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| **PI NAME** |  |
| **STUDY TITLE** |  |

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| **1.** | Was your research ever initiated? | Yes  No |
| **If NO,** explain and skip the rest of this form. | | |

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| **2.** | Your study must meet the following criteria in order to be closed:  \**Identifiable* means that the identity of the subject is or may be readily ascertained by the investigator or associated with the information. This includes a linked code. | | |
| A. | The research is permanently closed to enrollment. | Yes  No |
| B. | All interactions/interventions with subjects, or access to private identifiable information (including identifiable biological specimens) for the purpose of research data collection is complete. | Yes  No |
| C. | All use, study, and/or analysis (including manuscript preparation) of identifiable private information is complete. | Yes  No |
| **If NO** to any of the above, **STOP. Do not close this research with the IRB.** | | |

**Enrollment**

|  |  |
| --- | --- |
| **3.** | **Anticipated, IRB-approved enrollment number**: |

**Instructions:** Complete #4 **or** #5 – not both. For #4, please fill out each box – put “0” instead of leaving blank.

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| **Total Numbers enrolled since the beginning of the study** | | | |
| **4.** | a. | Adult participants (or LARs) who gave consent (do not include parents/guardians of minor participants) |  |
| b. | Minor participants (under 18) who gave assent (if applicable) |  |
| c. | Screen failures after consent/assent (Consented but did not meet inclusion/exclusion criteria) |  |
| d. | Passed screening and continued in the research |  |
| e. | Withdrew or were withdrawn by PI |  |
| f. | Completed the research |  |
| g. | Currently active (enrolled but has not completed all research procedures) |  |
| (A+B)-C=D & D-E-F=G  **If E+F+G is more than IRB approved enrollment number**, please explain: | | | |
|  | | | |
| **5.** | **If your research was granted a waiver of consent,** enter the number of individuals whose data, samples, etc. was collected. | |  |

**Study Information**

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| **6.** | Location of stored research-records:  \*\***Reminder**: You are required to retain research records (including copies of signed consent forms) **for at least 3 years** after completion of the research. If your sponsor or funding agency has a longer record retention requirement, you must follow its policy. | |
|  | | |
| **7.** | Since your last IRB review, have there been any of the following not reported to the IRB: | |
| Unanticipated Problems | Yes  No |
| Adverse Events | Yes  No |
| Protocol Deviations | Yes  No |
| Participant Complaints | Yes  No |
| **If yes** to any of the above, explain: | |
|  | | |
| **8.** | Since your last IRB review, were there any participants who withdrew or were withdrawn by the PI due to an adverse event, unanticipated problem, other reasons, or lost to follow-up?  **If yes**, explain: | Yes  No |
|  | | |
| **9.** | If the research results have been accepted for publication, poster presentation, conference presentation, etc., provide a citation and/or a copy of the article/presentation. | |

**Principal Investigator Attestation**

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| By submitting this form electronically through IRBNet, you (the Principal Investigator or designee) are certifying the information contained in this report is true, complete, and accurate to the best of your knowledge. You will receive an acknowledgement of closure once this report has been accepted. |