**Commonwealth of Massachusetts**

**Department of Developmental Services**

**Research Review Committee Meeting Minutes**

Date: December 6, 2024

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

Additional Attendees: Sofia Langman

**Agenda Items**

1. Administrative matters
2. “User evaluation of Bodhi: a self care app designed for people with intellectual and developmental disabilities (I/DD)” Dr. Krishna Venkatasubramanian, University of Rhode Island
3. “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
4. “The effects of noncontingent attention on self-isolation of adults in group home settings,” Haley Bayen, B.A., Vinfen

## HOUSEKEEPING

* Chair established quorum
* Chair summarized requirements for approval of research proposals pursuant to 115 CMR 10.08
* Chair presented proposals for discussion

### Review and Vote on November 1, 2024, Meeting Minutes

Outcome

* Chair moved for a vote and Committee members agreed to adopt November 1, 2024, meeting minutes

**“User evaluation of Bodhi: a self care app designed for people with intellectual and developmental disabilities (I/DD)”** Dr. Krishna Venkatasubramanian, University of Rhode Island

Discussion

* RRC discussed if proposal is a research project or designed to acquire user feedback
* RRC discussed clarifying proposal’s use of teleconference technology to ensure software being used protects privacy and security of participants
* RRC discussed need for inclusion of a mental health professional on the research team
* RRC discussed clarifying data usage rules ensuring that data collected for this study is used exclusively for this study
* RRC discussed clarifying notices provided to participants to ensure minimal confusion regarding previous participation in studies and proposal’s RRC approval status

Issues

* No end date for data retention proposed

Outcome

* Chair moved, and RRC members voted, to approve proposal conditional on ensuring adequate responses for issues and inquiries raised by RRC

**“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 need for an IRB as RRC cannot replace IRB in role and duties
* RRC discussed requesting notification from FDA and involved IRBs regarding potential adverse effects resulting from conduct or result of research proposed
* RRC discussed RRC authority to review and approve proposal

Outcome

* Chair moved, and RRC members voted, to defer decision pending consultation with General Counsel and Commissioner regarding proposal and RRC approval process

**“The effects of noncontingent attention on self-isolation of adults in group home settings,”** Haley Bayen, B.A., Vinfen

Discussion

* RRC discussed short time span for proposed research and possibility it might be too tailored to a particular individual or type of behavior
* RRC discussed if research site management is aware of potentially dysregulated behavior that individuals might engage in as a result of participation in proposed research
* RRC discussed if workplace supervisor is aware of proposed research

Issues

* Consent paperwork provided to participants appears prohibitively difficult to understand for proposed participant pool
* Proposal is attempting to use potentially unrealistic temporal tools to measure a behavior that might not be accurately indicative of intended research subject
* Proposal is well-written, presented, and argued; however, a conditional reinforcer is included in study concerning non-conditional factors
* Individuals participating might not think to opt out of research if it proves more of an irritant for participant(s) than intended, and might thus result in reinforcement of dysregulated behavior

Outcome

* Chair moved, and RRC members voted, to approve conditional on research proposal conforming to aforementioned issues and concerns

### CONDITIONALLY APROVED PROPOSALS

**“User evaluation of Bodhi: a self care app designed for people with intellectual and developmental disabilities (I/DD)”** Dr. Krishna Venkatasubramanian, University of Rhode Island

**“The effects of noncontingent attention on self-isolation of adults in group home settings,”** Haley Bayen, B.A., Vinfen

### DEFERED 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 January.