**Commonwealth of Massachusetts**

**Department of Developmental Services**

**Research Review Committee Meeting Minutes**

Date: 5/1/2020

By Phone: Erin Brown (Chairperson), Kathleen Gallagher, Frances Nwajei, Patricia Shook, Joshua Greenberg, Julie Moran & Janet George, Ronald Cabezas (observer/minutes).

**Agenda Items**

1. Administrative matters
2. “Angelman Syndrome Natural History Study,” Principal Investigator Dr. Wen-Hann Tan, Boston Children’s Hospital.
3. “A Non-Drug, Longitudinal Study to Enable Endpoint Development for Children and Adults with Angelman Syndrome,” Principal Investigator Dr. Wen-Hann Tan, Boston Children’s Hospital.

## HOUSEKEEPING

* Members had questions regarding the role of the RRC as a subcommittee in an on-going approved 3R Research project currently not up for a formal proposal.

### Review and Vote on February 27, 2020 Meeting Minutes

Outcome

* Chair moved for a vote, and Committee unanimously agreed to adopt the February 27, 2020 meeting minutes

**“Angelman Syndrome Natural History Study,” Principal Investigator Dr. Wen-Hann Tan, Boston Children’s Hospital.**

Discussion

* Chair summarized the study.

Issues

* Committee discussed the written consent guidelines of the study by the researcher and provided to the participant and or its Guardian. It was determined by the committee to have met the standard.

Outcome

* Chair moved for a vote, and Committee unanimously agreed to approve the study.
* Chair will draft correspondence to the researcher for response and welcomes the committee’s input.

**A Non-Drug, Longitudinal Study to Enable Endpoint Development for Children and Adults with Angelman Syndrome**

Discussion

* Chair summarized the study.
* Committee members have additional questions with regard to specific procedures and methods used by the researcher in this study.
* Committee agrees that it needs further clarification from the researcher before taking a vote.

Issues

* Committee has concerns with the blood draw procedure that may be required of the participant for genetic testing and in particular the need for the Sponsor of the study to keep the blood and its genetic material for future studies.
* Committee wants additional information pertaining to the safeguards needed for the participants in the study; specifically as it pertains to blood draw and electroencephalogram (EEG) testing by the researcher not explained in its application.
* Committee wants the researcher to address the procedures and outcomes for the participants who do not want to partake in blood draw methods as part of the study as that is not addressed in its application.

Outcome

* Chair moved for a vote, and the Committee unanimously agreed to defer voting until additional information is submitted to the Committee by the researcher.
* Chair will draft correspondence to the researcher for response and welcomes the committee’s input.

### APPROVED RESEARCH

### “Angelman Syndrome Natural History Study,” Principal Investigator Dr. Wen-Hann Tan, Boston Children’s Hospital.

### NON-APPROVED RESEARCH

“A Non-Drug, Longitudinal Study to Enable Endpoint Development for Children and Adults with Angelman Syndrome,” Dr. Wen-Hann Tan, Boston Children’s Hospital.

### CLOSING MATTERS

The next meeting of the Research Review Committee has been scheduled for TBD.