UTRGV	**The University of Texas Rio Grande Valley** **Institutional Review Board for the Protection of Human Subjects in Research** **Unanticipated Problem/Adverse Event Reporting Form**

Note that only events that are (1) unexpected in nature, severity or frequency AND, (2) related or possibly related to the research, AND (3) suggests that the research places the subjects or others at greater risk of psychological or physical harm was previously known or recognized need to be reported. Please see IRB handbook for additional guidance if needed.

Principal Investigator:		Phone:	
Department:		E-mail	
Title of Research Project:			
IRB Study No.:		IRB Approval Expiration Date	
The study is (check one):	☐ Currently in progress (open to enrollment) No. of subjects enrolled: No. of subjects still in treatment: ☐ Closed to enrollment (participants in follow-up)		
Date of Event: Date of awareness of event:			
Was this an internal or an external event	☐ Internal ☐ External (took place at another site in the context of a multicenter study or trial)		

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☐ Serious Adverse Event ☐ Other Unanticipated Problem	OHRP defines serious adverse event as any adverse event that: 1. results in death; 2. is life-threatening (places the subject at immediate risk of death from the event as it occurred); 3. results in inpatient hospitalization or prolongation of existing hospitalization; 4. results in a persistent or significant disability/incapacity; 5. results in a congenital anomaly/birth defect; or 6. based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Description of Event (give enough detail here to determine the rationale for study-or-treatment relatedness and determination of unexpected nature of event):

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Description of any and all steps and actions taken in response to the incident or to resolve the issue:

Number of similar experiences in this protocol:

Was the event reported within policy time frames (Events not meeting the definition of a serious adverse event must be reported within 5 business days. Events meeting the definition of a serious adverse event must be reported within 24 hours.)? If not, explain:

What was subject's participation level after the event?

- ☐ Subject stopped research participation
- ☐ Subject had already completed research
- ☐ Subject continued research participation
- ☐ Subject withdrew from further participation
- ☐ Subject continued participation/follow-up only
- ☐ Investigator withdrew subject from participation
- ☐ Other (describe):

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Effect on Research – In your judgment, should the research

☐ **continue as planned** with no changes to the research protocol or consent process. Explain why:

☐ **continue with changes** to the research protocol or consent process;

Attach proposed changes for IRB review and approval using a modification form.

☐ **suspend new subject enrollment** until the event is further examined;

☐ **be terminated** (stopped completely), with all subjects removed from research.

Have other agencies or sponsors been notified of this event?

☐ Yes (list agencies/sponsors notified including dates and methods used)

☐ No (describe steps to be taken to notify appropriate parties)

Does this study have a Data Safety Monitoring Board (DSMB)? ☐ Yes ☐ No

If yes, has the DSMB been notified? ☐ Yes ☐ No

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Investigator Assurance(s):

I have reviewed the contents of this form and hereby assure that the information provided is complete and accurate to the best of my knowledge.

_____ ☐ person filing report

Signature of Principal Investigator Date

_____ ☐ person filing report

Study Coordinator Date