IRB eProtocol

Unanticipated Problem Process Information Session

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IRB Administration Office

Updated 2/2023
2 eProtocol Functions

Implemented

August 1, 2022

- External IRB Submissions
- Unanticipated Problem (UP)Reports
Today’s Session

Unanticipated Problem Reports (UP) for eProtocol Submissions
eProtocol UP Process

Transitioning submitting eProtocol studies
Unanticipated Problem Reports

From: eIRBManger@wayne.edu

To: eProtocol
Current UP Process

All UP submissions use the:

• **Unanticipated Problem Report Form**
• **Unanticipated Problem Report Follow-Up Form**

available on the IRB’s website

[irb.wayne.edu](http://irb.wayne.edu)

eProtocol & Paper-Based Submissions
UP Submissions include the following:

• Full Board, Expedited, & Exempt
• External IRB Submission (Reliance on an outside IRB)
• Studies conducted without IRB approval

All UP types submit to the WSU IRB using:

Unanticipated Problem Report Form
Unanticipated Problem Report Follow-Up Form

available on the IRB’s website

irb.wayne.edu
Current UP Forms

will remain in use

• **Unanticipated Problem Report Form**
• **Unanticipated Problem Report Follow-Up Form**

These forms will be attached to the eProtocol UP submission
### Review of Current UP Form

**Unanticipated Problem Report Form**

Has 3 main reporting sections

|------------------------------------------|-----------------------------------------------|

<table>
<thead>
<tr>
<th>3. General Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>➢ Administrative Information &amp; PI Contact</td>
</tr>
<tr>
<td>➢ Corrective Actions</td>
</tr>
<tr>
<td>➢ Event Description</td>
</tr>
<tr>
<td>➢ PI Attestation &amp; Signature</td>
</tr>
</tbody>
</table>

*all information on one form with established criteria that defines each UP type*
# eProtocol UP Submission

has 3 Reporting Form Types

<table>
<thead>
<tr>
<th>1. Unanticipated Problems: Serious Adverse Events Form</th>
<th>2. Unanticipated Problems: Protocol Violation Form</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Report Form</td>
<td></td>
</tr>
</tbody>
</table>
**eProtocol UP Submission**

These 3 sections for **eProtocol**
are submitted as individual form types

<table>
<thead>
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</tr>
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<tr>
<td></td>
<td>3. General Report Form</td>
</tr>
</tbody>
</table>
eProtocol UP Submission Process

Who can submit a UP via eProtocol?

• Only key personnel that have edit capability in eProtocol for a submission

• Users with edit capability include
  • Personnel Information section:
    ✓ Principal Investigator
    ✓ All Co-investigators
    ✓ Study Coordinator/Regulatory
    ✓ Faculty Sponsor/Mentors
    ✓ Administrative Contacts

Key Personnel listed as “Other Personnel” do not have edit access. These personnel can only VIEW the application.
### eProtocol UP Submission

The UP Submitter will select one of the 3 UP form types for eProtocol:

<table>
<thead>
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<th>2. Unanticipated Problem: Protocol Violation Form</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3. General Report Form</td>
</tr>
</tbody>
</table>
The UP Submitter will complete & attach:

**Unanticipated Problem Report Form**

or

**Unanticipated Problem Report Follow-Up Form** from the IRB’s Website

for:

1. Serious Adverse Events
2. Protocol Violations/Deviations

**General Report** does not require submission of the UP Forms
Completing a UP submission for eProtocol

- Go to the WSU IRB’s Website (irb.wayne.edu)
- Select the IRB Forms tab
- Go to the Unanticipated Problem and Adverse Event Reports section

Click on the UP report form

(Please refer to the screenshot for detailed instructions on how to complete the UP submission through eProtocol.)
Completing a UP submission for eProtocol

Download & complete all sections of the UP Form & Save

Unanticipated Problems and Event Reporting Form

Section A: Administrative Information

- Name of PI
- Department (Email)
- Address
- Telephone
- Pager

Section B: Event Description

11. Date of Occurrence:
12. Date you became aware of occurrence:

Describe the event and how it occurred:

Section C: Corrective Actions

This section must be completed for all unanticipated problems. General reports do not need to complete this section.

- What action was taken at the site of the occurrence with regard to the study intervention, device, and procedure in response to this Unanticipated Problem? The PI is encouraged to take all necessary steps to rectify the problem.
  - N/A
  - No action taken
    - Event did not warrant action
  - Standard operating procedures were followed
  - Dose adjustment or other alteration of the intervention
  - Temporary discontinuation of study drug/device/procedure

Stop Date: 
Restart Date: 

Reason for resuming:
Completing a UP submission for eProtocol

Go to the eProtocol website
https://ksprodweb.ovpr.wayne.edu/
Log in using WSU Access ID & Password
Completing a UP submission for eProtocol

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.
Submitting an eProtocol UP Report

Select 1 of the 3 UP submissions Form Types:
- Report Form for General Report
- Serious Adverse Event
- Protocol Violation
Completing a UP submission for eProtocol

Complete the selected-UP Submission Form type

(I) Protocol Violation/Deviation

(II) Serious Adverse Event

(III) General Report

Note: Multiple UP submission types can be submitted a time. UP reports can also be submitted when there is an amendment or continuation in process.
Completing a UP submission for eProtocol

Select “Add” and Attach the completed UP Form

Then select “Submit Form” on the left side of the page

Note: General Reports DO NOT require submission/attaching the UP Report Form.
eProtocol UP Review Process

✓ The IRB UP Reviewer will be assigned the submission
✓ IRB UP Reviewer will receive an email alert to WSU email
IRB UP reviewer will make one of the following recommendations:

(I) approve the report as submitted (No Further Action-NFA)
(II) Request revisions (revisions are sent via eProtocol)
(III) Recommend full board review

All final UP memos are sent via eProtocol to study PI/Team with the reviewer or full board’s determinations
Full Board Review Determinations

✓ UP Review Determinations are the same:
✓ Non compliance,
✓ Serious Non-compliance
✓ Continuing Non-compliance
eProtocol UP Review Process

UP Review Determinations Notifications from eProtocol

✓ Approve:
  ✓ no further information is needed and determination made

✓ Specific Minor Revisions (Contingent):
  ✓ revisions to plan requested, compliance determination is made, does not come back to the full committee

✓ Defer (moved to next meeting):
  ✓ need more information cannot make a compliance determination
  ✓ For full board appropriate membership is not in attendance to make a determination
eProtocol UP Review Process

Review Determinations Notifications from eProtocol

- Notification e-mails are sent via eProtocol to the PI’s and study team members
- E-mails are sent to WSU email addresses

Guest Access ID Users:
Email Alerts are sent to the WSU email account. The IRB recommends forwarding your WSU email to an preferred email account.
Recap of eProtocol Submission/Review Steps

- Submitter selects one of the 3 UP submission avenues
  - Submitter completes the UP form available on the IRB's Website for:
    - (I) Adverse Events
    - (II) Protocol Violation

- UP is assigned to IRB Reviewer

- IRB Reviewer conducts review

- IRB reviewer has 3 options:
  - (I) request revisions,
  - (II) determines NFA,
  - (III) request full board review

- If full board review:
  - IRB administrator assigns to full board meeting agenda
  - UP memo sent via email in eProtocol

- Final determination made.
eProtocol UP Process Starting

August 1, 2022

Last day to accept paper based forms for eProtocol Submissions via eIRBManger@wayne.edu is August 15, 2022
The current UP forms have undergone minor editorial changes to include eProtocol instructions.

Paper-Based submissions still submit to eIRBManager@wayne.edu.

This implementation is for all eProtocol Submissions ONLY.

This will include External IRB UPs.

Current UP forms must be attached to eProtocol for:

- Serious Adverse Events
- Protocol Violations/Deviations

General Reports submissions do not need to attach the UP form to eProtocol.

Key Personnel with edit access can submit UP reports.

Starts August 1st
Last day for eProtocol submission to eIRBManager is August 15th.
Questions?
Need IRB Assistance or Information?

- Visit the IRB’s Education Website:  
  http://research.wayne.edu/irb/education

- E-mail the IRB: WSUIRIRBInfo@wayne.edu or IRBQuestions@wayne.edu

- Call the IRB Office: 313-577-1628

- Sign-up for the IRB list serv: email WSUIRIRBinfo@wayne.edu

- Attend the monthly webinar: Every 4th Tuesday (various topics discussed)

- Visit Virtual Office Hour: Every Tuesday 1:00 pm– 2:00 pm
WSU IRB Assistance

eProtocol IRB Virtual Training
Virtual Office Hours via Zoom
eProtocol real time assistance
No registration required

Tuesdays
1:00 pm – 2:00 pm
✓ Need Key Personnel CITI checks assistance?
✓ Key Personnel & Authorized Signatory questions?
✓ How to respond to revision requests?
✓ Where to find approval letters and IRB stamped documents?

Zoom Meeting Link
Zoom Meeting ID: 953 4534 4223
Passcode: 577514

Please make sure your name is stated on your Zoom profile. Attendees are placed in the waiting room until their turn.

Need group or individual training? Need an Introduction to eProtocol session?
Email: WSUIRBInfo@wayne.edu

Zoom Link & Credentials
Meeting ID: 953 4534 4223
Passcode: 577514