

Creighton University – InfoEd

IRB Reportable new Information 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.

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

2. Adding a Reportable New Information

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.

The screenshot shows the 'Locate Records' page in the v13 Portal. The page title is 'v13 Portal | Welcome SOM Test | Logout'. The navigation bar includes 'Home', 'My Profile', 'Locate My Records', 'Locate Records', 'Calendar', 'Messages', and 'Assignments'. A search bar on the right contains 'Quick Find'. The main content area shows 'Results found: 4' and a table of records. The table has columns for Record Type, Record Number, Record Owner / PI, Record Status, and Record Title. The records listed are:

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

The screenshot shows the 'Locate Records' page with the 'Edit' menu open for the first record (Record Number 2001916). The menu options are: Edit (Master Record), View (Initial Application (26-Apr-2021 Acknowledged)), Create New (Development), Info, Delete, and Bookmark Record. The table data is the same as in the previous screenshot.

Step 3: Using the Add box select Reportable New Information and then select the Add button.

The screenshot shows the 'Submissions' page for record 2001916. The page title is 'Testing 4.26.2021 (2) SOM Test - School of Medicine'. The navigation bar includes 'Submissions (1)', 'Linkages', and 'Approved Docs (1)'. The main content area shows a table of submissions. The table has columns for Type, Submission Number, Investigator Submitted On, Determination, Determination Date, and a Delete button. The submission listed is:

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

An 'Add' button is visible in the top right corner of the table, and a dropdown menu is open, showing options: Modifications, Annual, Continuing, or Project Termination, Reportable New Information (highlighted), and New WF Demo.

Step 4: Complete the Reportable New Information form.

Record Number: 2001916
Testing 4.26.2021 (2)
 SOM Test - School of Medicine

Human Subjects Protocol
 Edit Mode

Submissions (2) | Linkages | Approved Docs (1)

Home > Submissions > Reportable New Information > Submission

Submission: Personnel (1), Attachments (1)

Reportable New Information | Submission Number: 2001916-02 | Created on: 29-Apr-2021 | Status: 1 - In Development

Document/Form	Type	Status
Reportable New Information	Application	Incomplete

Submit (Mandatory Form)

Step 5: Complete the Reportable New Information form and select the Complete box at the top right corner of the form.

Creighton UNIVERSITY | Full Accreditation

Close | Print | Form History | Save | Complete

Updated By: SOM Test @ 29-Apr-2021 02:11:59 PM

PAGE 1 | ALL PAGES

PAGE 1

IRB Project Number: 2001916 | Submission Number: 2001916-02
 Study Title

Step 7: Once the Reportable New Information is complete select the submit button

Record Number: 2001916
Testing 4.26.2021 (2)
 SOM Test - School of Medicine

Human Subjects Protocol
 Edit Mode

Submissions (2) | Linkages | Approved Docs (1)

Home > Submissions > Reportable New Information > Submission

Submission: Personnel (1), Attachments (1)

Reportable New Information | Submission Number: 2001916-02 | Created on: 29-Apr-2021 | Status: 1 - In Development

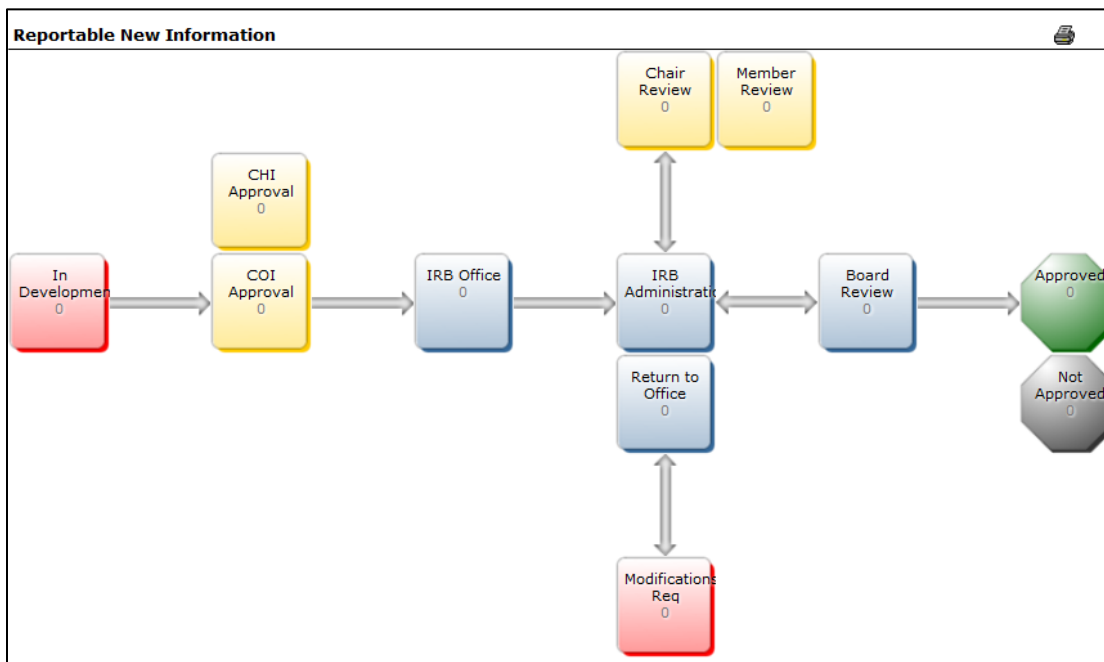
Document/Form	Type	Status
Reportable New Information	Application	Completed

Submit (Mandatory Form)

3. Reportable New Information 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

<input type="checkbox"/>	Record Type	Record Number	Record Owner / PI	Record Status	Record Title
<ul style="list-style-type: none"> Edit View Risk Create New 	col	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 Determination Date: 28-Apr-2021 Determination Date From: 28-Apr-2021 Determination Date To: 27-Apr-2022	- In Development	New Protocol Created for Password Test on 22-Apr-2021 12:00 PM
				- In Development	External Test on 22-Apr-2021 10:21 AM
<ul style="list-style-type: none"> Human Subjects Prote 				- In Development	QIP Testing 22-Apr-2021 10:19 AM

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

Record Number: 2001914
Return to Office Testing 4.23.2021
 Password Test - Creighton University

Human Subjects Protocol
 Edit Mode

Done Save

Submissions (2) | Linkages | Approved Docs

Home > Submissions > Reportable New Information > Submission

Submission
 Attachments (1)

Reportable New Information
 Submission Number: 2001914-02 | Created on: 28-Apr-2021 | Status: 3a IRB Administrators

Document/Form	Add	Type	Status	Show Current Route	(Route History)
Reportable New Information		Application	Completed		(Mandatory Form)

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.