



Institutional Review Board

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CONTINUING REVIEW APPLICATION

Please complete this form in its entirety. Please DO NOT copy and paste information from your initial application OR a previous continuing review application.

1. PARTICIPANT ENROLLMENT

The number of participants currently approved for this protocol can be found in Section 2 of your Initial Application, or in a recent Amendment, if an increase in enrollment was requested.

a. IRB Approved - Number of Participants: [Click here to enter text.](#)

Please provide the total number of participants enrolled during the last approval period in the table below.

PARTICIPANTS ENROLLED IN LAST APPROVAL PERIOD:		
Adults	Children/Adolescents	TOTAL:

Please provide the total number of participants enrolled to date in the table below.

TOTAL PARTICIPANTS ENROLLED TO DATE:		
Adults	Children/Adolescents	TOTAL:

b. Will the protocol remain open to participant enrollment? If enrollment will remain open, a copy of the CONSENT FORM(S) must be included with your application.

Yes No

Please indicate if this project was previously approved for a waiver of consent below.

[Click or tap here to enter text.](#)

c. Were there any participant withdrawals?

Yes No

If YES, please explain.

Click here to enter text.

2. SUMMARY

- a. Please provide a brief summary regarding the progress of the project. Please indicate if any additional risks have been identified. If YES, please explain.

Click here to enter text.

- b. Have there been any changes and/or [deviations](#) to the protocol that were not reviewed and approved by the IRB?

Yes No

If YES, please explain when the change and/or [deviation](#) occurred and why it was not reported at the time of the occurrence.

Click here to enter text.

- c. Were there any [adverse events](#) and/or [unanticipated problems](#) that occurred during the currently approved IRB protocol that were not previously reported?

Yes No

If YES, please provide an explanation of the [adverse event](#) and/or [unanticipated problem](#). Please explain when the event occurred and why it went unreported.

Click here to enter text.

- d. If you marked YES to question 2b and/or 2c above, please provide a Corrective Action Plan to address how those occurrences will be avoided and promptly reported in the future.

Click here to enter text.

3. SPECIFIC CHANGES

Investigators are not permitted to request changes beyond personnel and enrollment when submitting a Continuing Review. All additional changes must be requested through the submission of an [Amendment](#) application, in a separate submission package.

- a. Is an increase in enrollment being requested?

Yes No

If YES, please explain.

[Click here to enter text.](#)

b. Are any personnel changes being requested at this time?

Yes **No**

If YES, please explain.

[Click here to enter text.](#)

REQUIRED SIGNATURES:

By electronically signing this Continuing Review in IRBNet, the Principal Investigator certifies that the research has been conducted in accordance with the IRB-approved protocol.