**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.**

1. **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:** |
|  |  |  |

1. **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.

1. **Were there any participant withdrawals?**

[ ]  **Yes** [ ]  **No**

 **If YES, please explain.**

Click here to enter text.

1. **SUMMARY**
2. **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.

1. **Have there been any changes and/or** [**deviations**](https://research.umd.edu/research-resources/research-compliance/institutional-review-board-irb/irb-basics#definitions) **to the protocol that were not reviewed and approved by the IRB?**

[ ]  **Yes** [ ]  **No**

**If YES, please explain when the change and/or** [**deviation**](https://research.umd.edu/research-resources/research-compliance/institutional-review-board-irb/irb-basics#definitions) **occurred and why it was not reported at the time of the occurrence.**

Click here to enter text.

1. **Were there any** [**adverse events**](https://research.umd.edu/research-resources/research-compliance/institutional-review-board-irb/irb-basics#definitions) **and/or** [**unanticipated problems**](https://research.umd.edu/research-resources/research-compliance/institutional-review-board-irb/irb-basics#definitions) **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**](https://research.umd.edu/research-resources/research-compliance/institutional-review-board-irb/irb-basics#definitions) **and/or** [**unanticipated problem**](https://research.umd.edu/research-resources/research-compliance/institutional-review-board-irb/irb-basics#definitions)**. Please explain when the event occurred and why it went unreported.**

Click here to enter text.

1. **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.

1. **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**](https://research.umd.edu/research-resources/research-compliance/institutional-review-board-irb/irb-forms#amendmentapp) **application, in a separate submission package.**

1. **Is an increase in enrollment being requested?**

[ ]  **Yes** [ ]  **No**

 **If YES, please explain.**

Click here to enter text.

1. **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.**