



Opus Institutional Review Board

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Amendment/Modification to a Research Study

Protocol Information	
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is this a change to a prior approval from OPUS IRB?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is this a new Change?
	Protocol Name
	Protocol Number
	Opus IRB Number
	Name of Sponsor of Study
Yes <input type="checkbox"/> No <input type="checkbox"/>	If Sponsor is submitting for all active investigators check here
	Name of Principal Investigator
	Name of person completing the form
	Date
	Email of person completing the form
	Phone #

Resources	
Yes <input type="checkbox"/> No <input type="checkbox"/>	Are there adequate resources necessary to manage the amendment and protect participants?
	<input type="checkbox"/> Adequate time for the investigators to conduct and complete the research
	<input type="checkbox"/> Adequate number of qualified staff
	<input type="checkbox"/> Adequate facilities
	<input type="checkbox"/> Access to a population that will allow recruitment of the necessary number of participants
	<input type="checkbox"/> Availability of medical or psychosocial resources that participants may need as a consequence of the research

Research Protocol

The purposes of the research:

The scientific rationale:

The procedures to be performed:

A Description of the procedures being performed already for diagnostic or treatment purposes:

The risks and potential benefits of the research to participants:

CHECK ALL ADMENDMENT/MODIFICATION CHANGES

<input type="checkbox"/>	Site Information Change: Make change to 1572 if applicable and send with this change form
<input type="checkbox"/>	Change to the Informed Consent Form: Attach a copy to the current approved ICF with changes highlighted, bolded, or track change.
<input type="checkbox"/>	Protocol Change: Submit pages from protocol with changes highlighted, bolded, or track changes noted.
<input type="checkbox"/>	Change to Investigator Brochure/Manual/Addendum Submit change(s) with the changes highlighted, bolded, or track change.
<input type="checkbox"/>	Revision of Package Insert/Addition of Package Insert
<input type="checkbox"/>	Study Related Materials: Attach a copy of previously approved materials and a copy highlighted or bolded with changes to be approved.
<input type="checkbox"/>	Change for a reference or website: Provide an explanation of what is to be changed from and to
<input type="checkbox"/>	Other: Provide a detailed explanation.
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is this study actively enrolling subjects?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Are there any additional risks to subjects?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Will the protocol change also change the IRB approved consent form?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Will any of these changes affect your community attitude towards research?
Comments:	

There will be a delay to this submission form if all appropriate items are not completed.

Signature

Date