Commonwealth of Massachusetts Department of Developmental Services Research Review Committee Meeting Minutes Date: February 7, 2025

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

Additional Attendees: Sofia Langman

Agenda Items

- 1. Administrative matters
- "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 re-presented proposals for discussion
- □ Due to professional connections to researcher involved in first proposal, Joshua Greenberg notified that he would abstain from voting
- □ RRC discussed conflict of interest rules and behaviors, as well as potential sufficiency of appropriate disclosure followed by objective and rigorous review
- □ After RRC discussion, Joshua Greenberg's voting abstention was rescinded

Review and Vote on January 17, 2025, Meeting Minutes

Outcome

- □ Chair presented proposed amendments for January 17, 2025, meeting minutes
- □ Chair moved for a vote and Committee members agreed to adopt amended January 17, 2025, meeting minutes (Janet George 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

□ Chair noted that researcher was contacted pursuant to January 17, 2025 meeting, but RRC has not yet received a response

- □ RRC discussed that despite its psychiatry-focused nature, proposal uses psychological metrics and RRC questioned whether there was involvement by psychologist
- □ RRC discussed Massachusetts regulatory requirements and RRC duties vis-à-vis pharmaceutical corporations' market and nation-wide focus

Outcome

□ Chair moved, and RRC members voted to approve with conditions, namely the submission of informed consent form, as well as compliance with DDS regulations 115 CMR 10.08(2)-(4)

CONDITIONALLY APPROVED 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

Discussion of second proposal is deferred for next scheduled RRC meeting on March 7, 2025.