August 28, 2013

Mayo Clinic
Attn: Lewis R. Roberts, M.B. Ch.B., Ph.D.
200 First Street SW
Rochester, MN 55905

Dear Dr. Roberts:

Gilead Sciences, Inc. (together with its affiliates and subsidiaries, "**Gilead**") has reviewed the ongoing study entitled "Improving the Identification of Chronic Hepatitis B Infections among Somali Immigrants in Minnesota through Community-wide Screening" (the "**Study**") in connection with Gilead's proprietary drug Viread® (tenofovir disproxil fumarate) (the "**Drug**"), not used in the Study, to be conducted by the Mayo Clinic ("**Institution**") at multiple sites in the United States, under the direction of Lewis R. Roberts, M.B., Ch.B., Ph.D. (the "**Investigator**"), an employee of Institution (Institution and Investigator are collectively referred to herein as "**you**" and "**your**").

Based on the scientific and medical merit of this Study, effective August 28, 2013 (the "**Effective Date**"), Gilead is pleased to provide partial research support for the Study in an amount up to $161,494.80 USD for Study expenses itemized in Institution's Study budget dated June 17, 2013, based on an anticipated enrollment of 500 additional Study subjects for an aggregate of 806 Study subjects.

Gilead will provide research support according to the following schedule:

A. $30,198.80 upon execution of this letter agreement, receipt of the final protocol, and Institutional Review Board ("**IRB**") approval (covering IRB, first-year clinical research unit (CRU), initial 100 subjects, subjects remuneration, and overhead);

B. $9,000.00 upon notification of travel plan pre-approved by Gilead for subject recruitment and completion of Milestone A (covering travel);

C. $23,199.00 upon notification of enrollment of 100 subjects (covering an aggregate of 200 subjects, inclusive of subjects remuneration and overhead);

D. $23,199.00 upon notification of enrollment of 200 subjects (covering an aggregate of 300 subjects, inclusive of subjects remuneration and overhead);

E. $3,500.00 upon notification of second-year CRU due and payable (covering CRU);

F. $23,199.00 upon notification of enrollment of 300 subjects (covering an aggregate of 400 subjects, inclusive of subjects remuneration and overhead);

G. $23,199.00 upon notification of enrollment of 400 subjects (covering an aggregate of 500 subjects, inclusive of subjects remuneration and overhead);

H. $10,000.00 upon notification of enrollment of 500 subjects (covering post-enrollment through completion of subjects); and

I. $16,000.00 upon delivery to Gilead of (i) a copy of the high-level peer-review journal publication and all supporting data; or (ii) if there is no such publication, a copy of the manuscript submitted for such publication and all supporting data; or (iii) if the Study was not completed, a summary of Study findings and all supporting data.

If the actual number of subjects is lower than your anticipated enrollment, Gilead will have the right to request a refund for any funds not used or reduce future payments accordingly.

For notification of each payment due under the above schedule, please send an invoice to the following address including a reference to the Study number IN-US-174-0230 and, if provided by Gilead, the purchase order number:

Gilead Sciences, Inc.
Attn: Accounts Payable
P.O. Box 5469
San Mateo, CA 94402
Email: apinvoices@gilead.com

Gilead will make payment to:

Mayo Clinic
Attn: Research Finance
200 First Street SW
P.O. Box 4008
Rochester, MN 55903-4008
roberts.lewis@mayo.edu

Notwithstanding Gilead's desire to provide the support described in this letter agreement, you acknowledge that you have designed the Study, will manage the Study, and will take full responsibility for the Study, including responsibility for the research subjects whom you recruit. If, prior to the start of or at any point during the Study, Gilead is deemed to be a sponsor of the Study, Gilead will have the right to terminate this letter agreement and its support of the Study. Gilead also reserves the right to terminate support of this Study should any of the following occur: (i) applicable IRB approval is not obtained; (ii) the first patient is not enrolled within a reasonable period of time; (iii) enrollment does not proceed as anticipated by your Study design; (iv) the Study protocol is amended and such amendment materially changes the scientific and medical merit of the Study; or (v) preparation of the Study manuscript, or preparation of only a summary of Study findings if the Study was not completed, does not occur within a reasonable period of time following completion of the Study.

Gilead's agreement to provide this research support is conditioned on, and you agree to, the following:

1. You will finalize and be responsible for the Study's protocol and informed consent. You will provide a final copy of each to Gilead. If any later changes are made thereto, you will provide Gilead with a copy of them and a reasonable opportunity for review and comment prior to submission to the applicable IRB. You will, however, have the full and final discretion and responsibility over the protocol and informed consent, including any changes to them. Once you have obtained applicable IRB approval, you will send Gilead a final copy of the aforementioned documents and any amendments thereto. You will notify Gilead in writing prior to implementing any amendment to the protocol that is a material change to the Study.

2. You will be responsible for all necessary regulatory approvals for the Study and will conduct the Study in accordance with all applicable laws, rules, regulations and guidance, informed consent

requirements, the protocol, any investigator's brochure for the Study and any applicable IRB requirements. You will obtain proper informed consent from each participant in the Study, ensuring compliance with the Health Insurance Portability and Accountability Act and all other applicable laws, rules, regulations and guidelines governing data protection and privacy.

3. You will not commence the Study at each site unless and until you have received applicable IRB approval.

4. You are responsible for determining whether local or national law requires that your Study be registered publicly. If local or national law requires registration of your Study, you agree to register the Study and your results in accordance with those laws, rules and regulations and to notify Gilead of the registration once it has been completed. You understand that failure to register your Study, if required by law, may result in your inability to publish results of your Study.

5. . You will be responsible for the management of safety data from your Study and any associated regulatory reporting obligations for individual or periodic safety reports to the appropriate authorities and clinical investigators and applicable IRB in compliance with all applicable laws, rules, regulations and guidance.

6. You will alert Gilead Drug Safety & Public Health (DSPH) at the address below of any potential safety issues or any protocol amendments or changes to the informed consent arising from a safety concern associated with the Drug in your Study within 15 calendar days of first becoming aware of such event.

7. You will report in English all serious adverse reactions related to the Drug (SARs) and Special Situation Reports (SSRs) (reference Attachment A for definitions) with respect to the Drug, occurring during the Study to Gilead DSPH within 15 calendar days of first becoming aware of any such event and in accordance with applicable laws, rules, regulations and guidance. All reports addressed to Gilead will be sent to the attention of:

   Gilead Sciences, Inc.
   Drug Safety & Public Health
   333 Lakeside Dr.
   Foster City, CA 94404
   Fax: 650.522.5477
   Tel: 650.522.5114
   E-mail: Safety_FC@gilead.com

8. Upon Gilead's request, you will provide any additional information required to perform medical assessments of any safety information provided to Gilead. This includes provision of data in relation to blinded data if applicable. Gilead will request unblinding information for reports that are assessed as suspected Unexpected Serious Adverse Reactions (SUSARS). You will provide Gilead all reasonable assistance in providing any further information requested by Gilead. Gilead will send any such request for additional information to:

   Mayo Clinic
   Attn: Lewis R. Roberts, M.B. Ch.B., Ph.D.
   200 First Street SW
   Rochester, MN 55905

9. Gilead will forward investigator safety reports to you of any potential serious risks arising from its clinical trials within 15 calendar days from Gilead's awareness. As Study sponsor, you will be

responsible for the onward distribution of such investigator safety reports in compliance with all applicable laws, rules, regulations and guidance.

10. You will be responsible for the preparation of any periodic safety reports required for your Study (e.g. the Development Safety Update Report). For the avoidance of doubt, Gilead does not wish to routinely receive copies of such periodic safety reports. For blinded studies, you will forward additional information after end of study unblinding to Gilead DSPH as defined in clause 7 above.

11. In order for Gilead to determine receipt of all applicable reports from you, you will, upon completion of the Study, provide Gilead DSPH with a listing of all safety information that you have sent to Gilead, for reconciliation purposes. At a minimum the listing will contain protocol number, patient ID number, case reference number, Gilead product and event term.

12. Except for periodic safety reports, you will provide Gilead with a copy of all reports submitted to government agencies that are related to the Study, as well as any correspondence with such authorities related to the Study.

13. You will provide Gilead with a quarterly report on the status of the Study from the time of execution of this letter agreement until the Study has been completed, and at Gilead's request, any other information about the Study required for Gilead to comply with applicable laws, rules, regulations and guidance. You will provide Gilead with (i) a copy of the publication and all supporting data; or (ii) if there is no publication, a copy of the manuscript submitted for publication and all supporting data; or (iii) if the Study was not completed, a summary of Study findings and all supporting data prior to receiving your final milestone payment. Such supporting data shall include access to raw data in machine-readable format, upon request, if needed by Gilead for regulatory or risk management evaluation purposes. You hereby grant Gilead a non-exclusive, irrevocable, worldwide, perpetual, fully paid-up, royalty free, sub-licensable license to use all such data and reports for any lawful purpose.

14. You will ensure that there will be no patient identifiable information in any data, report, summary or finding you send to Gilead in accordance with this letter agreement, except as required or permitted by law or regulation or as authorized in the applicable informed consent form.

15. You represent and warrant that all of your personnel that may perform services hereunder are your employees or affiliates, and they will comply with the terms and conditions of this letter agreement as if each were a party hereto. Without limiting any of the foregoing, you may use third-party companies and institutions to perform the Study provided that you contractually bind any such companies or institutions to applicable terms at least as stringent as those found herein, including without limitation the obligation to convey to Institution all title and interest to inventions generated as a result of conducting the Study so that you can comply with your license grant obligations as set forth herein.

16. You acknowledge that personal data relating to the Institution, Investigator, and Study personnel will be processed, both manually and electronically on one or more databases and will be used by Gilead for the purposes of administration of this letter agreement in connection with the Study and in order to comply with any applicable laws and regulations. Personal data may be disclosed or transferred to Gilead and to representatives and contractors working on behalf of Gilead, and to regulatory authorities across the world. You will ensure that all necessary consents are in place to comply with the provisions of this section.

17. You will maintain in confidence, and only use for the Study, any confidential or proprietary information Gilead provides or discloses to you in connection with the Study.

18. You will provide Gilead with a copy of any proposed publication, including, but not limited to, manuscripts and abstracts, as well as a summary of any presentation relating to the Study at least 30 business days in advance of any submission to a journal or publication and 7 business days in advance of any submission for any scientific meeting. Upon Gilead's reasonable request, you will remove any of Gilead's confidential or proprietary information.

19. Ownership of inventions arising in connection with the Study shall be determined in accordance with inventorship under U.S. patent law. If you generate any inventions relating to the Drug and as a result of conducting the Study, you hereby grant to Gilead a non-exclusive, irrevocable, worldwide, fully paid-up, royalty free license to such inventions, including all patent rights, trade secrets, copyrights and other intellectual property, which license shall be freely sub-licensable to Gilead's affiliated companies and entities and to their contractual partners. It is expressly agreed that neither Institution nor Gilead transfers by operation of this letter agreement to the other party any right in or license to any patents, copyrights, or other proprietary right owned as of the commencement date of the letter agreement or arising outside of the research conducted under this letter agreement.

20. The research support will be used only for the Study, and you will refund to Gilead any funds that are not used for the Study upon completion or early termination of the Study. You will not bill any third parties, including any Federal or state health care programs or sources, nor will you seek any reimbursement for the cost of services funded or items purchased through the use of the research support provided under this letter agreement. You will not seek reimbursement from Gilead for any services or items which may be reimbursed to you by any other third party, including under Federal or state health care programs. You agree that the research support to be paid under this letter agreement constitutes the fair market value of the performance of Study-related activities to be conducted pursuant to this letter agreement and is unrelated to the volume or value of any referrals or other business otherwise generated between the you and Gilead.

21. Gilead's research support of your Study imposes no obligation, express or implied, for you to purchase, prescribe, provide favorable formulary status for, or otherwise support Gilead's products.

22. Neither party shall use the names or trademarks of the other party or of any of the other party's affiliated entities in any advertising, publicity, endorsement, or promotion unless the other party has provided prior written consent for the particular use contemplated. With regard to the use of Institution's name, all requests for approval pursuant to this Section must be submitted to the Mayo Clinic Public Affairs Business Relations Group, at the following E-mail address: BusinessRelations@mayo.edu at least five business days prior to date on which a response is needed. The terms of this section survive the termination, expiration, non-renewal, or rescission of this letter agreement.

23. The foregoing represents the entire agreement between Gilead and you regarding the Study, and there are no further commitments, obligations or understandings of any nature regarding the Study. This letter agreement will be effective as of the Effective Date and will terminate upon the completion of your obligations under the protocol and this letter agreement and Gilead's payment of the amounts identified above, if applicable. This letter agreement may only be amended with the mutual written consent of the parties.

24. This letter agreement shall be interpreted and enforced in accordance with the laws of the State of New York regardless of any choice of law principles.

[Signature Page Follows]

If this is acceptable to you, please sign both copies of this letter agreement in the space provided below and return one original to the attention of Clinical Contracts and Finance at Gilead Sciences, Inc., 333 Lakeside Drive, Foster City, CA 94404.

Sincerely,

GILEAD SCIENCES, INC.

By: _____
John McHutchison, M.D.
Senior Vice President
Liver Disease Therapeutics

ACCEPTED AND AGREED TO:

MAYO CLINIC

By: Virginia M. Bruce
Name: Virginia M. Bruce
Title: Director, Legal Contract Administration
10/1/13

Reviewed by Contracts Mgr ER

READ AND UNDERSTOOD BY:

INVESTIGATOR

By: _____
Lewis R. Roberts, M.B. Ch.B., Ph.D.
10/7/13

Back to Search Results

Description
Details
Sub-Projects
Publications
Patents
Outcomes
Clinical Studies
News and More
History
Similar Projects

Mayo Clinic Center for Clinical and Translational Science (CCaTS)

Project Number	Contact PI/Project Leader	Awardee Organization
5UL1TR000135-10	KHOSLA, SUNDEEP	MAYO CLINIC ROCHESTER

Description

Abstract Text

DESCRIPTION (provided by applicant): The overall goal of the Mayo Clinic CTSA is to continue to build a broad-based and integrated home for clinical and translational science (CTS) at Mayo Clinic that will ultimately improve human health. In this context, we seek to make the Mayo CTSA and the resources it leverages both an engine of efficiency for clinical and translational research and at the same time a driver of innovation. We also seek to integrate our local activities with consortium wide efforts directed at coordination and alignment. To achieve our goal we have six overarching specific aims for this renewal: Aim 1 - Train and maintain an outstanding multidisciplinary clinical and translational sciences workforce. This workforce includes teams of both investigators and support staff. Aim 2 - Eliminate barriers to the work of translation. This will be accomplished through a) continued efforts at regulatory and compliance streamlining, b) provision of outstanding design, biostatistics, and ethics support for investigators, and c) further integration of support services. Aim 3 - Collaborate with providers and communities to improve health care delivery and community health. This includes substantial commitments to practice-based research, community- engaged research and translating comparative effectiveness research into clinical practice. Aim 4 - Deploy advanced facilities and other core resources to increase the value of clinical research. With value defined in this context as the quotient of quality and cost, the goal is to increase quality, decrease costs, and provide resources to the full spectrum of clinical and translational investigation. Aim 5 - Stimulate novel research directions and methodologies by targeted support of innovative pilot and feasibility studies and fostering the development of novel methodologies. Aim 6 - Employ informatics to integrate and facilitate clinical and translational investigation. This encompasses a broad view of informatics including: a) developing a standardized electronic data capture and analysis tools for CTS, b) robust consultation and tools for medical informatics that leverage Mayo's commitments to electronic clinical systems, and c) bioinformatics services and capabilities that will help facilitate the application of the "new biology" to clinical and translational investigation. This vision is entirely consistent with the stated mission of Mayo Clinic: "To provide the best care to every patient every day through integrated clinical practice, education, and research."

Public Health Relevance Statement

(provided by applicant): Mayo Clinic Center for Translational Science Activities will bring together all the resources of the five schools within the Mayo Clinic College of Medicine and more than 100 years of scientific and medical research expertise, to discover innovative new methods that will speed the translation of research results into therapies, tools, and patient care practices that impact both our local and national communities by improving their health.

Mayo Clinic Hepatobiliary SPORE

Project Number
5P50CA210964-04

Contact PI/Project Leader
MC NIVEN, MARK A.Other PIs

Awardee Organization
MAYO CLINIC ROCHESTER

Contact PI/ Project Leader

Name
MC NIVEN, MARK A.

Title
PROFESSOR

Contact
View Email

Other PIs

Name
ROBERTS, LEWIS R

Program Official

Name
NOTHWEHR, STEVEN F

Contact
View Email

Organization

Name
MAYO CLINIC ROCHESTER

City
ROCHESTER

Country
UNITED STATES (US)

Department Type
Unavailable

Organization Type
Other Domestic Non-Profits

State Code
MN

Congressional District
01

Other Information

FOA
PAR-14-353

Study Section
ZCA1-RPRB-N(O1)

Fiscal Year
2021

Award Notice Date
12-August-2021

Administering Institutes or Centers
NATIONAL CANCER INSTITUTE

CFDA Code
397

DUNS Number
006471700

UEI
Y2K4F9RPRRG7

Project Start Date
10-September-2018

Project End Date
31-August-2023

Budget Start Date
01-September-2021

Budget End Date
31-August-2022

Back to Search Results

Description
Details
Sub-Projects
Publications
Patents
Outcomes
Clinical Studies
News and More
History
Similar Projects

Mayo Center for Cell Signaling in Gastroenterology

Project Number	Contact PI/Project Leader	Awardee Organization
5P30DK084567-14	LARUSSO, NICHOLAS F.	MAYO CLINIC ROCHESTER

Description

Abstract Text

PROJECT SUMMARY The overall objective of the Mayo Clinic Center for Cell Signaling in Gastroenterology (C-SiG) is to exploit signaling pathways in gastrointestinal cells to improve the health of patients with digestive diseases. To do this, C-SiG provides a robust infrastructure, thematic platforms, and career development opportunities to integrate and amplify impactful investigation along the discovery-translation-application paradigm. Our Research Base now consists of 68 scientists (15% growth) involving 18 departments and $23.7 million (direct costs, 2.5% growth) in digestive disease-related funding. Responding to members' evolving interests and scientific advances, we've re-aligned members into three interconnected Mechanistic Research Themes (intracellular signaling, cell-to-cell communication, and genetics/epigenetics), each intersecting with three Disease Focus Groups (liver pathobiology, enteric neurosciences, inflammation/transformation), a matrix that fosters both discovery and disease relevant investigation. Our ongoing CENTRAL HYPOTHESIS is that advances in care of patients with digestive diseases requires a facilitative infrastructure supporting meaningful interactions among multidisciplinary scientists investigating cellular mechanisms, pathways, and therapeutic targets to enhance rapid translation of basic discoveries into clinical trials. Our OVERALL SPECIFIC AIMS are to: i) Foster multidisciplinary research by expanding technical and collaborative capabilities of established GI scientists and attracting investigators from other disciplines; ii) Identify and nurture new GI investigators via a peer-reviewed Pilot and Feasibility (P/F) Program including career development workshops, curricula, and structured mentorship (19/26, 73% of P/F recipients achieving federal funding); iii) Offer core-based specialized equipment, technologies, methodologies, reagents, and expertise (Optical Microscopy, Clinical, and Gene Editing and Epigenomics Cores), with continuous core menu updates, quality assurance and assessments, and project management oversight in response to member feedback; iv) Support a robust Enrichment Program; and v) Promote interactions between C-SiG with other NIDDK centers at Mayo (e.g., PKD Center) and existing DDRCCs, especially in the Midwest (i.e., Midwest DDRCC Alliance). Our global efforts have resulted in 215 manuscripts, with 56% percent intra- and 44% inter-thematic publications (70% involving two or more members). Importantly, we've made critical advances in understanding disease pathogenesis relevant to signal transduction, cell-to-cell communication and genetics/epigenetics, thereby identifying potential disease modifying targets.

Public Health Relevance Statement

PROJECT NARRATIVE Gastrointestinal diseases and their complications have a significant negative effect on public health and incur considerable health care utilization costs. Research supported by this Center grant is critically important to advance our understanding of the mechanisms that underlie digestive diseases. This new knowledge can lead to practical applications for the diagnosis, prevention, monitoring, and treatment of digestive diseases.