Combined Informed Consent and HIPAA Authorization Template

VA Central IRB
VA Institutional Review Board for Multisite Studies

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by Aidar Health, Inc. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to gather vital sign data obtained from an FDA-approved device called MouthLab from patients who have been diagnosed with COVID-19 in the past. The data from all the patients enrolled in the study will be analyzed for trends that may help to predict which patients are most at risk for worsening health leading to hospitalizations and other healthcare utilization as a result of COVID-19.

The study lasts for 12-18 months, but your direct participation in the study is expected to last approximately 6 months. As part of the study, you will be required to use the MouthLab device twice daily for 6 months and complete monthly health-related surveys. At the end of the study, you will be required to return the MouthLab device, blood pressure cuff, and accompanying accessories to Aidar Health. Ensuring the return of the device is an important part of the study completion activity. All study procedures will take place remotely, which means you will never need to go to any VA location for any study visit.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There are no direct benefits of participating in the study, but your participation may benefit others in the future by contributing to the researchers' understanding of complications from the COVID-19 virus. If proven effective this technology can be used to better manage and monitor individuals at home thereby ensuring continuity of care.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Some people may choose not to participate in this study. Some reasons may include:

- Limited time/availability
- Concerns about data collected from the MouthLab device and surveys
- Issues or concerns with using new technology

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

Participant Name: _____ Date:_____

Title of Study: AIDI–Research & Development of a Multisensor-Based Technology for real-time automated detection of post-acute COVID-19 sequelae

Principal Investigator: Varsha Vimalananda, MD, MPH VA Facility: Bedford VAMC

Principal Investigator for Multisite Study: Varsha Vimalananda, MD, MPH

The Principal Investigator and person in charge of the study is Dr. Varsha Vimalananda at the Bedford VAMC. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is 781-687-4949.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

The goal of this research study is to see how the FDA-approved MouthLab device, a breathalyzer that can capture several important health vitals, can be used to predict future health complications in people who have been previously hospitalized with COVID-19. Despite research showing that new COVID-19 infection rates have dropped, the increased rates of morbidity, mortality, and organ dysfunction among COVID-19 survivors has become a focal aspect of health research. Veterans are at heightened risk of developing further health problems after contracting COVID-19 due to existing rates of kidney, cardiovascular, and pulmonary diseases. With the health data collected from the MouthLab device, the aim of this study is to create a prediction model that can be used to accurately identify future health complications among those who were hospitalized due to COVID-19 in the past.

HOW LONG WILL I BE IN THE STUDY?

Approximately 400 Veterans will participate in this study. Your individual participation in the project will take 6 months from the date of enrollment. The entire study may last for 12-18 months.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you decide to take part in this study, this is what will happen:

1. **Enrollment**: This meeting will last approximately 30-45 minutes and will involve you meeting with a Study Coordinator and completing the Phone Screening. If eligible and based on your availability you will be sent a combined informed consent and HIPAA authorization form. Either soon after screening or at a later time the study coordinator shall set up a call to verify your understanding of the study information and enroll you by having you sign on the form. The process will happen either by video or phone. During this visit, you will be asked to provide a Secondary Contact. This is an individual who you consent to our team contacting if we have trouble reaching you during your time in the study. We will not contact your Secondary Contact unless we have been unable to reach you for four weeks in a row.

2. **Baseline/Device Training**: Once you've received your MouthLab device and blood pressure cuff in the mail, you will meet with a Study Coordinator where they will train you on how to use the device and calibrate your device. This visit will last approximately 1-1.5 hours. This visit will take place remotely via video platform.
    a. You will be asked to return the device, blood pressure cuff, and accompanying accessories at the end of the study. Please do not throw away any of the boxes or packaging that comes with the device. Aidar will also include a return mailing label with the device.
3. **Daily Use of the MouthLab Device**: After the baseline/device training visit, you will need to use the MouthLab device twice daily every day for 6 months. Each measurement with the MouthLab device lasts for 60 seconds. The Study Coordinators might periodically contact you to remind you to use the device. You will not receive or have access to any of the data collected by the MouthLab device as part of this study. You will also not be notified of any readings, including abnormal ones, captured by the device.
    - It is very important to understand that in this study, you will not be able to see your readings and no one will be monitoring your device data for health problems. Instead, all the data collected goes towards developing the computer model to be used in the future to predict health problems.
4. **Monthly Health Surveys**: Once per month, you will be sent electronic health-related surveys. The first month survey will also include the Patient Intake Form that asks about your demographics and for a Secondary Contact. These surveys will be brief and shouldn't take you longer than 15 minutes to complete. You are free to skip any questions that you prefer not to answer.
    a. During the monthly survey, we may also contact you to ask some follow-up questions about some of your responses if you endorse being hospitalized or seeking medical care outside of the VA system within the past month.
    b. Once per month, you will also be asked to take a blood pressure reading and enter that information into your monthly survey response. This is to help keep your device calibrated.
    c. At the end of each month, you will be given $85 if you use the device twice daily and complete all surveys. More information about the incentives is listed later in this consent form.
5. **Termination**: In your sixth and final month of your time in the study, you will be sent a user experience survey in addition to the usual monthly health survey. The user experience survey will ask about your experience using the device.
6. **Returning the Device**: At the end of your time in the study, you must return the device, blood pressure cuff, and all accompanying accessories to Aidar Health using the return mailing label provided.

a. Once Aidar receives the returned device and after you complete the final surveys, you will be given a final incentive of $175.
b. We may contact you at the end of your last month in the study in order to remind you of these procedures, answer any questions you have, and/or help facilitate the shipment of the device back to Aidar Health.

If you visit an Emergency Room or are hospitalized at a non-VA medical center during your time in the study, you will be asked to sign a Release of Information form (VA 10-212) that authorizes our study team and study sponsor access to those medical records.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

Expectations and responsibilities of participants in our study are as follows:

- Use the MouthLab device twice daily for six months
- Return the MouthLab device at the end of the study or if you wish to withdraw or terminate your participation from the study. The study staff will contact you to coordinate the shipment of the package.
- Keep your virtual study appointments. If you miss an appointment, please contact our Study Coordinators to reschedule as soon as you know you will miss the appointment.
- Ask questions as you think of them.
- Tell the study investigator or research staff if you change your mind about participating in the study at any time.
- Tell the investigator or research staff if you believe you might be or have become pregnant during your time in the study.
- Complete your surveys, as instructed.
- While participating in this research study, we ask that you alert our study staff of your participation in another research project or your intent to join another research study. This is to make sure the results of the other research study do not invalidate our study's results.

During this study, our study staff might need to request copies of your medical records from non-VA facilities in the event of any ER visit or hospitalization at those facilities during the study. A VA Form Letter 10-212, which is a release of information form, will need to be signed for each different non-VA entity from which the medical records will be requested.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Every research study has possible risks or discomforts.

- There may be some minor discomfort to the teeth or gums when using the MouthLab device. This risk is minimal as the mouthpiece is intended to securely fit between the lips and gums of the subject like a scuba mouthpiece.
- There may be risk for infection if the mouthpiece is not washed regularly as instructed in the user manual.

In terms of pregnancy, women who are pregnant are excluded from this study because pregnancy induces physiological changes in the body that cannot be generalized to other populations and may affect the findings from the study.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help to better understand how to better predict COVID-19-related health complications in the future. If proven effective this technology can be used to better manage and monitor individuals at home thereby ensuring continuity of care.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Participation in this study will involve collecting private data about you, including:

- Your name, date of birth, mailing, and email address, etc. will be collected by the study sponsor to support device shipment.
- Your social security number (SSN)
  - Your SSN will be obtained to track your health record within the Veterans Health Administration (VHA) system.
  - Venmo,PayPal will also need your name, phone number mailing address, email address and bank account information to set up an account to help manage the study incentives that you may receive during the study.
  - VA ORD Qualtrics will need your email address to send you the monthly surveys.

Our team will protect your data in the following ways:

- Any collected data will not be shared with anyone outside of approved study staff members and other approved entities (see below).
- All data collected will be protected on encrypted electronic platforms and/or locked cabinets in locked offices only accessible by approved research members and the study sponsor and will be destroyed in compliance with VA regulations.
- Any identifiers collected as part of the research will be removed and will not be used or distributed for future research studies.
- Participants' identities will not be disclosed unless otherwise required by law or VA policy
- Confidentiality will not be maintained if harm to self or others is disclosed.

The results of this study may be used for publication or scientific purposes and will not include any information that could identify participants. There may be times where we will need to share your records with other entities. These might include the Food and Drug Administration (FDA), the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Institutional Review Board, Research Compliance officers, the local Research and Development Committee, and other study monitors.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Participant Name: _____ Date:_____

Title of Study: AIDI–Research & Development of a Multisensor-Based Technology for real-time automated detection of post-acute COVID-19 sequelae

Principal Investigator: Varsha Vimalananda, MD, MPH VA Facility: Bedford VAMC

Principal Investigator for Multisite Study: Varsha Vimalananda, MD, MPH

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as demographics, HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: Aidar Health, Inc., Venmo or PayPal VA ORD Qualtrics, VA Box.com, the Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO), the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, **Varsha Vimalananda, MD, MPH** and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

INCENTIVES

For your participation, you may be paid up to a total of $600 over the course of the study via Venmo or PayPal. Venmo is a part of PayPal and acts as a digital wallet that allows for funds to be transferred from one person to another. The study sponsor can transfer funds to your Venmo or PayPal account, and these funds can then be directly transferred to your bank account.

The schedule of your compensation will be as follows:

- Upon completion of all monthly study tasks, you will be sent $85.00 via Venmo every month for the first five months of the study.
- Upon completion of study tasks in the last month (6th month), completion of any closing surveys, and successful return of the MouthLab device, you will be sent $175 via Venmo or PayPal.
- You will only receive the incentives if you complete the study procedures.

If you do not already have a Venmo or PayPal account, you will need to create an account. You will be required to consent to the vendor's terms of use and agreement, including providing them some of your personal information, including your contact information and bank account and routing numbers. Venmo and PayPal have administrative, physical, and technical safeguards in place to protect your information and keep it confidential. Your personal information will not be shared by Venmo or PayPal, sold, used, or distributed for any other purpose outside of the outlined research study. Once you have created your account, you will need to provide your username to the study team so we can send you the earned incentive payments.

If you do not feel comfortable with creating or using a Venmo or PayPal account, the study sponsor can send your incentives via personal check directly to your home. Please inform a member of our study staff if this is your preference.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in our study is voluntary. You can withdraw from the study at any time. Your refusal to participate in the study will have no effect on any benefits you receive from the VA, your usual care received as a patient, or your relationships with your doctor or any staff member. If you wish to withdraw from the study, you will no longer be contacted by study staff to collect data. Any data collected prior to your withdrawal might still be used in final study analyses.

If you decide to withdraw from the study, the study staff will contact you to coordinate the return of the MouthLab device and accompanying accessories to Aidar Health, Inc.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION (Include if applicable)

Your participation in this study may be terminated under the following circumstances:

- Pregnancy
- Non-compliance with study tasks

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

For questions about our study or in the event of a research-related injury, please contact Dr. Varsha Vimalananda at 781-687-4949. To contact the Local Patient Advocate, please contact Laura Blake, LISW at 781-687-2612.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

Participant Name: _____ Date:_____

Title of Study: AIDI–Research & Development of a Multisensor-Based Technology for real-time automated detection of post-acute COVID-19 sequelae

Principal Investigator: Varsha Vimalananda, MD, MPH VA Facility: Bedford VAMC

Principal Investigator for Multisite Study: Varsha Vimalananda, MD, MPH

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ , Study Coordinator/Project Manager, has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 2/16/2023

LSI Approval Date: 10/31/2022

LSI Verification Date: 2/28/2023