UNIVERSITY of VIRGINIA HEALTH SYSTEM

The SCHOOL *of* MEDICINE
Office of the Dean

Office of Grants and Contracts

December 7, 2020

Robert A. Pike
Chief Grants Management Officer
Grants Management Branch, NIDDK
pikera@niddk.nih.gov

Mary K. Rosenberg
Section Chief, DEM Team
Grants Management Branch, NIDDK
rosenbergm@extra.niddk.nih.gov

Re: 5R01DK029953-38, "Mechanisms of Insulin Resistance in Man"

Dear Mr. Pike and Ms. Rosenberg:

As an authorized signatory for the University of Virginia, I am pleased to respond to your request for the clinical trial registration for Dr. Rita Basu's 5R01DK029953-38 award.

As discussed by Dr. Basu with the Program Officer, Dr. Karen Teff, Aim 1 does not meet the NIH definition of a clinical trial and is not registered as such. The clinical trial encompassed in Aim 2 of the award is registered at ClinicalTrials.gov with the number NCT04416204 and the registration documentation is attached. Aim 3 of this project is not anticipated to begin until year -40 of the award and clinical trial registration will be completed for Aim 3 closer to the start of that aim.

Please do not hestitate to contact us if we can provide any additional information. We appreciate your time and attention to this matter.

Sincerely,

Lauren B. Armstrong
Assistant Director, Office of Grants and Contracts
University of Virginia School of Medicine

Cc: Dr. Karen Teff

P.O. Box 800793 • Charlottesville, VA 22908-0793
Phone: 434-924-8426 • Fax: 434-924-8725 • uva_som_ogc@virginia.edu

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: December 1, 2020

ClinicalTrials.gov ID: NCT04416204

Study Identification

Unique Protocol ID:	22074
Brief Title:	Effect of High Carbohydrate vs. Low Carbohydrate Diet in Type 2 Diabetes
Official Title:	Role of Hepatic Glycogen on Nocturnal EGP in T2D
Secondary IDs:	

Study Status

Record Verification:	December 2020
Overall Status:	Recruiting
Study Start:	August 21, 2020 [Actual]
Primary Completion:	June 15, 2022 [Anticipated]
Study Completion:	June 15, 2024 [Anticipated]

Sponsor/Collaborators

Sponsor:	University of Virginia
Responsible Party:	Principal Investigator Investigator: Rita Basu, MD [rbasu] Official Title: Principal Investigator Affiliation: University of Virginia
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 22074 Board Name: UVA Institutional Review Board for Health Sciences Research Board Affiliation: University of Virginia Phone: 434-924-2620 Email: irbhsr@virginia.edu Address: UVA Institutional Review Board for Health Sciences Research Box 800483

Charlottesville, VA 22908

Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: The experimental approach in this study intends to investigate the role of hepatic glycogen content on nocturnal regulation of endogenous glucose production including the relative contributions of glycogenolysis and gluconeogenesis and the extent to which this differs between subjects with type 2 diabetes and subjects without diabetes. Both participants with type 2 diabetes and participants without diabetes will be studied after consuming either a low carbohydrate (no glycogen loading) or high carbohydrate (glycogen loading) diet.

Detailed Description:

Conditions

Conditions: Diabetes Mellitus
Diabetes Mellitus, Type 2

Keywords: Diabetes Mellitus
hepatic glycogen
endogenous glucose production

Study Design

Study Type: Interventional

Primary Purpose: Basic Science

Study Phase: N/A

Interventional Study Model: Crossover Assignment

Number of Arms: 2

Masking: None (Open Label)

Allocation: Randomized

Enrollment: 30 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Type 2 diabetes	High Carbohydrate (glycogen loading) Subjects will consume an isocaloric diet [60% carbs, 20% protein, 20% fat (33 kcal/kg/day)] for 3 days prior to the overnight study. Low carbohydrate (No Glycogen Loading) Subjects will consume an isocaloric diet [40% carbs, 20% protein, 40% fat (33 kcal/kg/day)] for 3 days prior to the overnight study.
Experimental: Participants without diabetes	High Carbohydrate (glycogen loading) Subjects will consume an isocaloric diet [60% carbs, 20% protein, 20% fat (33 kcal/kg/day)] for 3 days prior to the overnight study.

Arms	Assigned Interventions
	Low carbohydrate (No Glycogen Loading) Subjects will consume an isocaloric diet [40% carbs, 20% protein, 40% fat (33 kcal/kg/day)] for 3 days prior to the overnight study.

Outcome Measures

Primary Outcome Measure:

1. Hepatic glycogen content and rates of gluconeogenesis in subjects with type 2 diabetes
   1. Hepatic glycogen content will be measured with MRI after either glycogen loading or no glycogen loading meals. We will also measure the rates and contribution of Gluconeogenesis (GNG) to nocturnal Endogenous Glucose Production (EGP) using the deuterated water technique after either glycogen loading or no glycogen loading in subjects with type 2 diabetes.

   [Time Frame: Subjects will complete both glycogen loading and no glycogen loading visits within approximately 6 weeks]

Secondary Outcome Measure:

2. Rates of glycogenolysis in subjects with type 2 diabetes
   1. Rates and contribution of glycogenolysis (GLY) to nocturnal EGP will be measured using the deuterated water technique after glycogen loading and no glycogen loading in subjects with type 2 diabetes.

   [Time Frame: Subjects will complete both glycogen loading and no glycogen loading visits within approximately 6 weeks]
3. Rates of gluconeogenesis in healthy subjects
   2. Rates of GNG will be measured through the night using the deuterated water technique after either glycogen loading or no glycogen loading in healthy subjects.

   [Time Frame: Subjects will complete both glycogen loading and no glycogen loading visits within approximately 6 weeks]

Eligibility

Minimum Age:	30 Years
Maximum Age:	75 Years
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	Yes
Criteria:	Inclusion Criteria:

- Age 30-75
- BMI 27-40kg/m^2
- Participants with type 2 diabetes:
  - HbA1c less than or equal to 8.5% on lifestyle therapy or monotherapy with metformin or sulphonylureas (SU); or less than or equal to 7.5% on two oral hypoglycemic agents (Metformin and SU)

Exclusion Criteria:

- Pregnancy or breast feeding
- Morbidities precluding participation
- Participants with type 2 diabetes:

- Therapy with insulin
- SGLT2 inhibitors
- GLP-1 based approaches
- TZDs
- Unstable diabetic retinopathy
- Microalbuminuria
- Macrovascular disease
- Medications affecting GI motility (eg., erythromycin, pramlintide)
- Upper GI disorder/surgery

- Participants without diabetes:
  - Medications (except stable thyroid hormone or hormone replacement therapy) that could influence glucose tolerance
  - History of diabetes mellitus in first degree family members or prior history of diabetes mellitus or gestational diabetes, or pre-diabetes

Contacts/Locations

Central Contact Person: Alexandra Weaver
Telephone: 434-924-3512
Email: acw6qc@hscmail.mcc.virginia.edu

Central Contact Backup:

Study Officials:

Locations: **United States, Virginia**
University of Virginia
[Recruiting]
Charlottesville, Virginia, United States, 22908
Contact: Yadav Yogesh 434-924-4780 YY9NT@hscmail.mcc.virginia.edu
Principal Investigator: Rita Basu, MD

IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

03/02/2021

Lindsay Burns, Vice President - Neuroscience
Cassava Sciences, Inc.
7801 N. Capital of Texas Hwy, Ste. 260
Austin, TX 78731-1192

Reference: 4R44AG060878-02

Dear Dr. Lindsay Burns:

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

Grant Number: 4R44AG060878-02
PI Name: Dr. Lindsay Burns
Period of Performance: 09/01/2018 - 11/30/2020
NIH Institute/Center: National Institute on Aging (NIA)

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), NIH Grants Policy Statement, Section 4.1.3.1.

Official Study Title: A Phase 2a, Open-label, Multiple Dose, Safety, Pharmacokinetic and Biomarker Study of PTI-125 in Mild-to-moderate Alzheimer's Disease Patients
NCT Number: NCT03748706
Primary Completion Date: 05/2019

Compliance with the NIH policy is a term and condition of this grant award; however, the NIA has been unable to verify that results information has been submitted to ClincialTrials.gov for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

If you believe that you have complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please respond to this letter no later than 30 days from receipt of this letter with the following information pertaining to the above-referenced clinical trial(s):

- Evidence that clinical trial results information has been submitted to ClinicalTrials.gov.
- Evidence that submission of clinical trials results information is not required at this time.

Please submit this information to me at the e-mail address below.

Thank you for your attention to this important matter. Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

(b) (6)

Chief Grants Management Officer
National Institute on Aging
Gateway Building, Suite 2W100
7201 Wisconsin Avenue
Bethesda, MD 20814
traci.lafferty@nih.gov
301-496-8987

cc: Joel Snyderman, OER/OPERA
Philip Smith, OER/OPERA
Dr. Laurie Ryan, NIA Program Official

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

12/01/2020

Christopher Decelles, Sr. Grant & Contracts Administrator
Massachusetts General Hospital
399 Revolution Drive, Suite 735
Somerville, MA 02114

Reference: 5UH3CA189901-05

Dear Mr. Christopher Decelles:

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

Grant Number: 5UH3CA189901-05
PI Name: Dr. Tayyaba Hasan (Contact PI) and Dr. Jonathan P. Celli
Period of Performance: 09/19/2014 - 08/31/2021
NIH Institute/Center: National Cancer Institute (NCI)

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), NIH Grants Policy Statement, Section 4.1.3.1.

Official Study Title: Low-cost Enabling Technology for Image-guided Photodynamic Therapy (PDT) of Oral
NCT Number: NCT03638622
Primary Completion Date: 08/31/2019

Compliance with the NIH policy is a term and condition of this grant award; however, the NCI has been unable to verify that results information has been submitted to ClincialTrials.gov for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

If you believe that you have complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please respond to this letter no later than 30 days from receipt of this letter with the following information pertaining to the above-referenced clinical trial(s):

- Evidence that clinical trial results information has been submitted to ClinicalTrials.gov.
- Evidence that submission of clinical trials results information is not required at this time.

Please submit this information to me via e-mail crystal.wolfrey@nih.gov.

Thank you for your attention to this important matter. Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

(b) (6)

Crystal Wolfrey
Chief Grants Management Officer
National Cancer Institute
9609 Medical Center Drive, Room 2W472
Rockville, MD 20852

cc:

OER/OPERA
Dr. Lokesh Agrawal

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

03/01/2021
Gail Cusimano, Sr. Grants Associate
Johns Hopkins University
W400 Wyman Park Building
Baltimore, MD 21218-2680

Reference: 5R01DA026727-05

Dear Ms. Gail Cusimano:

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

Grant Number: 5R01DA026727-05
PI Name: Shruti H Mehta
Period of Performance: 09/01/2015 - 08/31/2018
NIH Institute/Center: National Institute on Drug Abuse (NIDA)

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), NIH Grants Policy Statement, Section 4.1.3.1.

Official Study Title: Role of Pegylated Interferon in Combination With Direct Acting Antivirals (DAAs) to Cure Hepatitis C As Soon As Possible (ASAP) - Hepatitis C [ASAP-C]
NCT Number: NCT03480932
Primary Completion Date: 11/02/2018

Compliance with the NIH policy is a term and condition of this grant award; however, the NIDA has been unable to verify that results information has been submitted to ClincialTrials.gov for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

If you believe that you have complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please respond to this letter no later than 30 days from receipt of this letter with the following information pertaining to the above-referenced clinical trial(s):

- Evidence that clinical trial results information has been submitted to ClinicalTrials.gov.
- Evidence that submission of clinical trials results information is not required at this time.

Please submit this information to me at the e-mail address below.

Thank you for your attention to this important matter. Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

(b) (6)

Pamela Fleming
Chief Grants Management Officer
National Institute on Drug Abuse
National Institutes of Health
3WFN MSC 6021
301 N Stonestreet Avenue
Bethesda, MD 20892
pfleming@nih.gov
(301) 480-1159

cc: Joel Snyderman, Chief Grants Compliance Officer, OER/OPERA
Philip Smith, Assistant Grants Compliance Officer, OER/OPERA
Dr. Raul N. Mandler, NIDA Program Official

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

03/01/2021
Lillian Rivera, Grants and Contracts Officer
University of Southern California
3720 S. Flower Street
3rd Floor
Los Angeles, CA 90089-0701

Reference: 5R01DA038965-04

Dear Ms. Lillian Rivera:

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

Grant Number: 5R01DA038965-04
PI Name: Ricky N. Bluthenthal
Period of Performance: 08/01/2015 - 06/30/2020
NIH Institute/Center: National Institute on Drug Abuse (NIDA)

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), NIH Grants Policy Statement, Section 4.1.3.1.

Official Study Title: Preventing Injection Initiation: The Change the Cycle Randomized Controlled Trial.
NCT Number: NCT02774954
Primary Completion Date: 11/2018

Compliance with the NIH policy is a term and condition of this grant award; however, the NIDA has been unable to verify that results information has been submitted to ClincialTrials.gov for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

If you believe that you have complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please respond to this letter no later than 30 days from receipt of this letter with the following information pertaining to the above-referenced clinical trial(s):

- Evidence that clinical trial results information has been submitted to ClinicalTrials.gov.
- Evidence that submission of clinical trials results information is not required at this time.

Please submit this information to me at the e-mail address below.

Thank you for your attention to this important matter. Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

(b) (6)

Pamela Fleming
Chief Grants Management Officer
National Institute on Drug Abuse
National Institutes of Health
3WFN MSC 6021
301 N Stonestreet Avenue
Bethesda, MD 20892
pfleming@nih.gov
(301) 480-1159

cc: Joel Snyderman, Chief Grants Compliance Officer, OER/OPERA
Philip Smith, Assistant Grants Compliance Officer, OER/OPERA
Dr. Richard A. Jenkins, NIDA Program Official

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

03/09/2021
Melinda Cotten, Associate Vice President Research Business Operations
University of Alabama at Birmingham
701 20th Street South
Birmingham, AL 35294

Reference: 5R01HD077872-05

Dear Ms. Melinda Cotten:

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

Grant Number: 5R01HD077872-05
PI Name: Dr. Jeanne Marrazzo
Period of Performance: 9/15/2013 - 05/31/2019
NIH Institute/Center: National Institute of Child Health and Human Development (NICHD)

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), NIH Grants Policy Statement, Section 4.1.3.1.

Official Study Title: Effects of Contraceptive Ring on Vaginal Microbiota, HIV Shedding and Local Immunity
NCT Number: NCT02445989
Primary Completion Date: 11/2018

Compliance with the NIH policy is a term and condition of this grant award; however, the NICHD has been unable to verify that results information has been submitted to ClincialTrials.gov for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

If you believe that you have complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please respond to this letter no later than 30 days from receipt of this letter with the following information pertaining to the above-referenced clinical trial(s):

- Evidence that clinical trial results information has been submitted to ClinicalTrials.gov.
- Evidence that submission of clinical trials results information is not required at this time.

Please submit this information to me at the e-mail address below.

Thank you for your attention to this important matter. Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

Mario Martinez, MPH
Acting Chief Grants Management Officer
National Institute of Child Health and Human Development
6710B Rockledge Dr – MSC 7004
Bethesda, MD 20892
Email: martinem@mail.nih.gov
Voice: (301) 402-4078

cc:

[OER/OPERA]
[IC Program Official]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

12/01/2020

Melissa Quintero, Director of Sponsor Program Administration
Baystate Medical Center, Inc.
759 Chestnut Street
Springfield, MA 01199

Reference: 5F32MH078388-02

Dear Ms. Melissa Quintero:

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

Grant Number: 5F32MH078388-02
PI Name: Dr. John Fanton
Period of Performance: 08/09/2007 - 08/08/2009
NIH Institute/Center: National Institute of Mental Health (NIMH)

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), NIH Grants Policy Statement, Section 4.1.3.1.

Official Study Title: Placebo vs. Extended Release Stimulant Crossover Trial in Preschoolers With ADHD
NCT Number: NCT00712699
Primary Completion Date: 08/2010

Compliance with the NIH policy is a term and condition of this grant award; however, the NIMH has been unable to verify that results information has been submitted to ClincialTrials.gov for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

If you believe that you have complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please respond to this letter no later than 30 days from receipt of this letter with the following information pertaining to the above-referenced clinical trial(s):

- Evidence that clinical trial results information has been submitted to ClinicalTrials.gov.
- Evidence that submission of clinical trials results information is not required at this time.

Please submit this information to me at the contact information below.

Thank you for your attention to this important matter. Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

Theresa Jarosik
Chief Grants Management Officer
National Institute of Mental Health
6001 Executive Blvd
Bethesda, MD 20892-9605
Ph: 301-443-3858
Email: tjarosik@mail.nih.gov

cc:

Philip Smith, Assistant Grants Compliance Officer, OPERA
Diane Dean, Director of the Division of Grants Compliance and Oversight, OPERA
Eugene Kane III, DrPH, MPH, Deputy Chief, Human Research Protection Branch, Office of the Clinical Research, NIMH
Jay Churchill, Ph.D., Program Officer, NIMH
Shelli Avenevoli, Ph.D., Acting Director, Division of Extramural Activities, NIMH
Becky Wagenaar-Miller, Ph.D., Acting Deputy Director, Division of Extramural Activities, NIMH

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: December 16, 2020

ClinicalTrials.gov ID: NCT00712699

Study Identification

Unique Protocol ID:	F32 MH078388
Brief Title:	Effectiveness of an Extended Release Stimulant Medication in Treating Preschool Children With ADHD
Official Title:	Placebo vs. Extended Release Stimulant Crossover Trial in Preschoolers With ADHD
Secondary IDs:	F32MH078388 [U.S. NIH Grant/Contract Award Number] DDTR BK-TKFND

Study Status

Record Verification:	December 2020
Overall Status:	Terminated [PI left the institution]
Study Start:	June 2008 []
Primary Completion:	August 2010 [Actual]
Study Completion:	August 2010 [Actual]

Sponsor/Collaborators

Sponsor:	Baystate Medical Center
Responsible Party:	Principal Investigator Investigator: john fanton [jfanton] Official Title: Primary Investigator Affiliation: Baystate Medical Center
Collaborators:	National Institute of Mental Health (NIMH)

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Unapproved/Uncleared Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 07-108 Board Name: Institutional Review Board Board Affiliation: Baystate Medical Center Phone: 413-794-3458 Email: maureen.noftall@bhs.org Address: Baystate Medical Center IRB 280 Chestnut St. 3rd floor Springfield, MA 01199
Data Monitoring:	No
FDA Regulated Intervention:	Yes
Section 801 Clinical Trial:	Yes

Study Description

Brief Summary:	This study will evaluate the safety and effectiveness of extended release mixed amphetamine salts in treating preschool children with attention deficit hyperactivity disorder.
Detailed Description:	Attention deficit hyperactivity disorder (ADHD) is a common developmental disorder that affects between 4% and 12% of school-aged children. Children with ADHD often show symptoms of hyperactivity, inattention, inability to sit still, trouble listening, excessive talking, and aggression. ADHD is generally not diagnosed and treated in children less than 6 years old because some symptoms of ADHD are difficult to distinguish from normal behaviors of preschool-aged children. However, some preschool children who exhibit symptoms indicative of ADHD and who have been carefully diagnosed by a health professional may benefit from early treatment to lower risk for functional impairment later in childhood. Currently, environmental changes, parent effectiveness training, and behavior therapy are the commonly used treatments for preschoolers with ADHD symptoms, but not all preschoolers respond well to such behavioral interventions. These children may benefit from medication treatment; however, the safety and effectiveness of ADHD medications in treating preschool-aged children is not well known. Extended release mixed amphetamine salts (XR-MAS), a stimulant medication, is a commonly prescribed and approved medication for treating ADHD in children 6 years and older. Further study is needed to determine how XR-MAS affects preschool-aged children with ADHD

symptoms. This study will compare the safety and effectiveness of XR-MAS versus placebo in treating preschool children with ADHD.

Participation in this study will last 6 weeks. All participants will first undergo rigorous psychiatric assessments to confirm their diagnosis of ADHD. Eligible participants will then be assigned randomly to receive treatment with either XR-MAS then placebo or placebo then XR-MAS. Participants will take their assigned XR-MAS or placebo medications for 3 weeks and then cross over to the other medication for an additional 3 weeks of treatment. Rating scale scores will be collected weekly from parents and teachers to assess symptom response and measures of safety.

Conditions

Conditions: Attention Deficit Disorder With Hyperactivity

Keywords: Preschool
Children
ADHD
Medication
Controlled Study
Placebo
Mixed Amphetamine Salts

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Crossover Assignment

Number of Arms: 2

Masking: Triple (Participant, Care Provider, Investigator)

Allocation: Randomized

Enrollment: 27 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Sequence 1: XR-MAS then placebo Depending on whether 1) child has had previous medication trial or 2) is on psychotropic medication at time of screening, children will either enter the washout period of 3 days before extended release mixed	Drug: Sequence 1: XR-MAS then placebo XR-MAS given in non-identifying 5 mg capsules with instructions to start 1 capsule (5 mg/d) for one week, then increase to 2 capsules (10 mg/d)

Arms	Assigned Interventions
amphetamine salts (XR-MAS) or placebo (PBO) is initiated or proceed directly to the active treatment sequence they were randomized to. Participants randomized to Sequence 1 first receive treatment with XR-MAR for 3 weeks and then placebo for 3 weeks. Flexible, forced dosing will start at 5 mg/day for the first week, increase to 10 mg/day for the second week and continue to 15 mg/day on the third week. No washout period otherwise occurs (XR-MAS is not clinically suspected to have lingering effects beyond initial dosing/day of administration), including the crossover week to PBO.	for week two, and 3 caps (15 mg/d) for week 3 following flexible, forced titration based on response and tolerance. Other Names: • Adderall XR • IND# 58,037 Drug: Sequence 2 Placebo then XR-MAS PBO given in non-identifying 5 mg capsules with instructions to start 1 capsule (5 mg/d) for one week, then increase to 2 capsules (10 mg/d) for week two, and 3 caps (15 mg/d) for week 3 following flexible, forced titration based on response and tolerance.
Experimental: Sequence 2 Placebo then XR-MAS Depending on whether 1) child has had previous medication trial or 2) is on psychotropic medication at time of screening, children will either enter the washout period of 3 days before extended release mixed amphetamine salts (XR-MAS) or placebo (PBO) is initiated or proceed directly to the active treatment sequence they were randomized to. Participants randomized to Sequence 2 will first receive treatment with PBO for 3 weeks and then XR-MAS for 3 weeks. Flexible, forced dosing will start at 5 mg/day for the first week, increase to 10 mg/day for the second week and continue to 15 mg/day on the third week. No washout period (stimulants are not clinically suspected to have lingering effects beyond initial dosing/day of administration)otherwise occurs, including the crossover week to XR-MAS.	Drug: Sequence 1: XR-MAS then placebo XR-MAS given in non-identifying 5 mg capsules with instructions to start 1 capsule (5 mg/d) for one week, then increase to 2 capsules (10 mg/d) for week two, and 3 caps (15 mg/d) for week 3 following flexible, forced titration based on response and tolerance. Other Names: • Adderall XR • IND# 58,037 Drug: Sequence 2 Placebo then XR-MAS PBO given in non-identifying 5 mg capsules with instructions to start 1 capsule (5 mg/d) for one week, then increase to 2 capsules (10 mg/d) for week two, and 3 caps (15 mg/d) for week 3 following flexible, forced titration based on response and tolerance.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 36 Months

Maximum Age: 66 Months

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Living at home for at least 6 months with parent or caregiver

- Enrolled in a structured school setting at least 2 half days a week with a minimum of 7 peers
- Full Scale Intelligence Quotient (FSIQ) of 70 or greater OR 72 or greater if bilingual
- Best estimate diagnosis based on clinical interview, Diagnostic Interview Schedule for Children, Child Behavior Checklist, and rating scales scores
- Symptoms present for at least 9 months
- Meets severity criteria for Clinical Global Impression-Severity with score of greater than or equal to 4 and Clinical Global Assessment Scale score of greater than or equal to 55
- Parent/caregiver can commit to 6 weekly sessions, including initial screening exams
- If on current psychotropic medication, will undergo a washout period of at least 3 days before study entry
- Not currently receiving psychotherapy or started psychotherapy within 30 days of study entry

Exclusion Criteria:

- Previous nonresponse to mixed amphetamine salts (defined as 2 weeks of persistent symptoms in spite of doses greater than or equal to 15 mg per day)
- Diagnosis of language-based or cognitive delay of more than 2 standard deviations below same-aged peers or diagnosis of mental retardation
- Pervasive developmental disorder or autism
- Significant developmental disorder (e.g., blindness, deafness, cerebral palsy, epilepsy, psychosis)
- Taking another psychotropic medication that cannot be discontinued
- Serious psychiatric disorder (e.g., bipolar, suicidality, tic disorder)
- Actively taking medication for certain medical conditions (e.g., hypertension, structural cardiac condition, glaucoma, hyperthyroidism)
- Allergy to mixed amphetamine salts
- History of physical, sexual, or emotional abuse that is clinically significant

Contacts/Locations

Central Contact Person: John H. Fanton, MD
Telephone: 413-794-7492
Email: john.fanton@baystatehealth.org

Central Contact Backup: Bruce D. Waslick, MD
Telephone: 413-794-1038
Email: bruce.waslick@baystatehealth.org

Study Officials: John H. Fanton, MD
Study Principal Investigator
Baystate Medical Center

Locations:

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Delayed Results

Delay Type	Extension
Requested Submission Date	December 2013
Explanation	Data analysis procedures experienced unanticipated delays with PI ability to access consultants. Consultants are fully engaged now, active with data analyses as scheduled and have prepared data sets for outcomes measure analyses. I have activated my statistical consulting team here at my sponsoring institution, clarified my data entry issues with Dr Dobbins this week via scheduled phone contact, and am now prepared to ask for a "do over" to enter results more precisely than my initial attempt alone, without statistical consultation.

8 pages Withheld in Full Pursuant to FOIA Exemption (b)(4) immediately following this page

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

Feb. 26 2021
Andrea J. Publow, Director – Government/Nonprofit Support
Virginia Commonwealth University
PO BOX 568
Richmond, VA 23298-0568

Reference: 5R01DK087913-05

Dear Ms. Andrea J. Publow:

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

Grant Number: 5R01DK087913-05
PI Name: Dr. Jasmohan S. Bajaj
Period of Performance: 04/01/2011 - 03/31/2017
NIH Institute/Center: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), NIH Grants Policy Statement, Section 4.1.3.1.

Official Study Title: Ramelteon for Treatment of Insomnia in Cirrhosis
NCT Number: NCT03091738
Primary Completion Date: 10/01/2018

Compliance with the NIH policy is a term and condition of this grant award; however, the NIDDK has been unable to verify that results information has been submitted to ClincialTrials.gov for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

If you believe that you have complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please respond to this letter no later than 30 days from receipt of this letter with the following information pertaining to the above-referenced clinical trial(s):

- Evidence that clinical trial results information has been submitted to ClinicalTrials.gov.
- Evidence that submission of clinical trials results information is not required at this time.

Please submit this information to me at the e-mail address below.

Thank you for your attention to this important matter. Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

(b) (6)

Sharon T. Bourque
Section Chief, DDN Team
Grants Management Branch
National Institute of Diabetes and Digestive and Kidney Disease
6707 Democracy Blvd.
Bethesda, MD 20892
bourques@extra.niddk.nih.gov 301-594-8846

cc:

Philip Smith OER/OPERA]
Dr. Averall Sherker

ID: 2015P001855 Low-cost Enabling Technology for Image-guided Photodynamic Therapy (PDT) of Oral Cancer Cancer. NCT03638622

Record Summary

Home Help

Record Status

In Progress → Entry Completed → Approved → **Released** → PRS Review → Public

Unrelease...

Record Owner:	th056	Access List:	[] Edit
Last Update:	12/21/2020 09:45 by th056	Upload:	Allowed
Initial Release:	08/16/2018	PRS Review:	Pending Review History
Initial Results Release:	12/21/2020	Public Site:	Last Public Release: 02/21/2020 View on ClinicalTrials.gov
Last Release:	12/21/2020 Receipt (PDF)	FDAAA:	ACT
Results Expected:	No later than August 31, 2020		
All Results Expected:	No later than August 31, 2020		

Spelling Preview Draft Receipt (PDF RTF) Download XML

View

Protocol Section

Identifiers: NCT03638622 Unique Protocol ID: 2015P001855 Secondary IDs: 5UH3CA189901-04

Brief Title: Low-cost Enabling Technology for Image-guided Photodynamic Therapy (PDT) of Oral Cancer Cancer. (UH3-India)

Module Status:

- Study Identification: ✓
- Study Status: ✓
- Sponsor/Collaborators: ✓
- Oversight: ✓
- Study Description: ✓
- Conditions: ✓
- Study Design: ✓

Arms and Interventions: ✓
Eligibility: ✓
Contacts/Locations: ✓
IPD Sharing Statement:
References:

View **Document Section**

Documents that may be uploaded include:

- Study Protocol and Statistical Analysis Plan - only required with results information for studies with a Primary Completion Date on or after January 18, 2017
- Informed Consent Form - optional under 42 CFR Part 11, but may be required by funder, including if study is conducted or supported by a Common Rule (45 CFR 46) department or agency

Uploaded PDF/A Documents: ✓

View **Results Section**

Module Status:

Participant Flow: ✓
Baseline Characteristics: ✓ 1 Note
Outcome Measures: ✓
Adverse Events: ✓
Certain Agreements: ✓
Limitations and Caveats:
Results Point of Contact: ✓

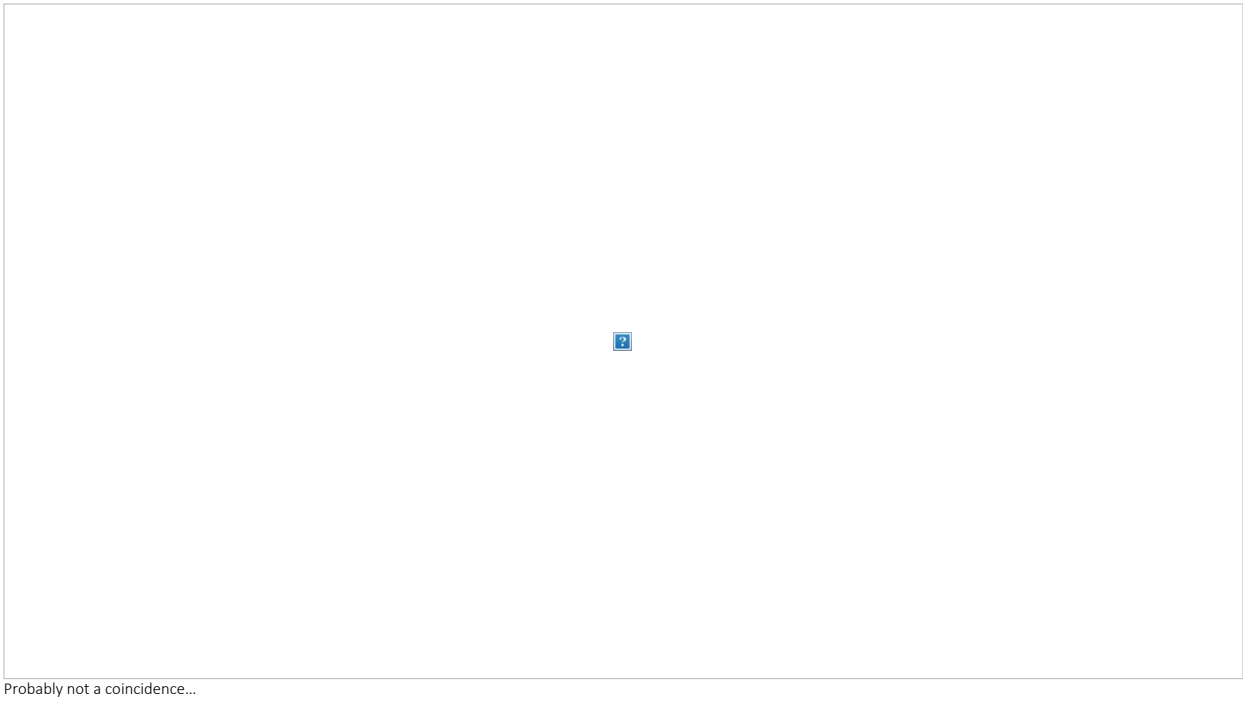
Add **Record Log**

12/17/2020 16:28 ClinicalTrials.gov
Uploaded Study Protocol dated 12/17/2020 was converted to valid PDF/A by PRS.

08/17/2018 14:10 ClinicalTrials.gov
PRS Review comments recorded. ClinicalTrials.gov QA11

From: Sherker, Averell (NIH/NIDDK) [E]
To: Bourque, Sharon (NIH/NIDDK) [E]; VCU DIROSPA
Cc: Pike, Robert (NIH/NIDDK) [E]; Smith, Philip (NIH/OD) [E]; Doherty, Dee (NIH/NIDDK) [E]
Subject: Re: CT Reporting Compliance for Dr. Bajaj DK87913
Date: Thursday, March 4, 2021 12:50:04 PM
Attachments: image001.png
image002.jpg
image003.jpg
image004.jpg

It looks like results were submitted two days ago (pending QC review



Probably not a coincidence…

Averell

From: Sharon Bourque <bourques@extra.niddk.nih.gov>
Date: Thursday, March 4, 2021 at 12:44
To: "dirospa@vcu.edu" <dirospa@vcu edu>
Cc: Robert Pike <pikera@niddk.nih.gov>, "Smith, Philip (NIH/OD) [E]" <philip.smith2@nih gov>, Averell Sherker <averell sherker@nih.gov>, "Doherty, Dee (NIH/NIDDK) [E]" <dohertyd@niddk.nih.gov>
Subject: RE: CT Reporting Compliance for Dr. Bajaj DK87913

Hi Mary:
At this time, I think we are good If there is any additional information needed, I will let you know

Thanks
Sharon

Sharon T. Bourque
Section Chief, DDN Team
Grants Management Branch
National Institute of Diabetes, Digestive and
Kidney Diseases, NIH, HHS
6707 Democracy Blvd Room 7305
Bethesda, MD 20892 MSC 5456
(use zip code 20817 for overnight delivery)
301-594-8846 tele
301-480-3504 fax
bourques@extra.niddk.nih.gov
NIH…Turning Discovery Into Health®

Celebration of Science at NIH
Watch how medical research saves lives and improves health

From: strawdermamm@vcu edu <strawdermamm@vcu edu> **On Behalf Of** VCU DIROSPA
Sent: Thursday, March 4, 2021 12:37 PM

To: Bourque, Sharon (NIH/NIDDK) [E] <bourques@extra niddk nih gov>
Cc: Pike, Robert (NIH/NIDDK) [E] <pikera@niddk nih gov>; Smith, Philip (NIH/OD) [E] <philip smith2@nih gov>; Sherker, Averell (NIH/NIDDK) [E] <averell sherker@nih gov>; Doherty, Dee (NIH/NIDDK) [E] <dohertyd@niddk nih gov>
Subject: Re: CT Reporting Compliance for Dr Bajaj DK87913

Thank you Sharon,
Our post award team notified you that this project has been reported in clinicaltrials gov Is there anything further you need from us?
thanks,

Mary

On Thu, Mar 4, 2021 at 12:25 PM Bourque, Sharon (NIH/NIDDK) [E] <bourques@extra niddk nih gov> wrote:

> Hi Mary:
> This is not an error After consultation, OPERA has noted that the title of the study is correctly stated and is clearly marked in the letter as "Official Study Title" and not "Grant or Project Title" In addition, Clinical trial studies are not required to share the same title as an associated grant and regularly do not share the same title
>
> Also, it has been pointed out that this grant is cited as an other study ID number for NCT03091738 in the ClinicalTrials gov record (https://clinicaltrials gov/ct2/show/NCT03091738?term=ramelteon&draw=2&rank=1
> Hope this clarifies this matter
>
> Thanks
> Sharon
>
> *Sharon T. Bourque*
> Section Chief, DDN Team
> Grants Management Branch
> National Institute of Diabetes, Digestive and
> Kidney Diseases, NIH, HHS
> 6707 Democracy Blvd Room 7305
> Bethesda, MD 20892 MSC 5456
> (use zip code 20817 for overnight delivery)
> 301-594-8846 tele
> 301-480-3504 fax
> bourques@extra.niddk.nih.gov
> **NIH...Turning Discovery Into Health®**
>
> **Celebration of Science at NIH**
> *Watch how medical research saves lives and improves health*

From: strawdermamm@vcu edu <strawdermamm@vcu edu> **On Behalf Of** VCU DIROSPA
Sent: Thursday, March 4, 2021 10:45 AM
To: Bourque, Sharon (NIH/NIDDK) [E] <bourques@extra niddk nih gov>
Cc: Pike, Robert (NIH/NIDDK) [E] <pikera@niddk nih gov>; Smith, Philip (NIH/OD) [E] <philip smith2@nih gov>; Sherker, Averell (NIH/NIDDK) [E] <averell sherker@nih gov>; Doherty, Dee (NIH/NIDDK) [E] <dohertyd@niddk nih gov>
Subject: Re: CT Reporting Compliance for Dr Bajaj DK87913

Sharon,
The title of the project in this award notice does not match the title of the project in the non-compliance letter - the grant numbers are the same

Award: Spectrum of Neuro-Cognitive Impairment in Cirrhosis
Grant number: 1R01DK087913-01A1
Non-compliance letter: Ramelteon for Treatment of Insomnia in Cirrhosis
Grant number: 5R01DK087913-05

There is a CT gov record for the study entitled Ramelteon for Treatment of Insomnia in Cirrhosis

Was this an error?

Thanks,

Mary

On Fri, Feb 26, 2021 at 10 02 AM Bourque, Sharon (NIH/NIDDK) [E] <bourques@extra niddk nih gov> wrote:

> Dear Ms Publow:
> Please see the attached letter regarding clinical trial reporting compliance for the above-referenced grant Please review and respond with the requested information within 30 days of receipt of this letter and email
>
> Thanks
> Sharon
>
> *Sharon T. Bourque*
> Section Chief, DDN Team
> Grants Management Branch

National Institute of Diabetes, Digestive and
Kidney Diseases, NIH, HHS
6707 Democracy Blvd Room 7305
Bethesda, MD 20892 MSC 5456
(use zip code 20817 for overnight delivery)
301-594-8846 tele
301-480-3504 fax
bourques@extra.niddk.nih.gov

NIH...Turning Discovery Into Health®

Celebration of Science at NIH

Watch how medical research saves lives and improves health

From: Rivera, Lillian
To: Fleming, Pam (NIH/NIDA) [E]
Cc: Rivera, Lillian
Subject: RE: CT Reporting Compliance Letter - DA38965
Date: Wednesday, April 14, 2021 12:13:22 PM
Attachments: image001.png
image002.jpg
Bluthenthal.Release receipt 4-8-21.pdf

Dear Ms. Fleming,

Dr. Bluthenthal advised me on Thursday, April 8 that it was submitted to **ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt**
Release Date: April 8, 2021
ClinicalTrials.gov ID: NCT02774954

I hope this resolves the issue below.

Thank you,
Lillian

Department of Contracts and Grants

Lillian A. Rivera
Contract and Grant Officer
USC, Department of Contracts and Grants
3720 S. Flower Street, 3rd Floor
MC 0701
Los Angeles, CA 90089-0701
Tel: 213-821-7120
FAX : 213-740-6070
Email: Lrivera@usc.edu

Fight On!!!

From: Fleming, Pam (NIH/NIDA) [E] <pfleming@nida.nih.gov>
Sent: Monday, April 12, 2021 7:44 AM
To: Lillian Ann Rivera <lrivera@usc.edu>
Subject: RE: CT Reporting Compliance Letter - DA38965

Good morning Ms. Rivera,

I'm following up on the attached letter, for which you confirmed your receipt on March 10th.

We had requested that you respond to this letter no later than 30 days with the following information pertaining to the Clinical Trial reporting pertaining to the aforementioned NIDA grant –

- Evidence that clinical trial results information has been submitted to ClinicalTrails.gov
- Evidence that submission of clinical trials results information is not required at this time

It has been over 30 days and we haven't yet received a response.

Can you please provide me with confirmation that the results of this clinical trial have been submitted to ClinicalTrails.gov, as required?

Thank you,

Pam

Pamela G. Fleming
Chief Grants Management Officer, NIDA
Phone: (301) 480-1159
pfleming@nida.nih.gov

Information for NIH Applicants and Recipients on COVID-19

From: Lillian Ann Rivera <lrivera@usc.edu>
Sent: Wednesday, March 10, 2021 12:46 PM
To: Fleming, Pam (NIH/NIDA) [E] <pfleming@nida.nih.gov>
Cc: Rivera, Lillian <lrivera@usc.edu>
Subject: RE: CT Reporting Compliance Letter - DA38965

Dear Ms. Fleming,

I confirm receipt of the letter.

Thank you,
Lillian

Department of Contracts and Grants

Lillian A. Rivera
Contract and Grant Officer
USC, Department of Contracts and Grants
3720 S. Flower Street, 3rd Floor
MC 0701
Los Angeles, CA 90089-0701
Tel: 213-821-7120
FAX : 213-740-6070
Email: Lrivera@usc.edu

Fight On!!!

From: Fleming, Pam (NIH/NIDA) [E] <pfleming@nida.nih.gov>
Sent: Wednesday, March 10, 2021 9:36 AM
To: Lillian Ann Rivera <lrivera@usc.edu>
Subject: CT Reporting Compliance Letter - DA38965

Good morning Ms. Rivera,

This past Monday, March 1st, I sent you the attached letter regarding clinical trial reporting compliance with a NIDA supported grant, via the NIH Secure Email Service.

I didn't receive a read receipt or reply recognizing receipt of this letter, so I'm not sure if you received my message via the NIH Secure Email Service.

Could you please provide me with confirmation of receipt of this letter?

Thank you for your attention.

Sincerely,

Pam

Pamela G. Fleming
Chief Grants Management Officer, NIDA
Phone: (301) 480-1159
pfleming@nida.nih.gov

Information for NIH Applicants and Recipients on COVID-19

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: April 8, 2021

ClinicalTrials.gov ID: NCT02774954

Study Identification

Unique Protocol ID:	HS-15-00243
Brief Title:	Change the Cycle: An RCT to Prevent Injection Initiation (CTC)
Official Title:	Preventing Injection Initiation: The Change the Cycle Randomized Controlled Trial.
Secondary IDs:	R01DA038965 [U.S. NIH Grant/Contract Award Number]

Study Status

Record Verification:	April 2021
Overall Status:	Completed
Study Start:	June 2016 [Actual]
Primary Completion:	November 2018 [Actual]
Study Completion:	November 2019 [Actual]

Sponsor/Collaborators

Sponsor:	University of Southern California
Responsible Party:	Principal Investigator Investigator: Ricky Bluthenthal [rbluthen] Official Title: Professor Affiliation: University of Southern California
Collaborators:	National Institute on Drug Abuse (NIDA) RTI International University of Toronto

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved
Approval Number: HS-15-00243
Board Name: Institutional Review Board - Health Sciences Campus
Board Affiliation: University of Southern California
Phone: 323-223-2340
Email: irb@usc.edu
Address:

LAC+USC Medical Center, General Hospital Suite 4700
1200 North State Street, Los Angeles, CA 90033

Data Monitoring: Yes

FDA Regulated Intervention: No

Study Description

Brief Summary: The study will test the efficacy of a hour long, one-on-one, active listening counseling session (called Change the Cycle or CTC) aimed at reducing behaviors among active people who inject drugs (PWID) that research has found to facilitate uptake of injection drug use among non-injectors. The study will involve ~1,100 PWID who will be randomized to CTC or an equal attention control intervention on improving nutrition. Participants will be recruited in Los Angeles and San Francisco, California and followed up at 6 and 12 months to determine changes in direct and indirect facilitation of injection initiation among non-injectors.

Detailed Description: The study goal is to conduct a large-scale randomized controlled trial (RCT) of the “Change the Cycle” (CTC) intervention. CTC is an hour long, single-session, one-on-one intervention that aims to reduce injection initiation by encouraging active PWID to not promote drug injection, model injection behavior, describe how to inject, or assist in injection initiations of non-injectors. CTC uses the Information-Motivation-Behavioral skills (IMB) model to achieve changes among active PWID through seven short modules. Information and motivational domains are addressed in guided conversations about (1) their own first injection episode and consequences, (2) past experiences initiating injection-naive people and consequences, (3) health, legal, and social risks related to injection drugs, (4) health, legal, social risks of initiating people, and (5) identifying their own behaviors that might promote injection among others. The behavioral skills are addressed through (6) skill-building discussions and consideration of common initiation scenarios, and (7) safer injection education.

Aim 1: To test the efficacy of CTC on reducing the number of non-injectors initiated into injection (counts) by PWID. Hypothesis 1: PWID who receive CTC will report initiating fewer non-injectors into drug injection at 6 and 12 months as compared with PWID in the control condition.

Aim 2: To test the efficacy of CTC on reducing the number of times PWID are asked to initiate (counts) someone into injection. Hypothesis 2: PWID who receive CTC will report having been asked fewer times to initiate someone into drug injection at 6 and 12 months as compared with PWID in the control condition.

Aim 3: To test whether injection initiation social learning risks (injecting in front of, describing injection to, and speaking positively about injection to non-injectors) act as mediational mechanisms for the efficacy of the CTC intervention on initiation and request-to-initiate outcomes. Hypothesis 3: Social learning variables will significantly mediate the association between the CTC intervention and episodes of initiating and being requested to initiate someone into drug injection at 6 and 12 months.

To achieve these aims, active PWID (N=1,076) will be randomly assigned to receive CTC or an equal attention control condition in Los Angeles (LA) and San Francisco (SF), CA. Injection initiation and injection initiation social learning variables will be collected at baseline, 6 months, and 12 months using computer-assisted personal-interviewing (CAPI). The equal attention control condition will focus on improving nutrition, specifically increasing fresh water intake and protein consumption, and will replicate CTC in length, theoretical foundation (IMB), and modality (1 on 1 personal session).

Conditions

Conditions: Substance Abuse, Intravenous
HIV
Heroin Dependence
Opioid Dependence
Cocaine Dependence
Amphetamine Dependence

Keywords: Change the cycle
social learning theory
people who inject drugs
injection drug use
Information, Motivation, Behavior Skills Model
Longitudinal cohort study

Study Design

Study Type: Interventional

Primary Purpose: Prevention

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment
This study compares 2 active listening, information-motivation-behavior skills interventions aimed at improving health behaviors among very low-income, drug using participants.

Number of Arms: 2

Masking: Single (Outcomes Assessor)

The statistician who is conducting the data analysis will not know the content of the intervention assignment.

Allocation: Randomized

Enrollment: 972 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Change the cycle CTC uses the Information-Motivation-Behavioral skills (IMB) model to achieve changes among active PWID through seven short modules. Information and motivational domains are addressed in guided conversations about (1) their own first injection episode and consequences, (2) past experiences initiating injection-naive people and consequences, (3) health, legal, and social risks related to injection drugs, (4) health, legal, social risks of initiating people, and (5) identifying their own behaviors that might promote injection among others. The behavioral skills domain is addressed through a (6) skill-building discussion and rehearsal of responses to possible initiation scenarios, and (7) safer injection education.	Behavioral: Change the Cycle See previous response Other Names: • CTC
Active Comparator: Nutrition The nutrition equal attention control intervention is a single-session, 60-minute Information-Motivation-Behavioral (IMB) skills-based intervention addressing healthy eating. The healthy eating intervention uses a one-on-one guided conversation between the interventionist and the participant. The intervention addresses (1) information about current eating patterns and recommendations for healthy alternatives (20 minutes), (2) motivations for improving healthy eating by providing feedback to participants on personal responsibility, a menu of alternative change options, a decision balance exercise, and eating goal setting (10 minutes), and (3) Behavioral Self-Management Component (30 minutes) that covers eating scenarios, participant responses, and healthy alternatives to the scenario and the participants feedback.	Behavioral: Change the Cycle See previous response Other Names: • CTC

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based: No

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

- Self-reported Injection an illicit drug in the last 30 days,
- visible evidence of injection such as track mark or stigmata,
- at least 18 years of age

Exclusion Criteria:

- Under 18 years of age,
- no self-reported drug injection in the last 30 days,
- no physical evidence of recent drug injection.

Contacts/Locations

Central Contact Person: Ricky Bluthenthal, PhD
Telephone: 323-442-8236
Email: rbluthen@usc.edu

Central Contact Backup: Alex Kral, PhD
Telephone: 415-848-1318
Email: akral@rti.org

Study Officials: Ricky Bluthenthal, PhD
Study Principal Investigator
University of Southern California

Locations: **United States, California**

University of Southern California
Los Angeles, California, United States, 90033
Contact: Ricky Bluthenthal, PhD 323-442-8236 rbluthen@usc.edu
Contact: Karina Dominguez, BA 323-442-7248 kdomingu@usc.edu

RTI International
San Francisco, California, United States, 94101
Contact: Alex Kral, PhD 415-848-1314 akral@rti.org
Contact: Lynn Wenger, MSW, MPH 415-848-1319 lynndee@rti.org

IPDSharing

Plan to Share IPD: Yes

Using the National Addiction and HIV Data Archive program (NAHDAP), we will provide our datasets and codebooks to researchers in a format that facilitates data-sharing. After the completion of the study, the dataset will be de-identified and made available for secondary analysis on the NAHDAP website (http://www.icpsr.umich.edu/icpsrweb/NAHDAP/). Researchers who request access will be given a password to access the data, documentation, and surveys. As part of the registration process, researchers will sign an agreement to adhere to the data coding guidelines that were developed for the project, will state their intentions for use, and will agree to inform the original investigators of their findings and publications for tracking purposes with acknowledgments to the granting agency. Because the respondents will be identified only by ID codes in the datasets, it will be impossible to identify individuals from the datasets.

Supporting Information:
Study Protocol
Informed Consent Form (ICF)

Time Frame:
June 2020

Access Criteria:
URL:

References

Citations:

Links:

Available IPD/Information:

Documents

Study Protocol and Statistical Analysis Plan
Document Date: February 22, 2018
Uploaded: 04/08/2021 12:53

Study Results

10 pages Withheld in Full Pursuant to FOIA Exemption (b)(4) immediately following this page

From:	Lindsay Burns
To:	Lafferty, Traci (NIH/NIA) [E]; lburns@paintrials.com
Cc:	Snyderman, Joel (NIH/OD) [E]; Smith, Philip (NIH/OD) [E]; Ryan, Laurie (NIH/NIA) [E]
Subject:	RE: Grant Number: 4R44AG060878 - 02 - (Clinical Trial Reporting Compliance)
Date:	Thursday, April 1, 2021 2:42:59 PM

Hi Traci,

Results of this study are now public on clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/results/NCT03748706?term=PTI-125&draw=2&rank=3

Results of the Phase 2b study should also be public soon.

Lindsay

From: Lafferty, Traci (NIH/NIA) [E] <laffertt@nia.nih.gov>
Sent: Tuesday, March 2, 2021 4:06 PM
To: lburns@paintrials.com
Cc: Snyderman, Joel (NIH/OD) [E] <snydermanj@mail.nih.gov>; Smith, Philip (NIH/OD) [E] <philip.smith2@nih.gov>; Ryan, Laurie (NIH/NIA) [E] <ryanl@mail.nih.gov>
Subject: Grant Number: 4R44AG060878 - 02 - (Clinical Trial Reporting Compliance)

Dear Dr. Burns,

Please see the attached letter regarding possible non-compliance with the results reporting requirements for Grant Number: R44AG060878.

Please acknowledge receipt of this email w/attachment.

Thank you,

Traci Lafferty
Chief Grants Management Officer
National Institute on Aging, NIH
301-496-8987

From: Cotten, Melinda
To: Martinez, Mario (NIH/NICHD) [E]
Cc: Smith, Philip (NIH/OD) [E]; Snyderman, Joel (NIH/OD) [E]; Marrazzo, Jeanne; Payson, Tabitha
Subject: RE: Potential Non-Compliance | Grant Number: 5R01HD077872 - 05 PI Name: MARRAZZO , JEANNE M
Date: Friday, March 26, 2021 1:06:29 PM

Dear Mario,

I apologize for the delay in responding. According to Dr. Marrazzo, the team is not ready to upload the clinical trial data because the analysis is not complete yet. It was delayed in part because of Dr. Marrazzo's move from University of Washington to UAB. She does have some preliminary results that have been presented at a conference.

Thank you,

Melinda

Melinda Cotten | Associate Vice President, Research Business Operations
UAB | The University of Alabama at Birmingham
AB 1170 | 701 20th Street South, Birmingham, AL 35294
P: 205.934.5266| mcotten@uab.edu

I often send emails outside standard work hours; please do not feel obligated to respond outside of yours.

From: Martinez, Mario (NIH/NICHD) [E] <martinem@mail.nih.gov>
Sent: Tuesday, March 9, 2021 11:20 AM
To: Cotten, Melinda <mcotten@uab.edu>
Cc: Smith, Philip (NIH/OD) [E] <philip.smith2@nih.gov>; Snyderman, Joel (NIH/OD) [E] <snydermanj@mail.nih.gov>
Subject: Potential Non-Compliance | Grant Number: 5R01HD077872 - 05 PI Name: MARRAZZO , JEANNE M

Dear Ms. Cotton,
Please review the attached Clinical Trial Compliance letter and respond acknowledging receipt of it for our records.

Regards,

Mario Martinez, M.P.H.
ACTING CGMO
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CHILD HEALTH AND HUMAN DEVELOPMENT
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BETHESDA, MD 20892
VOICE: (301) 402-4078

From:	Gail Cusimano
To:	Fleming, Pam (NIH/NIDA) [E]
Cc:	Shruti Mehta; Joanna Toma; Miye Schakne
Subject:	Reference: 5R01DA026727-05
Date:	Monday, March 29, 2021 4:57:17 PM
Attachments:	ClinicalTrials.gov PRS_ PRS Review History NCT03480932[2].pdf NIDA Response Mehta 29 Mar 2021.pdf CT Reporting Compliance Letter Final DA26727.pdf

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Dear Ms. Fleming,

Attached please find Dr. Mehta's response and supporting documentation in regards to your attached letter dated 3/01/2021.

If you need any additional information, please let me know.

Thanks,
Gail

Gail Cusimano
Sr. Grants Associate
Johns Hopkins University Research Administration
1101 E. 33rd Street
Baltimore, MD 21218
P: 443-997-1895
glc@jhu.edu
https://research.jhu.edu/jhura/

Please refer to JHU's COVID-19 Information source page and JHURA's website frequently, as they relate to our research operations, additional updates and resources.

ClinicalTrials.gov PRS
Protocol Registration and Results System

ID: R01DA026727 Role of Pegylated Interferon in Combination With DAAs to Cure Hepatitis C As Soon As Possible - Hepatitis C [ASAP-C] NCT03480932

PRS Review History

Event	User/Reviewer	Date/Time	
Release R D	schaknem	03/22/2021 13:26	View Release
Publish	QA37	03/14/2019 14:01	
Release	schaknem	03/14/2019 13:53	View Release
Publish	QA51	03/27/2018 13:10	
Release	schaknem	03/26/2018 13:41	View Release
Reset	QA42	02/01/2018 12:53	Review Comments (1) Viewed by Mehtas 7 time(s) -- last access: 03/20/2018 11:28
Release	schaknem	01/29/2018 11:14	View Release

JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

March 29, 2021

Pamela Fleming
Chief Grants Management Officer
National Institute on Drug Abuse
National Institutes of Health
3WFN MSC 6021
301 N Stonestreet Avenue
Bethesda, MD 20892

Reference: 5R01DA026727-05

Dear Ms. Fleming,

I am writing in response to the letter dated 1 March, 2021 regarding clinical trial results information submission requirements for clinical trial number NCT03480932, Role of Pegylated Interferon in Combination With Direct Acting Antivirals (DAAs) to Cure Hepatitis C As Soon As Possible (ASAP) – Hepatitis C [ASAP-C].

We have submitted all study results to clinicaltrials.gov. The record was released on 22 March, 2021 and is currently in PRS review. The requested documentation for this submission is attached.

Sincerely,

Shruti H. Mehta, PhD, MPH
Professor and Deputy Chair
Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health

cc: Joel Snyderman, Chief Grants Compliance Officer, OER/OPERA
Philip Smith, Assistant Grants Compliance Officer, OER/OPERA
Dr. Raul N. Mandler, NIDA Program Official

Department of Epidemiology
615 N. Wo fe Street, Su te E6546, Ba t more, MD 21205 443 287 3837 smehta3@jhu.edu

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

03/01/2021

Gail Cusimano, Sr. Grants Associate
Johns Hopkins University
W400 Wyman Park Building
Baltimore, MD 21218-2680

Reference: 5R01DA026727-05

Dear Ms. Gail Cusimano:

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

Grant Number: 5R01DA026727-05
PI Name: Shruti H Mehta
Period of Performance: 09/01/2015 - 08/31/2018
NIH Institute/Center: National Institute on Drug Abuse (NIDA)

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), NIH Grants Policy Statement, Section 4.1.3.1.

Official Study Title: Role of Pegylated Interferon in Combination With Direct Acting Antivirals (DAAs) to Cure Hepatitis C As Soon As Possible (ASAP) - Hepatitis C [ASAP-C]
NCT Number: NCT03480932
Primary Completion Date: 11/02/2018

Compliance with the NIH policy is a term and condition of this grant award; however, the NIDA has been unable to verify that results information has been submitted to ClincialTrials.gov for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

If you believe that you have complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please respond to this letter no later than 30 days from receipt of this letter with the following information pertaining to the above-referenced clinical trial(s):

- Evidence that clinical trial results information has been submitted to ClinicalTrials.gov.
- Evidence that submission of clinical trials results information is not required at this time.

Please submit this information to me at the e-mail address below.

Thank you for your attention to this important matter. Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

(b) (6)

Pamela Fleming
Chief Grants Management Officer
National Institute on Drug Abuse
National Institutes of Health
3WFN MSC 6021
301 N Stonestreet Avenue
Bethesda, MD 20892
pfleming@nih.gov
(301) 480-1159

cc: Joel Snyderman, Chief Grants Compliance Officer, OER/OPERA
Philip Smith, Assistant Grants Compliance Officer, OER/OPERA
Dr. Raul N. Mandler, NIDA Program Official

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

12/01/2020
Lauren B. Armstrong, Assistant Director for Operations
University of Virginia
PO BOX 800793
Charlottesville, VA 22908

Reference: 5R01DK029953-38

Dear Ms. Lauren B. Armstrong:

I am writing to you concerning potential non-compliance with clinical trial registration requirements for a clinical trial funded by the following NIH grant:

Grant Number: 5R01DK029953-38
PI Name: Dr. Rita Basu
Period of Performance: 05/01/1982 - 07/31/2024
NIH Institute/Center: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH Policy), NIH Grants Policy Statement, Chapter 4.1.3.1.

Study Title: Mechanisms of Insulin Resistance in Man (Aim 1,2,3)
Enrollment Start Date: 03/01/2020

Compliance with the NIH Policy is a term and condition of this grant award; however, NIDDK has been unable to verify that the above-referenced clinical trial has been registered in ClinicalTrials.gov. Under the NIH Policy, clinical trial registration information must be submitted to ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

If you believe that you have complied with all applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please respond to this letter no later than 30 days from the date you receive this letter with the NCT number – the unique identification code assigned to each clinical study registered in ClinicalTrials.gov, an explanation of why registration information is not required to be submitted at this time, or an explanation of why the above-referenced clinical trial is not subject to the NIH Policy and/or is not an "applicable clinical trial."

Please submit this information to me by email at the address below.

Thank you for your attention to this important matter. Please let me know if you have any questions concerning the information in this letter.

Sincerely,

Robert Pike
Chief Grants Management Officer
National Institute of Diabetes and Digestive and Kidney Diseases
pikera@niddk.nih.gov
301-594-8854

cc: OER/OPERA
Dr. Karen Teff