IRB eProtocol

Amendment Submissions
Amendment Session Outline

• **WSU IRB Amendments**
  – Amendments to IRB Applications (Overview)
  – Amendment Traditional Method vs eProtocol
  – Amendment Types

• **Submitting an eProtocol Amendment**
  – eProtocol Submission Requirement
  – One Amendment Form Type
  – Bundling Amendments
  – Starting an Amendment
  – Amendment Step by Step
  – 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

https://ksprodweb.ovpr.wayne.edu/
Starting an Amendment

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.

Scroll down to the **Approved Protocols** section on your IRB Dashboard.
Starting an Amendment

Select “Start an Amendment”
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.

– Attach Appendix N to the Attachments tab if appropriate.
Amendment Form Step by Step

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

<table>
<thead>
<tr>
<th>Amendment</th>
<th>Study Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel Information</td>
<td>Expedited Paragraphs</td>
</tr>
<tr>
<td>Participant Checklist</td>
<td>Summary &amp; Purpose</td>
</tr>
<tr>
<td>Study Location</td>
<td>Background, Rational...</td>
</tr>
<tr>
<td>VAMC Checklist</td>
<td>Participant Population</td>
</tr>
<tr>
<td>Protocol Checklist</td>
<td>Recruitment Process,...</td>
</tr>
<tr>
<td>Funding</td>
<td>Risks</td>
</tr>
<tr>
<td>DoD Questionnaire</td>
<td>Data Safety Monitori...</td>
</tr>
<tr>
<td>Protocol Information</td>
<td>Benefits</td>
</tr>
<tr>
<td>Addendum: Children a...</td>
<td>Procedures to Mainta...</td>
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<tr>
<td>Addendum: Pregnant W...</td>
<td>Consent Information</td>
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<tr>
<td>Addendum: Internatio...</td>
<td>Assent Information</td>
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<td>Addendum: Internet U...</td>
<td>HIPAA</td>
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<tr>
<td>Addendum: NIH Genomi...</td>
<td>Drugs, Biologic Agen...</td>
</tr>
<tr>
<td>Addendum</td>
<td>Attachments</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>List of sections (and questions) that have been changed/modified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Updates (Current)</td>
</tr>
<tr>
<td>Subject Checklist</td>
</tr>
<tr>
<td>Attachments</td>
</tr>
</tbody>
</table>
Amendment Form Step by Step

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

• 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.**

![Image of eProtocol System]

• Respond to the changes in the comments section
Questions?

Need Assistance contact the IRB Administration Office?
WSUIRBlog@wayne.edu
Tel# 313-577-1628