

# Cayuse IRB

# **Policy and Procedure Manual**

### **Table of Contents**

Cayuse IRB Policy and Procedure Manual	1
Submitting a New IRB Protocol	2
Purpose of the Policy	2
Procedures	2
Modification of an Existing Cayuse IRB Protocol	6
Purpose of the Policy	6
Procedures	6
Renewal/Continuing Review of an Existing Cayuse IRB Protocol	10
Purpose of the Policy	10
Procedures	10
Withdrawal of an Unsubmitted Cayuse IRB Protocol	13
Purpose of the Policy	13
Procedures	13
Closure of a Completed Cayuse IRB Protocol	17
Purpose of the Policy	17
Procedures	17
Reporting an Incident in Cayuse IRB	20
Purpose of the Policy	20
Procedures	20

# **Submitting a New IRB Protocol**

Policy Number: IRB101

Policy Date: 12/21/2017

### **Purpose of the Policy**

This policy provides guidelines for the submission of new IRB protocols in Cayuse IRB. The objective of this policy is to ensure users have the proper CITI Human Subject Protections training before being added as an investigator to a study and to ensure proper and consistent setup of new IRB protocols.

### Procedures

New IRB protocols may be entered by investigator's at any time. A pre-review will be done to determine if any items are missing. You will be made aware of any additional documentation or requirements within 10 business days of receipt by the ORSP. Typically, protocols that are classified as "Exempt" or "Expedited" will also have a determination made within the 10 business days. Each time revisions are requested, it may take up to 10 business days from receipt by the IRB staff before a determination can be made.

If it is determined that your study requires Full Convened Board Review, your study will be placed on the agenda for the next monthly meeting of the Board. To ensure your Full Board Protocol is reviewed promptly, it must be submitted by the <u>first of the month to be included on that month's agenda</u>.

NOTE: No protocols will be accepted if any researchers have not completed the required CITI training. <u>The protocol will be denied and returned without review</u>.

Log into the Cayuse Research Suite at the link: <u>https://uww.cayuse424.com</u>.

- Choose [Cayuse IRB]
- On the top left of the "Dashboard" page, your current role will be indicated. If you have more than one role, please select [Researcher] from the dropdown menu to beginning entering your study.

Cause	≡ Menu	Dashboard					🎫 🌲 🆀 Carol Katch
IRB	My Role: Analyst	(					+ New Study
Dashboard	Admin						
	Analyst			0			10
Studies	Researcher	1		Awaiting		0	0
E Cobalissians	Reviewer	In-Draft	m	Authorization		Pre-Review	Under Review
<ul> <li>Submissions</li> </ul>							

(Screen Shot 3)

- Choose the [+ New Study] tab at the top of the screen.
- Enter {*The Title of Your Study*}.
- Choose [
- Choose [+ New Submission]
- Choose [Initial]

On the Submission Details Page,

• Choose [Edit]

Follow the step-by-step instructions in the Cayuse IRB Initial Application. Most sections of the application must be answered.

Each section that needs to be completed will be listed in the pane at the left side of your screen. You can move between the sections by clicking on the section in the pane on the left side of your screen, or by using the forward/backward arrow keys on the top right side of your screen (see Screen Shot 4).

≡ Menu	III 🔎 🛓 Diane Directory of
STUDY REVIEW OF IRB Protocol Submission Procedure - Initial	
Sectors I.GENERALINFOR. 2. VULNERABLE RESEAR 1.1.6 Anticipated Start Date 06/08/2018	
(Screen Shot 4)	

The section is completed when it has a green checkmark next to it in this pane (see Screen Shot 5).

Cauuse	≡ Menu
IRB IRB	STUDY IRB NUMBER: IRB-FY2017-2018-14 This is an example of how to enter and IRB protocol - Initial
Dashboard	Sections 3 DESEADED DESIGNL& DECEDUDES
Studies	2. VULNERABLE R E
Submissions	* 3.a     Hypothesis(es)       3. RESEARCH DESIGN & P     (State the specific hypothesis(es) to be tested.)
✓ Tasks	

(Screen Shot 5)

- Choose [Complete Submission]
- Choose [Confirm] or you may [Cancel] and make changes.

Once you have "confirmed' your study, you will be taken to the Submission details page, and the status has now changed to "awaiting certification'. An email will be sent to the P.I., Co-Investigators and Student' Investigators for certification. Each investigator must login to Cayuse IRB and certify that they agree to the Investigator's Certification Statement.

There is a link to Cayuse IRB in the email however, you may also;

Log into the Cayuse Research Suite at the link: <u>https://uww.cayuse424.com</u>.

- Choose [Cayuse IRB]
- On the of the Dashboard page, Choose [Awaiting Authorization]
- Choose [The number of the protocol you wish to Certify]
- On the right side of the screen, Choose [Certify].
  - You may also choose to [Return] the protocol to the investigators to re-certify the protocol if changes were made by an investigator.
- Read Investigator's certification statement and Choose [Confirm].
  - The protocol will not proceed for the Administrative Review process until all investigators have certified their agreement.

Once all investigators have completed the certification process, they will receive an email notification that the study has been certified and sent to the IRB for review.

The Study is sent to an IRB Administrator (Analyst) for pre-view. You will be notified if any information is still required. If no additional information is required, the IRB Administrator will make a determination on the classification of the study. If the study is classified as "Exempt" or "Expedited" you will receive an email notice within approximately 10 working days. If the study is classified as "Full Board Review" you will be notified of the date and time of the IRB Meeting where it will be reviewed. Your attendance is encouraged, but not required at the meeting of the fully convened board.

# **Modification of an Existing Cayuse IRB Protocol**

Policy Number: IRB102

Policy Date: 12/21/2017

### Purpose of the Policy

This policy provides guidelines for the modification of existing IRB protocols in Cayuse IRB. The objective of this policy is to ensure proper and consistent modification of IRB protocols.

### **Procedures**

After a study has been approved by the UWW IRB, the only way to make changes is through a modification. A pre-review will be done to determine if any items are missing or if the modification you have requested changes the category of the protocol (e.g.: from expedited to Full Board). You will be made aware of any additional documentation or requirements within 10 business days of receipt by the ORSP. Typically, protocols that are classified as "Exempt" or "Expedited" will also have a determination made within the 10 business days. Each time revisions are requested, it may take up to 10 business days from receipt by the IRB staff before a determination can be made.

If it is determined that your study requires Full Convened Board Review, your study will be placed on the agenda for the next monthly meeting of the Board.

NOTE: No protocol modification will be accepted if any added researchers have not completed the required CITI training. <u>The protocol will be denied and returned without review</u>.

Log into the Cayuse Research Suite at the link: <u>https://uww.cayuse424.com</u>.

• Choose [Cayuse IRB]

On the Dashboard Page, if you have more than one role in Cayuse IRB, make sure your role is set at "Researcher".

Under my studies,

• Choose [The study number you wish to modify]



(Screen Shot 6)

- In the upper right corner, Choose [+ New Submission]
- From the drop down options, Choose [Modify]

≡ Menu		Study Details		A Frances Faculty
Studies Study Details				+ New Submission
	Study Details		Submissions	Recent
Approved				medera
IRB-FY2017-2018-26 My F	irst Study			Closure
D PDF © Orient				
Approval Date:	Expiration Date:	Organization:	Active Submissions:	
Sponsors: Americorp	Closed Date: N/A	Current Policy Pre-2018 Rule	1375	

(Screen Shot 7)

- On the left side of the screen, Choose [Edit]
- Complete the IRB Protocol Modification summary
- On the left section pane, select the section(s) you would like to modify.
- On the top ribbon, Choose [Save]
- On the left section pane, Choose [Complete Submission]
- Choose [Confirm], or you may cancel and make changes

• Choose [Proceed]

You may also Choose [Compare] at any time to review your changes. To leave the 'compare' screen, Choose [View Submission] from the upper left corner of the screen.

Just as when you submitted your original protocol, the section you chose to modify is completed when it has a green checkmark next to it in the pane on the left of the screen.

• Choose [Complete Submission].

Refer to Screen Shot 7 for placement of all of the above mentioned links.

≡ Menu	🦉 🛓 Frances Facult
study IRB NUMBER: IRB-FY2017- The Thursday	2018-27 y Study - Modification
Sections	1. IRB PROTOCOL MODIFICATION
Personnel and Proto 💙	Type of Modifcation
Funding	<ul> <li>(Select from the options below, the type of protocol modification that is being submitted. NOTE: Make sure to attach copies of modified or added documents for IRB approval.)</li> <li>Voluntary Modification         (If you wish to change any of the details of the study after it has been approved, you must submit a modification. These changes must be reviewed and approved by the IRB or its authorized representative before they are implemented. If you are also planning to renew your protocol, submit your modification and then submit the "IRB Protocol Renewal/Continuing Review" form.)     </li> <li>Required Modification         (If you have been required by the IRB to change the details of a study after it has been approved, you must submit the IRB Required Modification form. The changes you submit must be reviewed and approved by the IRB or it's authorized representative before they are implemented.)     </li> <li>General Information</li> </ul>
	(Briefly explain any changes, then you may go into the original protocol and make the specific changes to that section.)  C Change in Study Investigator(s) Briefly explain the change.  Adding a new Co-Investigator, Mr. Bazooka Joel

(Screen Shot 8)

An email will be sent to the P.I., Co-Investigators and Student' Investigators for certification. Each investigator must login to Cayuse IRB and certify that they agree to the Investigator's Certification Statement.

There is a link to Cayuse IRB in the email however, you may also;

Log into the Cayuse Research Suite at the link: <u>https://uww.cayuse424.com</u>.

- Choose [Cayuse IRB]
- On the of the "Dashboard" page, Choose [Awaiting Authorization]
- Choose [The number of the protocol you wish to Certify]
- On the right side of the screen, Choose [Certify].

- You may also choose to [Return] the protocol to the investigators to re-certify the protocol if changes were made by an investigator.
- Read Investigator's certification statement and Choose [Confirm].
  - The protocol will not proceed for the Administrative Review process until all investigators have certified their agreement.

Once all investigators have completed the certification process, they will receive an email notification that the study modification has been certified and sent to the IRB for review.

The Study is sent to an IRB Administrator (Analyst) for pre-view. You will be notified if any information is still required. If no additional information is required, the IRB Administrator will determine if the modification has changed the classification of the study. If the study is reclassified as "Exempt" or "Expedited" you will receive an email notice of status within approximately 10 working days. If the study was originally classified, or has been changed to a classification of "Full Board Review" you will be notified of the date and time of the IRB Meeting where it will be reviewed. Your attendance is encouraged, but not required at the meeting of the fully convened board.

# Renewal/Continuing Review of an Existing Cayuse IRB Protocol

Policy Number: IRB103

Policy Date: 12/21/2017

### **Purpose of the Policy**

This policy provides guidelines for the Renewal of existing IRB protocols in Cayuse IRB. The objective of this policy is to ensure proper and consistent renewal/continuing review of IRB protocols.

### **Procedures**

You will be sent an email at 90, 60, and 30 days before an existing IRB protocol is up for renewal/continuing review. If you intend to continue your research, you must submit and receive an approval to continue a study BEFORE it has expired. If the study expires before an approval has been received, you must CEASE all study activity (unless doing so will adversely affect the study participants), until approval has been received. Studies that have not been submitted within 10 days of expiration will be administratively closed by ORSP. You will be required to submit and receive approval of a new study if you wish to continue your research.

NOTE: No protocol renewals/continuing reviews will be accepted if any added researchers have not completed the required CITI training. The protocol will be returned without review.

Log into the Cayuse Research Suite at the link: <u>https://uww.cayuse424.com</u>.

• Choose [Cayuse IRB]

On the Dashboard Page, if you have more than one role in Cayuse IRB, make sure your role is set at "Researcher".

Under my studies,

• Choose [The study number you wish to renew].

- In the upper right corner, Choose [+ New Submission].
- From the drop down options, Choose [Renew].

E Menu		ш	焰 🛔 Diane Director-IR		
Studies Study Details					+ New Submission
	Study Details		Submissions		Renewal
Approved					Closure
IRB-FY2017-2018-45	This is a test of how to modify existing protocols in Cayuse IRB				
PDF The second					
Approval Date:	Expiration Date:	Organization:	Active Submissions:		
12-22-2017	N/A	Users loaded with unmatched Organization affiliation. Current Policy	Modification		
Sponsors:	Closed Date:				

(Screen Shot 9)

• On the left side of the screen, Choose [Edit].

≣ Menu		Submission Details						¥0	Diane Director-IRE
Studies Study Details Subm	ission Details								
1 In-Draft Submission is with resea	rchers	2 Awaiting Authorization Submission is awaiting certification or appr-	enter 👌	3 Pre-Review		A Under	r-Review Ission is with n	evlement	
Unsubmitted									
Renewal IRB PH0017-2018-45 · T	his is a test of how to modify exist	ing protocols in Cayuse IRB							
🖋 Edit 🛛 PDF 👻	1 Delete								
PI:	Current Analyst:	Decision:	Policy:		Required Tasks:				
Review Type: N/A	Review Board: N/A	Meeting Date: N/A	Pre-2010	Rule	<u>Complete Submission</u>				
Approvals Task His	tory								

(Screen Shot 10)

- Complete the IRB Protocol Renewal/Continuing Review summary
- On the top ribbon, Choose [Save]
- On the left section pane, Choose [Complete Submission]
- Choose [Confirm], or you may cancel and make changes
- Choose [Proceed]

study IRB NUMBER: IRB-FY This is a te	22017-2018-45 est of how to modify existing protocols in Cayuse IRB - Renewal	CREATE PDF	
Sections <			
Renewal/Continuin 🖌	Renewal/Continuing Review		
$\sim$	Renewal Template - When a study is nearing its expiration date, you must submit a renewal request in order to continue with the research, continue with the study.	The renewal will need	d to be approved before you can
Politing end to PI for certification?			
COMPLETE SUBMISSION	Briefly describe the progress on the completion of the study		
$\smile$	We are still collecting data and recruiting new participants.		
	Have there been any unexpected reactions, findings, or complications in the study since the last approval?		
	There have been no unexpected reactions or complications. We do not anticipate any new findings until data analysis begins.		
	Approximately how many more participants will be required to complete the study?		
	We plan to recruit an additional 50 participants. These additional numbers are still within the participant numbers we anticipated in our of	riginal protocol subm	Inoiceir

(Screen Shot 11)

- Read Investigator's certification statement and Choose [Confirm].
  - The protocol will not proceed for the Administrative Review process until all investigators have certified their agreement.

Once all investigators have completed the certification process, they will receive an email notification that the study modification has been certified and sent to the IRB for review.

The Study is sent to an IRB Administrator (Analyst) for pre-view. You will be notified if any information is still required. If the study was originally classified as "Full Board Review" you will be notified of the date and time of the IRB Meeting where it will be reviewed for renewal. Your attendance is encouraged, but not required at the meeting of the fully convened board.

# Withdrawal of an Unsubmitted Cayuse IRB Protocol

Policy Number: IRB104

Policy Date: 12/21/2017

### **Purpose of the Policy**

This policy provides instructions for the Withdrawal of an un-submitted IRB protocol in Cayuse IRB. The objective of this policy is to ensure proper withdrawal of IRB protocols that are no longer being considered for submission.

### Procedures

Only IRB protocols that have NOT been submitted to the IRB for review can be withdrawn. The researcher that has begun entry of the IRB submission that is being considered for withdrawal is the <u>only person</u> who has access to it, however ALL researchers that have been listed on the protocol must certify it's withdrawal – this will happen as part of the withdrawal procedure. No reminders or notifications will be sent regarding protocols that have been left un-submitted in the researchers Dashboard.

Log into the Cayuse Research Suite at the link: https://uww.cayuse424.com.

• Choose [Cayuse IRB]

On the Dashboard Page, if you have more than one role in Cayuse IRB, make sure your role is set at "Researcher".

Under the Studies tab,

• Choose [The study number you wish to withdraw].

My Role: Researcher	•						+ New Study
ľ	<b>2</b> In-Draft	Î	<b>1</b> Awaiting Authorization	ß	<b>0</b> Pre-Review		<b>O</b> Under Review
My Studies			My Tasks		Submis	sions by Type	
IRB-FY2017-2018-44	Testing		IRB-FY2017-2018-44	Certify Submission	Initial		3
IRB-FY2017-2018-45	This is a test of how to modify	existing	IRB-FY2017-2018-45	Complete Submission	Withdrav	/al	0
	protocols in Cayuse IRB		IRB-FY2017-2018-33	Complete Submission	Modificat	ion	2
IRB-FY2017-2018-33	This is a test of the Cayuse IRB submission process	protocol			Renewal		0
					Incident		0
					Closure		0
					Legacy		0
	View All		,	/iew All			

(Screen Shot 12)

- In the upper right corner, Choose [+ New Submission]
- From the drop down options, Choose [Withdraw]

	≡ Menu		Study Details					Diane Director-IRB
	Studies / Study Details					(		+ New Submission
		Study Details			Submissions			Withdrawal
	Ursubmitted IRB-FY2017-201	8-33 This is a test of the Cayuse IRB protocol su	ubmission process					
	Approval Date:	Expiration Date:	Organization:		Active Submissions:			
	N/A	N/A	N/A		• Initial			
	Sponsors: N/A	Closed Date: N/A	Current Policy Pre-2018 Rule					
rds	Key Contacts Team Member	Attachments Role		Number	Email			
	Diane Director-IRB	Principal Investigator		503-297-9043	rsp-compliance@uww.e	edu		

(Screen Shot 13)

You will receive a warning screen notifying you that if you withdraw the submission, you must reneter the protocol.

18-33 This is a te Withdrawal					×
	By creating this withdra Explicit of the study from revie NA will have to restart you Closed Dyou would like to proce NA	awal submission, you w. If you still wish to r application from th ed? <sup>ent Policy</sup> Pre-2018 Rule	will be withdra submit this sub e beginning. Are	wing the mission, you e you sure	
			Cancel	Withdraw	

(Screen Shot 14)

- Choose [Withdraw] or you may cancel.
- Choose [Complete Submission]

You will be taken to the 'Withdrawal page', where you will need to submit a reason for withdrawing the submission.

≡ Menu		III 🍂 🤐	🛔 Diane D	irector-IF
STUDY Index:	CREATE PDF	COMPARE		< >
Sections <				
Withdrawal				
Withdrawal - A withdrawal submission notifies the Compliance Office that you no longer wish to submi Withdrawn studies are marked as finalized and can no longer be modified. You may create a withdrawal created, until it has been approved. If the initial submission has been approved, you must create a closur wish to conduct the research. • What is your reason for withdrawing this submission?	t your initial submission submission at any poin e submission in order t	n and want to withdrav t once an initial submi to close the study if you	w the study. ssion has been u no longer	
B I <u>U</u> -S i≡ i≡ co La				

(Screen Shot 15)

- Choose [Complete Submission] from the left pane.
- Choose [Confirm] or you may cancel.
- Choose [Certify]

- Read Investigator's certification statement and Choose [Confirm].
- The protocol will not proceed for the Administrative Review process until all investigators have certified their agreement.

Once all investigators have completed the certification process, they will receive an email notification that the study withdrawal has been completed.

### **Closure of a Completed Cayuse IRB Protocol**

Policy Number: IRB105

Policy Date: 12/21/2017

### **Purpose of the Policy**

This policy provides instructions for the Closure of a competed IRB protocol in Cayuse IRB. The objective of this policy is to ensure proper and required closure documentation of IRB protocols that are no longer in progress.

### **Procedures**

You will be sent an email at 90, 60, and 30 days before an existing IRB protocol is up for renewal/continuing review. If you do not intend to continue your research, you must submit a closure report to inform the IRB of the status and any unanticipated results and/or findings from the completed study. Closure reports are a required as part of the IRB process. <u>Failure to provide a closure report may have adverse effects or may create delays in the approval of new studies.</u>

Log into the Cayuse Research Suite at the link: https://uww.cayuse424.com.

• Choose [Cayuse IRB]

On the Dashboard Page, if you have more than one role in Cayuse IRB, make sure your role is set at "Researcher".

On your Cayuse IRB Dashboard, or from the Studies tab,

• Choose [The study number you wish to close].

- In the upper right corner, Choose [+ New Submission]
- From the drop down options, Choose [Closure]

E Menu		Study Details		III 🗚 🚨 Diane Director-IRI
Studies / Study Details				+ New Submission
	Study Details		Submissions	Incident
Approved				Closure
IRB-FY2017-201	8-45 This is a test of how to modify existing protocols in (	Cayuse IRB		
D PDF				
Approval Date:	Expiration Date:	Organization:	Active Submissions:	
12-22-2017 Sponsors:	N/A Closed Date:	Users loaded with unmatched Organization affiliation. Current Policy	<u>Modification</u> Renewal	
N/A	N/A	Pre-2018 Rule		
Key Contacts	Attachments			
Team Member	Role	Number	Email	
Diane Director-IRB	Principal Investigator	503-297-9043	rsp-compliance@uww.edu	
Diane Director-IRB	Primary Contact	503-297-9043	rsp-compliance@uww.edu	

(Screen Shot 16)

- On the left side of the screen, Choose [Edit].
- On the Closure screen, specify why the study is being closed.
- Give a brief summary of the research results.
- You may attach a Final Report Summary.
- You may attach any additional documents.

Refer to Screen Shot 17 for a preview of the Protocol Closure form.

- CAK - Closure	CREATE PDF			
1. IRB PROPOSAL CLOSURE	ne. Closed studies are marked as finalized and can no longer he mo	difierd		
Consolition Cooler Consolition Consolitio				
Additional Attachments for IRB protocol records (Briefly describe and ottach any additional information you wish to keep with this protocol record.)				
	Additional Attachments for IRB protocol records  Item and attach any additional information you wish to keep with this protocol record.	CREATE POF CACK - Closure CREATE POF CREATE CREATE POF CREATE CREATE POF CREATE CREATE POF CREATE CREATE CREATE CREATE POF CREATE CREATE CREATE CREATE CREATE CREATE	CACK - Closure  Compare  Compare	CACK - Closure CACK

(Screen Shot 17)

- In the upper right corner, Choose [Save].
- In the left hand pane, Choose [Complete Submission].
- Choose [Confirm] or you may cancel and make changes.
- On the right side of the screen, Choose [Certify]
- Choose, [Confirm].
- On the right side of the screen, Choose [Proceed].

You will receive an email notification that the protocol has been submitted to the IRB Administrator for closure. Once it has been closed, you will also receive a notification indicating the process is complete.

# **Reporting an Incident in Cayuse IRB**

Policy Number: IRB106

Policy Date: 12/21/2017

### **Purpose of the Policy**

This policy provides instructions for reporting incidents, adverse effects, and unanticipated problems involving risks to subjects or others during a research study. Federal Guidelines require adverse effects must be reported and reviewed by the institutional IRB for review and determination of the steps to be taken.

### Procedures

### Serious Incidents:

If a serious incident such as a life-threatening illness, injury, or death occurs during the course of the study, the study investigators must immediately seek the appropriate medical treatment for the participant(s) and cease all study activities, unless stopping activities will be life-threatening to participants. The incident must be reported to the UW-Whitewater IRB via the Cayuse IRB Incident report within <u>three (3) days.</u> The IRB will assign an investigator to the incident who may contact the P.I. for additional information. A determination will be made on the proper procedures for next steps. Federal Guidelines require that serious incidents may need to be reported to the OHRP (Office for Human Research Protections) and any research sponsors. Research activities may not resume until notified by the UW-Whitewater IRB and may be terminated or suspended indefinitely as a result of the incident.

### Non-Serious Incidents:

In the event of a non-serious incident, the study may continue but must be reported to the UW-Whitewater IRB within <u>seven (7) days</u> via the Cayuse IRB incident report. The IRB Administrator and IRB Chair will review the incident report and depending upon the incident and severity, determine if the entire IRB needs to be consulted and if an investigator needs to be assigned to the incident for further review. They will also determine if the study needs to be suspended until the investigation has been completed. No studies will be suspended if suspension will create further complications for the participants. The investigators will be instructed on how to proceed and given deadlines as appropriate for changes and corrections.

Page 19 of 21

Last update: 12/18/2017

Federal Guidelines for reporting the incident will be reviewed by the IRB and completed as appropriate.

Log into the Cayuse Research Suite at the link: https://uww.cayuse424.com.

• Choose [Cayuse IRB]

On the Dashboard Page, if you have more than one role in Cayuse IRB, make sure your role is set at "Researcher".

On your Cayuse IRB Dashboard, or from the Studies tab,

- Choose [The study number for which you are reporting the incident].
- In the upper right corner, Choose [+ New Submission]
- From the drop down options, Choose [Incident]

≡ Menu		Study Details		 40	Diane Director-IRB
Studies Study Details				1	+ New Submission
	Study Details		Submissions	1	Incident
Approved IRB-FY2017-2018-45	This is a test of how to modify existing protocols in Cayuse IRB				
D PDF C Lunch					
Approval Date: 12-22-2017 Sponsors: N/A	Expiration Date: N/A Closed Date: N/A	Organization: Users loaded with unmatched Organization affiliation. Current Pollcy Pre-2018 Rule	Active Submissions: Modification Rensonal Incident Slosure Incident		

(Screen Shot 18)

• Under the study title, Choose [Edit]

Complete the Incident form to the best of your ability. Some of the fields are required.

- Once completed, Choose [Affirmation of Investigator] from the left side pane.
- Choose, [Your name] from the drop down selection.
- Choose, [Save] on the upper right side of your screen.

≡ Menu							🏴 🛔 Caro
study IRB NUMBER: IRB-FY Testing - Ir	2017-2018-44 1 <b>cident</b>					COMPARE	SAVE
ections <							
1. ADMINISTRATIVE DATA	2. AFFIRMATIO	N OF INVESTIGATOR					
2. AFFIRMATION O 🗸	As the Principal Investigator	r I am confirming that the information I I	have provided in this report is accu	rate and true.			
	Principal Investigator						
	Name	Organization	Address 800 West Main Street	Phone	Email		
		I A A THE A READ READ WITH A	OUD WEST MAIL SUPEL.				

(Screen Shot 19)

- Choose, [Complete Submission]
- On the Submissions page, Choose [Certify].
- Choose, [Confirm].

The P.I. is the only research team member who is required to certify the submission of an incident report.

Your submission will be reviewed by the IRB Administrator and you will be contacted with any further instructions.