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Award Number: W81XWH-10-1-0889

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

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REPORT DATE: October 2013

TYPE OF REPORT: Revised Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

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1. REPORT DATE October 2013		2. REPORT TYPE Revised Annual		3. DATES COVERED 30 September 2012 – 29 September 2013	
4. TITLE AND SUBTITLE Biomarkers for Autism and for Gastrointestinal and Sleep Problems in Autism				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-10-1-0889	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) George M. Anderson E-Mail: george.anderson@yale.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Yale University New Haven, CT 06520-8047				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The study is still collecting specimens. No interim data analysis has been performed at this point. As specified in the EWOFF request, data analysis will begin on or about June 1, 2014.					
15. SUBJECT TERMS URINARY MELATONIN, TODDLERS, AUTISM, SLEEP, gastrointestinal					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	4	19b. TELEPHONE NUMBER (include area code)

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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

In Year-3 we recruited N=20 autism subjects and N=44 typically developing subjects. We have now recruited a total of N=31 autism subjects and N=56 typically developing subjects. All samples collected as of 09-30-2013 have been extracted.

(4) Section III - Problem Areas

(a) Current problems:

Recruitment rates have improved and the recruitment target of N=45 typically developing subjects has been surpassed. However, we have submitted a request for an Extension Without Funds for the period 10-01-2013 through 09-30-2014 in order to meet the original target recruitment goal of N=45 autism subjects (14 autism subjects still needed).

(b) Anticipated problems and corrective action planned:

Given the ongoing studies of the Child Study Center, including a DoD-funded study of Dr. K. Chawarska, we expect to achieve the recruitment goal of N=45 autism subjects by or before 06-01-2014.

Key Research Accomplishments: Recruitment has improved, and the target sample numbers should be reached by June 2014. Data analysis will proceed at that time.

Reportable Outcomes: A total of N=31 autism subjects and N=56 typically developing subjects have been recruited.

Conclusions: We expect the improved recruitment rates experienced in the past year to continue through June, 2014.

References: None

Appendices: None