MERCK & CO., INC.
Kenilworth, N.J., U.S.A.

August 22, 2017

Andrew H. Talal, MD
CTRC-University at Buffalo
875 Ellicot St, 6090
Buffalo, NY 14203
USA

Dear Dr. Talal,

I am the Scientific Leadership & Research Manager assigned to your Investigator Initiated Study. I am happy to inform you the Merck Investigator Studies Program Review Committee (MISP-RC) has approved your study proposal entitled: "Education and Point of Care Diagnostics Increase Substance Users Initiation of HCV Care among Persons with Substance Use Disorders" for funding in the amount of $74,436.00 USD.

As we move forward, the following critical documents are needed for the study to start promptly and for shipment of drug supplies. **As a reminder, the study agreement must be signed by Merck and your institution before the study can commence. Merck will not pay or reimburse for work conducted by an investigator prior to a final executed agreement. In addition, if the agreement is not signed by both parties within 6 months of this letter, Merck has the right to cease study start up procedures and cancel approval of this study.**

☐ Approval letter from Institutional Review Board (IRB) / Ethics Review Committee (ERC)

☐ Final IRB approved protocol - ensure that version/date of protocol corresponds to IRB/ERC Approval letter

☐ Executed Study Agreement signed by Merck and the Institution

☐ Investigator's Curriculum Vitae (dated within the past two years)

☐ Payee Information: Electronic Fund Transfer. Complete Payee Information Form

☐ Confirmation of study posting www.clinicaltrials.gov (confirm by providing NCT number)

If you have any questions please feel free to contact me at the number listed below.

Sincerely,

Brian Gottshall

Brian Gottshall
Scientific Leadership & Research Manager - Hepatitis
Merck Investigator Initiated Studies Program / Scientific Engagements
Phone: 267-305-0814 | Fax: 267-305-6534
Email: brian_gottshall@merck.com

Cc: file

INVESTIGATOR SPONSORED CLINICAL TRIAL RESEARCH AGREEMENT

(US Single Site - Funding Only)

This Agreement is entered into as of the last date on the signature page hereof ("Effective Date"), by and between THE RESEARCH FOUNDATION FOR THE STATE UNIVERSITY OF NEW YORK, a non-profit, educational corporation organized and existing under the laws of the State of New York, with an office located at Clinical Research Office 875 Ellicott Street, Suite 6050, Buffalo New York 14203 acting on behalf of the University at Buffalo, hereinafter called "Institution, " and MERCK SHARP & DOHME CORP. with a place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033 USA, hereinafter called "Merck."

Institution shall have complete responsibility for all aspects of the conduct of an investigator initiated study through certain clinical research (the "Study"). The Study contemplated by this Agreement is of mutual interest and benefit to Institution and Merck, and will further the instructional and research objectives of Institution in a manner consistent with its status as a non-profit educational, research and health care institution. Merck, consistent with its commitment to clinical research, wishes to provide certain support to Institution on the terms and conditions described in this Agreement. Merck is entering into this Agreement with Institution with the understanding that Andrew H. Talal, M.D., M.P.H. ("Principal Investigator") shall be responsible on Institution's behalf for the conduct of the Study.

The parties hereto agree as follows:

1. Scope of Work

The Institution shall, and shall ensure that the Principal Investigator will, perform the Study in accordance with the terms of this Agreement and the final protocol including as it may be amended in accordance with the terms of this Agreement, for the Study entitled "Education and Point of Care Diagnostics Increase Substance Users Initiation of HCV Care among Persons with Substance Use Disorders" (the "Protocol"), which has been accepted by Merck in writing and incorporated into this Agreement by reference. Institution certifies that, to its best knowledge, its facilities and patient population are adequate to perform the Study contemplated by this Agreement and the Protocol. Merck and Institution agree, and Principal Investigator acknowledges, that, all aspects of the Study will be conducted in conformity with all applicable federal, state, local laws and regulations, including the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice: Consolidated Guideline, as adopted by the FDA, and other generally accepted standards of good clinical practice. Institution further agrees to ensure that the Principal Investigator will not conduct any research activities in the performance of the Study that are contrary to the provisions of the Protocol. Institution shall ensure that Principal Investigator will undertake the Study as the regulatory sponsor of the Protocol and will fulfill the requisite sponsor duties and obligations in conducting the Study.

Kaleida Health Foundation

June 25, 2018

Mr. Elliot Frank
c/o Dr. Andrew Talal
Department of Medicine
100 High St
Buffalo, NY 14203

Dear Mr. Frank:

I am writing this letter to confirm that Dr. Andrew Talal has been awarded a $3,067,590, Troup Fund Award to expand the Liver Center of Western New York, which will seek to contribute the establishment of the WNY region as a hub for comprehensive, quality and cutting edge clinical care in treatment of liver diseases as well as in the advancement of research in liver disease across the age spectrum.

This award will be made over a five year period beginning July 1, 2018. Dr. Talal will be expected to provide an annual summary of the progress made in this research accompanied by any related publications. Publications must acknowledge the funds received from the Kaleida Health Foundation Troup Fund. Time and Efforts reports must be submitted quarterly. Budget amendments must be submitted in writing and approved.

Expenditure reports must be provided quarterly to support these payments. Unspent funds must be returned to Kaleida Health Foundation at the end of the grant period.

Please note that the Troup Fund does not allow for indirect costs.

If there are any questions or concerns, I can be reached directly at 881-8240.

Sincerely,

Carol Horton
VP Kaleida Health Adult Foundation
CHorton3@KaleidaHealth.org

Patient-Centered HCV Care via Telemedicine for Individuals on Opiate Substitution Therapy: A Stepped Wedge Cluster Randomized Controlled Trial

Principal Investigator
Andrew Talal, MD, MPH

Organization

State University of New York

Funding Announcement

Improving Healthcare Systems

State

New York

Project Budget*

$7,004,591

Year Awarded

2016

Project Period*

60 months

Project Summary

Hepatitis C virus (HCV) affects almost 5 million people in the United States and is a major cause of chronic liver disease, liver fibrosis, cirrhosis, liver cancer, and death. Drug users are most affected by HCV, with 30–70 percent being chronically infected. However, very few drug users with HCV receive treatment. Reasons include lack of knowledge about the infection, distrust of their doctors, and difficulty navigating the healthcare system. While HCV treatment of drug users in methadone treatment programs has been shown to be effective, only a small number of programs have the ability to treat HCV onsite. Telemedicine, a type of videoconferencing, permits the doctor and the patient to interact even if they are not in the same location. Our project aims to establish telemedicine as a treatment approach for HCV for drug users in the familiar environment of a methadone clinic.

The primary aim of this project is to compare HCV treatment through telemedicine in a methadone clinic with usual care, which is referral to a liver specialist offsite. Our study will be conducted in 12 methadone clinics following the standard of care. At regular intervals, clinics will switch in a random order to the telemedicine approach. The study will be conducted over a five-year period. The primary outcome is the rate of viral eradication 12 weeks after completing HCV treatment. We will also measure patient satisfaction with the delivery of HCV care in both those treated via telemedicine and those treated by the liver specialist, differences in the number starting and completing treatment, and how much of the prescribed treatment is actually taken by the patient. As current approaches for HCV treatment of people recovering from addiction are highly unsuccessful, new models for HCV care in this population are needed. The major goal of our study is to provide such a model.

All hepatitis C antibody-positive patients in the methadone clinics will be able to participate in the recruitment phase of the study. Patients who participate in the recruitment phase and are HCV-infected will be able to participate in the study. Those who are ineligible for HCV treatment, or who are currently being treated elsewhere, will be excluded. Patients who will be treated in the clinics by telemedicine will have their hepatitis C medications delivered at the same time as their methadone.

The study will be conducted in a wide variety of methadone clinics located throughout New York State. We have partnered with clinics from urban and rural locations, which ensures a diverse patient population. We will recruit patients at each clinic to be part of a patient advisory committee. We will also recruit stakeholders from all domains relevant to HCV treatment at the federal, state, and local levels and from community-based organizations, and medical specialists from a diverse range of disciplines.

**All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.*

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May 23
Board of Governors Meeting
<http://www.pcori.org//events/2016/board-governors-meeting-3>

June 8
Advisory Panel on Addressing Disparities Summer 2016 Meeting
<http://www.pcori.org//events/2016/advisory-panel-addressing-disparities-summer-2016-meeting>

June 20
Cycle 2 2016 Comparison of Surgical and Nonsurgical Options for Management of Nonspecific Chronic Low Back Pain Applicant Town Hall
<http://www.pcori.org//events/2016/cycle-2-2016-comparison-surgical-and-nonsurgical-options-management-nonspecific-chroni-0>

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