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| **Use for a final report to close a study.** | | | | | | | | | | | | | |
| **IRB Docket No.:** | | |  | | | | | | | | | | |
| **Study Nickname:** | | |  | | | | | | | | | | |
| **Study Title:** | | |  | | | | | | | | | | |
| **Principal Investigator:**  **(Name, Email Address, Phone)** | | |  | | | | |  | | | |  | |
| **Additional Contact:**  **(Name, Email Address, Phone)** | | |  | | | | |  | | | |  | |
| **Enrollment Status** | | | | | | | | | | | | | |
| **Number of subjects enrolled:** | | | | Total | | Since last approval | | |  | **Number of subjects enrolled Study Wide:** | | | |
| **Number of subjects completed:** | | | |  | |  | | |  | | | |
| **At this investigator’s site(s):** | | | |  | |  | | |  | | | |
| **Total number of subjects enrolled at this investigator’s site(s) considered members of vulnerable populations:** | | | | | | | | | | | | | |
| Children | | Prisoners | | | Fetuses | | Cognitively Impaired | | | | Students/Employees | | Other/Unknown |
|  | |  | | |  | |  | | | |  | |  |
| **Date the study was closed** | | | | | | | | | | | | | |
| **Current Protocol Status** *Check all that are true or not applicable.*  *Submission of this report is appropriate only if all of the below are true.* | | | | | | | | | | | | | |
|  | The research is permanently closed to enrollment at this Institution. | | | | | | | | | | | | |
|  | All subjects enrolled at this Institution have completed all-research related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data. | | | | | | | | | | | | |
|  | No additional identifiable private information about the subjects is being obtained by this Institution’s investigator. | | | | | | | | | | | | |
|  | Analysis of private identifiable information at this Institution is completed. *(This can be checked even if a statistical center at another Institution will analyze private identifiable from subjects enrolled at this Institution.)* | | | | | | | | | | | | |

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| **Yes\*** | **No** | **The following Questions refer to all sites involved in the research since the last IRB continuing review:** |
|  |  | Have subjects experienced any harms (expected or unexpected)? |
|  |  | Have there been any unanticipated problems involving risks to subjects or others? |
|  |  | Have any subjects withdrawn from the research? |
|  |  | Have any subjects or others complained about the research? |
|  |  | In the opinion of the principal investigator, have the risks or potential benefits of this research changed? |
|  |  | Have there been any modifications to the research that have NOT been submitted? |
|  |  | Are there any problems that required prompt reporting that have NOT been submitted? |

Provide one copy of **all** of the following documents:

* Brief summary of any results of the research.
* A summary explanation or description for each question whose answer above is “\*Yes”

|  |  |
| --- | --- |
| **Investigator Acknowledgement** | |
| * By checking here, I attest that the information provided in this form is accurate. | Date: |