APPENDIX 3

**OKLAHOMA CHRISTIAN UNIVERSITY**

**HUMAN SUBJECTS RESEARCH PROGRESS REPORT FORM**

**(Required for Continuing Approval)**

**Progress reports should be submitted when data collection and/or data analysis is ongoing.**

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| **Responsible Project Investigator (RPI)** | | | | | | | |
| **Responsible Project Investigator: The RPI must be a member of OC faculty or staff who serves as the project**  **supervisor and is held accountable for all aspects of the project. Students cannot be listed as RPIs.** | | | | | | | |
| **First Name:** | | | | **Last Name:** | | | |
| **Telephone:** | | | | **Email:** | | | |
| **Department:** | | **IRB Identifier:** | | | | **Expiration Date:** | |
| **Complete Title of Research Project:** | | | | | **Code Name (one word):** | | | |
| **Indicate the dates for the period of time that this report covers. This must not exceed one year and must be retrospective. The following information is for the time interval of:** | | | | | | | |
| **Start Date (MM/DD/YY):** | | | | **End Date (MM/DD/YY):** (This is the date of the report.) | | | |
| **1. How is the project funded?**   1. Research is not funded (**Go to question 2**) 2. Research is funded   **1a. What is the type of funding source? (Check all that apply)**  \_\_Federal Grant or Contract  Agency Proposal Number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Grant Start Date (MM/DD/YY) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Grant End Date (MM/DD/YY) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_State or Municipal Grant or Contract  \_\_Private Foundation  \_\_Corporate contract  \_\_Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **1b. Who is the point of contact at the funding source?**  Name:  Mailing Address:  Telephone: Email: | | | | | | | |
|  | | | | | | | |
| **2. Please indicate the status of the research project:**   1. Active/Open to subject enrollment **(Please attach ONE (1) copy of the current consent form with each progress report and TWO (2) copies of the consent form with the original progress report. Provide consent forms that do not have the IRB stamp.)** 2. Active/Closed to subject entry   Date of closure to subject entry (MM/DD/YY): \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_\_   1. Closure is: \_\_\_\_\_\_Permanent \_\_\_\_\_\_Temporary **(If closure is temporary, please attach ONE (1) copy of the current consent form with each progress report and TWO (2) copies of the consent form with the original progress report. Provide consent forms that do not have the IRB stamp.)** | | | | | | | | |
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| **3. Has the research protocol or consent form changed in any way since the last approval?**   1. Yes **(Please attach a copy of any amendment(s) not previously submitted.)** 2. No | | | | | | | | |
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| **4. During the time interval described above (1 year time period this report covers), have you:**  **4a. Actively Enrolled Subjects**  Yes \_\_\_\_\_  No  number  **4b. Collected Follow-up Data**  Yes \_\_\_\_\_  No  number  **4c. Have any subjects withdrawn from the study?**  Yes \_\_\_\_\_  No  number  Note: The term WITHDRAWN means that the subject voluntarily withdrew or was removed from the study prior to study completion. | | | | | | | | |
|  | | | | | | | | |
| **5. Enrollment numbers for the time interval described above (1 year time period this report covers) for the categories below:**  Please fill in the table below. (This information is required for all studies that are NIH-sponsored. It is recommended, but not required, that other researchers provide this information.) | | | | | | | | |
| **Sex** | **Ethnicity** | | | | | | | |
| Male: | Black, Non-Hispanic: | | Native American/Alaskan: | | | | Caucasian, Non-Hispanic: | |
| Female: | Hispanic: | | Asian/Pacific Islander: | | | | Other/Unknown: | |
|  | | | | | | | | |
| **6. Provide the following information for the study population. This question covers the entire project period.**  1. Total number of subjects ACTIVELY in the protocol:\_\_\_\_\_\_\_  2. Total number of subjects WITHDRAWN since initiation of study:\_\_\_\_\_\_\_  3. Total number of subjects COMPLETED and OFF the study:\_\_\_\_\_\_\_  4. Total number of subjects enrolled SINCE INITIATION OF THIS STUDY**:\_\_\_\_\_\_\_**  **Note: The total of 1, 2 and 3 should equal the total given in 4.** | | | | | | | | |
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| **7. Were there any medical, legal, or practical difficulties that have been 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 **(If yes, please summarize below.)** * No | | | | | | | | |
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| **8. Were there any adverse events encountered during the study period?**   * Yes \_\_\_\_\_\_\_\_\_\_\_\_\_**(If yes, summarize below and provide a statement of trends e.g. more women affected)**   Number   * No **(go to 9)**   **8a. Have all adverse events been reported to the IRB?**   * Yes * No **(If there are any events that have NOT been reported to the Oklahoma Christian University Institutional Review Board, attach a letter of notification with an explanation. Serious adverse events MUST be reported to the Board within FIVE days of the investigator being notified.)** | | | | | | | | | | |
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| **9. Has any new information become available during the course of the research which may affect the subject’s willingness to continue participation in this study?**   1. Yes **(If yes, explain)** 2. No   **9a. Was the new information provided to the subjects?**   1. Yes **(If yes, attach written documentation)** 2. No | | | | | | | | | |
|  | | | | | | | | | |
| **10. 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 section MUST be completed.** | | | | | | | | |
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| **11. The RPI must document completion of HHS Training within 1 year of submission of the progress report.** ((Attach a copy of the RPI’s five Certificates for each of the five lessons in the “[Human Research Protection Foundational Training](https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/human-research-protection-foundational-training/index.html).”)  Date RPI completed HHS Training: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | |
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| **Responsible Project Investigator** (Must be original signature) **Date** | | | | | | | | |