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TITLE: Biomarkers for Autism and for Gastrointestinal and Sleep Problems in Autism

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## **Introduction**

The objective of the proposed research is to compare the production of melatonin by young children with autism (N=45) to typically developing children (N=45). Specifically, we will see if the nighttime excretion rate of melatonin sulfate is markedly lower in the children with autism, whether there is a subgroup of children with autism having very low excretion; whether low nighttime excretion of melatonin sulfate is associated with sleep problems; and whether low daytime melatonin sulfate excretion is associated with gastrointestinal problems.

## **Body**

As detailed in prior quarterly reports, all appropriate approvals have been obtained, though no recruitment of human subjects occurred during the Year 01; Quarters 01 and 02 due to need to first complete the approval process. In Quarters 3 and 4, 1 autism subject and 3 control subjects have been recruited.

In order to increase recruitment rates, we have sent proposed changes in the protocol to the Science Officer and other DoD personnel. As stated therein, recruitment for the study has not met target numbers over the first 2 quarters (Year 1, Q3 & Q4) of active recruitment. Based on discussions with parents of toddlers, including both study participants and non-participants, it appears that much of the problem is due to the burden imposed by the time and effort required. Parents are asked to collect two daytime and one overnight diaper, fill out two one-page questionnaires, complete a diaper collection data sheet, complete and sign two forms, and arrange a FedEx pick-up. In addition, the financial incentive of \$30 does not appear to be sufficient given the effort involved.

The following changes to the study are being requested in order to simplify the collection process, reduce the burden imposed, and increase the financial incentive.

- 1) Simplify and consolidate the sleep and GI questionnaires and the collection data sheet into one single-page Information sheet/Questionnaire (please see attached draft revised/consolidated form).
- 2) Collect one midday 11AM-3PM diaper (rather than one morning and one afternoon daytime diapers) and one nighttime diaper (no change to nighttime diaper collection).
- 3) Increase the financial incentive to \$100 for the return for the completed packet (consisting of two diapers, 1-page questionnaire/form, consent form and research authorization form).

Please note that results obtained from the diapers and questionnaires collected to date will be able to be used with the data obtained in the future. Also note that in preliminary discussion with the Yale IRB (Amy Blakeslee, CIP, CCRP, Senior IRB Regulatory Analyst), the increased financial incentive was considered to be appropriate.

In addition, increased recruitment efforts will be applied. This will include recruitment through word-of-mouth at local day-care centers for typically developing control subjects.

**Key Research Accomplishments**

None

**Reportable Outcomes**

None

**Conclusions**

None

**References**

None

**Appendices**

None