

Creighton University – InfoEd

IRB Modification Submission

Last update: May 2021

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If you need help accessing InfoEd or need a profile created contact the Research Compliance Office at:

Phone: 402-280-3074

Email: researchcomped@creighton.edu.

1. Login to InfoEd

Step 1: Go to <https://creighton.infoedglobal.com>

Step 2: Use the Creighton University single-sign-on (SSO) by selecting [Click Here](#).

or

Non-SSO users, using the login boxes enter in your assigned username and password.

Select the Sign in button.

Additional login and setup information is found in the InfoEd User Access Guide.

2. Adding a Modification

Modifications are used for all changes to an approved IRB protocol, ideally a record number should only have one modification request open at a time.

Step 1: Locate your protocol from Locate Records or a Locate Records search.

Record Type	Record Number	Record Owner / PI	Record Status	Record Title
Human Subjects Protocol	2001916	Test_SOM	Acknowledged	Testing 4.26.2021 (2)
Human Subjects Protocol	2001915	Test_SOM	1 - In Development	Testing 4.26.2021 (1)
Human Subjects Protocol	2001899	Test_SOM	1 - In Development	Exempt Category 3
Human Subjects Protocol	2001898	Test_SOM	1 - In Development	Exempt Category 2

Step 2: Hover over to select Edit, Master Record

Record Type	Record Number	Record Owner / PI	Record Status	Record Title
<ul style="list-style-type: none"> Edit View Create New Info Delete Bookmark Record 	Master Record	Initial Application (26-Apr-2021 Acknowledged)	1 - In Development	Testing 4.26.2021 (2)
				Testing 4.26.2021 (1)
	2001899	Test_SOM	1 - In Development	Exempt Category 3
	2001898	Test_SOM	1 - In Development	Exempt Category 2

Step 3: Using the Add box select Modifications and then select the Add button.

Type	Submission Number	Investigator Submitted On Date	Determination	Determination Date	Next Review Date	Expiration Date	Delete
Initial Application	2001916-01	26-Apr-2021	Acknowledged	26-Apr-2021	26-Apr-2021	25-Apr-2022	Delete

Step 4: Complete the Request for Modification form.

Record Number: 2002055 **New Protocol Created for Password Test on 29-Mar-2021 10:07 AM** Human Subjects Protocol

Done Save Password Test - Creighton University Edit Mode

Submissions (2) Linkages Approved Docs ?

Home > Submissions > Modifications > Submission

Submission **Modifications** Submission Number: 2002055-02 Created on: 06-Apr-2021 Status: In Development

Attachments (2)

Document/Form	Type	Status	
Creighton University HS eForm	Application	Incomplete	(Mandatory Form) <input type="button" value="Submit"/>
Request for Modification	Attachment	Incomplete	(Mandatory Form)

Step 5: Complete the Modification form by selecting the Complete box at the top right of the form.

Creighton UNIVERSITY Full Accreditation Close Print Form History Save Complete

Updated By: SOM Test @ 29-Apr-2021 01:50:11 PM

AMENDMENT/MODIFICATION

ALL PAGES

AMENDMENT/MODIFICATION

IRB Project Number: 2001916 Submission Number: 2001916-02

Study Title

Step 6: If the Modification form required an update to the Creighton University HS eForm.

Select the Creighton University HS eForm and uncheck the Complete box to make changes. Once changes are made, complete the form by checking the Complete box.

Creighton UNIVERSITY

Full Accreditation

Close Print Form History Save Submit Complete

Updated By: SOM Test @ 29-Apr-2021 01:37:32 PM

GENERAL INSTRUCTIONS

PERSONNEL

EXTERNAL

INVESTIGATORS/PERSONNEL

PROJECT SITES

FUNDING

CERTIFICATE OF CONFIDENTIALITY

CONFLICT OF INTEREST

RESOURCES

RESEARCH AND REVIEW

TYPE

GENERAL INSTRUCTIONS

Completion of this form is the first step in seeking human subject research approval at Creighton University. This form is to be completed by the Principal Investigator or his/her designee. All research personnel must complete required training, acknowledgements and financial disclosure per Creighton University [policy](#).

The Creighton University IRB will process your application, coordinate review and notify you of their determination.

Research activity may not begin until you receive notification of APPROVAL from the IRB Office. Submissions to the IRB Office that are incomplete will be returned and not forwarded to the Review Committee for action.

Protocol Number: 2001916 Submission Number: 2001916-02

Step 7: Once the Request for Modification and Creighton University HS eForm are complete select the Submit button to route the request.

Record Number: 2002055 **New Protocol Created for Password Test on 29-Mar-2021 10:07 AM** Human Subjects Protocol

Done Save Password Test - Creighton University Edit Mode

Submissions (2) Linkages Approved Docs ?

Home > Submissions > Modifications > Submission

Submission: Attachments (2)

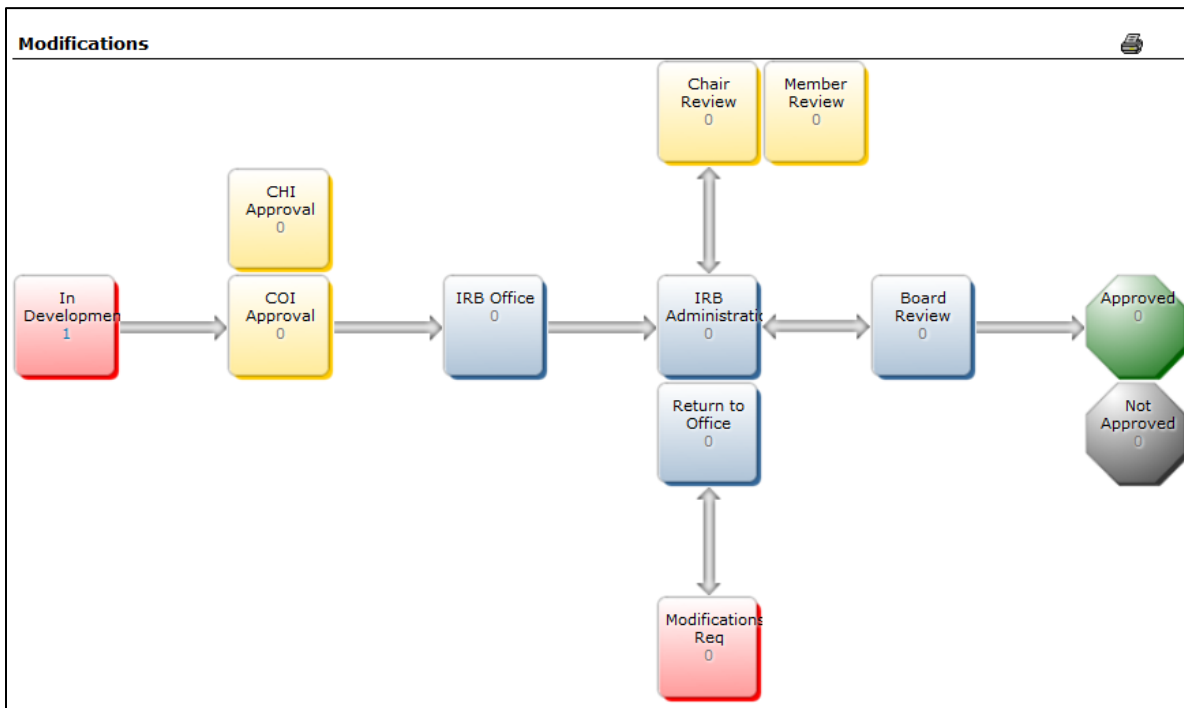
Modifications Submission Number: 2002055-02 Created on: 06-Apr-2021 **Status: In Development**

Document/Form	Type	Status	Submit
Creighton University HS eForm	Application	Incomplete	(Mandatory Form)
Request for Modification	Attachment	Incomplete	(Mandatory Form)

3. Modification Submission Workflow

An InfoEd submission should be followed through the Workflow Map. Each submission type has a Workflow Map which are made available through the Portal Configurations button on the Home tab.

InfoEd Submission Workflow Chart



4. Workflow Status

The current workflow status of a record number, protocol, is listed as the protocol status.

Drag a column header and drop it here to group by that column						
	Record Type	Record Number	Record Owner / PI	Record Status	Record Title	
<ul style="list-style-type: none"> Edit View Create New 	Protocol	2001914	Test, Password	7 - Approved	Return to Office Testing 4.23.2021	
				Minimal Risk	Print View	
<ul style="list-style-type: none"> Info Delete Bookmark Record 			Protocol Status: 7 - Approved	- In Development	New Protocol Created for Password Test on 22-Apr-2021 12:00 PM	
			Determination Date: 28-Apr-2021	- In Development	External Test on 22-Apr-2021 10:21 AM	
			Determination Date From: 28-Apr-2021	- In Development	QIP Testing 22-Apr-2021 10:19 AM	
			Determination Date To: 27-Apr-2022	- In Development		

The current workflow status of a submission is listed as Status at the submission level.

Record Number
2002055

New Protocol Created for Password Test on 29-Mar-2021 10:07 AM
Password Test - Creighton University

Human Subjects Protocol
Edit Mode

Done Save

Submissions (2) Linkages Approved Docs ?

Home > Submissions > Modifications > Submission

Submission
Attachments (2)

Modifications Submission Number: 2002055-02 Created on: 06-Apr-2021 **Status: In Development**

Document/Form	Type	Status	
Creighton University HS eForm	Application	Incomplete	(Mandatory Form)
Request for Modification	Attachment	Incomplete	(Mandatory Form)

Submit

Possible statuses and their respective descriptions are listed below:

Status:	Description:
In Development	The submission is incomplete and has not been submitted to the IRB Office.
Routing	The submission has been submitted and is waiting for Co-Investigator approval.
IRB Office	The submission has been received by the IRB Office.
IRB Administrator	The submission has been assigned to an IRB Administrator for review.
Modification Required	A response is required by the PI.
Member or Chair Review	The submission is with a reviewer and a determination has not been made.
On Agenda	The submission is on a Board Review agenda.
Approved	The IRB submission determination was approved by the IRB.
Acknowledge	The IRB submission determination was acknowledged by the IRB.