

Creighton University – InfoEd

IRB Initial Application Submission

Last update: August 2022

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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: <u>researchcomped@creighton.edu</u>.

1. Login to InfoEd

- **Step 1:** Go to <u>https://creighton.infoedglobal.com</u>
- **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. Create a New Protocol

The Initial Application is the first submission of a protocol Record Number, all submissions for that Record Number are listed within the Master Record on the Submission tab.

Step 1: Select the Human Protocol from the left menu. **Step 2:** Select Initial Application button under Create New

<u>Creighton</u>	Creighton UKIYEKSITY VI3 Portal Welcome Password Test Logout								
Home My Profile Locate M	ly Records Locate Records Calendar Messages	Assignments	Quick Find						
Sponsored Projects Financial Tracking	Human Protocol Create New								
Human Protocol	Human Protocol Initial Application		Annual, Continuing, or Project Termination						
Conflict of Interest	Reportable New Information	Copy from existing							
SPIN Accessing Records/Reporting									
	Locate records by using filters	Show a listing of A// my records							

3. Complete the Initial Application Creighton University HS eForm

Protocol Record Number is the number which is assigned to your protocol project. All protocol aspects (submissions) will be managed within the assigned Record Number.

Step 1: Select the Initial Application to continue with the protocol application. By selecting the Initial Application, InfoEd opens the initial application to the submission level._

Record Number 2002180 New Protocol Created for Password Test on 18-May-2021 8:08 AM Password Test Done Save					Prot	nan Subjects ocol Edit Mode	
Submissions (1) Linkage	es Approved Docs						?
Home > Submissions							
Submissions					New Submission	s cannot be added t	o this Protocol.
Туре	Submission Number	Investigator Submitted On Date	Determination	Determination Date	Determination Date From	Determination Date To	
Initial Application	2002180-01	N/A	In Development	N/A	N/A	N/A	Delete

Step 2: Select the Creighton University HS eForm to open and complete the application.

Record Number 2002180 Done Save	New Protocol Created for Passwol Password Test - Creighton University	rd Test on 18-May-202	1 8:08 AM		Human Subjects Protocol Edit Mode
Submissions (1) Li	nkages Approved Docs				?
Home > Submissions	Initial Application > Submission	Submission Humb	002100.01	Created on 19 Nov 2021	Statuat in Development
Submission	Initial Application	Submission Numb	Jer: 2002 180-01	Created on: 18-May-2021	Status: In Development
Attachments (1)	Document/Form Add	Туре	Status		Submit
	Creighton University HS eForm	Application	Incomplete		(Mandatory Form)

Step 3: Complete the HS eForm by stepping through the application form.

Remember to update the Project Title with your protocol title.

Office of the Provost Research Compliance

The Initial Application can be saved, close and re-entered using the Locate My Records or Locate Records tabs.



Step 4: Personnel, add all personnel associated with study

- **4.1:** Select one person as the principal investigator.
- 4.2: Students must add a mentor.



4:3: Projects conducted at a CHI facility must add Molly Davis, CHI Research Director as personnel.

4:4: SOM projects should include the SOM Research Department, add Sandra Byers as personnel.

4:5: External collaborators should be added to the External Investigators/Personnel section.

PERSONNEL

Add all Creighton personnel associated with this study. Use the yellow plus sign to create a new entry.

You must select one person as the principal investigator for this study by selecting the checkbox under 'Principal Investigator' then list the PI as an investigator in the 'role' drop–down. Any additional investigators should also be listed as such in the role drop–down.

IF THE PRINCIPAL INVESTIGATOR IS A STUDENT, YOU MUST LIST YOUR ADVISOR AS PERSONNEL WITH A ROLE DESIGNATION OF MENTOR.

Creighton learners affiliated with the School of Medicine (SOM): You must include the SOM Research Department by adding Sandra Byers, SOM Research Director, as personnel.

For projects conducted at a CHI facility: Your project requires Molly Davis, CHI Research Director, to be listed as personnel. Your project will be routed to the CHI Research Director for review and approval.

Start and End dates can be entered as mm/dd/yyyy, mm/dd/yy, mmddyy, mmddyyy, mm–dd–yyyy, mm–dd–yy 🖓

▼ 🗊			
Personnel			
Name Test, Password			
Principal Investigator	Start Date	End Date	* Role
Certifications Certification Begin TEST Certification17-Aug-20	End)21		
* Employer/Affiliation			
* Status			

EXTERNAL INVESTIGATORS/PERSONNEL

Outside Personnel Information - this section is only for personnel unaffiliated with Creighton University that may be collaborating on your study.

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4. Submit and Routing of Initial Application

Step 1: Select the Complete check box.

- Step 2: Select the Submit button.
- Step 3: Select the Submit button within routing.
- **Step 4:** InfoEd will send notifications to all listed personnel.

\circ \cdot 1	Class	Drint	Form History	Savo	Submit	Campiata 🗖	
Creight	Ciuse	FILL	Form History	Save	Submit		
UNIVED C	L T V						
UNIVERS	1 1 1 Personal Angestion Public						
					Update	d By: Password Tes	it @ 15-Apr-2021 12:49:55 PM
GENERAL IN STRUCTION S							
PERSONNEL							
EXTERNAL	GENERAL INSTRUCTIONS						
INVESTIGATORS/PERSONNEL						-	
PROJECT SITES	Completion of this form is the first step in seek	ing human suble	ect research an	proval at Creighton Ur	niversity. This		
FUNDING	form is to be completed by the Principal Invest	igator or his/her	designee. All r	esearch personnel mu	st complete		
CERTIFICATE OF	required training, acknowledgements and final	ncial disclosule	per creigniton t	oniversity <u>policy</u> .			
CONFIDENTIALITY	The Creighton University IRB will process your determination.	r application, coc	ordinate review	and notify you of their			
CONFLICT OF INTEREST	Research activity may not begin until you rece	ive notification o	f APPROVAL f	rom the IRB Office Sul	bmissions to		
RESOURCES	the IRB Office that are incomplete will be return	ned and not forw	varded to the R	eview Committee for a	ction.		
RESEARCH AND REVIEW							
TYPE	Protocol Number	Sub	mission Numbe	er			
ADDITIONAL UPLOADS	2001905	200	1905-01				
ALL PAGES	Testing Protocol for Instructions		7				
]							
	★ Was this protocol originally submitted and app Yes Mo	roved through IF	RBNet?				

5. Initial Application Submission Workflow

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

InfoEd Submission Workflow Chart





6. Workflow Status

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

)rag a	rag a column header and drop it here to group by that column							
		Record Type	Record Number	Record Owner / PI	Record Status	Record Title		
4	≡I	Edit 🕨	col 2001914	Test, Password	7 - Approved	Return to Office Testing 4.23.2021		
	Risk	View 🕨			Minimal Risk	Print View		
		Create New 🕨						
•	≡I	Info 🕨	Protocol St	atus: 7 - Approved	- In Development	New Protocol Created for Password Test on 22-Apr-2021 12:00 PM		
		Delete	Determination D	Date: 28-Apr-2021				
•	Ξ.	Bookmark Record	Determination Date F	rom: 28-Apr-2021	- In Development	External Test on 22-Apr-2021 10:21 AM		
×	≣	Human Subjects Proto	Determination Date	e To: 27-Apr-2022	- 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 2002180 Done Save	New Protocol Created for Password Test on 18-May-2021 8:08 AM Password Test - Creighton University				Human Subjects Protocol Edit Mode
Submissions (1) Linkage	es Approved Docs				?
Home > Submissions > Init	ial Application > Submission				
Submission	Initial Application	Submission Number: 2	002180-01	Created on: 18-May-2021	Status: In Development
Attachments (1)	Document/Form Add Creighton University HS eForm	Type Application	Status Incomplete		Submit (Manaatory Form)

Possible statuses and their respective descriptions are listed below:

Status:	Description:			
	The submission is incomplete and has not been submitted to the			
In Development	IRB Office.			
	The submission has been submitted and is waiting for Co-			
Routing	Investigator approval.			
IRB Office	The submission has been received by the IRB Office.			
	The submission has been assigned to an IRB Administrator for			
IRB Administrator	review.			



Modification Required	A response is required by the PI.			
Reassign	The Submission has been reassigned within the IRB Office.			
Member or Chair	The submission is with a reviewer and a determination has not			
Review	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.			