB for	ms							
View Sub Screen	4		PI: Sa	mple Nicole	MPA							
Attachments (4) View Event Audit			11.00	inpic, meore								
View Sten Audit	Event											
Generate Doc		Type: Continuing Review										
Send EMail			Instance:	Instance:								
Start xForm		C	ommittee: IR	В								
xForms (1)		Primary	Reviewer: Sa	Sample, Nicole MPA								
Show Deleted		Re	view Type: Ad	Administrative Office Review								
Reviews		A	tion Date: 10	10/26/2020								
Done	Origi	nal Full Boa	rd Meeting 10	/23/2020								
Recent Items			Date:									
-IMMC	Reviews (1)											
y Jane PA-C Action Type						• Revi	ewer					
BS FB Reviewer Recommendations Sample, Nice												
ry DO	 Note 	s (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	udy Repo	orts	Contacts	Administration					
	Event De	event Details: Continuing Review on 2020-001-1MMC										
Actions	Study-S	tudy-Site										
Update Event			Study:	2020-001-	тмм	IC						
Add Note			Title	Tosting IP	B for	me						
View Sub Screen			nuc.			1115						
Attachments (4) 🛛 🔫			PI:	Sample, N	icole	e MPA						
View Event Audit	Event											
View Step Audit			Type:	Continuing	ı Rev	view						
Generate Doc			Instance									
Send EMail			·	100								
Start xForm		C	ommittee:	: IRB								
xForms (1)		Primary	Reviewer:	: Sample, Nicole MPA								
Show Deleted		Rev	view Type:	Administrative Office Review								
Reviews		Ac	tion Date:	: 10/26/2020								
Done	Oriair	nal Full Boar	rd Meetina	10/23/202	0							
Decent Items			Date:	,,								
	Reviews (1)											
	Action Type						• Rev	lewer				
	~	nendations			Sam	ple, Nicole MP						
	Notes	5 (1)										

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.irbm	anager.com/attacl	nment/Attachme	ntList.aspx?Ow	ningGuid=6b3568					
UnityPoint Health	Home Meetings	Create Study	/ Reports	Contacts	Administratio					
	Attachments									
Actions										
Add Attachment	Study-Site									
Tag Attachments	PI Sample, Nicole MPA									
target	Attachments on Event Continuing Review Started 10/22/2020 o									
Export	Attachments (3)		Action	Name	Name					
Show Deleted	 Generated Docs (1) 	-	er 😝 🗎 🗅 🗟	📑 🗙 test attac	test attachment.docx					
Done			er 😝 🗎 🗈 🔒	📑 🗙 test attac	hment.docx					
Recent Items			🕑 🖼 📄 🗋 🧮 🗶 test attachment.docx							

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	ents							
tudy-§	Site							
		PI Sam	ple, Nicole	MPA				
ttachr	nents on E	vent Continuin	g Review	Started 1	0/22/2020 on 2020-0	001-IMMC		
· Attachm	ients (3)	-	1	Manaa			Attached 🔺	Туре
Generat	ed Docs (1)		' 🛛 🗎 🗎 🗎	K <u>New.Approva</u>	al.Stipulations Met.docx		10/22/2020 3:30 PM ET	Approval Letter

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.