

UCSD Agreement No. _____

COLLABORATOR Agreement No. _____

AGREEMENT
BETWEEN
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, SAN DIEGO
AND
NEW YORK CITY DEPARTMENT OF HEALTH

This MEMORANDUM OF UNDERSTANDING is hereby made and entered into between the New York City Department of Health (“DOHMH”) having its principal office located at 42-09 28th Street, Queens, New York, hereinafter referred to as COLLABORATOR and The Regents of the University of California on behalf of its San Diego campus referred to as UCSD located at 9500 Gilman Drive, MC-0507, San Diego, California 92093-0707 (together, the “parties”).

A. PURPOSE:

DOHMH's Bureau of Tuberculosis Control (BTBC) is charged with the identification and treatment of persons with active tuberculosis disease in New York City and considers outpatient directly observed therapy (DOT) as the standard of care for managing tuberculosis. The purpose of this Agreement is to develop a framework of cooperation between DOHMH (“COLLABORATOR”) and the UCSD to pilot-test and evaluate a technology-driven system called Video Directly Observed Therapy (VDOT), which utilizes smart phones to remotely monitor tuberculosis (TB) treatment adherence. With the VDOT System, participants selected by DOHMH's BTBC make a video recording of themselves taking each dose of medication, which is sent to a secure website where a DOHMH TB care provider can view the video and verify compliance. The original pilot study (Phase I and II) was funded through the National Institutes of Health (Grant #R21-AJ088236; PI: R. Garfein). Results from the pilot study showed that VDOT effectively substituted for daily in-person patient visits and simplified DOT administration, thereby greatly reducing costs while improving patient outcomes. Given the success of the first two phases of the VDOT study UCSD received additional funding to scale-up the prototype VDOT System (Phase III) and demonstrate its adaptability in a variety of health department settings. The objective of Phase III is to test the VDOT System technology through the TB Control Programs at multiple health departments to ensure correct functioning and gain additional knowledge to inform the development of effective VDOT protocols and training materials. COLLABORATOR will serve as a site for Phase III.

B. TERM OF AGREEMENT

This agreement is executed as of the date of last signature and is effective through September 2015 unless sooner terminated by either party to this Agreement in accordance with the provisions set forth in the Termination section of this Agreement. If for any reason, the activities of the pilot study with DOHMH's BTBC selected participants (“Participants”) have not been completed by the date on which the initial term of this Agreement is to expire, the Parties to this Agreement may renew this Agreement in writing for part or all of an additional two year period.

C. UCSD SHALL:

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The UCSD team will be responsible for:

1. Providing the Client Management System (CMS) and Video Recording and Transfer (VRT) application for use by COLLABORATOR.
2. Providing COLLABORATOR with the following equipment and services from the Verizon Foundation:
 - a. Fifty smart phones with front and rear facing cameras and 2-year service plans. Up to 150 additional phones may be provided if they are made available to UCSD by the Verizon Foundation.
 - b. One phone case for each phone provided, which includes a kick stand to prop up the phone during VDOT video recording.
3. Updating and providing training materials for COLLABORATOR tailored to meet the Program's operational and the needs of the Participants.
4. Working in conjunction with COLLABORATOR to translate Participants educational materials as appropriate based on the predominate languages of the TB patient population.
5. Visiting the site to ensure proper VDOT system set-up and train COLLABORATOR staff to monitor Participants using VDOT.
6. Assisting COLLABORATOR to troubleshoot technical problems and obtain reports using the CMS.
7. Providing COLLABORATOR with a detailed list of variables pertaining to the Participants TB treatment needed for the study analyses (i.e., treatment outcome, chest x-ray results, sputum test results, etc.).
8. Sharing with COLLABORATOR the questions and aggregated responses (not linked to individual patients) to surveys the UCSD team obtains through telephone interviews with participants.
9. The safeguard and security of Participants' videos on its Health Insurance Portability and Accountability Act of 1996 ("HIPAA") Security Rule compliant servers and to delete all Participants' videos on such servers on the date set by DOHMH.

D. COLLABORATOR ("DOHMH") SHALL:

The COLLABORATOR will be responsible for pilot testing the scaled-up version of the CMS and VRT application with their active TB patients and provide feedback on the modifications, effectiveness, utilization, and potential enhancements to the system. The COLLABORATOR will be responsible for:

1. Identifying potential VDOT study participants.
2. The pilot study required by this Agreement shall be conducted in accordance with research protocols reviewed and approved by the Institutional Review Boards of DOHMH and shall include guidelines and standards governing the consent required of all potential participants.
3. Securing the necessary written informed consent from each person who will participant in the VDOT pilot study.

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4. Enrolling and training, consenting Participants in the pilot study on proper usage of the cell phones and VRT application.
5. After written consent is secured from the Participant, providing UCSD with the contact information only from Participants who consent to allow UCSD to conduct pre- and post-VDOT telephone interviews.
6. Maintaining inventory control over study phones, which includes:
 - a. Keeping a log of phones that have been distributed to, and returned by, participants;
 - b. Obtaining signatures from Participants on Terms of Phone Use form indicating that these terms are understood and agreed to. This form will be kept by the COLLABORATOR and not shared with UCSD or Verizon Foundation;
 - c. Retrieving phones from Participants at the end of the study, and providing them with a Phone Receipt form signed by a COLLABORATOR staff member.
7. A pre-designated COLLABORATOR staff member (VDOT Monitor) will be responsible for observing Participants videos daily until the end of treatment (or 18 months, whichever is shorter) via a secure website and recording information about the video including video status (video received/not received), medication status (meds taken/not taken), video quality information, audio quality information, comments made by the participant during the video, and other notes the VDOT Monitor might find relevant.

E. NON-FUND OBLIGATING DOCUMENT.

1. This Agreement is neither a fiscal nor a funds obligation document. Each party to this Agreement shall be fiscally responsible for their own portion work performed under the Agreement.
2. Nothing in this Agreement will be deemed to be a commitment or obligation of New York City funds for this VDOT study. Neither the City of New York nor DOHMH BTBC will pay any money or make in-kind payments to UCSD or the Verizon Foundation for use of smart phones, software, licenses, other equipment, or any material and/or support received for this VDOT study.
3. The UCSD will make no monetary or in-kind payments (other than the equipment described above) for the aggregated data it receives from the DOHMH BTBC.

F. PARTICIPANT HEALTH INFORMATION.

All medical or mental health information identifiable of a Participant received by UCSD or DOHMH in the course of its performance under this Agreement shall be kept confidential and shall not be used or disclosed except as set forth in this Agreement or as permitted by applicable law. UCSD and DOHMH represents and warrants that its policies regarding use and disclosure of patient information are compliant with all applicable state, federal, and local laws, including, but not limited to HIPAA and its implementing regulations.

G. CONFIDENTIALITY.

1. The Parties to this Agreement agree:

- a. Each party to this Agreement shall keep and maintain confidential that information it learns on its own or receives from the other party whether directly or indirectly, during or otherwise in connection with this study to the fullest extent required by applicable Federal and State laws of the Party possessing such confidential information. "Confidential Information" includes but is not limited to the following:
 - (i) Study Participants' medical records and information;
 - (ii) Study Participants' personally identifiable information;
 - (iii) Individual healthcare provider-identifiable information; and
 - (iv) Any nonpublic information about UCSD and DOHMH's protocols and operations.
- b. Any information considered by the disclosing party to be confidential will be clearly marked by the disclosing party in writing, as "Confidential Information" and sent only to the receiving party's Principal Investigator; however, items described above in paragraph (a), (i), (ii) and (iii) shall be automatically deemed Confidential Information without further identification, whether received in writing or orally. Any oral information conveyed to the receiving party by the disclosing party shall be followed by a written communication within three (3) days that said information will be considered "Confidential Information." Except as required by applicable state laws of the party possessing the Confidential Information, applicable federal laws and/or by court order, the receiving party will not disclose Confidential Information. This obligation does not apply to information that was known to the receiving party prior to its receipt from the disclosing party, that is independently developed by the receiving party, or becomes known at any time to third parties through no fault of receiving party.
- c. Each party to this Agreement will use a reasonable degree of care to protect the Confidentiality Information in its possession, and utilize best practice methods (e.g. encryption of electronic records) and ensure methods used to protect such Confidential Information are compliant with all applicable federal laws, including, HIPAA, and with all applicable state and local laws of the Party possessing the Confidential Information.
- d. The obligation under this section G to hold and protect "Confidential Information" is subject to applicable federal laws and the laws of the state of the Party possessing such information; and therefore the release of Confidential Information in compliance with those laws will not constitute a breach or threatened breach of this Agreement. The terms of this section shall survive the expiration or termination of this Agreement.
- e. The Confidential Information a Party obtains or learns under, or in connection with this Agreement shall be used only for the purpose of this Agreement; shall not be disclosed to any third parties; and shall only be shall disclosed if written consent is obtained from the

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person to whom such information pertains to, or as otherwise authorized by applicable federal, New York State or California State laws.

- f. UCSD shall store survey answers from Participants separately from the Participants' contact information to protect the confidentiality of Participants' data and utilize best practice methods (e.g. encryption of electronic records) to protect the confidentiality of such information.
- g. Videos from the VDOT study will only be viewed by authorized DOHMH BTBC and UCSD Study staff.

H. Maintenance of TB Patient Records:

The DOHMH shall continue to have sole custody and maintenance of the medical records of any individual TB participant it had prior to this VDOT study and shall not provide copies of any records, forms, or disclose identifying information about individual patients receiving Video DOT or other services from BTBC to any person except in accordance with the written consent from the person to whom such information pertains to or as otherwise authorized by applicable federal or New York State.

The UCSD shall refer any requests for aggregated data prepared by the DOHMH to the DOHMH.

I. Limited Liability to employees and third parties:

- 1. The Parties agree:
 - a. It is understood that neither party to this Agreement is the agent of the other and neither is liable for the wrongful acts, liabilities, breach of Participants' personal identifiable information, obligations or negligence of the other. Each party shall be responsible for its own negligent acts or omissions and those of its officers, employees, agents or students (if applicable), howsoever caused, to the extent allowed by their respective state laws.
 - b. Neither party shall be liable to the other party for any lost profits, lost revenues, or any incidental, indirect, consequential, special, punitive, or exemplary damages of any kind, regardless of whether either party was advised, had other reason to know, or in fact knew of, the possibility thereof.
 - c. Any equipment and services provided by UCSD under this Agreement are provided as is without any warranty.
 - d. No benefit is intended for any third parties.
 - e. THE PARTIES ACKNOWLEDGE THAT THE WORK SET FORTH IN ARTICLES C AND D IS EXPERIMENTAL IN NATURE AND NEITHER PARTY MAKES A

WARRANTY OF ANY KIND, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, WARRANTIES AGAINST INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

J. MISCELLANEOUS

1. Independent Contractor Status

The Parties to this Agreement shall be independent contractors and shall not be considered partners, agents, employees or representatives of the other party.

2. Publication:

- a. There shall be no restrictions on the publication of the final aggregated data (de-identified data) by either party.
- b. Either party shall have the right to independently publish the aggregated data collected under this Agreement or aggregated data collected under the VDOT study, in reports, in the media and scientific journals, information regarding findings.
- c. If the UCSD publishes a work dealing with any aspect of performance under this Agreement, or of the results and accomplishments attained from such performance, and UCSD owns the copyrights of such work, the DOHMH shall have a royalty free, non-exclusive and irrevocable license to reproduce, publish or otherwise use it for any purpose.
- d. Acknowledgments: All any material for publication bearing on the work performed or data collected under this Agreement shall acknowledge the DOHMH BTBC.
- c. No Party shall use the name of the other in any publication, news release, promotion, advertisement or other public announcement, whether written or oral, that endorses services, organizations or products, without prior written approval of the other.
- f. The provisions of this section shall survive the completion or termination of this Agreement.

3. Termination:

Either party shall have the right to terminate this Agreement, without cause, provided that written notice of termination is given at least thirty (30) days prior to the effective date of the proposed termination to the other party. Should this Agreement be terminated, the parties shall establish a plan for termination that will avoid to the maximum extent practicable disruption to the project.

4. Non-Assignment/Subcontractor

This Agreement shall neither be assigned nor subcontracted by either party, in whole or in part, without the prior written consent of both parties.

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5. **Legal Compliance.**

- a. Notwithstanding any other provision in this Agreement, the parties remain responsible for ensuring that any service provided pursuant to this contract, complies with all applicable laws.
- b. The parties agree to be bound by federal rules governing Equal Employment Opportunity, Non-Discrimination, Conflicts of Interest and Immigration.

6. **Participation In Similar Activities.** This agreement in no way restricts UCSD or DOHMH from participating in similar activities with other public or private agencies, organizations, and individuals.

7. **Merger.** This Agreement contains all the terms and conditions agreed upon by the parties hereto, and no other agreement, oral or otherwise, regarding the subject matter of this MOU, shall be deemed to exist or to bind any of the parties hereto, or to vary any other of the terms contained herein.

8. **Modification And Notices.**

Modifications to this agreement shall be made by mutual consent of the parties, by the issuance of a written modification, signed and dated by authorized officials, prior to any changes being performed.

Notices:

All notices and request to be provided by either party are to be in writing, and mailed or otherwise delivered to these parties at the addresses specified below:

COLLABORATOR (DOHMH):

New York City Department of Health and Mental Hygiene
Bureau of Tuberculosis Control
42-09 28th Street, 21st Floor
Queens, New York, 11101
Attn: Joseph Burzynski, MD MPH
Title: Assistant Commissioner, Director

UCSD

Authorized Official:

Rachel Sievert
Principal Contract Officer
UCSD OCGA
9500 Gilman Drive #0934
La Jolla, CA 92093
(858) 534-3335
rsievert@ucsd.edu

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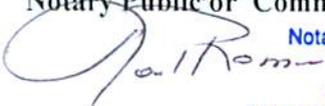
IN WITNESS WHEREOF, the parties hereto have executed this agreement as of the last written date below.

FOR: COLLABORATOR:

Date: 12/03/2013


Patsy Yang, DrPH
Executive Deputy Commissioner and Chief Operating Officer

Subscribed and sworn to before me this 3rd day of DECEMBER, 2013

Notary Public or Commissioner of Deeds

PAUL ROMAN
Notary Public- State of New York
No. 01R06134864
Qualified in Kings County
My Commission Expires October 11, 2017

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA ON BEHALF OF ITS SAN DIEGO CAMPUS:

Date: 12-11-13


Rachel Sievert, Principal Contract Officer
Office of Contract & Grant Administration

Subscribed and sworn to before me this _____ day of _____, 2013

Notary Public or Commissioner of Deeds

Reviewed and Approved by
UCSD Contract Officer


12/13

UCSD

Authorized Official:

Rachel Sievert
Principal Contract Officer
UCSD OCGA
9500 Gilman Drive #0934
La Jolla, CA 92093
(858) 534-3335
rsievert@ucsd.edu

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OFFICE OF THE ACCO
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