Guide for Reporting Unanticipated Problems, Protocol Deviations and Other Events to the IRB Administration Office at Wayne State University (WSU)

Principal investigators must report any of the following to the IRB as soon as possible, **but within 5 working days after the investigator first learns of the event**. **Refer to the IRB policy on Unanticipated Problems for definitions and reporting procedures and guidelines.**

External IRB Event Reporting: Studies in which an external or commercial IRB is the IRB of record must also submit local events using this form. Please also follow the IRB of record's unanticipated problem reporting process.

Examples of events to be reported in the Serious Unanticipated Problems section of the form (Section D):

• **Adverse device effects**	• A **change in FDA labeling** or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
• **Adverse events** or injuries that are serious, and unanticipated	• **Change to the protocol** taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
• **Local Deaths**	• **Change in vulnerable populations**
• **Any breaches of confidentiality**	• **Research conducted without prior WSU IRB approval**
• **Sponsor directed reporting**	• **Audit findings,** or any negative actions by a government oversight office
• **New information** indicating an unanticipated change in risks or potential benefits	• **Any litigation, arbitration, or settlements** initiated related to human research protections
• **Protocol deviations**, violations, or other accidental or unintentional changes to the protocol or procedures involving risk or with the potential to recur.	• **Any negative press coverage**
• **Complaint of a participant** when the complaint indicates unanticipated risks or cannot be resolved by the research team	• **Other problem** or finding (e.g., loss of study data) that an investigator believes could impact the safety of the research.

Examples of events to be reported in the Protocol Violation/ Non-Compliance section of the form (Section E):

- Lapse in IRB Approval when there have been multiple occurrences, and/or research activity occurred during the lapse.
- Non-IRB approved personnel conducting research activities
- Deviations from IRB recruiting and consenting policy and procedures. Examples include:
  - Omissions of signatures, dates, initials.
  - Consent documented on outdated consent form or on form without the presence of an IRB approval stamp
- Exceeding the IRB approved enrollment numbers

Examples of events to be reported in the General Report section of the form (Section F):

Note: General reports do not require reporting to the IRB unless required by the sponsor or funding agency.

- Audit, inspection or inquiry by a federal agency that does not indicate unanticipated risks or non-compliance
- Written reports of study monitors

Open and save form using Adobe or software that allows for digital signature.

- eProtocol Submissions: **Attach this form and any supporting documents to the selected UP submission type: Serious Adverse Event or Protocol Violation.**
- Paper Based Submissions: **Place the Unanticipated Problem Report Form, attachments/supporting documents in a single zip file and email to: eIRBManager@wayne.edu Email Subject: UP REPORT (PI Name and IRB#)**

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 Academica 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:	☐ N/A	***E-mail**	

Section B: Protocol Information

4.	IRB #	☐ External IRB Submission
5.	Project Title:	

6.	Name of Funding Source:	Federal Funding? ☐ Yes ☐ No DoD Funding? ☐ Yes ☐ No	
7.	Is this a VA study?	☐ Yes – report to the VA, as well. ☐ No	
8.	Is this a multicenter study? Note: If WSU is not the IRB of record please also follow the reviewing IRB's UP reporting process.		☐ Yes ☐ No **– go directly to Q#11**
9.	Is the WSU site serving as the Coordinating Center for the study?		☐ Yes ☐ No
10.	How will information on this Unanticipated Problem be shared with other sites?		☐ N/A

Section C: Event Description

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

13.	How many participants have been enrolled in the study to date?		☐ N/A
14.	How many participants are actively receiving study treatment?		☐ N/A
	a) Does the Study involve procedures and/or follow-up necessary for the safety and well-being of the enrolled participants which cannot be suspended? If Yes. Describe:		☐ Yes: ☐ No
15.	Participant ID:	Age:	☐ N/A
16.	Sponsor AE #: **Attach copy of report and email to the IRB Office: eIRBManager@wayne.edu.** **Include the form, current Informed Consents and all supporting documentation from sponsor and/or PI in a zip file. Please label file with the IRB number and PI's name.**		☐ N/A
17.	Does the problem involve the participant signing the wrong consent or no consent was obtained?		☐ Yes ☐ No
	(**a**) How many participants were involved?		

	(b) Describe the differences between the appropriate consent form and the consent formed signed by the participant. **Note:** If this applies, please attach highlighted copies of the consent forms with this report form.	
18.	At the time of the occurrence of the Unanticipated Problem, state where the participant was in the protocol process (e.g., visit 6 of a 12 visit study):	☐ N/A
19.	Have similar events occurred with this study in the past? If yes, describe:	☐ Yes ☐ No

20.	**(a)** Has the event been reported to the sponsor?	☐ N/A ☐ Yes ☐ No
	(b) Have any participants been notified of the event?	☐ N/A ☐ Yes ☐ No
21.	Provide any other information that could be of importance to the IRB in its review:	

Section D: Unanticipated Problems that are Adverse Events

If this section does not apply to the event you are reporting, check N/A and skip to Section E		☐ **N/A**
22.	Is the adverse event unanticipated in nature, severity, or frequency? • Unanticipated events are events that are not listed in the informed consent form, investigator's brochure, drug or device insert, or any other study related documents.	☐ Yes ☐ No
23.	Is the adverse event related or possibly related to participation in the research? • related events may be definitely, probably, or possibly related	☐ Yes ☐ No
24.	Describe the risks (including any potential or suspected risks) the event placed on participants	

25.	**Select the adverse event that best characterizes the type of event.** • If the study or participant has multiple unanticipated problems submit separate reports **The following events must be reported to the IRB within 5 working days from the day you learned about the event . If this section does not apply to the event you are reporting then select N/A and go to section E.** ☐ N/A
☐	**Adverse device effect** that is serious, unanticipated, and related (related events may be definitely, probably, or possibly related)
☐	**Adverse event** or injury that is serious, unanticipated, and related (related events may be definitely, probably, or possibly related)
☐	**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. Was death due to disease progression? ☐ Yes ☐ No
☐	**Any Breach of confidentiality**
☐	**Sponsor directed reporting**: • event that requires prompt reporting to the sponsor according to the protocol, or funding agency • sponsor-imposed suspension for risk
☐	**New information** indicating an unanticipated change in risks or potential benefits such as: • Literature/scientific reports or other published findings, • Data and Safety Monitoring Board (DSMB) reports, • Interim analyses • Other oversight committee/monitoring reports
☐	**Protocol violations/deviations**, or other accidental or unintentional changes to the protocol or procedures involving risk or with the potential to recur. For example: a. Failure to draw safety labs b. Participant enrolled who does not meet enrollment criteria
☐	**Complaint of a participant** when the complaint cannot be resolved by the research team.
☐	**A change in FDA labeling** or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
☐	**Change to the protocol** taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
☐	**Change in vulnerable populations not previously approved by the IRB** (e.g., enrollment or inclusion of vulnerable populations without prior IRB approval, or when an existing subject becomes a member of a vulnerable population when the study does not have prior IRB approval for inclusion of the vulnerable population- such as the incarceration of a subject in a protocol not approved for the enrollment of prisoners)
☐	**Research conducted without prior WSU IRB approval**
☐	**Other problem** or finding (e.g., loss of study data, etc.) that an investigator believes could impact the safety of the research.
	Note: The following events must be reported within 48 hours after becoming aware of the event.
☐	**Any negative actions by a government oversight office**, including, but not limited to: • OHRP Determination Letters, • FDA Warning Letters, • FDA 483 Inspection Reports • Any corresponding compliance actions taken under non-US authorities related to human research protections.
☐	Any litigation, arbitration, or settlements initiated related to human research protections
☐	Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding conduct of the research

Section E: Unanticipated Problems that are Protocol Violations

26.	**If this section does not apply to the event you are reporting, select N/A and skip to section F**	☐ **N/A**
27.	Is the protocol violation unanticipated in nature, severity, or frequency?	☐ Yes ☐ No
28.	Did the protocol violation involve risk to participants (including potential or suspected risks)? If yes, Describe the risks:	☐ Yes ☐ No
29.	**Select the protocol deviation that best characterizes the type of event.** • If the study or participant has multiple protocol deviations submit separate reports	
☐	DSMB reports that indicate unanticipated risks	
☐	Lapse in IRB Approval	☐ IRB approval for this study has lapsed more than one time. ☐ Research activities occurred during the lapse in IRB approval (this involves data collection and/or any interaction and/or interventions with participants). If research activities occurred during the lapse were they necessary for the safety of the participants? Yes ☐ No ☐ If Yes, describe: ☐ Reporting lapse in approval at the request of the IRB. **If neither of these situations above apply to this study's lapse in IRB approval: STOP: You do not need to submit an unanticipated problem report to the IRB.**
☐	Non-IRB approved personnel conducting research activities	

☐	Deviations from IRB recruiting and consenting policy and procedures. Examples include: • Omissions of signatures, dates, initials. • Consent documented on inappropriate or outdated consent forms, or consent documents without the presence of an IRB approval stamp
☐	Exceeding the IRB approved enrollment numbers
☐	Other:

Section F: General Reports

Note: These events do not require IRB reporting.

If this section does not apply to the event you are reporting, select N/A and skip to Section H	☐ **N/A**

30.	**Select the protocol deviation that best characterizes the type of event.** • If the study or participant has multiple protocol deviations submit separate reports
☐	Audit, inspection or inquiry by a federal agency that does not indicate unanticipated risks or non-compliance
☐	Written reports of study monitors
☐	Other Specify:

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:

- ☐ Permanent discontinuation of study drug/device/procedure **Date:**
- ☐ Other - describe the specific care provided and steps taken to correct the problem:

32.	What action is being taken to **prevent** reoccurrence of the reported Unanticipated Problem?	
	a.	Please describe a detailed Corrective Action Plan. Note: The PI is encouraged to take all necessary steps to prevent the problem from happening again.

	b.	**Describe how this corrective action plan differs from the process already in place at the time of the unanticipated problem.**
	c.	**Describe how you will evaluate the effectiveness of the corrective action plan.**

33. Select all that applies to your corrective action plan:

☐ **Education:** Select the group education was offered to, and provide details in the spaces below:
Topic:

Date of Education:	☐ Research Staff Education
Education Provided by:	☐ Clinical/Hospital Staff
Attended by:	☐ Other Education Details:

☐ **Process Improvement**: Select all items below that apply to your process improvement plan:

☐ **Checklist:**
Select the checklist(s) to the right
that you will be using in your process improvement plan.
Note: Submit checklist with the UP Report

- ☐ Study Visit
- ☐ Inclusion/Exclusion Criteria
- ☐ Consent Process
- ☐ Consent Version Tracking
- ☐ Regulatory Document Tracking
- ☐ Other :

☐ **Regulatory Document Management:** Details:

☐ **Calendar Management (example: electronic reminders):** Details:

☐	**Key Personnel Management**: Details:
☐	**Screening/Recruitment/Enrollment/Consent Process:** Details:
☐	**Investigational Product Management**: Details:
☐	**Compensation Management**: Details:
☐	**Privacy and Confidentiality**: Details:

☐ **Communication Improvement Plan Details**

☐ Paper/Electronic: Details

☐ Oncore/Database: Details:

☐ Other Details

34.	Is the Unanticipated Problem being reported currently listed in the informed consent? ☐ Yes - attach hard copy of the consent form with **highlighted relevant text** ☐ No - attach the **current consent** ☐ N/A

35.	**Consent/Protocol/Proposal Modifications**	
	As a result of this Unanticipated Problem, will any changes be made to the informed consent and/or the protocol? **For Clinical Trials Studies:** The PI should consider what the Sponsor recommends, but make an independent decision	☐ Yes, added to: - *Immediately* submit a separate amendment ☐ Consent documents ☐ Protocol ☐ Yes, Sponsor felt it did not need to be added, but I, the PI, want it added to: ☐ Consent documents ☐ Protocol ☐ No, justify why this event will not be added to the consent &/or protocol: ☐ No, Sponsor felt it did not need to be added and I, the PI, agree Comments, if any:

36.	**Informing Participants**
	How will currently enrolled participants be informed of the Unanticipated Problem? ☐ Re-consent on updated consent form ☐ Consent addendum (submit as a full board amendment) ☐ Notification (e.g., letter, phone contact, verbal) **Attach copy of notification** ☐ Not informed – **Justify why:**

Section H: Principal Investigator Attestation and Signature

37.	**Attestation:** As the principal investigator for this study, my signature below indicates that I have carefully reviewed this PROBLEM REPORT and find the information provided to be complete and accurate. _____ _____ **Signature of Principal Investigator ONLY** **Date** **(MUST be the signature of the PI listed on the protocol)** **Open and save form using Adobe or software that allows for digital signature.**

Please attached all applicable supplemental/supportive documents with this submission.