

## RESEARCH REVIEW COMMITTEE - ADVISORY TO PRINCIPAL INVESTIGATORS JULY, 2015

### **Authority and Role of the Department's Research Review Committee**

The authority of the Research Review Committee (the "Committee") derives from two sources, the first being the Department's statutory mandate to "take cognizance of all matters affecting the welfare of the intellectually disabled citizens of the commonwealth." M.G.L. c. 19B, §1. Pursuant to this authority, the Department has promulgated regulations, 115 CMR 10.00, which create the Committee and establish a process for safeguarding the human and privacy rights of persons with intellectual disability, and others connected to the Department who may be a participant in research.

The Committee derives additional authority from federal regulations intended to protect participants of federally-funded research. The federal regulations, 45 CFR 46.101, et seq., require that an "institutional review board" or "IRB" review all research by or involving the institution and enforce standards concerning informed consent and risk-benefit analysis. The Committee is intended to be the Department's IRB for purposes of federally-funded research.

All research with relevance to intellectual disabilities or intellectual disability services, involving recipients of any Department services or private information or data concerning such recipients must be reviewed by the Committee unless no Department facility or no Department operated, licensed or contracted program or service is involved in any way in the research. All such research involving Department employees or staff of any program or service operated, licensed or contracted by the Department must also be reviewed by the Committee.

The Committee has authority to approve research proposals, disapprove them, or approve them under conditions. Research required to be reviewed by the Committee may not proceed without the approval of the Committee.

### **Goals of the Research Review Committee**

The Committee is charged with the responsibility of protection of the rights of Department consumers who may be participants in research. At the same time, the existence of a research review process reflects appreciation for the fact that well-conceived research is an indispensable tool for the advancement of knowledge concerning the needs (social, medical, learning, emotional) of persons with intellectual disabilities. By its review of research, the Committee seeks to encourage valuable research while at the same time preserving the rights of the participants through a close examination of such matters as the procedures to maintain confidentiality, the information provided to participants, the steps taken to ensure valid informed consent is obtained, the risks of the research and the safeguards in place to minimize the risks to participants, and the potential benefits as well as costs to individuals from participating in the research.

## **INSTRUCTIONS FOR SUBMISSIONS OF RESEARCH PROPOSALS TO THE RRC**

### **SECTION A - General Information**

The Committee generally meets on the first Friday of each month at 10:00 a.m. at the Worcester Regional Office located at 324 Clark Street, Worcester, MA 01606. This meeting schedule is subject to change as necessary to accommodate Committee members or invited guests. Scheduling of interim meetings occurs from time to time in the discretion of the Committee.

A proposal for research and supporting documents should be submitted to the Committee chairperson no later than three weeks prior to the meeting at which the proposal is to be considered. Proposals received after this period will be considered at the next meeting. Research proposals must be in writing and eight copies submitted to the Committee. Proposals should be mailed to:

**Chairperson**  
**Research Review Committee**  
c/o Ryan Valente James Stillerman  
**Department of Developmental Service**  
**500 Harrison Avenue**  
**Boston, MA 02118**

To determine when the next meeting of the Committee will be held, investigators may call Ryan Valente at (617) 624-7716 or James Stillerman at (617) 624-7813. Any questions regarding the Research Review Committee, this advisory, or the Committee's review process may be directed to the Chairperson of the Committee, John C. Geenty Jr., at (508) 845-9111 Ext 1021.

Certain proposals, which, by their nature, present minimal risk of harm, may meet the requirements for expedited review. After submission, investigators will be notified if their proposals will be subject to full Committee review or expedited review.

### **SECTION B - Contents of Submission**

The information provided on attached RRC Forms 1, 2, plus an appropriate research protocol will provide the basis for the review. All questions should be answered on these RRC forms. Where applicable, a reference to the appropriate page number in the protocol can be given.

**Peer Review** - At the time the proposal is submitted to the Committee, the investigator must also submit evidence of favorable peer review. For investigators (including students) affiliated with a hospital or university, this requirement can be met by submission of a copy of written approval of the proposal by the hospital's or university's institutional review board. For investigators who are not affiliated with a hospital or university, the investigator must instead submit with RRC Form #1 three letters of approval of the proposal from three independent peers knowledgeable in the field of the proposed research.

### **SECTION C - Presentation by Investigator**

In cases where the Committee has many questions or where the nature of the research is such that additional explanation by the investigator would be helpful to the Committee's understanding of the research, the Committee may require the investigator's presence at the meeting at which it is considering the research. The investigator would be notified of the time and place of the meeting and alerted to particular issues identified by the Committee, which require or would benefit from further explanation. The investigator should be prepared to give a brief and informative overview of the research proposal.

### **SECTION D - Notification to Investigator**

Within 10 days after its consideration of the research, the Committee will notify the investigator regarding whether the research is approved, disapproved, approved contingent upon certain modifications, or approved subject to certain conditions. In the latter two instances, approval will be withheld until the Committee receives written confirmation to its satisfaction that the modifications have been made or that the conditions will be satisfied. After the research is approved, the investigator must submit to the Committee an annual progress report (RRC Form #3), as well as a final report upon completion of the research. Also, any alterations to a previously approved research protocol must be approved by the Committee before they can be implemented by the investigator. Follow-up communication concerning modifications and conditions of approval can usually be accomplished through written correspondence between the investigator and committee chairperson.