|  |  |  |  |
| --- | --- | --- | --- |
| **Use for continuing review.**  **If modifications are being requested, submit a separate request for a modification.** | | | |
| **IRB Docket No.:** |  | | |
| **Study Nickname:** |  | | |
| **Study Title:** |  | | |
| **Principal Investigator:**  **(Name, Email Address, Phone)** |  |  |  |
| **Additional Contact:**  **(Name, Email Address, Phone)** |  |  |  |

| **Names of all UML Personnel involved in the design, conduct, or reporting of the research** | | | | | |
| --- | --- | --- | --- | --- | --- |
| Date of CITI Training | Name & Email Address | Degrees | Role in the research | Involved in consent? | Financial interest related to the research? |
|  |  |  |  |  | Yes  No |
|  |  |  |  |  | Yes  No |
|  |  |  |  |  | Yes  No |
|  |  |  |  |  | Yes  No |
|  |  |  |  |  | Yes  No |
|  |  |  |  |  | Yes  No |
|  |  |  |  |  | Yes  No |
|  |  |  |  |  | Yes  No |
|  |  |  |  |  | Yes  No |
|  |  |  |  |  | Yes  No |

|  |  |  |  |  |  |  |  |  |  |  |  |
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| **Enrollment Status** | | | | | | | | | | | |
| **Number of subjects enrolled:** | | | | Total | | Since last approval | |  | **Number of subjects enrolled Study Wide:** | | |
| **At this investigator’s site(s):** | | | |  | |  | |  | | |
| **Total number of subjects enrolled at this investigator’s site(s) are considered members of vulnerable populations:** | | | | | | | | | | | |
| Children | | Prisoners | | | Fetuses | | Cognitively Impaired | | | Students/Employees | Other/Unknown |
|  | |  | | |  | |  | | |  |  |
| **Current Protocol Status** *Check all that are true or not applicable* | | | | | | | | | | | |
|  | 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.)* | | | | | | | | | | |
| **If all above items are checked, the research may be closed following this review. If so, add an attachment which indicates if subjects will be notified of the closure and if not, justify.**  **Otherwise, the Human Research must undergo continuing review.** | | | | | | | | | | | |
|  | Active | | | | | | | | | | |
|  | Active, but enrollment is on hold | | | | | | | | | | |
|  | No subjects have been enrolled and no additional risks have been identified | | | | | | | | | | |
|  | The remaining protocol activities are limited to data analysis only. | | | | | | | | | | |
|  | The protocol remains active only for long-term follow-up of subjects. | | | | | | | | | | |
| **Financial Interest Declaration** | | | | | | | | | | | |
| * “Immediate Family” means spouse, domestic partner, children, parents, spouse’s parents, and dependents. * “Financial Interest Related to the Research” means any of the following interests in the ***sponsor, product or service being tested, or competitor of the sponsor*** held by the individual or the individual’s immediate family as defined above:   + Ownership interest of any value including, but not limited to stocks and options, exclusive of interests in publicly-traded, diversified mutual funds.   + Compensation of any amount including, but not limited to honoraria, consultant fees, royalties, or other income.   + Proprietary interest of any value including, but not limited to patents, trademarks, copyrights, and licensing agreements.   + Board or executive relationship, regardless of compensation. | | | | | | | | | | | |
| Yes  No | | | Do any investigators or research staff have a financial interest related to the research that was not described in a previous application? | | | | | | | | |
| **\*If yes, you must complete the disclosure process by contacting** conflicts@uml.edu | | | | | | | | | | | |

| **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 subjects experienced any benefits? |
|  |  | 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? |
|  |  | Have there been any publications in the literature relevant to the risks or potential benefits of the research? |
|  |  | Have there been any interim findings? |
|  |  | Have there been any multi-center trial reports? |
|  |  | Have there been any data safety monitoring board reports? |
|  |  | 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? |
|  |  | Have there been any other relevant information regarding this research, especially information about risks associated with the research? |

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

* Brief summary of the progress of the research.
* A summary explanation or description for each question whose answer above is “\*Yes”
* Clean copies of all consent documents that need to be date stamped. *(Not required if the protocol is permanently closed to enrollment.)*

|  |  |
| --- | --- |
| **Investigator Acknowledgment** | |
| **The following check boxes must be checked before sending:**  By checking below you are verifying that:   * **Yes**  You have obtained the financial interest status (“Yes” or “No”) for each member of the research staff. * **Yes**  You have obtained the agreement of each research staff to his/her role in the research. * **Yes**  You have obtained the agreement, if applicable, of any other department (outside of your own department) being asked to serve as a recruitment or study conduct site. * **Yes**  You will conduct this Human Research in accordance with requirements in the INVESTIGATOR MANUAL (HRP-910). * **Yes**  You have received appropriate approvals from your department chair or supervisor and it has been determined that all departmental requirements are met and that the investigator has adequate resources to conduct this Human Research in terms of time, facilities, staff, access to a subject population, and resources for care that subjects may need. | |
| By checking here, I attest that the information provided in this form is accurate. | Date: |