



# IRB eProtocol

## Amendment Submissions

eProtocol





## Amendment Session Outline

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  - Amendment Traditional Method vs eProtocol
  - Amendment Types
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  - One Amendment Form Type
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  - Submitting an Amendment
- **Questions**





## Amendments to IRB applications

(Overview)

The WSU IRB must review all amendments to an IRB Application.

All revisions must be approved by the IRB before implementation *(except for participant safety)*.

The criteria for approval of all revisions made to an IRB approved research protocol are found at 45 CFR 46.111, 38 CFR 16.111, and 21 CFR 56.111.





# Amendments to IRB applications

## (Overview)

### Revisions range from minor corrections:

- correct a simple typographical error in the consent form
- Addition of a study site
- Participant materials

### To significant changes:

- Study design changes
- Addition of vulnerable groups
- Addition of risk

See tool which provides examples of expedited vs Full Board Changes





## Amendments to IRB applications

### Traditional method vs eProtocol

The traditional process for submitting an amendment to the WSU IRB is to determine which type of amendment you will need to submit and then select the appropriate amendment form.





## Amendments to IRB applications

Current WSU IRB Amendment Form Types:

- Change in PI
- Key Personnel
- Expedited Amendment
- Full Board Amendment
- Coordinating Center Form

**Possibly 5 variations of a WSU IRB Amendment Submission**





# Submitting an eProtocol Amendment (eProtocol Submission Requirement)

The protocol must have been previously reviewed  
and approved in eProtocol.

If not the amendment must be submitted via the  
traditional IRB amendment submission process.







# Submitting an eProtocol Amendment (one Amendment Form Type)

eProtocol consists of one Amendment Form

- No change in PI Form
- No Key Personnel Amendment Form
- No Full Board Amendment Form
- No Expedited Amendment Form







## Submitting an eProtocol Amendment

**An amendment can only be created for an approved protocol.**

Only one amendment can be submitted at a time.  
This is a mechanism by which eProtocol maintains protocol versioning.

The entire submission is considered the Protocol.

Therefore for eProtocol we encourage  
**bundling amendments.**





## Submitting an eProtocol Amendment (Bundling an Amendment)

You can combine expedited revisions, key personnel changes, or full board revisions to one amendment.

*Note: if there are elements to the amendment that consist of full board revisions the amendment will be considered a full board amendment.*



# System Requirements Reminder

- WSU Access ID & Password is required for log in

If you do not have an access ID & Password please sign up for one today

- Supported by Firefox & Safari web browsers



- CITI Training by all key personnel



**CITI Training must remain up to date for all key personnel  
The Basic Refresher course must be completed before submission**



# Submitting an eProtocol Amendment

## Log on to eProtocol

Wayne State University

KEY SOLUTIONS  
Comprehensive IT for Research

version 2.5.63.5

**ePROTOCOL**

Welcome to the Wayne State University eProtocol system - a powerful and efficient way to submit, track and approve research protocols and Conflict of Interest disclosures.  
Browser Requirements: **This site requires Firefox 12 and higher or Apple Safari.** Using older browsers, non-compatible browsers or disabling browser features, such as Javascript, cookies and SSL, will reduce site functionality.

**Log in Here**

Username   
Password



<https://ksprodweb.ovpr.wayne.edu/>

# Starting an Amendment

Scroll down to the **Approved Protocols** section on your IRB Dashboard

Approved Protocols						
Protocol ID	Principal Investigator	Approval Date	Last Approval Date	Expiration Date	Review Decision	Form Type
<a href="#">IRB-17-10-0349</a>	Reese	11/14/2017	11/14/2017	N/A	Full Review	NEW
<a href="#">IRB-17-11-0385</a>		11/14/2017	11/14/2017	11/13/2018	Full Review	NEW
<a href="#">IRB-17-10-0341</a>	Bu			10/24/2018	Full Review	NEW

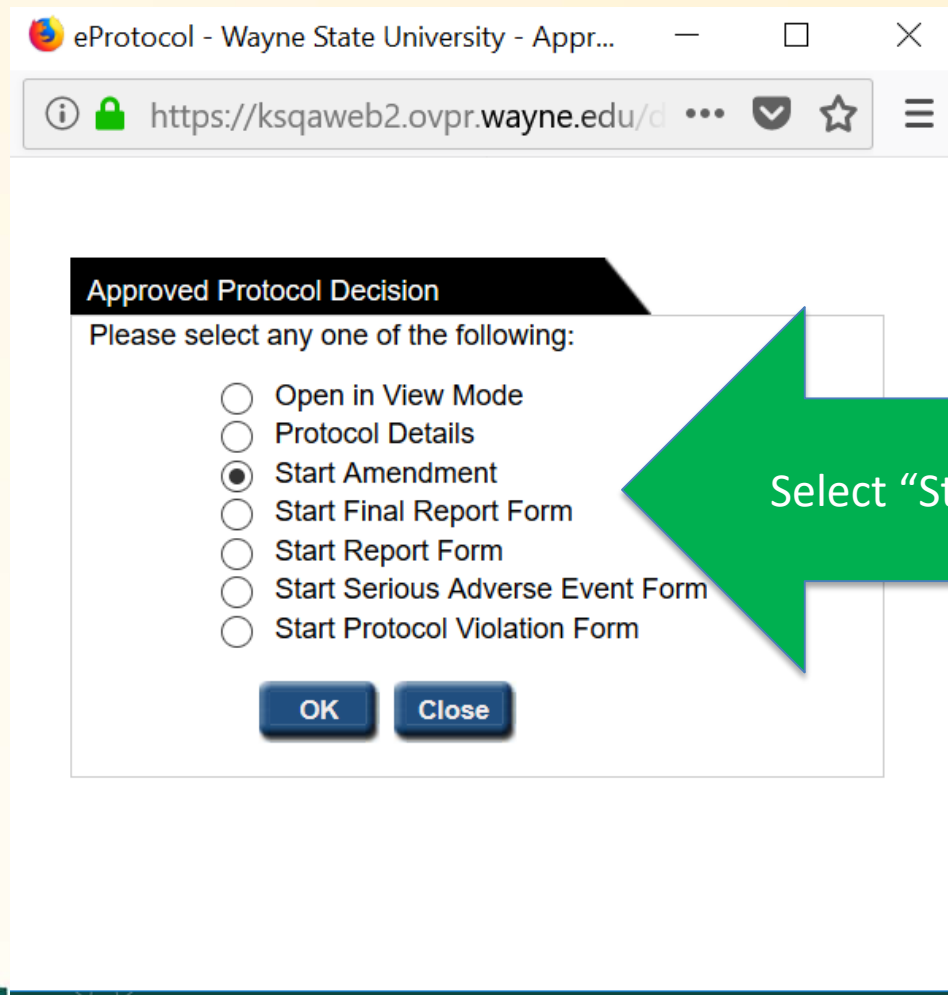
Click on the Protocol's ID Number

Key Personnel that have edit capability for a submission can start and submit an amendment.

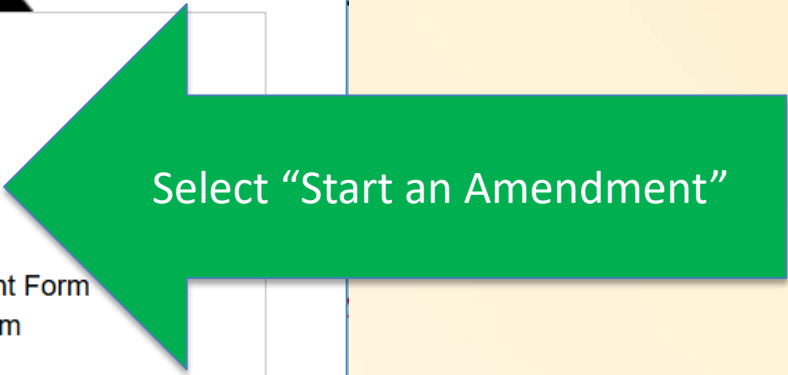
- Those listed under **Personnel Information** as: PI, Co-Investigator, Study Coordinator, Administrative Contact have edit capability.
- Key personnel listed as "Other Personnel" **do not** have edit capability



# Starting an Amendment



The screenshot shows a web browser window titled "eProtocol - Wayne State University - Appr...". The address bar displays "https://ksqaweb2.ovpr.wayne.edu/d...". The main content area features a dialog box with a black header "Approved Protocol Decision". Below the header, the text "Please select any one of the following:" is followed by a list of radio button options: "Open in View Mode", "Protocol Details", "Start Amendment", "Start Final Report Form", "Start Report Form", "Start Serious Adverse Event Form", and "Start Protocol Violation Form". The "Start Amendment" option is selected. At the bottom of the dialog box are two buttons: "OK" and "Close".



# Amendment Form Step by Step

Complete all applicable sections of the Amendment Form or select  
“N/A”

## eProtocol Amendment Form's Sections:

- **Key Personnel Modifications**
- **Protocol Form Modifications**
- **Protocol Document/Study Design Modifications**
- **Consent/Assents/Scripts/Information Sheets**
- **Consent Waiver or Alteration of Consent**
- **Investigator Brochure/Package Insert**
- **Other**
  - Study on hold notification
  - Study off hold notification
  - Study closed to accrual
  - other





# Amendment Form Step by Step

## COVID-19 Amendments:

- Complete the Question regarding modifications due to COVID-19, *if applicable*.

### PROTOCOL DOCUMENT/STUDY DESIGN MODIFICATIONS

N/A, No Protocol Document/Study Design Modifications go to next section

Are study procedures being modified due to COVID-19? If yes, please describe the changes.

Yes  No

enter description |

*If changes reflective of COVID-19 are being made to the consent/assent documents please proceed to the CONSENT/ASSENT/SCRIPTS/INFORMATION SHEETS section of this form. If applicable, please attach revised consent or assents in the Consent Information or Assent Information sections. This would include adding an addendum consent document. All other documents should be included for the Protocol Information-Attachments section.*

Are changes to the Protocol document being made?

Yes  No

- Attach Appendix N to the Attachments tab if appropriate

The screenshot displays the eProtocol system interface. On the left, a vertical navigation menu lists various sections: Amendment, Personnel Information, Participant Checklist, Study Location, VAMC Checklist, Protocol Checklist, Funding, DoD Questionnaire, Protocol Information, and Study Details. The main content area shows the 'Attachment' form with fields for Document Type (set to 'Appendix N: Resumption of Clinical Research PI'), Attachment (with a 'Browse...' button and 'No file selected.'), and Document Name. A 'Save | Cancel' button is visible at the top right of the form. Overlaid on the form is a Mozilla Firefox browser window showing the URL 'https://ksprodweb.ovpr.wayne.edu/FORM\_ATTACHMENTS.do?PTL\_SECTI'. Below the browser window, a banner reads 'Approved Stamped Documents - Amendment 1'. On the right side of the interface, there are buttons for 'Cons...', 'Delete', and 'or to being in Proposals,'.

# Amendment Form Step by Step

- Please proceed to the appropriate section(s) of the eProtocol form and make changes.

<b>Amendment</b>
<b>Personnel Information</b>
<b>Participant Checklist</b>
<b>Study Location</b>
<b>VAMC Checklist</b>
<b>Protocol Checklist</b>
<b>Funding</b>
<b>DoD Questionnaire</b>
<b>Protocol Information</b>
<b>Addendum: Children a...</b>
<b>Addendum: Pregnant W...</b>
<b>Addendum: Internatio...</b>
<b>Addendum: Internet U...</b>
<b>Addendum: NIH Genomi...</b>

<b>Study Details</b>
<b>Expedited Paragraphs</b>
<b>Summary &amp; Purpose</b>
<b>Background, Rational...</b>
<b>Participant Population</b>
<b>Recruitment Process,...</b>
<b>Risks</b>
<b>Data Safety Monitori...</b>
<b>Benefits</b>
<b>Procedures to Mainta...</b>
<b>Consent Information</b>
<b>Assent Information</b>
<b>HIPAA</b>
<b>Drugs, Biologic Agen...</b>
<b>Attachments</b>



# Amendment Form Step by Step

- As you make changes throughout the form a list develops at the end of the form of the changes that have been made
- Refer to the Labeling Attachments documents be sure to update name of documents (revised, current, with the

List of sections (and questions) that have been changed/modified

[Updates \(Current\)](#)

[Subject Checklist](#)

[Attachments](#)

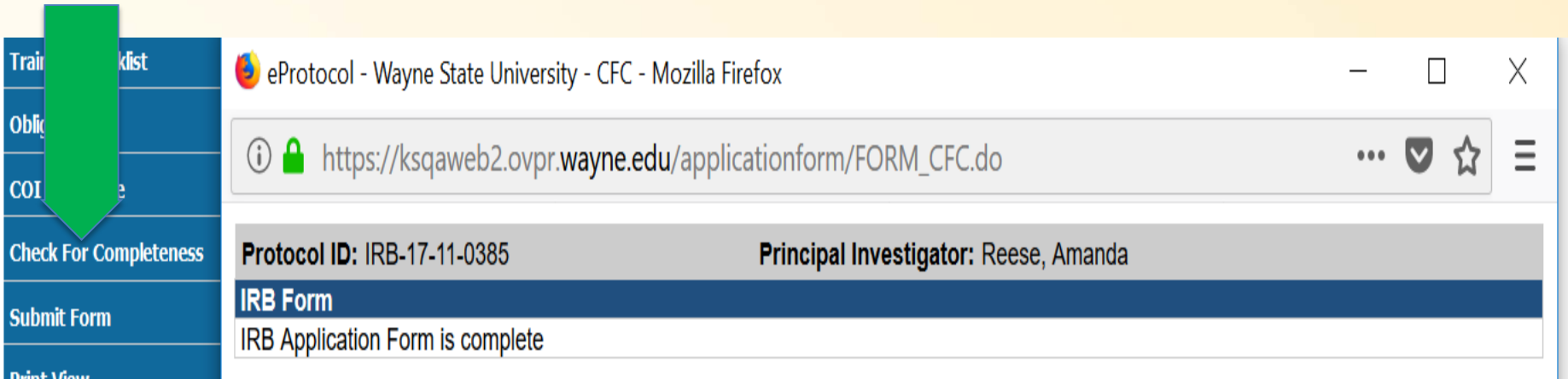
Previous

Next



# Amendment Form Step by Step

- When the form is completed select “Check for Completeness” this will provide a list of any missing information



The screenshot shows a web browser window titled "eProtocol - Wayne State University - CFC - Mozilla Firefox". The address bar displays the URL "https://ksqaweb2.ovpr.wayne.edu/applicationform/FORM\_CFC.do". The page content includes a sidebar on the left with a green arrow pointing to the "Check For Completeness" button. The main content area shows the following information:

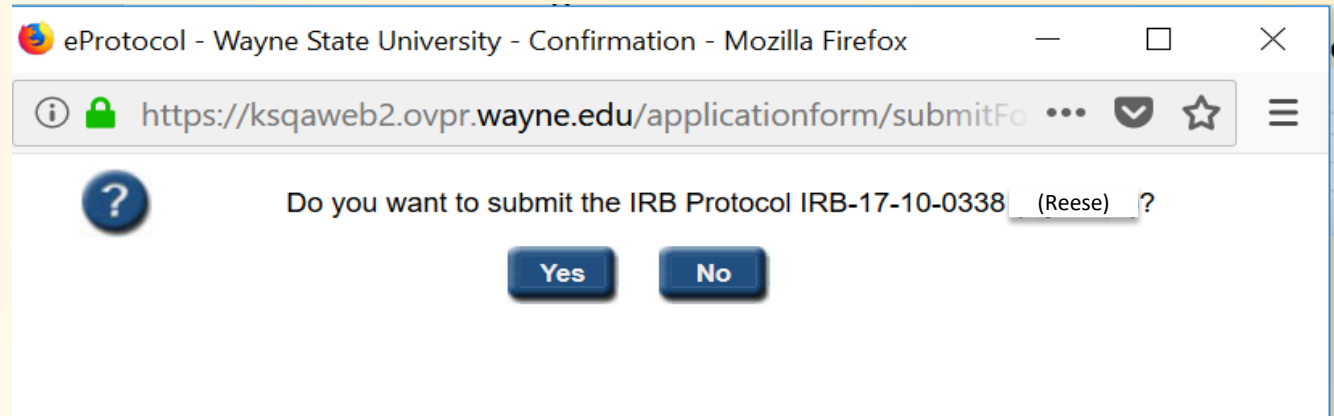
<b>Protocol ID:</b> IRB-17-11-0385	<b>Principal Investigator:</b> Reese, Amanda
<b>IRB Form</b>	
IRB Application Form is complete	

- When nothing is missing a message will appear “IRB Application Form is complete”.

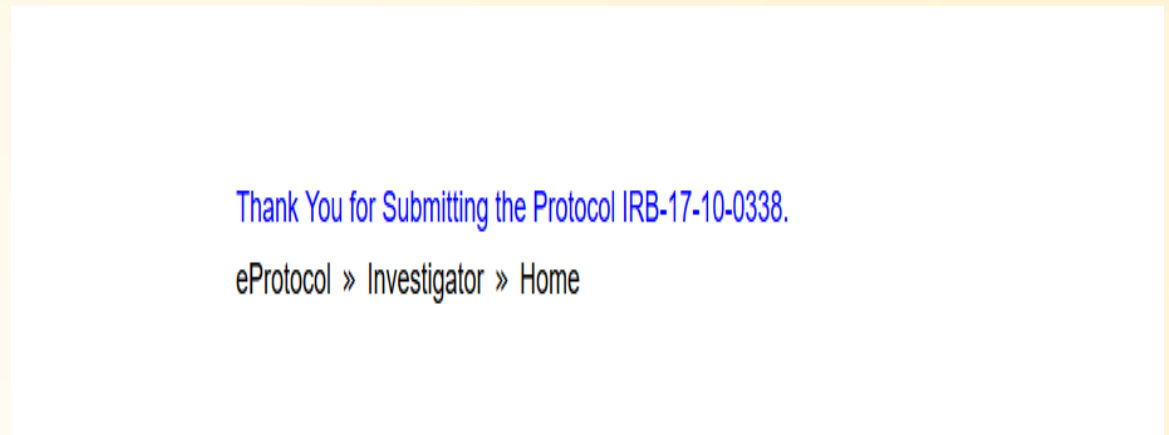


# Submitting an Amendment

- When ready to submit select “submit Form”



- Once submitted a message will appear “Thank you for Submitting...”



# Responding to Revisions

- If Revisions are requested an email is sent via the eProtocol System
- Revision Requests are found under the **Protocol Event** section
- It will indicate **comments sent cycle 1, cycle 2, etc.**

AMENDMENT					
Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
<a href="#">IRB-20-05-1481</a>	Reese, Amanda	SUBMITTED TO IRB	SUBMITTED	B3	07/16/2020

CONTINUING REVIEW

Currently there are no Continuing Review protocols.

- Respond to the changes in the comments section

Comments

Select Section:  
Amendment

make changes please |

Response Necessary for Approval  Suggestion Not Necessary for Approval

Save & Add Comment



# Questions?



Need Assistance contact the IRB Administration Office?

[WSUIRInfo@wayne.edu](mailto:WSUIRInfo@wayne.edu)

Tel# 313-577-1628

