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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **IRB Number:** | | | | | | |  | | | | | | | | | | | | | | | |
| **Protocol Name:** | | | | | | |  | | | | | | | | | | | | | | | |
| **Investigator:** | | | | | | |  | | | | | | | | | | | | | | | |
| **Primary Contact:** | | | | | | |  | | | | | | | | | | | | | | | |
| **Enrollment Status** | | | | | | | | | | | | | | | | | | | | | | |
| **Number of subjects enrolled:** | | | | | | | | Total | | | | Since last approval | | | | Study Wide | | | | |
| At this investigator’s site(s): | | | | | | | |  | | | |  | | | |  | | | | |
| **Total number of subjects approved for enrollment:** | | | | | | | | | | | | | | | | | | | | | | |
| **Ethnicity of subjects enrolled:** | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | Caucasian | | | Black not Hispanic | | Hispanic or Latino | | Pacific Islander | Native American or Alaskan | | | Asian | | | Other | | Total |
| a. Male Adults | | | | | |  | | |  | |  | |  |  | | |  | | |  | |  |
| b. Female Adults | | | | | |  | | |  | |  | |  |  | | |  | | |  | |  |
| c. Male Children | | | | | |  | | |  | |  | |  |  | | |  | | |  | |  |
| d. Female Children | | | | | |  | | |  | |  | |  |  | | |  | | |  | |  |
| TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE (a+b+c+d) | | | | | | | | | | | | | | | | | | | | | |  |
| **Total number of subjects enrolled at this investigator’s site(s) considered members of vulnerable populations:** | | | | | | | | | | | | | | | | | | | | | | |
| Prisoners | | | | | Fetuses | | | | | Cognitively Impaired | | | | |  | | | | Other/Unknown | | | |
|  | | | | |  | | | | |  | | | | |  | | | |  | | | |
| **Current Protocol Status[[1]](#footnote-1)**  *Check all that apply* | | | | | | | | | | | | | | | | | | | | | | |
|  | The research is permanently closed to enrollment at this organization. | | | | | | | | | | | | | | | | | | | | | |
|  | All subjects enrolled at this organization 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 organization’s investigator. | | | | | | | | | | | | | | | | | | | | | |
|  | Analysis of private identifiable information at this organization is completed. *(This can be checked even if a statistical center at another organization will analyze private identifiable from subjects enrolled at this organization.)* | | | | | | | | | | | | | | | | | | | | | |
|  | **If all above are checked, this will be the last continuing review of this protocol.** | | | | | | | | | | | | | | | | | | | | | |
|  | Active and open to enrollment | | | | | | | | | | | | | | | | | | | | | |
|  | The remaining protocol activities are limited to data analysis. | | | | | | | | | | | | | | | | | | | | | |
|  | The protocol remains active only for long-term follow-up of subjects. | | | | | | | | | | | | | | | | | | | | | |
| **Financial Interest Declaration** | | | | | | | | | | | | | | | | | | | | | | |
| * “Immediate Family” means spouse, domestic partner, children, 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:   + 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.   + Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center. | | | | | | | | | | | | | | | | | | | | | | |
| Yes  No | | | | Do any personnel involved in the design, conduct, or reporting of the research have a financial interest related to the research that was not described in a previous application? **If yes, provide the Conflict of Interests Committee’s determination regarding the financial interest.** | | | | | | | | | | | | | | | | | | |
| **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? (discussion of circumstances and reasons must be provided) | | | | | | | | | | | | | | | | | | | |
|  | |  | Have any subjects or others complained about the research? | | | | | | | | | | | | | | | | | | | |
|  | |  | Have there been any publications in the literature relevant to risks or potential benefits? | | | | | | | | | | | | | | | | | | | |
|  | |  | 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 changed? | | | | | | | | | | | | | | | | | | | |
|  | |  | Have there been any modifications to the research? | | | | | | | | | | | | | | | | | | | |
|  | |  | Are there any problems that required prompt reporting that have NOT been submitted? | | | | | | | | | | | | | | | | | | | |
|  | |  | Have there been any regulatory actions that could affect safety and risk assessments? | | | | | | | | | | | | | | | | | | | |
|  | |  | Have there been any other relevant information regarding this research, especially information about risks? | | | | | | | | | | | | | | | | | | | |
|  | |  | Have there been any internal or local serious adverse events in Veterans Administration (VA) research? | | | | | | | | | | | | | | | | | | | |
| **\*Attach a summary explanation or description for each question whose answer is “Yes.”** | | | | | | | | | | | | | | | | | | | | | | |
| Provide one copy of the following documents:   * Brief summary of the progress of the research. * Explanation of any “Yes” responses to items in above sections. * **Clean** copies of all previously stamped approval documents (Consent Form(s), Advertisements/Brochures, Surveys, Data Collection Tools, etc.) *(Not required if protocol is permanently closed to enrollment.)* * Copy of sponsor’s progress report or annual report, if available. * Point-by-point response *(When in response to modifications to secure approval, deferral, or disapproval.)* | | | | | | | | | | | | | | | | | | | | | | |
| **Department Chair or Supervisor Approval** | | | | | | | | | | | | | | | | | | | | | | |
| I have reviewed this application and determined that all departmental requirements are met and that the investigator has adequate resources to conduct the Human Research in terms of time, facilities, staff, access to a subject population, and resources for care than subjects may need. | | | | | | | | | | | | | | | | | | | | | | |
| Departmental Chair or Supervisor Signature | | | | | | | | | | | | | | | | | | Date | | | | |
|  | | | | | | | | | | | | | | | | | |  | | | | |
| **Investigator Acknowledgement** | | | | | | | | | | | | | | | | | | | | | | |
| By signing below you are verifying that you will conduct this Human Research in accordance with requirements in the [INVESTIGATOR MANUAL](https://drexel.edu/~/media/9BD48849D3AB41A883D7BC7662E858D1.ashx). | | | | | | | | | | | | | | | | | | | | | | |
| Investigator signature | | | | | | | | | | | | | | | | | | Date | | | | |
|  | | | | | | | | | | | | | | | | | |  | | | | |

1. For multicenter studies, this refers to the status of the protocol under the supervision of the investigator, not to the status of the protocol at all centers. [↑](#footnote-ref-1)