**Commonwealth of Massachusetts**

**Department of Developmental Services**

**Research Review Committee Meeting Minutes**

Date: January 17, 2025

By Teams: Erin Brown (Chairperson), Patricia Shook, Joshua Greenberg, Joseph Meyer, Joseph Weru, Deborah Dreyfus, and Freddy Torbey (observer/minutes)

Additional Attendees: Sofia Langman, Karen Kiley-Brabeck

**Agenda Items**

1. Administrative matters
2. “A Randomized, Double-blind, Placebo-controlled, Parallel Group Study of BPN14770 in Male Adults (Aged 18 to 45) with Fragile X Syndrome”, Isha Jalnapurkar, MD, UMass Chan Medical School
3. “Mitigation of Countercontrol Behavior: A Review of Case Studies”, Joseph Tacosik, M.A., BCBA, LABA

## HOUSEKEEPING

* Chair established quorum
* Chair summarized requirements for approval of research proposals pursuant to 115 CMR 10.08
* Chair presented proposals for discussion
* Joshua Greenberg lost connection at 1:22 PM and returned at approximately 1:35 PM
* Guest Karen Kiley-Brabeck exited meeting at 2:02 PM

### Review and Vote on December 6, 2024, Meeting Minutes

Outcome

* Chair moved for a vote and Committee members agreed to adopt December 6, 2024, meeting minutes (Joseph Weru and Kathleen Gallagher abstained due to absence)

**“A Randomized, Double-blind, Placebo-controlled, Parallel Group Study of BPN14770 in Male Adults (Aged 18 to 45) with Fragile X Syndrome”**, Isha Jalnapurkar, MD, UMass Chan Medical School

Discussion

* RRC discussed associated drug corporation’s retention of a professional IRB for this study
* RRC member Joshua Greenberg discussed prior professional associations with researcher and her institute
* RRC discussed proposed modality of ongoing research, as well as ability to draw relevant scientific results
* RRC discussed role in proposed study, as its currently ongoing nature poses the question of RRC ability to deny individuals receiving care from participating
* RRC discussed continued use of placebo in study considering research results having already proven usefulness of proposed medication; however, pharmaceutical corporation’s financial backing raises threshold for scrutiny and might validate current methodology
* RRC discussed that due to nature as pharmaceutical-backed study, ability of researchers to make changes to proposed study is particularly limited
* RRC discussed possibility of a regulatory requirement for individuals and their guardians to receive court-approval prior to participation due to possibility of more than minimal harm arising from the proposed research
* RRC discussed individual will and benefit, and denial thereof, from participating in study with existing knowledge that the drug has already had some noticeable positive effect: 1) Individuals might be refused the right to participate and receive the most likely effective medication dependent on RRC decision; 2) additionally, study design will inherently exclude a group of individuals from positive medical results by including them in the placebo group without possibility of exit; and finally, 3) all individuals will eventually lose access to the medication once the study has ended, regardless of positive medical effects shown
* RRC discussed that due to the non-FDA approved nature of researched drug, DDS MAP certified staff who traditionally administer drugs will not be able to provide it

Issues

* Optional exit interview comes attached to a $125 reward in cash to the guardian dependent on completion, posing ethical questions for individuals as well as guardians participating in the study and exit interviews
* Documents submitted did not include an example of the informed consent form, additionally, informed consent must be done under RRC supervision

Outcome

* Chair moved, and RRC members voted to postpone decision and vote on proposal until next meeting, scheduled on 02/07/2025

### POSTPONED PROPOSALS

**“A Randomized, Double-blind, Placebo-controlled, Parallel Group Study of BPN14770 in Male Adults (Aged 18 to 45) with Fragile X Syndrome”**, Isha Jalnapurkar, MD, UMass Chan Medical School

### CLOSING MATTERS

Next meeting is scheduled for February 7, 2025.