



## Continuing Review Progress Report or Notification of Study Completion

<b>IRB Number:</b>				
<b>Protocol Title:</b>				
<b>Principal Investigator:</b>		<b>Email:</b>		
<b>Primary Contact:</b>		<b>Email:</b>		
Indicate which you are requesting: <input type="checkbox"/> <b>Continuing Review</b> <input type="checkbox"/> <b>Study Completion</b>				
Submission Instructions: <ul style="list-style-type: none"> <li>The IRB must maintain a record of this report with the investigator's signature.</li> <li>Remember, if anything has changed with your study (study staff, funding source, informed consent, protocol, etc.); submit a Modification of Approved Research form to address these.</li> <li>Note, there is a separate continuing approval form for Humanitarian Use Device (HUD).</li> <li>For any questions on this form or the submission process contact the IRB Office 918-561-1400.</li> </ul>				
<b>Current Protocol Status</b>				
<b>Project Ongoing (Check One)</b>				
<input type="checkbox"/> Project is a retrospective chart review and does not involve any subject interaction.				
<input type="checkbox"/> Actively enrolling subjects.				
<input type="checkbox"/> Enrollment is suspended as of . Provide a brief explanation of why:				
<input type="checkbox"/> Enrollment is permanently closed as of . - Are subjects still receiving research-related intervention? <input type="checkbox"/> *Yes; <input type="checkbox"/> No *If yes, what does the research-related intervention consist of? - Are subjects on long-term follow-up? <input type="checkbox"/> Yes; <input type="checkbox"/> No				
<input type="checkbox"/> Private identifiable information still being analyzed				
<b>Project Not Started</b>				
<input type="checkbox"/> Explain why the project was not started (waiting for sponsor, staffing issues, etc.)				
<b>Project Completed (none of the above are applicable)</b>				
<input type="checkbox"/> Submit this form. Note – 'documents to be submitted' does not apply				
<b>Enrollment Status <i>For Retrospective Chart Reviews skip to "Research Summary for Retrospective Chart Reviews"</i></b>				
<b>Number of subjects enrolled (not including screen failures):</b>				
	Since initial approval	Since last continuing review	Male from initial approval (indicate if unknown)	Female from initial approval (indicate if unknown)
Total enrolled under local PI:				
For multi-site trials: Total enrolled at all sites				
<b>Research Summary (Refer to the time period since initial study approval or since last continuing review approval)</b>				
(a) Have the expected harms/adverse events been consistent with the expected severity and frequency? <input type="checkbox"/> Yes <input type="checkbox"/> No, summarize what occurred, where and when it occurred, and if it has been reported to the IRB: <input type="checkbox"/> No harms or adverse events have occurred				

- (b) Have there been any unanticipated problems involving risks to subjects or others, including those that have not been previously reported to the IRB?
- ☐ Yes, explain:  
☐ No
- (c) Have subjects experienced any unexpected benefits?
- ☐ Yes, explain:  
☐ No
- (d) Have any subjects withdrawn or been withdrawn from the research?
- ☐ Yes, explain:  
☐ No
- (e) Have any subjects or others complained about the research?
- ☐ Yes, explain:  
☐ No
- (f) Have there been any publications or any other relevant information regarding this research, especially information about risks associated with the research (FDA alerts/recalls)?
- ☐ Yes, explain and include if not previously submitted:  
☐ No
- (g) Have there been any interim findings, multi-center trial reports, or data safety monitoring board reports?
- ☐ Yes, explain and include if not previously submitted:  
If yes, does the DSMB report confirm that the study is still safe to continue?  
☐ No
- (h) In the opinion of the investigator, have the risks or potential benefits of this research changed?
- ☐ Yes, explain:  
☐ No
- (i) Is the investigator responsible for the conduct of the study at multiple sites?
- ☐ Yes, attach a summary of the investigator's oversight activities since the last review performed by the OSU CHS IRB. Include documentation of activities that demonstrate protocol adherence, informed consent process, monitoring of adverse events and communication with other IRBs as applicable. Identify the number of subjects enrolled at each site.  
☐ No

**Research Summary for Retrospective Chart Reviews ONLY**

**Number of subject records used in this study:**

	Since initial approval	Since last continuing review
Total enrolled under local PI:		
For multi-site trials: Total enrolled at all sites		

- (a) Have there been any unanticipated problems involving risks to subjects or others, including those that have not been previously reported to the IRB (misplaced or lost data, data accessed by unapproved personnel)?
- ☐ Yes summarize what occurred, where and when it occurred, and if it has been reported to the IRB:  
☐ No
- (b) Where is the data stored, including both paper and electronic data?
- (c) Who has access to the identifiable data?

(d) Summarize the research activity that has occurred to date (i.e. continuing to access charts, data collection complete, statistical analysis being conducted):

(e) Have there been any interim findings?

#### Documents to be Submitted

	Version # and/or Date as applicable
Copy of latest signed consent form with all references to participant's name censored (i.e. blacked out, whiteout)	
Current Approved Consent Form(s) <i>N/A if closed to enrollment</i>	
DSMB and Study Progress Reports (if applicable)	
Other applicable study documents not previously submitted (publications, FDA alerts, etc.):	

#### Financial Interest Declaration

- "Financial Interest Related to the Research" means any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family:
  - Ownership interest of any value including, but not limited to stocks and options exclusive of interests in publicly-traded, diversified mutual funds.
  - Compensation of any amount including, but not limited to honoraria, consultant fees, royalties, or other income.
  - Proprietary interest of any value including, but not limited to, a patents, trademarks, copyrights, and licensing agreements.
  - Board or executive relationship, regardless of compensation.

Yes <input type="checkbox"/>	No <input type="checkbox"/>	Do any investigators or research staff have a financial interest related to the research that was not described in a previous application or annual research conflict of interest disclosure form? <i>If yes, attach an explanation.</i>
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#### Investigator Acknowledgement

For Continuing Review: I agree to conduct this Human Research in accordance with applicable regulations and the organization's policies and procedures.

Study Completion: As principal investigator, I verify that the information provided is complete and accurate. I request that this study be closed.

Investigator signature	Date