



Opus Institutional Review Board

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 info@opusirb.com

Continuing Review Form

Sponsor, Protocol Name and Protocol Number	
	OPUS IRB Number
	Principle Investigator
	Sponsor
	Initial Protocol Number Protocol Version Number Protocol Date
	Drug / Device Name
Yes <input type="checkbox"/> No <input type="checkbox"/> Does this protocol have a sub study that your site is participating in? If Yes, please list below the separate information regarding subject participation in sub-study(ies).	
Type of Report Interval <input type="checkbox"/> Annual <input type="checkbox"/> Final Retirement <input type="checkbox"/>	
	Date Report Due
	Date 1 st Subject Consented
Study Status	
<input type="checkbox"/>	Pending contract; study not started yet
<input type="checkbox"/>	Open and enrolling
<input type="checkbox"/>	Enrollment closed; subjects in follow-up. Date enrollment closed
<input type="checkbox"/>	All follow-up completed; study in data analysis.
<input type="checkbox"/>	Awaiting final closure by Sponsor
<input type="checkbox"/>	This is a request to close and retire the study

Resources

Yes No

Are there adequate resources necessary to continue the research and protect participants?

- Adequate time for the investigators to conduct and complete the research
- Adequate number of qualified staff
- Adequate facilities
- Access to a population that will allow recruitment of the necessary number of participants
- 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:

Participant Information

Total Number	Category
	Total Screened
	Total Enrolled
	Total Active
	Total Withdrawn by Investigator and reason for withdrawal(s) for each
	Total Withdrawn (drop outs – subject withdrew him/herself and reason for withdrawal(s) for each)
	Total Lost to Follow-Up
Total Completed Completed all study activities Deaths	
Note: Active Subjects + Withdrawn Subjects = Enrolled Subjects If this is your first report after starting the study, enclose or upload a copy of a consent form you are using for this study that has been signed by a subject (black out subject's name except initials)	

Amendments and Changes

List any protocol amendments, protocol revisions, administrative changes, etc. since initial approval by OPUS IRB or since the last report that have not been reported to OPUS IRB. Attach an explanation and forward a copy of the change(s) immediately. Include version number(s) and dates.

Protocol Amendment	Version # and /or date	ICF Change?
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
Yes <input type="checkbox"/> No <input type="checkbox"/> Has new information involving risks or benefits to subjects or others become available? If Yes, Explain		

Yes No Has the current risk/benefit assessment changed based on study results?
If Yes, Explain

Yes No Based on your experience with this study, should changes be made to the consent form?
If Yes, Explain

Yes No Have there been any deaths, hospitalizations, or serious illnesses whether or not thought to be associated with the study agent to any subject not previously reported?
If Yes, Explain

Yes No Has this study been suspended or terminated by any other IRB?
If Yes, Explain

Yes No Have there been any unanticipated problems involving risks to participants or others not previously reported?
If Yes, Explain

Yes No Is there any recent literature available that has not been submitted ?
If yes, please attach

Yes No Are there any interim findings not reported?"
If yes, explain or attach report

Yes No Are there any relevant multi-center reports available?
If yes, explain or attach report

List all SAEs from your site(s) to date:

Subject Initials or ID	SAE	Date Reported to IRB

Yes No Have there been any changes in community or state laws relating to clinical research?

If Yes, Explain

Yes No Have there been any changes in community attitudes towards medical research?

If Yes, Explain

Yes No Have you been audited by the FDA, sponsor or another IRB since your last report?

If Yes, Explain

Since your last report, have you consented any subjects from the following groups? (Please explain below for the supporting documentation for any "yes" answers.)

Yes No Non English Speaking Subjects

Yes No Limited readers or Illiterate subjects

Yes No Cognitively Impaired

Yes No Anyone using a legally authorized representative for consent

Yes No Students, Employees

Yes No Visually Impaired (unable to read consent due to vision)

Yes No Emergency Use

Yes No Ineligible Subjects

Yes No Wrong version of consent used

Yes No Enrolled without consent

Yes No Subject who is in another study

Yes No Life Threatening Illness (traumatized, comatose, emergency or critically ill)

Yes No Economically Disadvantaged

Yes <input type="checkbox"/> No <input type="checkbox"/> Total Number Female Subjects Enrolled
Yes <input type="checkbox"/> No <input type="checkbox"/> Total Number Male Subjects Enrolled
Yes <input type="checkbox"/> No <input type="checkbox"/> Total Number Children or Minors Enrolled
<p>Indicate ethnic and racial breakdown of subjects enrolled:</p> <p style="padding-left: 40px;">Caucasian</p> <p style="padding-left: 40px;">Latino</p> <p style="padding-left: 40px;">African American / Black</p> <p style="padding-left: 40px;">American Indian</p> <p style="padding-left: 40px;">Alaska Native</p> <p style="padding-left: 40px;">Asian</p> <p style="padding-left: 40px;">Other</p>
<p>Explain if consented from any of the above groups:</p>

Events		
Since your last report, have any of these events occurred at your site?		
Event	Event Occurred	Approved by or Submitted to IRB?
Change in Principal Investigator If yes, Name:	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Change in Sub-investigator(s) – deletion If yes, Name:	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Change in Sub-investigator(s) – addition If yes, Name:	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Change in Study Staff (addition or deletion of CRC, regulatory, pharmacist, etc.) If yes, explain	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Addition of site location If yes, explain	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Deletion of site location	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>

If yes, explain			
Change in compensation for subjects	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Subject Complaints	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, explain			
Advertisements, including print, radio, TV, internet, audio (<i>send copy</i>)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Protocol Deviations (provide complete list) – <i>upload or attach</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
License renewal for MDs, Pharmacist(s), RN(s) – upload or attach copy	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Change in financial or non-financial conflict of interest for any investigator. If so, <i>upload or attach documentation or financial disclosure form.</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Updated CV for any Investigator or Coordinator	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Changes in status of board certifications, hospital privileges, licensure of any investigator on the study –explanation: If yes, explain	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Criminal charges against any investigator or study personnel (do not include traffic violations) – upload or please explain below: If yes, explain	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Medical, Nursing or Pharmacy Board complaints, investigations or actions – upload or explain below: If yes, explain	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>

Any IRB suspend or terminate approval of any study at your site. Please explain below: If yes, explain	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Any IRB impose restriction(s) or sanctions on any study at your site. Please explain below: If yes, explain	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Subject who has become incarcerated	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Pregnancy of study subject	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>

Monitoring Events											
Yes <input type="checkbox"/> No <input type="checkbox"/>	Have you had any monitoring visits since your last IRB continuing review report? If yes, provide dates										
* Upload or attach copy of monitoring letters or correspondence received.											
Yes <input type="checkbox"/> No <input type="checkbox"/>	Have there been any Data Safety Monitoring Board (DSMB) or other Safety Reports / Annual Reports or Other Reports from the DSMB or Sponsor? If yes, attach copy (unless previously submitted to IRB) List Report and Date Submitted to IRB:										
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%; padding: 5px;">Report</th> <th style="width: 40%; padding: 5px;">Date</th> </tr> </thead> <tbody> <tr><td style="height: 20px;"> </td><td> </td></tr> <tr><td style="height: 20px;"> </td><td> </td></tr> <tr><td style="height: 20px;"> </td><td> </td></tr> <tr><td style="height: 20px;"> </td><td> </td></tr> </tbody> </table>	Report	Date									
Report	Date										
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is there other information available of which OPUS IRB should be aware? If yes, explain										

List any Good Clinical Practices (GCP) training that has been obtained since last report (accredited programs).

Personnel	Training Course	Date

Contact Information

Person Completing this Report

	Telephone
	Fax
	Email

Monitor (CRA) for this Study

	Telephone
	Fax
	Email

HIPAA Privacy Officer

	Telephone
	Fax
	Email

I have reviewed the information provided on this form and all attachments and certify that the information provided is true and accurate.

Signature of Principal Investigator

Date