

Modification of Approved Human Research

Use to request a modification to previously approved research	
IRB Number:	
Protocol Name:	
Investigator:	
Primary Contact:	
Numbers of Subjects Enrolled Locally:	
<p>Does this modification include a change in study personnel? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, if any contact information has changed or any study personnel have been added and are not currently in the IRB database, a Contact Information Form must be completed and included with this submission.</p>	
Study Status as a Result of this Modification	
<input type="checkbox"/>	Enrollment is suspended. Effective Date: _____ If not previously reported, please explain:
<input type="checkbox"/>	Enrollment is suspended. Request to re-open upon approval of this revision/addition.
<input type="checkbox"/>	Actively enrolling subjects.
<input type="checkbox"/>	<p>Enrollment is permanently closed. Effective Date: _____</p> <ul style="list-style-type: none"> - Are subjects receiving active intervention? <input type="checkbox"/> Yes <input type="checkbox"/> No - Are subjects on long-term follow-up? <input type="checkbox"/> Yes <input type="checkbox"/> No
Summarize the Modification or Attach a Summary:	
<p>Explain what the plan is for communicating these changes to the subject(s). If these changes will not be communicated to subject(s), explain why:</p>	

Provide the following when they have been *modified* or are new, and submit to the OSU CHS IRB

Documents	Version # and/or Date (as applicable)	Check Box if Submitting with this Modification
Protocol		<input type="checkbox"/>
Data Collection Instruments (if investigator initiated research)		<input type="checkbox"/>
All written material to be provided to or meant to be seen or heard by subjects, including:		
Evaluation Instruments (to be completed by subjects) and Surveys		<input type="checkbox"/>
Advertisements (printed, audio, and video)		<input type="checkbox"/>
Recruitment Materials (letters, phone scripts, posters)		<input type="checkbox"/>
Consent Documents or Information Sheets		<input type="checkbox"/>
Foreign language version of any written material to be provided to or		<input type="checkbox"/>

meant to be seen or heard by subjects.		
If consent will not be documented in writing, a script of information to be provided orally		<input type="checkbox"/>
Provide the following documents when they exist:		
Grant Application		<input type="checkbox"/>
Investigator's brochure for each investigational drug/biologic		<input type="checkbox"/>
Package insert for each marketed drug/biologic		<input type="checkbox"/>
Product information for each investigational device		<input type="checkbox"/>
Contact Information Form <i>(for all new individuals and any individuals with updated information)</i>		<input type="checkbox"/>
Other:		<input type="checkbox"/>
Other:		<input type="checkbox"/>
Other:		<input type="checkbox"/>

Investigator Acknowledgement	
I agree to conduct this Human Research in accordance with applicable regulations and the organization's policies and procedures.	
Investigator Signature	Date