



UNIVERSITY OF  
SOUTHERN MAINE

**HANDWRITTEN SUBMISSIONS ARE NOT ACCEPTED**

## REQUEST FOR CONTINUING REVIEW/STUDY COMPLETION

Instructions: Complete this form if your protocol needs continuing review, or if the status of the protocol has changed (e.g., from active to non-active or completed or discontinued). All continuing research must be reviewed and re-approved prior to the IRB expiration date. Please turn in this continuing review form and supporting materials 60 days prior to the IRB expiration date of your study to the Office of Research Compliance. Failure to submit timely continuing review materials will result in Administrative Hold/Termination of Research Activities. Please label all attachments.

PRINCIPAL INVESTIGATOR			
Principal Investigator:	Email:	Are you: <input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student <input type="checkbox"/> Other	Estimated Project Duration: Start Date: End Date:
Address:		Department:	Phone Number: (    )
Study Title:		Previously Assigned Protocol Number:	This study is: <input type="checkbox"/> Active <input type="checkbox"/> Not Active <input type="checkbox"/> Completed or Discontinued

RESEARCH INFORMATION			
<b>1. Total Number of subjects enrolled since the previous approval date:</b>	<b>1a. Total Number of subjects enrolled in the study to date:</b>	<b>2. Have any subjects experienced any unanticipated social (e.g. financial, occupational), psychological (e.g. emotional), or physical problems as a result of this study:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>2a. If YES, please explain:</b>
<b>3. Have any subjects in your study died (either as a result of your study or not):</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>4. Have any subjects decided to withdraw from this study:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>5. Have you asked any subjects to withdraw from this study:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>3a. If Yes, please explain:</b>	<b>4a. If Yes, please explain:</b>	<b>5a. If Yes, please explain:</b>	
<b>6. Will this study use an online survey in its methodology?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No		<b>6a. If yes, please describe:</b>	
<b>7. Will this study offer compensation for participation?</b> <input type="checkbox"/> Yes If Yes, how much? <input type="checkbox"/> No	<b>8. Will this study involve the transfer from a covered entity as defined under HIPPA of protected health information (PHI) to you?</b> <input type="checkbox"/> Yes (If yes, continue to number 8a) <input type="checkbox"/> No (If no, continue to number 10)	<b>8a. Prior to the transfer of this information, will all 18 identifiers be stripped?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>9. Will you be submitting a Data Use Agreement or Business Associates Agreement?</b> <input type="checkbox"/> Yes (If yes, continue to number 9a) <input type="checkbox"/> No (If no, continue to number 10)

<p><b>9a. Has the Data Use Agreement or Business Associates Agreement been reviewed by system council?</b>  <input type="checkbox"/> Yes  <input type="checkbox"/> No</p>	<p><b>10. Since the last protocol approval date is there any new information that may indicate an increased risk of social, psychological, or physical harm to subjects in the study?</b>  <input type="checkbox"/> Yes  <input type="checkbox"/> No</p>	<p><b>11. Please list any changes in key personnel:</b></p> <table border="1"> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> </table>								

**ADDITIONAL DOCUMENTATION**

**11. Please provide a brief (no more than 1/2 page) summary of your research findings to date. If no findings or trends are yet evident, please explain why.**

**12. Please attach a copy of the consent form that you plan to use during the next approval period (even if there have been no revisions). If there have been revisions of the consent form since the last approval, please provide TWO copies of the revised consent form, one which has the changes highlighted.**

**SIGNATURES**

**Original Signatures are required. The application will not be processed until all signatures are obtained.**

**Signature of Principal Investigator**  
 The undersigned accept(s) responsibility for the study, including adherence to DHHS, FDA, and USM policies regarding protections of the rights and welfare of human subjects participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies.

<b>Print Name of Principal Investigator:</b>	<b>Signature of Principal Investigator:</b>	<b>Date:</b>
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**Signature of Faculty Research Supervisor – Required for Student Research**  
 By signing this form, the faculty research supervisor attests that (s)he has read the attached protocol submitted for IRB review, and agrees to provide appropriate education and supervision of the student investigator, above.

<b>Print Name of Faculty Supervisor:</b>	<b>Signature of Faculty Supervisor:</b>	<b>Date:</b>
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**Office of Research Compliance**

**Inter-Campus Mail:**

178 Science Bldg.  
 Portland Campus

**U.S. Mail**

Office of Research Compliance  
 University of Southern Maine  
 P.O. Box 9300  
 Portland, ME 04104-9300

**Drop box**

Located at the entrance to the New Science Wing, across from room 178

**Questions? Please call: (207) 780-4268**

**E-mail: usmirb@usm.maine.edu**