AWARD NUMBER: W81XWH-17-1-0253

TITLE: Cannabidivarin (CBDV) Versus Placebo in Children with Autism Spectrum Disorder (ASD)

PRINCIPAL INVESTIGATOR: Eric Hollander, MD

CONTRACTING ORGANIZATION:
ALBERT EINSTEIN COLLEGE OF MEDICINE, INC
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REPORT DATE: 08/31/2019

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

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The CDC currently estimates 1 in 59 children have Autism Spectrum Disorder (ASD). Children with ASD have problems with social communication, irritability, repetitive behaviors, impulsivity, temper tantrums, and a high caregiver burden. The only medications approved by the FDA for symptoms of ASD are aripiprazole and risperidone. Both of these are used to reduce irritability but have short-term and long-term side effects.

During year two of this project, we finalized contract with GW Pharmaceuticals for the drug supply and secured additional financial support for this project, i.e. costs of electronic data capture (EDC) system development and its implementation. We signed contract with GW Pharmaceuticals on 11/16/2018 and its amendment was executed on 03/20/2019. Drug supply was received at AECOM/MMC site on 03/20/2019.
A subcontract between AECOM/MMC and NYU was executed on 08/09/2019. We have projected a total of 16 subjects enrolled by this point at the two sites, including both AECOM/MMC and NYU. Total number of subjects enrolled at AECOM/MMC site is 9 (out of 8 projected for AECOM/MMC site). Total number of subjects enrolled at NYU site is 0 to date. NYU site is in process of being activated.
This double-blind randomized placebo-controlled study will test the efficacy and safety of a new medication, cannabidivarin (CBDV), to treat autism in children ages 5-18. CBDV is non-psychoactive, is derived from the cannabis plant, but has effects opposite to THC. Approximately 100 patients will be enrolled at Montefiore and NYU sites during the duration of the study. The study lasts up to 16 weeks, and during this time, patients will come 9 times for study visits. Mood, social and cognitive functions will be assessed by the means of research questionnaires. All adverse effects will be reported. We will assess the effects of CBDV versus placebo on irritability and social functions in patients with ASD.

15. SUBJECT TERMS

NONE LISTED

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
					USAMRMC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			**19b. TELEPHONE NUMBER** *(include area code)*
U	U		Unclassified	23	

Standard Form 298 (Rev. 8-98)
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TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The CDC currently estimates 1 in 59 children have Autism Spectrum Disorder (ASD). Children with ASD have problems with social communication, irritability, repetitive behaviors, impulsivity, temper tantrums, and a high caregiver burden. The only medications approved by the FDA for symptoms of ASD are aripiprazole and risperidone. Both of these are used to reduce irritability but have short-term and long-term side effects. This double-blind randomized placebo-controlled study will test the efficacy and safety of a new medication, cannabidivarin (CBDV), to treat autism in children ages 5-18. CBDV is non-psychoactive, is derived from the cannabis plant, but has effects opposite to THC. Approximately 100 patients will be enrolled at Montefiore and NYU sites during the duration of the study. The study lasts up to 16 weeks, and during this time, patients will come 9 times for study visits. Mood, social and cognitive functions will be assessed by the means of research questionnaires. All adverse effects will be reported. We will assess the effects of CBDV versus placebo on irritability and social functions in patients with ASD.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Cannabidivarin, Autism spectrum Disorders, irritability, cannabinoids, autism, repetitive behaviors

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

	Timeline	AECOM/Monte	NYU
Major Task 1: Preparatory Stage	Months		
Subtask 1: Prepare and Submit Regulatory Documents			
Coordinate with Sites and GW Pharma for clinical trial agreements (CTAs) submission	1-4	100%, 11/16/2018	99%
Coordinate with Sites and GW Pharma for nondisclosure agreements (NDAs).	1-4	06/03/2016	06/03/2016
Coordination with GW Pharma and other sites for the continued work on the submission or re-submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration. The Investigators plan to submit the IND application prior to study start so that approval is underway when the funding period begins.	1-4	IND application submitted on 01/19/2018. IND may proceed status granted on 04/02/2018. Annual IND report receipt acknowledged on 07/31/2019.	Same status as at AECOM/ MMC
Refine eligibility criteria, exclusion criteria, screening protocol	1-4	100%	100%
Finalize consent form & human subjects protocol	1-4	100%	100%
Finalize recruitment materials	1-4	100%	100%

Coordinate with Sites for the US Army Medical Research and Material Command Office of Research Protections (ORP) and the Human Research Protection Office (HRPO) Submission	1-4	100%	100%
Coordinate with Sites for IRB protocol submission	1-4	100%	100%
Coordinate with Sites for CTSA sponsored Clinical Research Center (CRC) approval	1-4	90%	90%
Submit amendments, adverse events and protocol deviations as needed	As Needed	As needed	As needed
Coordinate with Sites for annual IRB report for continuing review	Annually	Approved 11/12/2018 till 11/11/2019	Approved 03/20/2019
Milestone Achieved: Local IRB approval at AECOM/Monte and NYU	4	05/15/2018	05/02/2018
Milestone Achieved: HRPO and ORP approval for protocol	4	05/25/2018	2/5/2019
Subtask 2: Training of Study Staff			
Coordinate with Sites for Coordinator training	4-6	100%, 06/01/2018	100%, 06/01/2018
Coordinate with Sites for training Raters until 100% concordance	4-6	100%, 06/01/2018	100% 06/01/2018
Complete Regulatory Binders	4-6	100%	100%
Create Manual of Operations	4-6	100%	100%
Milestone Achieved: Research staff trained and Regulatory procedures set up	4-6	06/01/2018	06/01/18
Subtask 3: Facilitate Communication Between Sites and Staff			
Coordinate with Sites bi-weekly meetings to review study goals, recruitment and enrollment	1-48	100%	100%
Milestone Achieved: Bi-weekly meetings completed throughout study	1-48	Study is ongoing	Study is ongoing
Subtask 4: Assessments and Surveys Preparation			
Finalize assessment measurements	4-6	100%	100%
Order all assessments and distribute across sites	4-6	100%	100%
Prepare Patient Study Binders including surveys and source documents	4-6	100%	100%
Milestone Achieved: All study materials prepared for patient enrollment	4-6	100%	100%
Subtask 5: Receipt of Study Drug			
Develop protocol with pharmacy for storage and dispensing of study drug/placebo and randomization protocol	1-4	08/01/2018	08/01/2018
Work with GW Pharma to ship study drug and placebo to sites	6	***Drug shipped by GW to the US depot on 2/5/19; received at the US depot on 02/15/19; received at AECOM/MMC on 03/20/19***	***Drug shipped by GW to the US depot on 2/5/19; received at the US depot on 02/15/19. Site delivery is in process. SOP finalized.***

Milestone Achieved: Receipt of Study Drug and Placebo	6	Achieved	Pending
Subtask 6: Data Management Preparation			
Coordinate with Sites for flow chart for study steps, data collection and database requirements	4-6	100%	100%
Develop and Maintain Electronic Database at AECOM	4-48	50%, study is ongoing	50%, study is ongoing
Milestone Achieved: Electronic database prepared and maintained throughout study	4-48	Study is ongoing	Study is ongoing
Major Task : Participant Recruitment and Enrollment			
Subtask 1: Begin Subject Recruitment			
Contact patients in site databases	6-42	100%, study is ongoing	100%, study is ongoing
Advertise using internet and radio advertisements and study flyers	6-42	50%, study is ongoing	50%, study is ongoing
Milestone Achieved: All patients in databases contacted	6	100%, ongoing	100%, ongoing
Milestone Achieved: 1st Advertisements are placed	6	50%, study is ongoing	50%, study is ongoing
Subtask 2: Conduct Study			
Consent and screen potential patients and review I/E criteria (n=100)	6-42	Ongoing	Pending
Evaluate and assign eligible participants to one of the two randomized groups	6-42	Ongoing	Pending
Participants complete assigned condition over 12 weeks	6-42	Ongoing	Pending
Assess all participants at the appropriate study visits	6-42	Ongoing	Pending
Milestone Achieved: Study Begins	6	April 12 2019	Pending
Milestone Achieved: 1st Patient Consented and Enrolled	6	April 12 2019	Pending
Milestone Achieved: Last Patient Consented and Enrolled	42	Ongoing	Pending

What was accomplished under these goals?

Major Task 1: Preparatory Stage.

Subtask 1: Prepare and Submit Regulatory Documents.

-Coordinate with Sites and GW Pharma for Clinical Trial Agreements (CTA) Submission.

We regularly discussed all contract-related issues with Dr. Dhanonjoy C. Saha, Director of Office of Grant Support at AECOM/MMC. Furthermore, we conducted a series of conference calls for CTA negotiation and revisions with Deirdre Flaherty, Head of Pipeline Programs at GW Pharma, which occurred on 9/11/17, 10/20/17 and 10/23/17.

On 01/22/2018 we conducted a meeting between Dr. Eric Hollander (AECOM/MMC), Dr. Vera Nezgovorova (AECOM/MMC), Deirdre Flaherty (GW Pharma) and James Ryan (GW Pharma Contract Specialist) to finalize terms of statistical support for the project and discuss study drug dispense questions. Same day, a revised draft of the CTA was received for review by Dr. Dhanonjoy C. Saha, Director of Office of Grant support at AECOM/MMC. On 02/07/2018 we conducted a meeting with Attorney Laura Wilson-Youngblood, Assistant Counsel at AECOM/MMC, to review the terms before she could proceed for further negotiation of final details with GW Pharma.

On 03/16/18 a call between Attorney Laura Wilson-Youngblood, Assistant Counsel at AECOM/MMC, Deirdre Flaherty (GW Pharma), James Ryan (GW Pharma Contract Specialist), Dr. Eric Hollander (AECOM/MMC) and Dr. Vera Nezgovorova (AECOM/MMC) occurred to further negotiate details of the CTA with GW Pharma with an emphasis on Steering Committee charter development. It was decided that AECOM/MMC will proceed with CTA

signature with GW Pharma, and a subcontract will be than issued between AECOM/MMC and NYU to document the terms of collaboration for this study. Subcontract between AECOM/MMC and NYU is currently being finalized.

Following that call, CTA updated by GW Pharma was reviewed by Einstein legal team, which included Lara Jean Ancona, Esq., Partner at Garfunkel Wild firm. Feedback on breaking the blind for the analyses; rights and liabilities of GW Pharma and feedback on publications committee has been incorporated. CTA and Steering Committee Charter were submitted for GW Pharma review on 03/30/18. To further address final terms of the agreement, a call between Dr. Volker Knappertz (Chief Medical Officer at GW Pharma), Deirdre Flaherty (GW Pharma) and Dr. Eric Hollander (AECOM/MMC) occurred on 05/03/18, where key points of the CTA were reviewed prior to its execution by legal teams on both sides. On 05/10/2018 Einstein legal team, comprising Attorney Laura Wilson-Youngblood, Assistant Counsel at AECOM/MMC and Lara Jean Ancona, Esq., Partner at Garfunkel Wild firm, had a call with James Ryan (GW Pharma Contract Specialist) to finalize terms of the CTA. Revisions to the contract in regards to IP and data analysis provisions were incorporated by GW Pharma contract department and Einstein legal team and sent to GW Pharma contract division for approval on 06/13/2018. GW Pharma contract division completed review of the revised contract terms on 07/18/2018. Dr. Eric Hollander (AECOM/MMC), Dr. Orrin Devinsky (NYU) and Dr. Volker Knappelz (Chief Medical Officer at GW Pharma) had a call on 07/20/2018 to discuss IP provisions for the CTA finalization. Einstein legal team had a series of calls with Cynthia Clark, attorney from Greenwich Biosciences (US subsidiary of GW Pharmaceuticals) on 07/18/2018, 08/07/2018, 08/20/2018 and 08/28/2018 to discuss IP provisions. Following these calls a budget was prepared to reflect additional funds that would be provided by GW to cover the creation of a study specific EDC (Electronic data capture solution), additional staff and pharmacy support, and for safety labs requested by the FDA. Budget was prepared for AECOM/MMC and NYU sites and submitted on 09/12/2018. On September 26 2018 Dr. Eric Hollander (AECOM/MMC), Casara Jean Ferretti (AECOM/MMC), Dr. Vera Nezgovorova (AECOM/MCC) had a call with GW Pharma financial team to review the submitted budget. Additional follow-up communication, which included calls and emails in regards to budget justification were conducted bi-weekly during October 2018 between AECOM/MMC team and GW Pharma team. On 11/16/18 GW Pharma finalized approval of the additional funding support, and the CTA contract between AECOM/MMC and GW Pharma was signed by GW Pharma. **An amended contract between AECOM/MMC and GW was executed on 03/20/2019. Subcontract between AECOM/MMC and NYU was signed on 08/09/2019.**

- *Coordinate with Sites and GW Pharma for Nondisclosure Agreements (NDA).*

Two-way confidentiality agreement between Montefiore Medical Center and GW Pharma has been signed as of June 3 2016, and the copy of the executed CDA is on file.

-Coordinate with GW Pharma and other sites for the continued work on the submission or resubmission of an Investigational New Drug (IND) Application to the U.S. Food and Drug Administration.

During current reporting period, we obtained a study May proceed letter from an Investigational New Drug (IND) Application to the U.S. Food and Drug Administration.

This work was preceded by a series of email communications and phone calls organized by Kevin Hong (AECOM/MMC)) and Karen Twigden (GW Pharma), which took place on 7/26/17, 7/28/17, 8/7/17, 8/10/17, and 8/16/17. Dr. Hollander and Kevin Hong organized and participated in a meeting with Dr. Orrin Devinsky, Latoya King, and Anjanette Burns at NYU to review logistic obstacles and regulatory challenges associated with IND submission. Following that meeting on 9/11/2017, Dr. Hollander and GW Pharma agreed to delay IND application submission. It was suggested to wait until release of Edition 6 of the Investigator's Brochure (IB), as it would include updated pharmacokinetics and dosage regimen data pertinent to the upcoming IND submission. Upon release of IB edition 6 by GW Pharmaceuticals in preparation of our IND submission, we conducted a series of meetings with Dr. Michelle Wellborn (GW Pharma consultant) and Deirdre Flaherty (GW Pharma), which occurred on 11/22/2017, 11/27/2017 and 01/17/2018. Investigational New Drug Application to the U.S. Food and Drug Administration was submitted by us on 01/19/2018. It was received into Neurology Division Office on 02/01/2018 with assigned IND # 138371. Study May Proceed letter from Department of Health and Human services, Food and Drug Administration, Division of Psychiatry Products, Office of Drug Evaluation I, Center for Drug Evaluation and Research was received on 04/02/18 with non-hold comments. These non-hold clinical and clinical pharmacology comments were incorporated in the study protocol. On 04/13/18 a call between Deirdre Flaherty (GW Pharma), Carole Baker (GW Pharma), Daniel Checketts (statistician, GW Pharma) Dr. Eric Hollander (AECOM/MMC) and Dr. Vera Nezgovorova

(AECOM/MMC) occurred, where FDA may proceed letter comments with an emphasis on a strategy of incorporation of statistical feedback received were discussed. Non-hold statistical comments from the FDA Study May proceed letter are currently being incorporated in the protocol. Annual IND report was submitted on 07/22/2019 and its receipt was acknowledged on 07/31/2019.

- *BNE application submission.*

On 10/9/17, Dr. Eric Hollander and Kevin Hong consulted Dr. Sheryl Haut, Director of the Adult Epilepsy Program and Chief of Neurology Service at AECOM/MMC, who had worked with a Cannabidiol containing compound from GW Pharma in the past to inquire about unanticipated challenges for the study implementation and were advised on importance of tandem submission to the Institutional Review Board and to the New York State Department of Health, Bureau of Narcotic Enforcement (BNE) for the timely BNE inspection scheduling and application processing.

We submitted application to the New York State Department of Health, Bureau of Narcotic Enforcement (BNE) for Class 7 Individual Researcher and Class 9 Importer licenses approvals in tandem with our IRB submission. Our BNE application was received as of 11/7/2017. Soon after AECOM/MMC Investigational Drug Service Pharmacy received BNE inspection for GW Pharma safe, which was approved. On 01/16/2018 after submitting conditional IRB approval notice for AECOM/MMC site, we were advised by Michele Mulloy, Regulatory Compliance Section Manager, Bureau of Narcotic Enforcement (BNE), that we would need to provide final unconditional IRB approval letter and IND approval letter from the FDA prior to the BNE final review and approval. Following FDA study May Proceed letter receipt on 04/02/18, we received an IRB approval letter without IND clause, which satisfied Bureau of Narcotic Enforcement (BNE) requirements. Case number for BNE inspection was assigned. As we were moving forward with BNE inspection, we were advised that an independent safe designated only for Dr. Hollander study would be required as a condition for BNE approval. Reconditioned Amsec Plate Steel Safe Model 2230 (right swing) UL-TL-30 1 Group 1R radiological lock: SG560 UL group 1 lock, SGD550 dial w/ 10" spindle; SGR167 ring, SC, SPKL was successfully ordered and installed on 04/16/18. Inspector Johnson from the BNE completed site and safe inspection on 04/18/18. BNE review was completed on 04/25/18. Dr. Hollander received Class 7 Individual Researcher and Class 9 Importer licenses approvals on 05/11/2018.

- *DEA application submission.*

We communicated with Terrance Woodworth (GW Pharma consultant) and were advised to submit DEA application upon submission of our IND application prior to the IND approval by the FDA. Thus on 02/09/2018 we submitted DEA Schedule I application, which included the following items:
-DEA application form 225
-Certification that an IND application was submitted
-PI signed and dated CV
-Cover Letter
-Application Fee
-Copy of conditionally IRB approved study protocol
-IND acknowledgement letter

BNE approval and IND approval by the FDA are required for the subsequent DEA approval. IND approval by the FDA was received on 04/02/2018. However, in order to expedite DEA approval, we scheduled DEA Inspection on site. Inspector Rivera completed DEA inspection at AECOM/MMC on 04/11/18. Additional DEA inspection to approve reconditioned Amsec Plate Steel Safe Model 2230 (right swing) UL-TL-30 1 Group 1R radiological lock: SG560 UL group 1 lock, SGD550 dial w/ 10" spindle; SGR167 ring, SC, SPKL was conducted by Inspector Rivera on 05/18/2018. DEA Schedule I license was received on June 26 2018. Upon DEA annual renewal requirements, it was renewed on September 5 2018.

- *Finalize consent form and human subjects protocol*

After programmatic review and subsequent follow-up communications with Dr. Stan Niu, Science Officer at the Department of Defense, requested changes in the protocol have been incorporated. After a conference call on

10/20/17 between Dr. Eric Hollander (AECOM/MMC), Dr. Orrin Devinsky (NYU), Dr. Volker Knappertz (Chief Medical Office at GW Pharma), Deirdre Flaherty (GW Pharma), James Ryan (Contract specialist at GW Pharma), Dr. Vera Nezgovorova (AECOM/MMC), Kevin Hong (AECOM/MMC), Danya Schlussel (AECOM/MMC) and Dr. Bonnie Taylor (AECOM/MMC), language was added to eligibility criteria regarding parent consent and child assent; exclusion criteria were specified regarding history of drug abuse. As the protocol was finalized, Dr. Hollander deemed that these additions were not substantive, and that they would not affect study recruitment process or statistical power.

Following a meeting on 11/22/17 between Dr. Eric Hollander (AECOM/MMC), Dr. Orrin Devinsky (NYU), Deirdre Flaherty (GW Pharma), Dr. Terrance Woodworth (GW Pharma), Dr. Michelle Wellborn (GW Pharma), Dr. Kenneth Sommerville (GW Pharma) Dr. Vera Nezgovorova (AECOM/MMC), Danya Schlussel (AECOM/MMC) and Dr. Bonnie Taylor (AECOM/MMC), language was added to human subjects protocol to include safety assessments. It was concluded that Columbia Suicide Severity Rating Scale will be administered in the beginning of each study visit. Following this meeting schedule of events was updated to include safety labs. As an additional statistical analysis not affecting statistical power, age of subject was proposed to be a covariate. Appendix A on P450 Drug Interactions, Flockchart table and Appendix B on U91A9 or U9T2B7 potential interactions were added to the human subjects protocol. Informed consent was revised to include language specifying potentials benefits to the study participant. IDSMC (Independent Data Safety Monitoring Committee) charter was developed and its members were confirmed. As the protocol and informed consent were finalized, Dr. Hollander deemed that these additions were not substantive, and that they would not affect study recruitment process or statistical power.

The following changes were made to the study protocol and ICF following HRPO ORP comments received on 02/13/18, and were IRB approved on 03/28/18:

1. Protocol: Section L: As required by the Human Research Protections Office (HRPO)/U.S. Army Medical Research and Materiel Command (USAMRMC) the role and responsibilities of the Research Monitor have been modified and now include: May discuss the protocol with the investigators, interview subjects, and consult with others outside the study about the research; Shall have the authority to stop the protocol, remove subjects from the protocol, and take any necessary steps to protect the safety and well-being of subjects until the IRB can assess the Monitor's report; Shall have the responsibility to promptly report their observations and findings to the IRB or other designated official; Is required to review all unanticipated problems involving risks to subjects or others, serious adverse events and all subject deaths associated with the protocol and provide an unbiased written report of the event. At a minimum, the research monitor must comment on the outcomes of the event or problem and in the case of a serious adverse event or death, comment on the relationship to participation in the study. The research monitor must also indicate whether he/she concurs with the details of the report provided by the principal investigator. Reports for events determined by either the investigator or research monitor to be possibly or definitely related to participation and report of events resulting in death must be promptly forwarded to the USAMRMC ORP HRPO.
2. Protocol: Section C7: As required by the Human Research Protections Office (HRPO)/U.S. Army Medical Research and Materiel Command (USAMRMC), the protocol must describe how participation in the research is intended to be beneficial to each subject participating in the study and the benefit(s) must apply to both the treatment and placebo groups. This section has been modified accordingly.
3. Consent Form: Page 7: The “Benefits” section of the ICF has been modified according to #2 above

Following non-substantial changes were made and approved by Einstein IRB#1, East on 12/13/2018 with reference #047991:

Addition of Investigator Brochure Edition 7, September 18.

Amendment to the study protocol:

1. change of version of VABS-II scales to VABS-3
2. addition of MERS scale
3. per FDA non-hold comments:

a) Laboratory safety studies were added to Week 2 study visit to identify any abnormality occurring early in the study drug exposure.
b) As it was recommended to monitor blood levels during the titration phase as well, to ensure safe use of the background medications that are mainly metabolized by CYP2C19, CYP3A4, UGT1A9, or UGT2B7, we will monitor for plasma drug levels of VPA, Lamotrigine, Oxcarbazepine, Phenytoin and Clobazam if applicable to any patient. Other medications may be monitored on a patient by patient basis, if there are safety concerns suspected to be related to a drug-drug interaction.
c) language was added, that the exclusion of medications that are potent inhibitors or inducers of CYP2C9 is not required.
d) language was added, that study drug is administered with food consistently throughout the study.
e) protocol wording on section C1 (page 10) and H (page 25) was amended to indicate that only patients with ABC-I≥18 will be included rather that refer to 'stratified for marked irritability' and 'stratified for ABC-I≥18'.
f) the protocol text for 'Analysis in regard to ABC-SW' is amended to specify more clearly the planned analysis.
4. Addition of GW Pharmaceuticals as additional funding source.

Amendment to informed consent:
1. Change of VABS-II to VABS-3 scales (as new version of VABS appeared).
2. Addition of GW Pharmaceuticals as additional funding source.

Following non-substantial changes were made and approved by Einstein IRB#1, East on 03/27/2019 with reference # 051122:

1. Adding second location for the CRC (1300 Morris park ave) at 1572 form.
2. Changes in the protocol:
a) removing line "module 4 will be used in this study" for ADOS-2 scale on page 17 of the protocol
b) removing Social Responsiveness Scale (SRS) from baseline assessments (p. 20 of the protocol)
c) adding Dr. J. Battaglia as research monitor (p.26 of the protocol).

On 04/08/2019 first IDSMC meeting has occurred, and following that meeting was decided to add sesame oil allergy as an exclusion criterion to the study protocol on page 12.

Following non-substantial changes were made and approved by Einstein IRB#1, East on 04/15/2019 with reference # 051762:
addition of sesame oil allergy as an exclusion criteria to the study protocol on page 12.

- *Finalize recruitment materials.*

Drafting of recruitment materials, including flyers, advertisements, and referral solicitations was completed.

-Coordinate with sites for the US Army Medical Research and Material Command Office of Research Protections (ORP) and the Human Research Protection Office (HRPO) Submission.

HRPO received our initial submission on 10/31/17. The following items were included:
-HRPO Protocol Submission Form
-Principal Investigator CV, Independent Medical Monitor bio-sketch
-Documentation of Human Subjects Training for all the Investigators at the Einstein site
-Updated FDA Form 1572
-Informed Consent, Assent, HIPAA forms
-Letters of Support from Collaborating Institutions (NYU, GW Pharma)
-Updated Research Protocol
-Peer and Programmatic Review of Protocol
-Email Correspondence with Protocol Changes
-Study Instruments and Data Collection Forms. The following items were included:
-Aberrant Behavior Checklist (ABC) – Irritability, Social Withdrawal
-Repetitive Behavior Scale – Revised (RBS-R)
-Pediatric Quality of Life Inventory (PedsQL) Family Impact Module

-Vineland Adaptive Behavior Scale – II (VABS-II)
-Clinical Global Impression Scale – Improvement, Severity (CGI-I, CGI-S)
-IQ Test: Stanford-Binet Intelligence Scales, 5e
-Autism Diagnostic Observation Schedule – II (ADOS-II)
-Social Responsiveness Scale (SRS)

On 02/08/2018 upon request we submitted to Dr. Margaret Frederick additional items from AECOM/MMC site, and then our application was routed by her to the Approval Authority by COB for HRPO pre-review. Following items were included in this additional submission:

-Investigators Brochure Edition 6, GW Pharmaceuticals
-Einstein IRB conditional approval notice
-Conditionally IRB approved Research Protocol
-Conditionally IRB approved Informed Consent, Assent and informed consent feedback tool.
-IND acknowledgement letter
-CITI GCP certificate of Dr. A. Djukic (medical monitor)
- Human subject's protection training of Dr. A.Djukic (medical monitor)

On 02/13/18 we received following comments from HRPO:
A. Required Information/Documents.

1. Provide the final IRB submission package, approval memo, and stamped consent and assent forms when available.
2. Ensure that the IRB approval memo or other communication from the IRB states the risk category for the inclusion of children (either 45 CFR 46.404, 45 CFR 46.405, or 45 CFR 46.406).

B. Revisions to be made to the protocol.

1. The role and responsibilities of the Research Monitor, Dr. Djukic, must include the following.
    a) May discuss the protocol with the investigators, interview subjects, and consult with others outside the study about the research.
    b) Shall have the authority to stop the protocol, remove subjects from the protocol, and take any necessary steps to protect the safety and well-being of subjects until the IRB can assess the Monitor's report.
    c) Shall have the responsibility to promptly report their observations and findings to the IRB or other designated official.
    d) Is required to review all unanticipated problems involving risks to subjects or others, serious adverse events and all subject deaths associated with the protocol and provide an unbiased written report of the event. At a minimum, the research monitor must comment on the outcomes of the event or problem and in the case of a serious adverse event or death, comment on the relationship to participation in the study. The research monitor must also indicate whether he/she concurs with the details of the report provided by the principal investigator. Reports for events determined by either the investigator or research monitor to be possibly or definitely related to participation and report of events resulting in death must be promptly forwarded to the USAMRMC ORP HRPO.

2. BENEFITS to subjects - The protocol states in Section C7 that "It may or may not directly benefit the subjects." The consent form states on page 7 that "There may or may not be a direct medical benefit to you from being in this research study." As this protocol involves an experiment where the primary purpose is to determine the effect of the intervention, the requirements under 10 USC 980 apply. Since the protocol requires the informed consent from a legally authorized representative or parent, the protocol must describe how participation in the research is intended to be beneficial to each subject participating in the study. This cannot include monetary compensation or possible benefit from the study drug, as the benefit is not yet known and not all subjects will receive the study drug. The benefit(s) must apply to both the treatment and placebo groups. The benefit(s) can take many forms. The protocol could possibly include providing education to the families on strategies to handle irritability or other symptoms of ASD, or providing feedback to the families on the results from the behavioral testing that may help them handle

symptoms of ASD. These are just suggestions. The PI must revised Section C7 to describe the benefit(s) to the subjects.

C. Revisions to be made to the consent form (Version dated 9 February 2017).

1. BENEFITS to subjects - Once the protocol has been updated to describe the benefit to the subjects, the description of this benefit must be added to the consent form page 7.

They were addressed as summarized above and approved by HRPO for the IRB submission.
On 03/23/18 revised protocol and ICF were submitted to IRB and were approved on 03/28/18. After obtaining FDA study May Proceed letter on 04/02/18, we then submitted it to HRPO as well on 04/03/2018. On 04/13/18 we confirmed with Dr. Gloria Lawrence, Dr. Margaret Frederick successor from ORP HRPO, that the only outstanding item for HRPO approval is unconditional IRB approval (pending BNE and DEA approval).

We submitted NYU IRB approval to HRPO ORP on 05/02/2018 as it was received.

On 05/16/2018 we submitted to ORP HRPO Albert Einstein College of Medicine Institutional Review Board (Einstein IRB #1, East) Approval letter #035849. ORP HRPO approval for AECOM/MMC site HRPO Log Number A-20351.a was granted on 05/25/2018.
On 01/14/2019 ORP HRPO accepted Albert Einstein College of Medicine Continuing Review report and supporting documents. ORP HRPO approval for NYU site HRPO Log Number A-20351.b was granted on 02/05/2019, **and NYU site Continuing review was received by HRPO ORP on 04/01/2019.**

On 05/02/2019 AECOM/MMC submitted following amendment to the study protocol to ORP HRPO (Log Number A-20351.a)
1) change in Independent Research Monitor name to Dr. Battaglia (his CV and GCP training are on file)
2) addition of exclusion criteria (allergy to sesame oil) on page 12 of the protocol.

-*Coordinate with sites for IRB protocol submission.*

Albert Einstein College of Medicine Institutional Review Board (Einstein IRB #1, East) received our initial IRB submission on 11/1/17. The following items were included: research protocol, parent consent/HIPAA forms, child assent form.

On 12/13/2017 Dr. Eric Hollander (AECOM/MMC) participated in Einstein IRB review meeting of the study protocol. Questions on frequency of Independent Data Safety Monitoring Committee (IDSMC) meetings, benefits to the child and psychoactive properties of CBDV have arisen, and were addressed during the meeting and in following the meeting correspondence.

On 01/08/2018 AECOM/MMC site received conditional IRB approval pending IND approval from the FDA, DEA license for schedule I substance, approval from Bureau of Narcotics, DEA approval to Pharmacy for additional storage space.

On 04/03/2018 AECOM/MMC site received conditional IRB approval pending approval from Bureau of Narcotics, DEA license for schedule I substance and DEA approval to Pharmacy for additional storage space.

On 05/11/2018 AECOM/MMC site received conditional IRB approval pending DEA license for schedule I substance and DEA approval to Pharmacy for additional storage space.

On 05/15/2018 AECOM/MMC site received Albert Einstein College of Medicine Institutional Review Board (Einstein IRB #1, East) Approval letter #035849.

DEA license for Schedule I substance and DEA approval to Pharmacy for additional storage space (letter from Clemencia Solorzano were submitted as amendment and acknowledged by Albert Einstein College of Medicine Institutional Review Board (Einstein IRB #1, East).

Progress report was submitted to Albert Einstein College of Medicine Institutional Review Board (Einstein IRB #1, East) on 11/2/2018. Study protocol was reapproved on 11/12/2018 with reference # 046713. On 12/13/2018 Albert Einstein College of Medicine Institutional Review Board (Einstein IRB#1, East) approved protocol amendment with reference # 047991.

On 03/27/2019 AECOM/MMC site received Albert Einstein College of Medicine Institutional Review Board approval #051123 for the protocol amendment. Non-substantial changes were made as outlined on pp.7

On 04/15/2019 AECOM/MMC site received Albert Einstein College of Medicine Institutional Review Board approval #051762 for the protocol amendment. Non-substantial changes were made as outlined on pp.7

Dr. Orrin Devinsky submitted to the New York University Langone Medical Center IRB #6 on 02/16/2018. His submission was delayed by the requirement to obtain IND # prior to the submission. AECOM/MMC site shared all IRB approved documents with NYU site to facilitate their submission, as we obtained IND#138371 as of 02/07/2018 in the mail. NYU site subsequently amended their IRB submission once HRPO comments were addressed by AECOM/MMC site and FDA study May Proceed letter was received on 04/02/2018. NYU site received IRB approval on 05/02/2018. This approval was submitted as amendment and acknowledged by Albert Einstein College of Medicine Institutional Review Board (Einstein IRB #1, East).
NYU site submitted Continuing review to their IRB on 03/15/2019 and received protocol reapproval on 03/20/2019.
NYU site submitted protocol amendments (same as Einstein site, outlined on p.7) on 04/19/19 and received approval on 05/14/2019.

Coordinate with sites for CTSA-sponsored Clinical Research Center (CRC) approval.

Application for Einstein-Montefiore CTSA-sponsored ICTR Clinical Research Center (CRC) was received on 11/10/2017. The following items were included: research protocol, parent consent form, child assent form, PI bio-sketch, study budget, projected use of CRC resources. We obtained ICTR approval notice on 11/28/2017 pending unconditional IRB approval. Following Albert Einstein College of Medicine Institutional Review Board (Einstein IRB #1, East) Approval letter #035849 receipt on 05/15/2018 we submitted it to ICTR and conducted CRC initiation visit. Dr. Orrin Devinsky completed submission for NYU CTSA-sponsored CRC. His submission was delayed by the requirement to obtain IND # prior to the submission. NYU site IRB approval was granted on 05/02/2018.

Submit amendments, adverse events, and protocol deviations as needed.

All amendments, adverse events, and protocol deviations will be reported and documented as they arise.

Coordinate with sites for annual IRB report for continuing review.

As the study progressed, investigators and coordinators at AECOM/MMC, NYU, and GW Pharma communicated regularly in regard to initial IRB submissions and remain accountable for timely review of all regulatory activities relevant to annual IRB reporting. Progress report was submitted to Albert Einstein College of Medicine Institutional Review Board (Einstein IRB #1, East) on 11/2/2018. Study protocol was reapproved on 11/12/2018 with reference # 046713.

NYU site submitted Continuing review to their IRB on 03/15/2019 and received protocol reapproval on 03/20/2019.
NYU site submitted protocol amendments (same as Einstein site, outlined on p.7) on 04/19/19 and received approval on 05/14/2019.

Subtask 2: Training of Study Staff

Rater training was conducted on 06/01/2018. We completed regulatory binders and created manual of operations and IDSMC charter.

Subtask 3: Facilitate Communication between Sites and Staff

We coordinate with NYU site weekly to review study goals and status of regulatory documents submission

Subtask 4: Assessments and Surveys Preparation

We finalized assessment measurements. We ordered study assessments and currently distribute them across sites. We prepared patient study binders including surveys and source documents.

Subtask 5: Receipt of Study Drug

We finalized with pharmacy protocol for storage and dispensing of study drug/placebo and randomization.
On 01/31/2018 Dr. Eric Hollander (AECOM/MMC) and Dr. Vera Nezgovorova (AECOM/MMC) met with Manager of Investigational Pharmacy at AECOM/MMC Dr. Clemencia Solorzano and Dr. Mark Sinett, Director of Clinical Services at AECOM/MMC to review dispensing of study drug/placebo strategy and confirmed storage space in GW designated safe, which is currently BNE and DEA approved.

As we were moving forward with BNE inspection, we were advised that an independent safe designated only for Dr. Hollander study would be required as a condition for BNE approval. Reconditioned Amsec Plate Steel Safe Model 2230 (right swing) UL-TL-30 1 Group 1R radiological lock: SG560 UL group 1 lock, SGD550 dial w/ 10" spindle; SGR167 ring, SC, SPKL was successfully ordered and installed on 04/16/18. We completed randomization protocol preparation on 08/01/2018.

We continue to work with GW Pharma to schedule shipping of the study drug and placebo to sites upon contract finalization. On 09/27/2018, 10/19/18, 12/7/18, 1/9/19 we conducted a series of call between Dr. Clemencia Solorzano, Manager of Investigational Pharmacy at AECOM/MMC, Dr. Freda Afrifa (Pharmacist at AECOM/MMC) and GW Pharma team involved in drug shipment and operations (Hetal Patel, PharmD and Jan Joscak, PharmD). Randomization table was finalized. We prepared end-use letter for drug shipment. **Due to unforeseen issues with drug labeling occurred from the GW side drug shipment was delayed, and was shipped from UK to the US depot on 02/05/2019. Study drug was received at the US depot on 02/15/2019, and was received at AECOM/MMC pharmacy on 03/20/19. On 03/25/2019 AECOM/MMC site staff members completed training on pharmacy operating procedures required for successful execution of this study protocol. Both sites have a copy of pharmacy related procedures manual on file.**

Subtask 6: Data Management Preparation
Follow-up communication, which included calls and emails in regards to budget justification were conducted bi-weekly during October 2018 between AECOM/MMC team and GW Pharma team. GW agreed to provide funding support for the creation of a study-specific EDC (electronic data capture solution) using the Bioforum data masters. **On 11/16/18 GW Pharma finalized approval of the additional funding support, and the CTA contract between AECOM/MMC and GW Pharma was signed by GW Pharma. AECOM/MMC signed a contract with Bioforum Data Masters on 01/30/2019. During the reporting period, we initiated the design and validation of e-CRFs and currently complete UAT testing phase.**

Major Task: Participant Recruitment and Enrollment

Subtask 1: Begin Subject recruitment.

Currently, patients have been contacted in site databases, and **over 100 patients** were identified. First patient was screened on 04/12/2019 and randomized on 04/26/2019.

Subtask 2: Conduct study.
Study is ongoing. We have projected a total of 16 subjects enrolled by this point at the two sites, including AECOM/MMC and NYU. Total number of subjects enrolled at AECOM/MMC site is 9 (out of 8 projected for AECOM/MMC site). Total number of subjects enrolled at NYU site is 0 to date. NYU site is in process of being

activated.Screening and enrollment data, enrolled subjects characteristics and listing of adverse events are summarized in Table 1, 2 and 3 below.

Table 1: Screening and Enrollment Data

Total Enrolled	Total Waiting to Randomize	Total Randomized	Total Screen Failures	Total Dropped Out	Total Completed
9	3	5	1	0	1

Table 2: Subject Characteristics Enrolled

	Statistic	Total
Gender	n (%)	9 (100%) Female 2 (22.2%) Male 7 (77.8%)
Age (yrs)	N mean (std) median min : max	9 11.1 (3.88) 10 5 : 17
Age (yrs)		
Category 1: 5-6	n (%)	1 (11.1%)
Category 2: 7-12	n (%)	5 (55.5%)
Category 3: 13-18	n (%)	3 (33.3%)
Race		
American Indian/Alaskan Native	n (%)	0 (0%)
Asian	n (%)	0 (0%)
Black / African American	n (%)	1 (11.1%)
Native Hawaiian / Pacific Islander	n (%)	0 (0%)
White	n (%)	8 (88.9%)
Mixed Race	n (%)	0 (0%)
Unknown/Not reported	n (%)	0 (0%)
Ethnicity		
Hispanic	n (%)	4 (44.4%)
Non-Hispanic	n (%)	5 (55.5%)

Table 3: Listing of Adverse Events

System Organ Class	Adverse Event	Severity	Serious
General disorders and Administration site conditions	Fatigue	Mild	No
	Fever	Mild	No
	Poor Appetite	Mild	No
	Vomiting	Mild	No
	Constipation	Mild	No
	Sleep Disturbance	Mild	No

Human Use Regulatory Protocols

TOTAL PROTOCOLS: One human subject research protocol will be required to complete the Statement of Work.

PROTOCOL (1 of 1 total):

HRPO Log Number A-20351.a and b

Title: Cannabidivarin (CBDV) vs. Placebo in Children with Autism Spectrum Disorder (ASD) Target required for clinical significance: TBD

Target approved for clinical significance: TBD

SUBMITTED TO AND APPROVED BY:

ORP HRPO, initial submission 10/31/17, documents submitted by Dr. Margaret Frederick (HRPO) to the Approval Authority by COB for pre-review on 02/08/2018. Comments received on 02/13/18, addressed and approved by HRPO and Einstein IRB (03/28/18). NYU IRB approval submitted to ORP HRPO on 05/02/2018. Einstein IRB#1 Approval letter #035849 submitted to ORP HRPO on 05/16/2018. ORP HRPO approval for AECOM/MMC site HRPO Log Number A-20351.a granted on 05/25/2018. ORP HRPO approval for NYU site was granted on 02/05/2019. **NYU site Continuing review was received by HRPO ORP on 04/01/2019.**

On 01/14/2019 ORP HRPO accepted Albert Einstein College of Medicine Continuing Review report and supporting documents. On 05/02/2019 AECOM/MMC submitted an amendment to the study protocol to ORP HRPO.

Albert Einstein College of Medicine Institutional Review Board (Einstein IRB #1, East), initial submission 11/1/17.
On 01/08/2018 AECOM/MMC site received conditional IRB approval pending IND approval from the FDA, DEA license for schedule I substance, approval from Bureau of Narcotics, DEA approval to Pharmacy for additional storage space.

On 04/03/2018 AECOM/MMC site received conditional IRB approval pending approval from Bureau of Narcotics, DEA license for schedule I substance, DEA approval to Pharmacy for additional storage space.

On 05/11/2018 AECOM/MMC site received conditional IRB approval pending DEA license for schedule I substance and DEA approval to Pharmacy for additional storage space.

On 05/15/2018 AECOM/MMC site received Albert Einstein College of Medicine Institutional Review Board (Einstein IRB #1, East) Approval letter #035849. Progress report was submitted to Albert Einstein College of Medicine Institutional Review Board (Einstein IRB #1, East) on 11/2/2018. It was reapproved on 11/12/2018 with reference # 046713

On 12/13/2018 AECOM/MMC site received Albert Einstein College of Medicine Institutional Review Board approval #047991 for the protocol amendment. Non-substantial changes were made as outlined above on pp.6-7.

On 03/27/2019 AECOM/MMC site received Albert Einstein College of Medicine Institutional Review Board approval #051123 for the protocol amendment. Non-substantial changes were made as outlined on pp.7

On 04/15/2019 AECOM/MMC site received Albert Einstein College of Medicine Institutional Review Board approval #051762 for the protocol amendment. Non-substantial changes were made as outlined on pp.7

New York University Langone Medical Center IRB #6, initially submitted 02/16/18 and amended after HRPO and IND non-hold comments. Approval letter received on 05/02/2018. **NYU site submitted Continuing review to their IRB on 03/15/2019 and received protocol reapproval on 03/20/2019. NYU site submitted protocol amendments (same as Einstein site, outlined on p.7) on 04/19/19 and received approval on 05/14/2019.**

New York State Department of Health, Bureau of Narcotic Enforcement (BNE), initial submission received 11/7/17, currently under review. BNE inspection (including safe and site inspection) completed on 04/18/18 by Inspector Johnson. Class 7 Individual Researcher and Class 9 Importer licenses approvals received on 05/11/2018.

Drug Enforcement Administration (DEA), Drug and Chemical Evaluation Section, initial submission for Schedule I license received on 02/13/18. DEA inspection completed on 04/11/2018 by Inspector Rivera. Additional inspection for the new safe is scheduled for 05/18/2018 with Inspector Rivera. DEA schedule I license was granted on June 26 2018. . Upon DEA annual renewal requirements, it was renewed 09/05/2018 and is valid through 10/31/2019.

STATUS:
We have projected a total of 16 subjects enrolled by this point at the two sites, including AECOM/MMC and NYU. Total number of subjects enrolled at AECOM/MMC site is 9 (out of 8 projected for AECOM/MMC site). Total number of subjects enrolled at NYU site is 0 to date. NYU site is in process of being activated.

What opportunities for training and professional development has the project provided?
Nothing to report

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Nothing to Report, study is ongoing

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

During next reporting period NYU site will begin subject enrollment. We will continue to meet patient enrollment targets at both sites (AECOM/MMC and NYU). Interview of Dr. Eric Hollander with Dr. Sanjay Gupta featuring study outline will be broadcasted on CNN on 09/29/2019. We expect this broadcast to increase our recruitment both at AECOM/MMC and NYU sites.

4. IMPACT: D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

We experienced a delay in a start-up of NYU site. Subcontract between AECOM/MMC and NYU was executed on 08/09/2019. NYU site will start subject enrollment shortly.

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

Publications, conference papers, and presentations
Report only the major publication(s) resulting from the work under this award.

Journal publications.

Vera Nezgovorova, Casara Jean Ferretti, Erin Shanahan, Danya Schlussel, Bonnie Paige Taylor, Genoveva Uzunova, Kevin Hong, Orrin Devinsky and Eric Hollander. "Cannabinoids in autism spectrum disorders". Pediatric drugs. Manuscript is currently being resubmitted. Acknowledgement of federal support in the body of the manuscript.

Books or other non-periodical, one-time publications.

Nothing to report

Other presentations.

- In previous reporting period study outline was presented at Department of Psychiatry Grand Rounds on 11/15/2018 at AECOM/MMC; on 11/30/2018 at Annual Isabelle Rapin Conference on Communication Disorders at Rose F. Kennedy Intellectual and Developmental Disabilities Research Center (IDDRC) at AECOM/MMC; in November 2018 at the Autism Speaks conference in New York; in December 2018 at American College of Neuropsychopharmacology conference panel entitled "No Longer Tarred With the Same Brush? Evidence for the Therapeutic Potential of Cannabidiol: Implications for Regulatory Policy". Interview with Dr. Hollander about the study outline was aired on NPR on 12/4/2018.
- Study outline was presented by Dr. Eric Hollander on April 25 2019 at the Department of Psychiatry and Behavioral Sciences Grand Rounds at Stanford University.
- Study outline was presented by Dr. Eric Hollander on May 18 at American Psychiatric Association meeting in San-Francisco at the "Essentials of cutting-edge evidence based treatments for Autism Spectrum Disorders" symposia, chaired by Dr. Eric Hollander (PI).
- Study outline was presented by Dr. Hollander at Cannagather Congressional Update meeting in

NYC on August 20 2019 in a joint panel featuring Dr. Hollander and Rep. Carolyn Maloney (Congresswoman, NYC 12).

- As we enrolled first patient in the study, publication about the study is about to appear at Einstein magazine (this issue will be published in October 2019, and a copy will be kept on file and forwarded to the funding agency with a relevant quarterly report).
- Interview of Dr. Eric Hollander with Dr. Sanjay Gupta about this study on CNN will be aired on 09/29/2019 and links about it will appear on CNN social media accounts (Facebook, Twitter). We expect this broadcast to increase our recruitment both at AECOM/MMC and NYU sites.

Website(s) or other Internet site(s)

https://www.autismeye.com/us-army-cannabis/ Autism Eye publication
https://www.childrenshospitals.org/newsroom/childrens-hospitals-today/articles/2018/03/military-funds-research-of-cannabis-based-autism-treatment-for-kids
Children's Hospital association newsroom
http://www.montefiore.org/body.cfm?id=1738&action=detail&ref=1375
Montefiore news release
https://www.newsweek.com/2018/02/23/really-good-weed-why-cannabis-may-be-worlds-most-effective-remedy-core-806758.html
Newsweek magazine publication
https://nypost.com/2018/05/02/clinical-trials-will-test-if-cannabis-compound-can-treat-autism/
NY post publication

Technologies or techniques

Nothing to report

Inventions, patent applications, and/or licenses

Not applicable at this point

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Funding support:

Name: Eric Hollander
Project Role: Principal Investigator (AECOM/MMC Site):
Nearest Person Month Worked: 1.8 months, 15%

Contribution to Project: Dr. Hollander has performed work in monitoring study progress and development, protocol finalization. He oversaw regulatory documents submissions and assured that award reporting requirements are met.
Funding support: no change

Name: Bonnie Taylor, PhD
Project Role: Study Coordinator/Rater Researcher Identifier:
Nearest Person Month Worked: 1.8 months, 15%
Contribution to Project: Dr. Taylor has performed work in the areas of regulatory and source documents preparation and protocol development.
Funding support: no change

Name: Casara Ferretti
Project Role: Study Coordinator/Rater
Nearest Person Month Worked: 0.6 months, 5%
Contribution to Project: Ms. Ferretti has performed work in the areas of grant writing, protocol drafting, and advertising materials preparation
Funding support: no change

Name: Vera Nezgovorova, MD
Project Role: Study/Regulatory Coordinator:
Nearest Person Month Worked: 3 months, 25%
Contribution to Project: Dr. Nezgovorova has performed work in the areas of regulatory documents preparation, protocol development, NYS BNE/DEA licensure, inter-sites communication and report writing.
Funding support: AECOM/MMC

Name: Erin Shanahan
Project Role: Study Coordinator:
Nearest Person Month Worked: 0.6 months, 5%
Contribution to Project: Ms. Shanahan has performed work in the areas of advertising materials preparation, regulatory documents preparation and submission.
Funding support: AECOM/MMC

Name: Orrin Devinsky
Project Role: Principal Investigator (NYU Site) :
Nearest Person Month Worked: 1.2 months, 10%
Contribution to Project: Dr. Devinsky has performed work in monitoring study progress and development, protocol finalization. He oversaw regulatory documents submissions and assured that award reporting requirements are met.
Funding support: no change

Name: Latoya King
Project Role: Study Coordinator (NYU Site):
Nearest Person Month Worked: 3 months, 25%
Contribution to Project: Ms. King has performed work in the areas of regulatory documents preparation and submission.
Funding support: no change

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

NYU Langone Comprehensive Epilepsy Center Collaboration and sub-contractor on the award as

8. SPECIAL REPORTING REQUIREMENTS

Not applicable

9. APPENDICES: *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*