



IRB eProtocol

Unanticipated Problem Process Information Session



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IRB Administration Office



2 eProtocol Functions

Implemented

August 1, 2022

- External IRB Submissions
- Unanticipated Problem (UP) Reports



Today's Session

Unanticipated Problem Reports (UP) for eProtocol Submissions

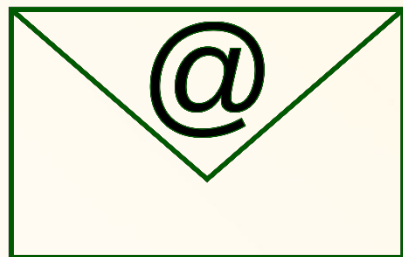


eProtocol UP Process

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

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

**1. Unanticipated Problems:
Adverse Events**

**2. Unanticipated Problems:
Protocol Violations**

3. General Reports

➤ **Administrative Information &
PI Contact**

➤ **Event Description**

➤ **Corrective Actions**

➤ **PI Attestation & Signature**

all information on one form

with established criteria that defines each UP type



eProtocol UP Submission



has 3 Reporting Form Types

**1. Unanticipated Problems:
Serious Adverse Events Form**

**2. Unanticipated Problems:
Protocol Violation Form**

3. Report Form



eProtocol UP Submission



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

**1. Unanticipated Problems:
Serious Adverse Events Form**

**2. Unanticipated Problems:
Protocol Violation Form**

3. General Report Form



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

**1. Unanticipated Problem:
Serious Adverse Events Form**

**2. Unanticipated Problem:
Protocol Violation Form**

3. General Report Form



eProtocol UP Submission Process



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

→ ↻ <https://research.wayne.edu/irb/forms-requirements-categories#Unexpected> 📄 ☆ 🛡️

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Institutional Review Board

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Institutional Review Board

Coronavirus: COVID-19

Human Research Protection
Program's Policies and Procedures

Meetings and deadlines

**IRB forms and submission
requirements**

Informed consent/assent templates

ClinicalTrials.gov Requirements

Common Rule Changes - NEW!

Education

Unanticipated Problem and Adverse Event Reports

(Unanticipated) Unexpected Problems and *reportable* Adverse Events must be reported to the IRB as soon as possible, but **within 5 working days**.

PLEASE ALSO USE THESE FORMS FOR eProtocol UP REPORTING:

- [Unanticipated Problems & Event Reporting Form \(pdf\)](#) (updated 10/2021) must be completed and signed as an Adobe Acrobat document. Previous version accepted until 10/2021.
- [Unanticipated Problem Follow-up Form \(pdf\)](#) (updated June 2022) must be completed and signed as an Adobe Acrobat document. Previous version accepted until August 15, 2022.

To submit an Unanticipated Problem via eProtocol:

- [Log into eProtocol](#)
- Look for "Approved Protocols" on the submitter's dashboard:

Click on the UP report form

Completing a UP submission for eProtocol

Download & complete all sections of the UP Form & Save



IRB Administration Office
87 E. Canfield, Second Floor
Detroit, MI 48201
Telephone# (313) 577-1628
<http://irb.wayne.edu/index.php>

Unanticipated Problems and Event Reporting Form

- Use this form to report all unanticipated problems, protocol deviations and other events
- Select one of the three reporting categories: Serious Adverse Event, Protocol Violation, and/or General Report
- If the IRB reviewer requests an Unanticipated Problem Follow- Up report, use the Unanticipated Problem *Follow-up* Form
- **On this form, "WSU" refers to any study conducted at either Wayne State University, Detroit Medical Center, Karmanos Cancer Institute, or J. D. Dingell VAMC.**
- **Clinical Trials Studies:** Please include this form, followed by the Sponsor's report, and then then any internal tracking forms/coversheets used.
- An email address is required for IRB submissions. Correspondence concerning this submission will be sent to the WSU email address. If you currently use a non wayne.edu email as your primary email account, please forward your wayne.edu email to your primary e-mail. Forwarding wayne.edu email can be completed by logging into the WSU Academics profile.

Section A: Administrative Information

1.	Name of PI			
2.	Department		*E-mail	
	Address		Telephone	
				Pager
3.	Form completed by:		Date:	
	Telephone		*E-mail	
	Name of Faculty Sponsor/ Faculty Supervisor:	<input type="checkbox"/> N/A	*E-mail	

Section C: Event Description

11.	Date of Occurrence:	
12.	Date you became aware of occurrence:	
Describe the event and how it occurred:		

Section G: Corrective Actions

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

31. 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 restarting:

Completing a UP submission for 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.

Go to the eProtocol website
<https://ksprodweb.ovpr.wayne.edu/>
Log in using WSU Access ID & Password

User ID

Password

Login



Completing a UP submission for eProtocol

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
IRB-22-06-4516		06/30/2022	06/30/2022	06/29/2025	Panel Manager Review	NEW
IRB-22-04-4490			04/30/2022	04/30/2024	Designated 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



Submitting an eProtocol UP Report

eProtocol - Wayne State University ...

https://ksqaweb.ovpr.wayne.ed

Approved Protocol Decision

Please select any one of the following:

- Open in View Mode
- Protocol Details
- Start Amendment
- Start Final Report Form
- Start Report Form
- Start Serious Adverse Event Form
- Start Protocol Violation Form

OK Close

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

Protocol Violation/Deviation Submission

Please complete items below and then attach the Unanticipated Problem (UP) and Event Reporting Form

This form is used to submit events that are Protocol Violations/Deviations, and/or Non-Compliance.

Please note: Serious Unanticipated Problems must be reported as a Serious Adverse Event submission. If this is a Serious Adverse Event STOP do not submit this form. Submit the Serious Adverse Event eProtocol Form.

Select the Protocol Violations and/or Non-Compliance events that apply:

- Lapse in IRB Approval when there have been multiple occurrences and/or research activity conducted during the lapse period.
- Non-IRB approved personnel conducting research activities
- Deviations from IRB recruiting and consenting policy and procedures. Examples include:
 - (I) Omission of signatures, dates, initials
 - (II) Consent documented on an outdated consent/assent/information sheet
 - (III) consent/assent obtained on a document without the presences of an IRB approval stamp
- Exceeding the IRB approved enrollment numbers
- DSMB report that indicate unanticipated risks
- Other

(II) Serious Adverse Event

Serious Adverse Event Submission

Please complete items below and then attach the IRB's Unanticipated Problem (UP) and Event Reporting Form. If this is a Protocol Violation STOP do not submit this form, submit the Protocol Violation eProtocol Form.

This form is used to submit Serious Unanticipated Problems/Serious Adverse Events

The following events must be reported to the IRB within 5 working days from the day you learned about the event

Select the Serious Unanticipated Problems/Serious Adverse Events that apply:

- Adverse device effects
- Adverse event or injuries that are serious, and unanticipated
- Local Death:
Regardless of relationship to study treatment or procedure or device implant, over the duration of study treatment and for up to 30 days after the last dose of study treatment or device implant procedure, or a death that the PI feels is significant and requires reporting.

(III) General Report

General Report Form Cover Sheet

This form is used to submit General Report/Miscellaneous items as listed below.

Modifications to the research, submission of safety reports, and DSMB reports must be submitted as an amendment.

The Unanticipated Problems and Event Reporting Form is not required for this submission to the IRB.

NOTE: If it is determined that the event reported on this form is a Protocol Violation/Deviation or Serious Adverse Event, this report will be returned or withdrawn by the IRB for submission of a Protocol Violation/Deviation or Serious Adverse Event.

Select the general report items that apply:

Audit, inspection or inquiry by a federal agency that does not indicate unanticipated risks or non-compliance

Written reports of study monitors

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

Attach the UP form here and all other supporting documents:

The UP form is available at:

<https://research.wayne.edu/irb/forms-requirements-categories#Unexpected>

Attachment

Add

Select "Add" and Attach the completed UP Form

Unanticipated Problem and Event Reporting Form

Name	Attached Date	Submitted Date
<input type="checkbox"/> Unanticipated Problem and event report Form date 6.2022	08/17/2022	

5. Is the Unanticipated Problems (UP) and Event Reporting Form attached?

Yes No

6. The Protocol Violation Section (Section E) of the UP Form is complete.

Yes No

7. The Corrective Action section (Section G) of the UP form is complete.

Yes No

Previous Next

Previous Next

Protocol Violation Form

Training Checklist

Submit Form

Print View

Get Protocol

Event

Then select "Submit Form" on the left side of the page

This is used to submit events that are Protocol Violations/Deviations, and/or Non-Compliance.

Please note: Serious Unanticipated Problems must be reported as a Serious Adverse Event submission. If this is a Serious Adverse Event STOP do not submit this form. Submit the Serious Adverse Event eProtocol Form.

Select the Protocol Violations and/or Non-Compliance events that apply:

Lapse in IRB Approval when there have been multiple occurrences and/or research activity conducted during the lapse period.



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



eProtocol UP Review Process



- ✓ **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**



eProtocol UP Review Process



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



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



UP Implementation Summary

- ✓ 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:** WSUIRBInfo@wayne.edu or IRBQuestions@wayne.edu
- **Call the IRB Office: 313-577-1628**
- **Sign-up for the IRB list serv:** email WSUIRBInfo@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

