**Final Report for Human Subject Research Protocol**

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| To be Completed by Project Investigator (PI) | | | | | | |
| Last Name | | | First Name | | | |
| Museum/Center | | | | | | |
| Phone | | | Email | | | |
| Project Title | | | | | | |
| Protocol # | | | Date of Submission | | | |
| Entire Project Period (Start Date – End Date) | | | | | | |
| Indicate the dates for the period of time that this report covers: | | | | | | |
| Report Start Date | | | Report End Date | | | |
| *If you are a Smithsonian affiliated person, please provide the following:* | | | | | | |
| *Type:*  Fellow  Research Associate  Visiting Researcher  Contractor  Other: | | | | | | |
| Name of Smithsonian Sponsor: | | | | | | |
| Phone | | | Email | | | |
|  | | | | | | |
| * 1. Was the project externally funded (grant/contract/interagency agreement)?   Research was not externally funded *(go to question 2)*  Research was externally funded (grant, contract, IAA) | | | | | | |
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| * 1. What was the funding source? (Check all that apply)   Grant or Contract – Proposal ID or Designated Code:  Other, please specify: | | | | | | |
|  | | | | | | |
| 1. Please indicate the status of the research project:   Closed to new subject enrollment/ Data analysis only  Date of closure to subject entry (MM/DD/YYYY):  Complete and closed | | | | | | |
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| 1. During the project period described above, have you: | | | | | | |
| * 1. Actively Enrolled Subjects  NO  YES How many? | | | | | |  |
| * 1. Collected Follow-Up Data  NO  YES How many? | | | | | |  |
| * 1. Did any subjects withdraw from the study?  NO  YES How many? | | | | | |  |
| *Note: The term “withdrawn” means that the subject voluntarily withdrew or was removed from the study prior to study completion.* | | | | | | |
|  | | | | | | |
| 1. Enrollment numbers for the project period described above for the categories below: | | | | | | |
| *Ethnicity* | Hispanic | | | Non-Hispanic | | |
| *Sex* | *Racial Category* | | | | | |
| Male: | Black | Native American/ Alaskan | | | Caucasian | |
| Female: | Multiracial | Asian/Pacific Islander | | | Other | |
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| 1. Provide the following information for study population. This question covers the entire project period. | |
| * 1. Total number of subjects ENROLLED in the study  (you gathered data from these subjects): |  |
| * 1. Total number of subjects WITHDRAWN since initiation of study: |  |
|  | |
| 1. Were there any medical, legal, or practical difficulties that were encountered in this time interval of the study aside from adverse events? For example, difficulties would include complaints of subjects, logistic problems of performance, or any difficulties that may pertain to the rights of subjects.  YES, please explain below  NO | |
|  | |
| * 1. Were there any adverse events (injury, confidentiality breach) encountered during the study period?   YES, please explain below \_\_\_\_\_\_\_\_\_  NO *(go to question 8)*  Total # | |
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| 7.2. Have all adverse events been reported to the IRB?  YES  NO *(if there are any adverse events that have NOT been reported to the IRB, attached a letter of notification with an explanation. Serious adverse events MUST be reported to the IRB*  *immediately following the investigator being notified.)*  Not Applicable, there were no adverse events | |
|  | |
| 8.1 Did any new information become available during the course of the research which may have affected the subjects’ willingness to continue participation in this study?  YES, please explain below  NO | |
|  | |
| 8.2. Was the new information provided to the subjects’?  YES (please attach written documentation)  NO  Not Applicable, no new information | |
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| 9. Please provide, or attach, a brief overview of research/ results/ observations obtained to date. Include a copy of ANY publications that have resulted from this research. *Note: This question must be completed*. | |
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| 10. Were there any changes or additions regarding the Smithsonian employees, or affiliated persons proposing, conducting, or assisting with the research projects?  YES  NO  *If yes, please provide the name, phone number, and email of each person and a brief description of his/her role as it relates to the Smithsonian Institution. Please provide certification of human subjects training, the training date, and provider (e.g., OSP, NIH, CITI).* | |
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| **CERTIFICATION** | |
| Neither I nor any of my associates in this research project, to my knowledge, has a real or apparent conflict of interest that would lead me or my associates to misrepresent the research, the treatment of human subjects, and the facts contained in this report.  This is correct  This is not correct (please explain below) | |
|  | |
| By submitting this report, I certify that all of the information contained in this application is accurate and complete.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Investigator’s Signature Date | |
| *If the investigator is a Smithsonian “affiliated person”.*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Smithsonian Sponsor’s Signature Date  *Note: Sponsor’s signature indicates your active interest and/or involvement in the proposed project.* | |