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| Logo | **APPLICATION Status Report, Renew or Close** |
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| **Study Title:** |       |

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| **QUESTIONS** |
| **1. Provide a summary** of the research progress since your last Continuing Review (or since your initial IRB approval was granted, if this is your first Continuing Review). Provide the summary in the text box below, or upload a document (such as a NIH Progress Report) to Question 7 on the Zipline Continuing Review smart form. If you upload a document, provide the document name in the text box below. |
|  |       |
| **2. Subject number details.** If your study has more than one group of subjects: Fill in the table below by providing the number of subjects in each group who have **completed** all study procedures and involvement. Note that the number of subjects who have *completed* the study may be different than the number of subjects that have *enrolled*, as reported in the *Zipline SmartForm*.  |
|  | **Subject group name or description** | **# of subject completions at the time of the last Status Report** | **# of subject completions since the last Status Report** | **Total number of subject completions** |
|  |       |       |       |       |
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| **3. Funding.** 1. Has your funding and any no-cost extensions expired or will it expire in the next year?
 |
|  |  | **a. Yes**, funding is expired 🡪 Which funding source(s) expired?      **b**. **Yes,** funding will expire in the next year. 🡪 Which funding source(s) will expire?       |
|  |
|  |  | **c. No**,funding is active. |
|  |  | **d. Not Applicable**.This research is not funded. |
| 1. Have you received any funding not already submitted as a Modification?
 |
|  |  | **No** |  |
|  |  | **Yes** | 🡪 If yes, describe the funding source here and submit a Modification to add it to the research. |
|  |  |  |       |
| **4. Explanation of unchecked items.** The ***Zipline*** Continuing Review SmartForm asks you to consider a series of statements and to indicate which ones apply to your study. Provide a summary explanation of the items you left unchecked. Specifically, you should provide a summary explanation in the boxes below if: |
| **a.** Subjects **DID** experience unexpected harm.  |
|  |       |
| **b.** Anticipated adverse events **DID** take place with greater frequency or severity than expected.  |
|       |
| **c.** Subjects **DID** withdraw from the study or were withdrawn. |
|  |       |
| **d.** Unanticipated problems involving risks to subjects or others **DID** occur.  |
|  |       |
| **e.** Complaints about the study **DID** occur. |
|  |       |
| **f.** Publications in the literature relevant to risks or potential benefits **DID** occur. |
|  |       |
| **g.** Interim findings **HAVE** been identified**.** |
|  |       |
| **h.** Multi-center trial reports **WERE** issued**.** |
|  |       |
| **i.** Data safety monitoring reports **WERE** issued. |
|  |       |
| **j.** Regulatory actions **DID** occur that could affect safety and risk assessments. |
|  |       |
| **k.** Other relevant information regarding this study **DID** become available, especially information about risks. |
|  |       |
| **l.** In the opinion of the PI, the risks and potential benefits **HAVE** changed. |
|  |       |
| **m.** All modifications to the protocol have **NOT** been submitted to the IRB**.** |
|  |       |
| **n.** All problems that require prompt reporting to the IRB have **NOT** been submitted. |
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**5. Additional Information**

1. Have any audits or third party monitoringoccurred in the last approval period?

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|  |  | **No** |  |
|  |  | **Yes** | 🡪 If yes, explain. |
|  |  |  |       |
| 1. Have any new limitations on, or a suspension of, a relevant license or medical privilegeoccurred in the last approval period?

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **No** |  |
|  |  | **Yes** | 🡪 If yes, explain. |
|  |  |  |       |

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