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|  | Delaware Health and Social Services (DHSS) **Human Subjects Review Board (HSRB) Project Report Form**  Rev. 11-27-17 |

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| 1. **Report Information** |
| Type of report:  Interim  Final |
| Report date: |

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| 1. **General Project Information** | |
| Project Title: | |
| Lead Organization: | |
| Brief description of project (one or two sentences): | |
| Date of original HSRB review: | Other HSRB review date(s): |

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| 1. **Contact Information** | | | |
| Principal Investigator’s Name: | | | |
| Title: | | | |
| Business/Organization: | | |  |
| Business Street Address: | | | City: |
| State: | Zip: | | |
| Email Address: | | | |
| Work Phone: | | Cell Phone: | |
| Co-Investigator’s Name (if applicable): | | | |
| Title: | | | |
| Business/Organization: | | | |
| Address (if different than project director): | | | |
| Email Address: | | | |
| Work Phone: | | Cell Phone: | |

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| 1. **Project Status (Check as many as apply)** | | |
| Initiated | Date initiated: | |
| Open | | |
| Closed to new subjects | Date closed to new subjects: | |
| Closed | Date closed: | |
| On hold | Date of hold: | Reason for hold: |
| Cancelled | Date of cancellation: | Reason for cancellation: |

***If the project involves recruitment of human subjects, complete Sections V–X below. If not, skip to Section XI.***

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| 1. **Human Subject Counts** | |
| **Subjects involved in study** |  |
| Number active |  |
| Number completed |  |
| Number lost to follow-up |  |
| Subtotal: subjects involved in study |  |
| **Subjects dropped from study** |  |
| Dropped voluntarily |  |
| Dropped by investigator |  |
| Dropped due to project-related death |  |
| Dropped due non-project-related death |  |
| Dropped due to other adverse events |  |
| Subtotal: subjects dropped from study |  |
| **Persons who declined to participant** |  |
| Subtotal: persons who declined to participate |  |
| **Total** |  |
| Total of all persons (sum of three subtotals) |  |

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| 1. **Subjects Lost to Follow-Up or Dropped** |
| Provide an explanation of subjects lost due to follow-up and/or dropped during the study and steps taken to ameliorate adverse impacts, if applicable. |

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| 1. **Other Problems - Anticipated** |
| Describe any additional problems or adverse events that occurred that were anticipated and described in the original application to the HSRB. |

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| 1. **Other Problems - Unanticipated** |
| Describe any additional problems or adverse events not anticipated that resulted in harm or potential harm to subjects. (NOTE: unanticipated problems that result in harm or unanticipated harm must be reported immediately to the HSRB. This response represents a summary of the already-reported information.) |

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| 1. **Decreased Capacity** |
| Did any of the subjects experience decreased capacity after the study began such that they were no longer able to give informed consent?  Yes  No |
| If yes: |
| How was the issue addressed in each instance? |
| Were surrogate decision-makers consulted? |
| Did such individuals continue in the study? |

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| 1. **Complaints** |
| Have you received any complaints about the research over the past year?  Yes  No |
| If yes, summarize and describe steps taken to address the concerns expressed: |

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| 1. **New Information** |
| Has any additional information become available about this study or related studies which needs to be provided to subjects and/or the HSRB?  Yes  No |
| If yes:  Describe the new information. |
| Describe whether the new information has been used or will be used to modify the project. |
| Describe whether or not information will be provided to participants no longer involved in the project and if so, how. |

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| 1. **Additional Documentation (to be attached)** | |
| **Interim Report** | **Final Report** |
| Narrative summary of preliminary findings and project status  Current consent form (if applicable) | Executive summary with project findings |

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| 1. **Signature** | |
| Principal Investigator’s Signature: | Date: |
| Principal Investigator’s Name: | |