

Date Sent: _____

**PRINCIPAL INVESTIGATOR ANNUAL REPORT
to
RESEARCH REVIEW COMMITTEE**

**Department of Developmental Services
Commonwealth of Massachusetts**

<p>1. DDS Log # _____</p> <p>2. Project Title: _____</p> <p>3. Principal Investigator(s): _____ _____</p> <p>4. Last Date of Approval by RRC: _____</p>

5. Please list any changes in PI, addresses of PI, or title of research project.

6. Is this project still being conducted? Yes ___ No ___

If "No", is cessation permanent? Yes ___ No ___

Reason for termination: _____

7. Briefly describe below under Item # 19 any problems encountered in obtaining informed consent.

8. Is the research you are conducting different in any way from the proposal that was approved by the Research Review Committee? Yes ___ No ___

9. Have you in any way altered the research protocol approved by the Research Review Committee? Yes ___ No ___

Do you plan to alter it? Yes ___ No ___

If the answer is "Yes" to either question, describe below under Item # 19 the alterations.

10. Have there been changes in the consent form(s) previously reviewed by the Research Review Committee?

Yes ___ No ____ . If "Yes", attach a photocopy of the consent form currently being used.

11. During the past twelve (12) months, how many participants have been involved in this research study? _____

How many of these participants are under guardianship? _____

12. Was written consent appropriately obtained from either participant or guardian?

Yes ___ No ____ . If "No", please explain. _____

13. How many copies of the signed consent were produced? _____

Where are the signed consent forms now? _____

14. Was an original signed consent form placed in the participant's personal file?

Yes ___ No ____

15. Did the participants receive a copy of the consent form? Yes ___ No ____

16. Were there any injuries to participants as a result of being involved in this study? If "Yes", explain in detail below under Item # 19 the nature and circumstances of each injury, including any treatment provided to the injured party. Yes ___ No ____

17. Were there any unanticipated problems involving risk to participants or others since this study was last reviewed by the Research Review Committee? If "Yes", please explain below under Item #19. Yes ___ No ____

