

Problem Reporting Form

Instructions:

Serious Adverse Events, unanticipated problems involving increased risks to subjects or others, or non-compliance with the protocol must be reported to the IRB as soon as you are aware of the event.

<i>For IRB Use Only</i>
Protocol #: HS
IRB Approval Expiration Date:
Chair/ IRB Designee:
Submission Date:

<i>Type of Event/ Problem</i>
<p>Check One: <input type="checkbox"/> Initial Report of Problem <input type="checkbox"/> Follow-Up report (Date of Initial Report _____)</p> <p>(See definitions section at the end of the document for explanations)</p> <p><input type="checkbox"/> Serious Adverse Event (SAE; report if the event is <i>unanticipated</i> and <i>related</i> to the study procedures or intervention. Life threatening SAEs must be reported <i>immediately</i>; all other SAEs should be reported with 48 hours. The relatedness assessment should be made by the PI or appropriately qualified sub-investigator)</p> <p><input type="checkbox"/> Unanticipated Problem Involving Increased Risk to Subjects (confidentiality breach, etc.)</p> <p><input type="checkbox"/> Protocol Deviation/ Violation/ Non-Compliance (Not IRB approved change) (report <i>unintentional</i> deviations from protocol that <i>increase</i> risks to subjects or damage the scientific integrity of the study data and report all <i>intentional</i> changes made without prior IRB approval, including any changes to eliminate immediate risk to subjects)</p> <p><input type="checkbox"/> Subject Complaint</p> <p><input type="checkbox"/> Other</p>

PART 1	
Investigator Information	
Last Name:	First Name:
Museum/ Center:	
Phone:	Email:
<i>If you are a Smithsonian affiliated person, please provide the following:</i>	
Type of affiliation: <input type="checkbox"/> Fellow <input type="checkbox"/> Research Associate <input type="checkbox"/> Visiting Researcher <input type="checkbox"/> Other:	
Name of Smithsonian Sponsor:	
Phone:	Email:
Project/ Study Information	
Project Title:	
Protocol Approval Date:	Protocol Expiration Date:
PART 2	
Event Information	
<input type="checkbox"/> Internal Event: (Check all that apply) <input type="checkbox"/> Smithsonian Institution (SI) Visitor <input type="checkbox"/> SI Employee <input type="checkbox"/> SI Fellow/Intern <input type="checkbox"/> SI Volunteer <input type="checkbox"/> SI affiliated person <input type="checkbox"/> SI Visitor <input type="checkbox"/> Other _____	
<input type="checkbox"/> External Event: For external events, you may supply any information provided by the sponsor or investigator provided that it satisfies the event description information below. <i>Non-SI site NOT involving any SI visitor(s), or SI employees, affiliated persons, or volunteers.</i>	
Event Description	
Date(s) of Event/ Problem:	Participant ID, if applicable : (<i>DO NOT include personal identifiers</i>)
Participant(s) Age:	Participant(s) Gender:
<input type="checkbox"/> Check this box if additional document(s) are provided and specify the attachment documents:	

<p>2.1 Provide (a) detailed description of the reportable research event, and (b) how and/or why it occurred or (c) a description of plan, and (d) why, in your opinion, the event is unanticipated and related.</p>		
<p>2.2 Explain procedures taken to address the problem.</p>		
<p>2.3 Describe outcome of event: (Include: Increase risk to subject? Violation of subject’s rights, safety, or welfare? Affect study integrity? Has the subject discontinued from the study or will s/he continue in the research study? etc).</p>		
<p>2.4 Describe a corrective action plan to prevent future occurrences (implemented/ to be implemented) (if applicable).</p>		
<p>PART 3</p>		
<p>Attestation and Required Signature</p>		
<p>My signature indicated that I have reviewed and assessed the event(s) described above and the information provided in this report is accurate and complete.</p>		
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> <p>_____</p> <p>Principal Investigator’s Signature</p> </td> <td style="width: 50%; border: none;"> <p>_____</p> <p>Date</p> </td> </tr> </table>	<p>_____</p> <p>Principal Investigator’s Signature</p>	<p>_____</p> <p>Date</p>
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<p><u>If</u> the principal investigator is a Smithsonian “affiliated person”.</p>		
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<p>_____</p> <p>Unit Director’s Signature</p>	<p>_____</p> <p>Date</p>	

PART 4
Definitions
<p>Serious Adverse Event: Any adverse event temporally associated with the subject’s participation in research that meets any of the following criteria:</p> <ol style="list-style-type: none"> 1. Results in death 2. Is life-threatening (places the subject is at immediate risk of death from the event as it occurred) 3. Requires inpatient hospitalization or prolongation of existing hospitalization 4. Results in a persistent or significant disability/incapacity 5. Any other adverse event that, 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
<p>Unexpected Serious Adverse Event: Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either: (1) known or foreseeable risk of SAEs associated with the procedures involved in the research that are described in the IRB-approved research protocol/informed consent document, etc., or (2) the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject’s predisposing risk factor profile for the adverse event.</p>
<p>Unanticipated Problem Involving Risk to Subjects or Others: Any incident, experience, or outcome that meets all of the following criteria: (1) unexpected (in terms of nature, severity, or frequency); (2) related or possibly related to a subject’s participation in the research; and (3) suggests that research places subjects at a greater risk of harm related to the research than was previously know or recognized.</p>
<p>Protocol Deviation/ Violation/ Non-Compliance: A failure to adhere to the IRB-approved protocol. Examples are ineligible participants who were included in the research by mistake, instances where the intervention or other procedure differed from that outlined in the protocol, or modifying IRB-approved protocol documents (e.g. questionnaires, consent forms, etc.) without prior IRB review/ approval.</p>