**Application for Continuing Review**

*In order to facilitate IRB re-review of your project and to avoid unnecessary delays, your Application for Continuing Review must be complete. Answer each question as completely as possible. If an answer to any question cannot be provided, provide an explanation for the missing answer. Please include sufficient detail to allow the IRB to perform a thorough Continuing Review. Failure to provide this detail may delay re-approval of your project and could result in a suspension of the research. All suspensions will be promptly reported to the FDA or applicable regulatory body.*

**Application Submission Date: **

**Protocol ID #:  Current Protocol Version: **

**Study Title: **

**Principle Investigator: **

**Initial IRB Approval Date:  Type of Initial Review:** [ ]  Full Board

 [ ]  Expedited

**ENROLLMENT INFORMATION**

Accrual Target according to protocol:  Local accrual target (if multicenter study): 

Total # Local participants enrolled to date: 

* # of local participants currently receiving study intervention: 
* # of local participants who completed study intervention: 
* # of local participants in follow-up: 
* # of local participants terminated early or who have chosen to withdraw from the study: 
	+ Describe *specific* reasons for withdrawals or terminations and how many participants each:

****

How is overall study recruitment progressing compared to the intended schedule? If concerns exist, what is the plan to address them?

****

How is recruitment in racial and ethnic categories progressing compared to intended schedule?

****

If concerns exist, what is the plan to address them?

****

**Research Status**

*(Check the appropriate box below to indicate the status of your study.)*

[ ]  The study has received full approval from the IRB and the study is open to accrual

[ ]  The study has been fully approved by the IRB, but is not yet open to accrual

[ ]  The study is not completed but is temporarily not accruing participants. Participants currently enrolled have had study

intervention suspended.

 Temporary Closure/Intervention Suspension Date: ****

Describe reason for Temporary Closure/Intervention Suspension:

****

[ ]  The study has permanently closed to accrual, however, enrolled participants are still receiving study intervention.

Closure to Accrual Date: ****

[ ]  The Study is permanently closed to accrual and all participants have completed study intervention. Participants are either in follow-up phase or have finished participation in the study.

 Closure to Accrual Date: ****

[ ]  The study is withdrawn by the Study Chair prior to IRB final approval or withdrawn prior to activation by the coordinating group.

*(Once withdrawn, all study activity must stop and the study will have to be submitted to the IRB and reviewed as a new Study.)*

[ ]  The study is Completed:

*(The study is considered completed and permanently closed with the IRB only when all the following questions have been answered “yes”.)*

a. The study has been permanently closed to accrual at all local study sites.

[ ]  Yes [ ]  No

b. All study participants have completed study intervention and interactions at all local study sites.

[ ]  Yes [ ]  No

c. All study-related collection of identifiable private information about the participants is complete at all local study sites

[ ]  Yes [ ]  No

d. Analysis of identifiable data is complete at all local study sites

[ ]  Yes [ ]  No

e. The study has met its primary objectives and a final study report/publication has been submitted. If yes, provide a copy of the final study report/publication.

[ ]  Yes [ ]  No

If the study was stopped earlier than planned please explain why:

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**OTHER STUDY INFORMATION**

*(Include new relevant information that has become available since the last continuing review approval, or initial review approval if this is the first review for continuation)*

* Have any findings from this study been presented or published other than to a Data Safety Monitoring Board?

[ ]  Yes [ ]  No If yes, attach the presentation or publication(s)

* To the PI’s knowledge, has any publication or relevant information relating to the participants’ risk and benefits on this study become available? This would include any new information about the drugs or procedures used in this study, as well as any new information on alternative therapies for the condition being studied.

[ ]  Yes [ ]  No If yes, attach the publication(s) or relevant information

* Have there been any changes in the research activity, revisions, amendments, or any editorial or administrative updates to the protocol, model consent form, or study participant questionnaires since the last review?

[ ]  Yes [ ]  No

If yes, please list all changes, revisions, amendments, and/or editorial or administrative updates since the last continuing review approval or initial review approval if this is the first review for continuation. Include the respective Protocol Version Dates or Update Dates.

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* Have the financial conflict of interest disclosures of the PI or any persons listed on the protocol who are involved in the development or coordination of the study changed?

[ ]  Yes [ ]  No If yes, new Conflict of Interest Statement must be included.

**ADVERSE EVENT AND UNANTICIPATED PROBLEM INFORMATION**

*(Include new relevant information that has become available since the last continuing review approval, or initial review approval if this is the first review for continuation)*

Date of last DSMB or Safety monitoring meeting (month/year)

* How is the study monitored for safety?

[ ]  Data and Safety Monitoring Board (DSMB) ****

[ ]  Safety Monitoring Committee

[ ]  Not applicable / Other, explain: 

If no DSMB or safety monitoring committee is being used, state when and how the continued progress of the study was last monitored/reviewed and state results from that discussion:

****

Number of local participants reporting AEs: 

* Have there been any incidents, experiences, participant complaints, or outcomes that indicate participants or others may be at greater risk of harm (physical or otherwise) than previously anticipated?

[ ]  Yes [ ]  No

* Have there been any unanticipated problems?

[ ]  Yes [ ]  No

If yes to either question above, please provide a description of the unanticipated problem and any corrective action plan implemented.

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