(For committee use only)

RRC Log# _____

PRIMARY REVIEWER _____

RESEARCH PROPOSAL APPLICATION
SUBMISSION TO RESEARCH REVIEW COMMITTEE

If you require further assistance in completing this form or in your dealings with the Research Review Committee (RRC), contact John C. Geenty Jr., Chairperson, (508) 845-9111 ext. 1021. Please be brief in your responses below. However, if more space is needed use additional paper. The Principal Investigator must initial and date the bottom of every page. Please mail eight copies of this Application to Ryan Valente and James Stillerman, Research and Review Committee, Department of Developmental Services, 500 Harrison Avenue, Boston, MA 02118.

SECTION A

1. Title of Study:

2a. Principal Investigator (name/address/telephone #)

2b. Co-investigator (s) and affiliation:

3. Expected Starting Date:_____ **4. Expected Completion Date:_____**

5. Location(s) where the study will be conducted?

6. Has your study or a similar one been previously reviewed by the Department of Developmental Services or by the Department of Mental Health?
☐Yes ☐No
If yes, please describe the circumstances.

____ ____
P.I. Date

____ ____
P.I. Date

7. Has the study or a similar one been rejected by any review group or committee? ☐Yes ☐No If yes, please provide details.

SECTION B

Summary of the Research Protocol

8. List the purposes and objectives of the research.

9. Describe the research method(s) and procedure(s) to be used.

10a. What are the direct benefits of the research to the participant? If there is no direct benefit knowledge that might benefit persons with intellectual disabilities or their families or the field of intellectual disabilities.

10b Why should persons with intellectual disabilities participate in the study?

10c. Can research questions be answered through the use of persons without intellectual disabilities? If no, please explain.

SECTION C

Study Population

11. Number of participants _____ 12. Age range of participations_____

13. Source of participants:

14. List all criteria for including participants in the study.

15. List all criteria for excluding individuals from the study.

16. To your knowledge, will any participant also be participating in other research studies? ☐Yes ☐No
If yes, please describe.

17. *Describe how you will recruit participants. Recruitment should address how conflict of interest, preliminary access to person health information and freedom from coercion will be addressed.

A. Direct person-to-person solicitation (participant, family, guardian, provider) ☐
B. Telephone ☐
C. Letter ☐
D. Notices ☐
E. Electronic ☐
F. Video ☐
G. Audio ☐
H. Other (explain) ☐

***If the participants are to be recruited under A & B, please include an outline of the oral presentation. For items C, D, and E please submit verbatim copies--e.g., letter, notices, advertisements.**

____ P.I. ____ Date

18. Describe the type of private information that will be sought?

19. Describe how the research may affect the care or treatment of the participant during the research and after the research has ended.

20a. What rewards, remuneration, or other incentives will be used to recruit participants?

20b. Describe any foreseeable cost (s) to the individual as a result of participating in the research (e.g., lost wages, travel and parking expenses, lunch, etc.), and any compensation or reimbursement that will be offered to the participant to offset such cost(s).

21. Attach a budget showing the project expenditures and sources and amounts of funding for the project.

22. Do you intend to rely on the Department of Developmental Services or provider resources for assistance in conducting the research, collecting data, or providing private information?

☐ **Yes** ☐ **No**

If yes, describe.

SECTION D

Interventions/Measurements Solely for Research Purposes

23. Will blood samples be required? If yes, describe. ☐Yes ☐No
Specify the important features of the blood collection, including the volume of research blood obtained in each collection, along with the frequency and duration of the collection (e.g., 10 ml at noon and 8 p.m., one day every two weeks for a six-month period).

Is it known or anticipated that any participant will also have blood drawn for other purposes during the study period? ☐Yes ☐No

24. Please indicate any of the following you propose to use:

- **a. Educational Tests** ☐
- **b. Questionnaires** ☐
- **c. Psychological Tests** ☐
- **d. Educational Materials (curriculum, books)** ☐
- **e. Interview** ☐
- **f. Diary** ☐

25. Will the study involve the use of drugs? ☐Yes ☐No
If yes, explain.

SECTION E

Confidentiality--Privacy--Coercion

26. Does this activity utilize data collected for other purposes? ☐Yes ☐No
(e.g., hospital records, electronic, video, audio)

a. If yes, please specify the source of the data to be utilized and how the data will be retrieved and reviewed.

b. Could any of the recorded data contain personal or sensitive information? ☐Yes ☐No
If yes, how do you propose to code and where will you maintain confidentiality of the data?

27. Describe the safeguards that will be implemented to maintain confidentiality of the private information obtained during the research. This must include safeguards for any electronic transmission and storage, audio, or videotaping, and the like.

28. Describe the manner of disposal of the private information at the termination of the study. This must include safeguards for any electronic transmission or recording, audio, or videotaping, and the like.

29. Aside from possible loss of confidentiality, could any part of this activity be seen as invading the privacy of the participants of this study? ☐Yes ☐NO
If yes, explain and describe proposed safeguards.

30. Does any part of this activity have the potential for coercion of the participant?
☐Yes ☐No. If yes, explain and describe proposed safeguards.

31a. Describe the type of final product to be produced, its intended use and the manner of dissemination or publication.

31b. Do you or others intend to establish copyright, patents, or any other rights to the product? ☐Yes ☐No
If yes, identify the organization or persons in whom such rights are vested.

SECTION F

Risks: Physiological or Psychological

32a. Is there a foreseeable risk of physical injury resulting from participation in the research? ☐Yes ☐No

If yes, describe the likelihood and seriousness of the risk.

****Note: Include in your discussion an explanation of why the risks identified under 32(a-c) should be considered reasonable in relation to the anticipated benefits to participants and in relation to the importance of the knowledge that may reasonably be expected to result from the research.**

32b. Aside from possible loss of confidentiality, is there a foreseeable risk of psychological injury resulting from participation in the research? ☐Yes ☐No

If yes, describe the likelihood and seriousness of the risk.

32c. List any other foreseeable risk to the participant (e.g. social, economic, legal), and if applicable, provide a full discussion of the likelihood and potential and seriousness of the risk (s). (See ** on page 7)

SECTION G

Informed Consent

A written informed consent from the subject or from a legally responsible representative of the subject is normally required from research participants. The proposed consent form should be included with the materials submitted to the RRC. The consent form must include all the points listed on the attached checklist (RRC Form #2).

33. Describe how it will be determined that individuals you are seeking to include in the study have the capacity to consent to participate. For example, researchers may rely on Human Rights Committees, institutional staff, clinicians who know the individual, or a guardian, if one is established.

34. If necessary, how will guardians be contacted?

35. If you do not propose to obtain consent, please provide your rationale.

36. Describe the manner in which informed consent will be obtained (who, how, when).

37. Audio/video taping and the like is considered personal health information. Will these types of information be utilized? If so, which?

INVESTIGATOR'S STATEMENT:

I UNDERSTAND THAT I AM RESPONSIBLE FOR THE ACCURACY OF THE STATEMENTS MADE IN THIS PROTOCOL AND FOR THE CONDUCT OF THE RESEARCH.

Principal Investigator **Date**