Project Closure Report

 Syracuse VA Institutional Review Board

(Syracuse , Canandaigua & Bath VAMC)

***This form is completed when a research project that was approved by the VA IRB is completed or ends for any reason. Once a Project Closure Report is submitted, no more data may be collected and no identifiable data may be analyzed.***

**I. Project Identification**

|  |  |
| --- | --- |
| **Title of Project** |  |
| **Principal Investigator** |  |
| **VA IRB Project #** |       |
| **PI Contact Information** | Phone:       E-mail:       Assigned VAMC:       |
| **Date of Closure** |        |
| **Reason for Closure****(Check one)** | [ ]  Project [ ]  Project Not Started [ ]  VA IRB  Completed or Cancelled Approval Lapsed  |

**II.** **Number of Participants Enrolled and/or Subject Data Used**

|  |  |
| --- | --- |
| **Participant/Subject Data Element *(Please complete all applicable fields)*** | **Number of Participants/Subjects** |
|  |  |
| **Since Last Continuing Review** |  |
| Total Enrolled  |  |
| Total Withdrawn/Dropped Out  |  |
|  |  |
| *The following must be completed if the data was collected:* |  |
|  |  |
| Total Males |  |
| Total Females |  |
|  |  |
| Total From Vulnerable Population *(Specify Category: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)* |  |
|  |  |
| Total African-American |  |
| Total Caucasian |  |
| Total Asian/Pacific Islander |  |
| Total American Indian/Alaska Native |  |
| Total Hispanic Origin |  |
| Total Other |  |
| ***Please list the specific reasons for participant withdrawal or dropout and the number of participants withdrawing or dropping out for each reason since the last continuing review. Add as many lines as needed.*****Reason for Withdrawal/Drop Out Number Withdrawn or Dropped**                        |
| **For Entire Study** |  |
| Total Enrolled |  |
| Total Withdrawn/Dropped Out  |  |
|  |  |
| *The following must be completed if the data was collected:* |  |
|  |  |
| Total Males |  |
| Total Females |  |
|  |  |
| Total From Vulnerable Population *(Specify Category: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)* |  |
|  |  |
| Total African-American |  |
| Total Caucasian |  |
| Total Asian/Pacific Islander |  |
| Total American Indian/Alaska Native |  |
| Total Hispanic  |  |

**III. Adverse Events, Unanticipated Problems, and Complaints**

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| ***Have there been any adverse events, unanticipated problems, or complaints since the last continuing review approval that were not reported to the VA IRB? Please check one of the boxes below.*** |
| [ ]  N/A. This was an exempt study.[ ]  No. All adverse events, unanticipated problems, and complaints have been previously reported.[ ]  Yes. *(If yes, please attach a VA IRB Form: Report of an Unanticipated Problem)* |

**IV. Summary of Project Conclusions or Reasons for Closure/Lapse**

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| ***Please provide a brief summary of your conclusions or the reasons for the project closure or lapse of approval. If the results of the project were or are to be published please provide a copy of the publication or an abstract.*** |
|  |

**V. Data Storage**

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| ***Please indicate how the data is being stored, how long it will be stored, and whether it is de-identified.*** |
|  |

**VI. Investigator Certification**

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| ***The principal investigator must check one of the boxes below and sign and date the form.*** |

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| --- | --- |
| **[ ]**  | I understand that I may submit this report only if none of the participants are receiving any project interventions. |
|  | No identifiable data is being collected on any of the participants and all data analysis is complete or no identifiable data is being used in the remaining analysis. |
|  | If follow-up procedures are being done they are for clinical purposes only. |
|  | All data generated as part of this project will be maintained in accordance with all VA and other federal information security requirements. |
| [ ]  | No participants were enrolled and/or no identified data was collected or generated. |

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|  | Signed |  | Date |  |