



**DELAWARE HEALTH AND SOCIAL SERVICES
HSRB PROJECT REPORT
Revised January 2007**

INTERIM REPORT

FINAL REPORT

Original Review Date: _____

Date of Previous Review: _____

1. Title of Project:

2. Principal Investigator (name, mailing address, phone #, e-mail address):

3. Co-Investigators (name, mailing address, phone #, e-mail address):

4. Has the study been initiated? Yes _____ No _____

5. Please provide a brief (no more than 2 sentences, if possible) description of this project.

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6. How many potential subjects were approached to enter into the project? _____

(must equal GRAND TOTAL below)

- a. Subject status:
- 1. Active (a1)
 - 2. Completed (a2)
 - 3. Lost to follow-up (a3)
- (Attach explanations)*
- Total** (sum of a1, a2, a3) **(a)**

- b. Subjects **dropped** from study, categorized by reason:
- 1. Voluntarily (b1)
- (Attach explanations)*
- 2. By investigator (b2)
- (Attach explanations for dropping each subject)*
- 3. Due to Adverse Events(both ‘anticipated’ and ‘unanticipated’). (b3)
- (Attach explanation for each subject dropped due to an adverse event and include a description of steps taken to ameliorate the adverse impact)*
- 4. Due to project-related death during active phase of study (b4)
- (Attach explanations of deaths.)*
- 5. Due to non-project-related death during active phase of study.. (b5)
- Total Subjects Dropped** (sum of b1, b2, b3, b4, & b5)... _____ **(b)**

- c. Potential subjects who **declined** to participate: (c)
- (Attach summary/tabulation/analysis of reasons subjects gave for declining)*
- d. **GRAND TOTAL** (sum of a, b & c) **(d)**

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7. What is the status of this project?

- a. Open _____
- b. Closed to subject accrual Date _____
- c. Closed Date _____
 If closed: reason _____
- d. On hold Date _____
 If on hold: reason _____
- e. Cancelled Date _____
 If cancelled: reason _____

8. Describe any additional adverse events not covered in item 6b that occurred over the reporting period. Specify the steps taken to ameliorate the adverse impact. (This item covers events that were foreseeable in the project's design/methodology, the type of events that were described/anticipated when the project was reviewed initially by the Board.)

9. Summarize any **unanticipated** problems resulting in harm or potential harm to subjects, including the number of subjects involved (attach relevant reports or documents). Include a description of intervention(s) used for subjects adversely affected. [Note: This section should be a summary of information that has already been provided to the Board, as it is mandatory that such reports be submitted IMMEDIATELY upon the occurrence of any such unanticipated problems.]

10. For projects utilizing questionnaires, please respond to all of the following:

- a) Delineate any specific question(s) that **one** or more subjects did not answer. The actual question(s) should be listed – with the number of persons who did not answer.
- b) If respondent(s) displayed significant stress when a 'refused' question was posed, identify that question and describe how the stress was ameliorated.
- c) For those questions with a **significant** number of non-responses, please discuss the ramifications (for instance, should changes of any kind be made to the study's design – if the study is still in progress? If the project is over, are there changes that, in retrospect, you would have made – now that this information is known?).

11. Did any of the subjects experience decreased capacity after the study began, such that they were no longer able to give informed consent or voluntarily withdraw from participation? If so, how was that issue addressed in each instance? Were surrogate decision makers consulted? Did such individuals in fact continue in the study?

12. Have you received any complaints about the research over the past year? If yes, please summarize and describe steps taken to resolve the concerns expressed.

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13. Please describe any additional or new information that has become available on this study **or related studies** which: (a) subjects need to know, particularly information that might affect their willingness to continue to participate, and/or (b) the Board needs to know ~~ in particular, anything that could affect the level of risk attributable to the project. If there is such information, how has it been or how **will** it be used to modify the project? If such information should be shared with participants no longer involved with the project, how will the information be provided to them?

For INTERIM REPORTs, attach a Narrative describing the Project's status and detailing any preliminary Project findings. Also attach a copy of the current consent form.

For FINAL REPORTs, attach Executive Summary with Project findings.

INVESTIGATOR'S SIGNATURE

REPORT DATE