MetroWest Medical Center IRB
85 Lincoln Street, Framingham, MA 01702

Report of an Unanticipated Problem

MetroWest Medical Center IRB (MWMCIRB) requires that all unanticipated problems are promptly reported to the IRB. *An unanticipated problem is any unforeseen event or events that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research.*

A. Study Information			
1.	Date:	MWMC Study Number:	Protocol Number:
2.	Name of Study:		
3.	Study Article:		
4.	Name of Principal Investigator:		

B. Information Regarding Report		
1.	Date of Violation: _____	Date Reported to Sponsor: _____
2.	What is being reported?	
	☐ Protocol Deviation/Exception	☐ Subject or staff complaint
	☐ Serious Adverse Event ***If reporting an SAE please complete an SAE Report Form and submit with this report***	☐ Any changes that significantly affect the conduct of the trial
	☐ Changes made to the research without prior IRB approval	☐ New information that might affect adversely the safety of the subjects or conduct of the study
3.	Does the event meet the definition of an Unanticipated Problem? **check all that apply* ☐ Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied ☐ Related or possibly related to participation in the research (in this guidance document, possible related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research) and	

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	☐ Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously know or recognized
4.	Provide a brief description of the problem. If the event was unrelated or expected, explain why it is being submitted: _____ _____

5.	Describe steps taken to resolve the problem and procedures implemented to avoid similar problems in the future: _____ _____

Name of Person Completing Form (contact person for questions):	
Name:	
Title:	
Phone Number:	
Fax Number:	
Email Address:	
Date:	Signature:

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PLEASE EMAIL COMPLETED FORMS AND REQUIRED DOCUMENTS TO MWMCIRB@mwmc.com you will receive an acknowledgement once all required information has been submitted.

Examples of Unanticipated Problems:

- An investigator collects individually identifiable information and stores them on a laptop computer without encryption. The computer is stolen. This was a) unexpected; b) related to participation in the research; and c) placed the subjects at a greater risk of psychological and social harm than was previously known or recognized.
- As a result of a processing error, a subject in a multi-center trial receives a dose of study drug 10 times higher than dictated by the protocol. While the subject experienced no detectable harm or adverse effect, this constitutes an unanticipated problem for the institution where the dosing error occurred.
- Subjects with cancer are enrolled in a clinical trial evaluating an investigational biologic product derived from human sera. After several subjects received the product a study audit reveals it was obtained from donors not appropriately screened and tested for viral contaminants. . This was a) unexpected; b) related to participation in the research; and c) placed the subjects at a greater risk.

NOTE – these examples were taken from Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects – www.hhs.gov/OHRP/policy