



UNIVERSITY OF SOUTHERN MAINE

IRB Adverse Event Report Form

Instructions: All adverse events of physical or psychological harm or injuries, threats to privacy or safety or attrition of human subjects must be communicated to the Office of Research Compliance within 10 days of the adverse if at USM, or within 10 days of notification for events at other sites. Submit reports of all fatal or life-threatening events to the ORC within 24 hours of the event if at USM, or within 24 hours of receiving notification for events at other sites. All unanticipated adverse events that include human research subjects in federally sponsored research will be reported to the Department of Health and Human Services Office of Human Subjects Protections as well as any federal agency or sponsor that provides funding for the research study. Please attach supporting documents, and a copy of the current consent form. For expected events please highlight the section of the consent form that lists the event. If you wish to change the consent form, please submit it with a Protocol Revision and Amendment Form, with the changes highlighted. Federal regulations (45 CFR 46.117(a) requires IRB approval for consent form alteration.

PRINCIPAL INVESTIGATOR			
Principal Investigator:	Date:	Phone Number:	Email Address:
Mailing Address:		<input type="checkbox"/> Initial Report <input type="checkbox"/> Follow-up Report	Protocol Number:
Study Title:			
1. Site of Adverse Event:	2. Date of Adverse Event:	3. Brief Summary of the Event:	
4. Severity: <input type="checkbox"/> Moderate (enough discomfort to interfere with usual activity) <input type="checkbox"/> Severe (incapacitated the subject; hospitalization) <input type="checkbox"/> Fatal		5. In your judgment, was the event caused by procedures associated with this protocol? <input type="checkbox"/> Not related <input type="checkbox"/> Unlikely <input type="checkbox"/> Possibly <input type="checkbox"/> Probably <input type="checkbox"/> Definitely Related	
5a. Please explain and attach supporting documents:		6. Should the Informed Consent, or any other portion of this study, be modified as a result of this event? <input type="checkbox"/> Yes <input type="checkbox"/> No	
6a. If yes to question 6, please attach modified documents, with all modifications in bold print or highlighted.			

Signature of Investigator:		Date:
Signature of ORC Coordinator:		Date:
Comments:		

Please submit materials to the USM ORC, 178 Science Building, New Wing, Portland Campus.

Questions: Please call 207 780-4268