**Research Status Report – Seeking Ongoing Approval**

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| --- | --- |
| **PI Name:** Click or tap here to enter text. | **IRB Number:** Click or tap here to enter text. |
| **Protocol Title:** Click or tap here to enter text. | |
| **Date of initial approval:** Click or tap to enter a date. | |

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| Estimated study completion date:Click or tap to enter a date. | |
| Current status of the research:  Open to enrollment but no subjects have been enrolled to date  Open to enrollment and subjects have been enrolled  Closed to enrollment, but subjects are still “active” on the protocol regimen or undergoing procedures or interventions for the research  Closed to enrollment, but follow-up of subjects (or data collection) continues  Closed to enrollment, but analysis of identifiable or coded data continues  Suspended or on hold. Explain: Click or tap here to enter text.  Other. Explain: Click or tap here to enter text. | |
| ☐ Yes ☐ No | Have there been any changes in funding for this study?  If Yes, please explain: Click or tap here to enter text. |
| ☐ Yes ☐ No | Are any changes in funding planned for or anticipated in the next 12 months?  If Yes, please explain: Click or tap here to enter text.  **Please Note:** Changes in funding must be reported to the IRB before expending any of the new funding. Changes in funding sometimes trigger additional regulatory requirements that must be addressed before moving forward with the research. Likewise, the loss or end of funding may remove requirements. |
|  | How many subjects have been enrolled in this study since inception?  Click or tap here to enter text. |
| ☐ Yes ☐ No | Have there been any changes to investigators or other research team members that have not yet been submitted to the IRB?  If Yes, please explain: Click or tap here to enter text. |
| ☐ Yes ☐ No | Have there been any changes made to the research or research materials that have not yet been submitted to the IRB?  If Yes, please explain: Click or tap here to enter text. |
| ☐ Yes ☐ No | Is there any new information or literature that suggests a change in what was previously understood about the research by the IRB, or that may impact the rights, welfare, or willingness of subjects to continue in the research, that has not yet been submitted to the IRB?  If Yes, please explain: Click or tap here to enter text. |
| ☐ Yes ☐ No | Have there been any problems or complaints associated with the research that have not yet been reported to the IRB?  If Yes, please explain: Click or tap here to enter text. |

**Please submit the following with this form:**

* Current human subjects training (CITI) documentation for each investigator and research team member.
* Any changes or reports identified in research protocol that have not previously been submitted to the IRB

**PRINCIPAL INVESTIGATOR’S STATEMENT**

By entering my name and the date below, I certify that the information provided in this report is, to the best of my knowledge, accurate.

**Name**: Click or tap here to enter text. **Date**: Click or tap to enter a date.

**Signature**: