



**HANDWRITTEN SUBMISSIONS ARE NOT ACCEPTED**

**PROTOCOL REVISION AND AMENDMENT FORM**

**Instructions:**

Please complete this form and attach your research documents with any changes to it. (Such as consent forms, supportive materials, flyers, questionnaires, surveys, letters, etc.) Revisions can be defined as a revised or new version and Amendments can be defined as a correction or alteration. \*It is important that you fill in all information below. Use N/A where applicable. Whenever possible, use your USM mail and email addresses, and phone numbers.

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	THE CURRENT STATUS OF THE USM PROJECT IS: <input type="checkbox"/> Currently in Progress (# of Subjects entered: ) <input type="checkbox"/> Project Not Yet Started (No Subjects entered) <input type="checkbox"/> Closed to Subject Entry (Remains Active)
Address:		Department:	Phone Number: ( )
Study Title:		Protocol Number:	
<b>THIS SUBMISSION CHANGES THE STATUS OF THIS STUDY IN THE FOLLOWING WAY(S):</b>			
<input type="checkbox"/> Protocol Revision		<input type="checkbox"/> Addendum (New) Consent Form	
<input type="checkbox"/> Protocol Amendment		<input type="checkbox"/> Revised Consent Form	
<input type="checkbox"/> Closed to Subject Entry*		<input type="checkbox"/> Other (specify):	
*If you would like to terminate this study, please submit a Study Completion form.			

RESEARCH INFORMATION			
<p><b>1. Briefly describe and explain the reason for the revision or amendment as an attachment. Include a copy of the affected protocol pages, with specific changes highlighted. Please highlight, or otherwise indicate, any changes/revisions/additions to a consent form, protocol, or research questionnaire, or the PRAF will be returned to you. With significant changes to your protocol, please submit a revised Proposal Summary, labeled, highlighted where your changes occur, and placed in the order listed below:</b></p> <p>A. Introduction            B. Specific Aims            C. Methods of Data Collection and Analysis (Qualitative and Quantitative)            D. Description of the subject population, research setting, subject recruitment procedure.            E. Informed consent procedure (if consent needed)            F. Provisions for subject and data confidentiality            G. Statement of potential research risks to subjects (e.g. breach of confidentiality, treatment complications)            H. Statement of potential research benefits to subjects (Monetary compensation is not a benefit of participation)            I. Investigator experience (Attach a current copy of your C.V. unless you submitted one previously with this study)</p>			
<p><b>2. Does this revision/amendment revise or add genetic component?</b></p> <input type="checkbox"/> Yes <input type="checkbox"/> No	<p><b>3. Does this change affect subject participation (e.g. procedures, risks, costs, etc.)?</b></p> <input type="checkbox"/> Yes <input type="checkbox"/> No	<p><b>4. Does this change affect the consent document?</b></p> <input type="checkbox"/> Yes <input type="checkbox"/> No	<p><b>4a. Discuss Changes Here (If yes to question 4, please include the revised consent form with the changes highlighted):</b></p>

<b>5. Will this revision/amendment use an online survey in its methodology?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No		<b>5a. If yes, please describe:</b>	
<b>6. Will this study offer compensation for participation?</b> <input type="checkbox"/> Yes If Yes, how much? <input type="checkbox"/> No	<b>7. 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 7a) <input type="checkbox"/> No (If no, continue to signatures)	<b>7a. Prior to the transfer of this information, will all 18 identifiers be stripped?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>8. Will you be submitting a Data Use Agreement or Business Associates Agreement?</b> <input type="checkbox"/> Yes (If yes, continue to number 8a) <input type="checkbox"/> No (If no, continue to signatures)		<b>8a. Has the Data Use Agreement or Business Associates Agreement been reviewed by system council?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	

<b>SIGNATURES</b>
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**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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