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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**
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| 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**
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| 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**
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| 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**
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| 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**
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| 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**
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| 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)**
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| **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**
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| Principal Investigator’s Signature:  | Date:  |
| Principal Investigator’s Name:  |