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

Follow-Up Unanticipated Problem Report

- All Submission Forms must be the current form date and computer generated. Handwritten forms will not be accepted.
- **Open and save form using Adobe or software that allows for digital signature.** Instructions: Steps for Signing a PDF Form with a Digital ID
- **Paper Based Submissions: Email this form and any supporting documents to: eIRBManager@wayne.edu**
- **eProtocol Submissions:** Attach this form and any supporting documents to the selected UP submission type: Serious Adverse Event or Protocol Violation.

Section A: Administrative Information

1.	Name of PI		Date:	
2.	Department		E-Mail:	
	Telephone:		PI's Pager:	
	Address			
3.	Form Completed By			
	Telephone		E-mail:	

Section B: Protocol Information

4.	IRB#		☐ External IRB Submission
5.	Protocol Title		
6.	Funding Source		

7.	Status of Protocol:	☐ Open to accrual ☐ Closed to accrual/active intervention continues ☐ Closed to accrual/ all research-related interventions completed (participants remain in follow-up only) ☐ Closed		
8.	Date of Unanticipated Problem/Event (should be the same date as the original form)			
9.	Date WSU PI became aware of Unanticipated Problem (should be the same date as the original form)			
10.	Participant ID:		Age:	
11.	Sponsor AE #: (Attach copy of report. Please submit this form, current Informed Consents and all supporting documentation from sponsor and/or PI to The IRB Administration Office)			☐ NA
12.	Describe new information obtained about the original Unanticipated Problem. **If the follow-up report is death, clarify if the death was due to disease progression or the Unanticipated problem.**			

13.	Follow-up Report Status to WSU Provide additional information on the original problem. **This information should supplement the original report, not duplicate it.** Follow-up #:	
14.	What **additional** action was taken at the site of the occurrence with regard to the study intervention/device/procedure in response to this Unanticipated Problem? ☐ No action taken ☐ Dose adjustment or other alteration of the intervention ☐ Temporary discontinuation of study drug/device/procedure **Stop Date**: **Restart Date**: **Reason for restarting**:	☐ N/A

15.	☐ Permanent discontinuation of study drug/device/procedure **Date:** Are there any study procedures and/or follow-up that cannot be suspended to protect the safety and well-being of participants? ☐Yes ☐ No If Yes, Describe: How many participants are continuing with study procedures and/or follow-up for their safety and well-being? What additional steps are being done to monitor the safety of these participants? Have all participants been notified of the occurrence and actions being taken? ☐Yes ☐ No ☐ Other (Describe in detail the specific care provided/steps taken to remediate the problem.):	☐ N/A

16.	What **additional** action is being taken to prevent reoccurrence of the reported Unanticipated Problem? ☐ None ☐ Monitoring ☐ Education ☐ Other **Describe any of the above that are checked:**

17.	As a result of this Unanticipated Problem will any change(s) be made to the informed consent and/or the protocol? ☐ Yes (Immediately submit a separate amendment and revised informed consent and/or protocol for full board review) Date of Amendment submission: If any changes have been made to the protocol or informed consent since the original problem submission, please describe. Date of Amendment submission: Describe: ☐ No, justify why this event will not be added to the consent:

18.	How will currently enrolled participants be informed of the Unanticipated Problem? ☐ Re-consent ☐ Consent addendum (submit as a full board amendment) ☐ Notification (e.g., letter, phone contact, verbal) Attach copy of notification ☐ Not informed (Justify):
19.	**Declaration: As the Principal Investigator for this study, my signature below indicates that I have carefully reviewed this follow-up PROBLEM Report and find the additional 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.
Instructions: Steps for Signing a PDF Form with a Digital ID