Study Title

Wearable Assisted Viral Evidence (WAVE) Study A decentralized, prospective study exploring the relationship between passively-collected data from wearable activity devices and respiratory viral infections

ClinicalTrials.gov Identifier

NCT06207929

Document Name

Informed Consent_v2

Document Date

21-Dec-2023

Technical Instructions for the Informed Consent Process

In the next portion you will be asked to complete the following steps:

1. Review and sign the Experimental Research Subject's Bills of Rights. Please note: Everyone will be asked to review and sign this document even if you are not a resident of California
2. Review and sign the Informed Consent Form
3. Re-enter your username and password for your Evidation account to authenticate your signature for this document
2. Review and sign the Authorization to Release Protected Health Information (PHI) for Research
4. Review, complete, and sign the Consent to Participate in this Clinical Research Study - Optional Saliva Sample Collection
5. Re-enter your username and password for your Evidation account to authenticate your signature for this document

Under California law, all California residents must be provided the California Experimental Subject's Bill of Rights. In an effort to comply with the highest standards of clinical research, we ask that all participants, regardless of state of residency, confirm that they have received this document in order to proceed. If you have questions, please reach out to Study Support at wavestudy@evidation.com

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in a research study. As a research participant, you have the following rights:

1. You have the right to be told of the nature and purpose of this study.
2. You have the right to be told about the research procedures, any drugs and/or wearables to be utilized and whether any of these are different from what would be used in standard practice.
3. You have the right to be told about any risks, discomforts or side effects that might reasonably occur as a result of this study.
4. You have the right to be told about any benefits you can reasonably expect from participating in this study.
5. You have the right to be told about other choices and how they may be better or worse than being in this study. These choices may include other procedures, drugs, or wearables.
6. You have the right to be told what kind of treatment will be available if this study causes any complications.
7. You have the right to have an opportunity to ask questions about this study and any procedures involved. You may ask these questions before or at any time during this study.
8. You have the right to refuse to participate in this study or withdraw from this study at any time. This decision will not affect any care you receive from your healthcare provider.
9. You have the right to receive a copy of this form, as well as the signed and dated written consent form for this study.
10. You have the right to be free of any pressure to decide whether you want to be a part of this study.

By signing below, you acknowledge and agree that you have read the information contained on this form and that you fully understand your rights as a research participant.

Electronic signature (please type name below) Date:

CONSENT TO PARTICIPATE IN THIS CLINICAL RESEARCH STUDY

TITLE: Wearable Assisted Viral Evidence (WAVE) Study A decentralized, prospective study exploring the relationship between passively-collected data from wearable activity devices and respiratory viral infections

PROTOCOL NO.: WCG IRB Protocol #20235269

SPONSOR: Evidation Health, Inc

PRINCIPAL INVESTIGATOR: Ernesto Ramirez, PhD, BS, MS
63 Bovet Rd #146
San Mateo, California 94220
United States

STUDY RELATED CONTACT INFORMATION: **Evidation Studies**
415-650-4741 (Voicemail available 24/7)
wavestudy@evidation.com

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your permission (consent) to take part in a research study. This section provides a summary. It describes key information to help you decide if you want to take part. Later sections of this document will provide other important details you need to know.

What should I know about this research?
Your participation is voluntary (optional). You can decide to take part now and drop out later and it will not be held against you. If you sign this form, you are giving your permission (or consent) to participate in this study.

You can also agree to participate in this study and withdraw any time if you change your mind later.

If you do NOT want to participate in the study or decide to withdraw from the study later, this will not be held against you (you will not experience any penalty or loss of benefits to which you are otherwise entitled).

Why is this research being done?
The purpose of this research is to see if data from wearable devices (wrist-worn devices such as a Fitbit,

Garmin, or Apple Watch), lab tests, and surveys can be used to tell if someone has a respiratory illness (flu, COVID-19, or respiratory syncytial virus) and to better understand these illnesses, from the beginning of symptoms to recovery.

What will I be asked to do if I agree to take part in this research?
If you decide to take part in this research study you will be asked to

- complete daily and weekly surveys
- wear a compatible wearable device for at least 10 hours a day
- complete 16 nasal swab kits (including returning the kit as soon as possible within 24 hours of completing the test using the provided shipping materials).

Could taking part in this research hurt me?
You may experience discomfort, nasal irritation and/or a minor nosebleed from the nasal swabs. Incorrect use of at-home sample collection kits can cause harm if, for example, the liquid solutions in the kit touch a person's skin or eyes or if the parts of the test such as small vials containing the liquid solutions are swallowed. Another potential risk is that your study information could be subject to unauthorized access and your data could be linked to you.

Will taking part in this research benefit me?
It is not expected that you will personally benefit from this research.

How long will I be in this research?
We expect that your taking part in this research will last about 10 weeks.

What else should I know about this research?
The nasal swab kits are for Investigational Use Only. The performance characteristics of this product have not been established. These kits will be used for research purposes only. You and your healthcare provider will **not** receive the results of the nasal swab tests completed as part of this research study. No diagnosis or treatments will be provided as part of this research study. If you need any medical advice, please contact your healthcare provider.

The principal investigator for this research, Dr. Ernesto Ramirez, as well as members of the study research staff, are employees of Evidation Health, the sponsor of this research, and may hold private equity in the company. Please contact Evidation Studies Support to ask any further questions you might have about this matter.

What other choices do I have besides taking part in this research?
This is not a treatment study. Your alternative is to not take part in this research study.

DETAILED RESEARCH CONSENT

What do I need to know?
Taking part in this study is voluntary. You can choose not to take part in the study. You can also agree to participate in this study and change your mind later. This is not a medical treatment study. The alternative is not to take part in this study.

Why is this study being done?
Evidation is sponsoring the study and is running the study on their Evidation Studies platform. The Biomedical Advanced Research and Development Authority (BARDA), which is part of the U.S. Department of Health and Human Services, is funding this study and is a research collaborator with Evidation.

This study's primary goal is to explore whether data from wearable devices (for example, steps, sleep and heart rate) and data from surveys can be used to tell if someone has a respiratory illness and better understand the course of illness (from the start of symptoms to full recovery from illness).

How many people will take part in the study?
Around 10,000 people will take part in the study.

Who is funding the study?
Evidation is sponsoring the study and BARDA is funding this study. BARDA is also a research collaborator on the study.

What do I have to do to enroll in this study?
After you sign this consent form, you will be asked to complete the following steps. You'll be considered enrolled in the study once all of the steps below are completed.

- Complete a screening questionnaire to determine your eligibility
- Have your identity verified by Experian Information Solutions, Inc., a third-party vendor, to determine your eligibility. You may be asked to complete identity verification steps. These could include receiving a one-time password to your phone and/or completing a quiz with information about yourself. Some individuals may be unable to have their identity verified by this vendor, and will not be able to continue in the study.
- To meet study requirements, we will then determine if there is available space in the study based on characteristics like your age, sex at birth, and race and ethnicity. This is done to ensure that findings from this research apply to as broad a range of people as possible. There is a chance you may not be able to participate in the study even though you are otherwise eligible.

- Complete an initial survey about your medical history and general health. You will have 7 days to complete this.
- Have your wearable device data checked, to determine your eligibility.
    - We will check whether you have a wearable device connected to the Evidation platform. If you already have a compatible Fitbit, Apple Watch (via Apple Health), or Garmin connected to the Evidation platform, we will link the data from your device to this study. If available, we will link up to 60 days of your activity data prior to you enrolling in this study.
    - We will need to verify that you have a certain amount of wearable data before you are considered eligible to continue. If you do not have the required amount of data to continue, we'll ask you to wear your device as much as possible for up to approximately 30 days so that we can verify your data. If we're not able to verify your data within that time, you will be considered ineligible to continue in the study.
    - If we determine that you do not have a compatible wearable device, you may be shipped a Fitbit while supplies last. Once you receive and connect the Fitbit, you will enter a pre-enrollment period that is expected to last about one week, but may last up to approximately 30 days depending on how often you wear the Fitbit. If we are not able to verify that you completed these steps, you may not be able to fully enroll and participate in the study and may be asked to return the Fitbit.
- Receive your complete set of nasal swab kits
    - Once we determine that you have enough wearable device data to be eligible, our lab partner, MTL, will ship you your complete set of nasal swab kits to be used for the duration of the study. Once we are notified that your nasal swab kits have been delivered, you will be considered enrolled.

What do I have to do to participate once I am enrolled?
Once you are enrolled, you will be asked to complete the following activities for the next approximately 10 weeks:

- Respond to **daily surveys** about whether you experienced symptoms of respiratory illness and symptom severity. These will begin one day after you enrolled, and be sent out at approximately 7 A.M. daily in your timezone until the end of the study.
- **Complete two at-home nasal swab samples per week for 8 weeks (16 kits total).**
    - You should only complete a kit when you are prompted by email on “test days”, which will occur on the same days each week
    - Be sure to write the date you completed the sample on the tube. Without this, we may not be able to process your sample.
- **Ship back each nasal swab sample <u>within 24 hours</u> of collecting each sample**. Pre-paid return shipping labels will be provided by study researchers, at no cost to you.
    - Because this is a time-sensitive activity, **we ask you to collect your sample and ship back your sample on the same day.**

    - Using a separate survey, we will ask you to confirm that you shipped your sample the day after each test day
- Respond to **weekly surveys** about stress, sleep, work productivity, healthcare visits, hospitalizations, and lifestyle changes
- **Wear your wearable device all the time** or for a minimum of 10 hours per day, as many days as possible.

Throughout the study, Evidation staff will monitor whether you are completing study-related tasks (for example, completing surveys or nasal swab kits). You may be contacted by email, text message, and/or phone call with reminders to complete study activities.

Approximately 2,000 of the people who enroll will be asked to take part in an optional saliva sample test. Evidation will select people for this optional study activity. Additional details will be provided in a separate consent form. You can still take part in the WAVE Study if you do not want to participate in this additional testing.

How long will I be in this research study?
The study will take approximately 70 to 100 days (about 10 to 14 weeks) to complete depending on how much wearable device data is available via your Evidation account. Approximately 70 days (10 weeks) of this is considered active study participation after you enroll which includes responding to daily and weekly surveys and submitting nasal swab samples. Additional time of approximately 30 days (4 weeks) may be allowed before you enroll (after you complete the initial survey) for you to sync the necessary amount of wearable data and receive any study supplies in the mail prior to the active study participation period.

- If you already have a compatible Fitbit, Apple Watch or Garmin, and have the required amount of wearable device data, you will be able to enroll after your nasal swab kits are delivered.
    - If you have a compatible device but do not have the required amount of data, we may ask you to wear your device for approximately 30 days or until you sync enough wearable data to be considered eligible
- If we provide you with a Fitbit, we will ask you to wear your device for approximately 30 days or until you sync enough wearable data to be considered eligible.
    - If you have not synced enough wearable data to be considered eligible at the end 30 days, you may be withdrawn from the study and asked to return the Fitbit.

You can choose to stop participating in the study at any time. You do this by contacting your study team or using your Study Dashboard to contact support.

How long will you collect Study Data from me?
Evidation will collect information from you before you are enrolled in the study and during the active study participation period. This is used to confirm your identity and eligibility to take part in this study and to complete the study objectives.

Survey data collection starts on the date you complete this consent form and up to a maximum period of 110 days afterwards. We may stop collection before that period. Reasons we may stop collecting data are:

- if you complete all the study activities
- if you do not complete study activities as instructed
- if you are disqualified or withdrawn by the study team
- if you withdraw your consent
- or if the study ends.

Activity data from wearable devices will be collected up to 60 days prior to enrollment, if available, and up to a maximum of 80 days after enrollment.

What Study Data will you collect from me?
If you are able to enroll in the study we will collect the following information:

- Name, current mailing address, email and phone number
    - Your contact information may be used to communicate with you, send you study materials, and to follow-up with you on any adverse events you report to us, but are not analyzed as part of this research study.
    - Your contact information will be shared with other 3rd parties described below, for the purposes of conducting the study.
- Recruitment information
    - The method that you used to download the Evidation app (if applicable), and the way in which you learned about the study and/or Evidation app (for example, Facebook advertisement, Evidation offer).
- Study Data
    - All screening and survey data you provide to Evidation staff as part of this study, including:
        - Demographic information (for example, gender, education level, ZIP code)
        - Your medical history
        - Your quality of life (for example, stress and sleep)
        - Symptoms related to flu, COVID-19, or RSV
        - Medications and healthcare visits related to flu, COVID-19, or RSV
        - Lifestyle and behaviors related to your exposure
    - Activity data from your Fitbit/Apple Watch/Garmin (for the approximately 10-week duration of the study and up to approximately 60 days before enrollment, where available. For example:
        - Physical activity (for example, steps, wheelchair pushes, workouts, energy or calories burned)
        - Sleep performance (for example, duration, stages, disturbances, latency, overall quality)
        - Heart rate and heart rate variability (if available)
        - Body temperature (if available)

- Oxygen saturation (if available)
- Respiratory rate (if available)
- Stand time (if available)
- Physical capacity (for example, VO2 max; if available)
- Stress (if available)
- Handwashing (if available)
- NOTE: If you are provided a Fitbit as part of the study, you will be asked to download the Fitbit app. We recommend that you select "Allow All" when prompted to connect your device. However, only "heart rate" and "activity and exercise" are required for enrollment. If you select "Allow All", only the activity data listed above will be used as part of Study Data.
- Note: Apple Watch (via the Apple Health app), Garmin, and Fitbit wearable devices capture additional data that may be shared with the Evidation consumer platform. However, the final analysis data set, including data shared with BARDA, will only include those data types specified above.
- Note: If you have an iPhone and have connected Apple Health to your Evidation account, we may collect and use activity data that originates from your paired iPhone, such as steps and/or or energy/calories burned, in combination with data that originates from your paired Apple Watch, Fitbit, or Garmin device.

o Lab results from nasal swabs

This research will not have an effect on your care. The nasal swab kits are investigational and will be used for research purposes only. Neither you nor your doctor will receive the results from the nasal swabs tests.

How will my Study Data be used?

The Evidation research staff and BARDA will use your Study Data to see whether data from wearable devices, lab tests, and surveys can be used to tell if someone has a respiratory illness. Study Data may also be used for research related to this study, to advance other research, and to design future studies. The Evidation research staff may use your Study Data to identify future research or other opportunities for which you may qualify. Taking part in such future research is voluntary and may require you to sign a new consent form.

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

How will my Study Data be kept safe?
Evidation takes steps to keep your Study Data confidential. We will remove your personally identifiable information (PII) and replace it with a code to create Coded Study Data. Your PII, like your name and phone number, is only collected for limited purposes. For example, we may use it to communicate with or to pay you.

We will only publicly share results from this study using a summary of the Study Data from all people. Research results will never contain your name and we will never publicly report your responses.

> **> Read more: Privacy**
> Your Study Data will be stored securely at all times on limited access, encrypted servers by Evidation Health and BARDA. Only authorized staff can view Study Data and all analysis will be done using Coded Study Data. This means that any identifying information like your name and contact information will be removed.

Who will have access to my Study Data?
If you choose to take part, the Evidation researchers will have access to Coded Study Data (Study Data where your personally identifiable information such as your name is replaced with a code). Examples of Coded Study Data on Evidation Studies include all screening and survey data, activity data from your wearable device, and lab results from the nasal swab tests.

A limited number of authorized Evidation Study staff members will have access to your name and contact information. Study staff may need to use this information to contact you if they have questions about your Study Data. But, this information will be stored separately from the Study Data.

The Evidation staff will maintain your Study Data and will disclose your Coded Study Data to BARDA. At any time during this study or after this study is over, BARDA may share summary or coded study results (without your personally identifiable information) with research partners, vendors, or other third-parties for secondary research. This secondary research is research that is not part of this study, and the research is not planned yet; it will be performed in the future. You will not be told about the secondary research. BARDA may also share these results and data with its employees and representatives, including affiliated companies.

Evidation may share your Coded Study Data with approved external research partners for secondary research. This secondary research is research that is not part of this study, and the research is not planned yet; it will be performed in the future. You will not be told about the secondary research. Evidation may also share a summary of study results with external research partners and in scientific publications. Your name and contact information will NOT be shared to reduce the possibility that you could be identified from your data. Summary study results may be sent outside of the U.S.

This research will not have an effect on your care. Neither you nor your doctor will receive your Study Data.

External vendors will have access to portions of your Coded Study Data needed to complete their portions of the study activities. They may also have access to your contact information so that they may communicate with you.

Certain outside companies will be involved in handling and storing your personally identifiable information for the study. These companies are called vendors. They may have access to some of your Study Data for the following reasons:

Vendor	Type of information	Purpose
Experian, Inc.	Your name, date of birth, mailing address, email address, and phone number	To verify identity as part of the study enrollment process. Experian's privacy policy can be found here: https://www.experian.com/help/privacy-policy.html
Hibbert	Your name and mailing address	To provide you with study materials. Hibbert's privacy policy can be found here: http://hibbert.com/privacy-policy/
Molecular Testing Labs (MTL)	Your name and mailing address	To provide you with nasal swab kits and process your test samples. MTL's privacy policy can be found here: https://moleculartestinglabs.com/privacy-policy/
Tremendous, Inc.	Your name, address, telephone number, email	To send you payment for the study. Tremendous' full privacy statement can be viewed by visiting https://www.tremendous.com/privacy.

Regulatory authorities like the Department of Health and Human Services or the Food and Drug Administration (FDA) and the Institutional Review Board (IRB) may see your data as part of their oversight activities.

Will I be paid for participating?

Yes, you will receive up to a total of $141 for completing all study activities. You will only earn payment if you are eligible to enroll and follow the study procedures. If you receive a Fitbit as part of your study supplies, you will be able to keep it - an approximately $100 retail value.

This table below outlines each study activity and the payment timeline:

Study Activity	Maximum Payment	When to Expect Payment
ID verification and completion of initial survey	$10.00	Within approximately 4 weeks of completion of enrollment
Successful wearable data verification	$10.00	

Daily Surveys (70 surveys)		Within approximately 4 weeks of the final weekly survey
Complete 10-30 surveys	$8.00	
Complete 31-50 surveys	$9.00	
Complete 51-70 surveys	$10.00	
Weekly Surveys (10 surveys, $3 each)	$30.00	
Nasal swab samples (16 samples, $4 each)	$64.00	
Total possible payment	**$141.00**	

NOTE: Evidation will pay you for the study activities you complete on time, as instructed. We will not pay you for study activities completed late or left incomplete. We will not pay you for completing any extra activities.

If you fail to follow study instructions multiple times, we will not pay you for certain activities that were completed incorrectly. We may also ask you to return any study-provided Fitbit device (if you receive one) prior to receiving payment. Examples of incorrectly completing study activities include but are not limited to:

- Repeatedly submitting empty nasal swab samples
- Repeatedly submitting nasal swab samples without the date of collection
- Repeatedly submitting more than two nasal swab samples in the same week (which may occur from returning samples late)

If you get payment of $600 or more from Evidation in a calendar year, Tremendous will ask you to fill out a W9 form. The W9 form asks for information like your name, address, and social security number. Tremendous will then send you a 1099 form for tax purposes.

Please note, this payment could be any combination of money, equipment, or devices that add up to $600 or more. This includes payment from **all** Evidation studies in which you take part.

If you are paid $600 or more your taxes may be affected. Please reach out to a tax professional for more information or further questions.

> Read more: Payment
Evidation staff will send your first $10 within 4 weeks after completion of enrollment.

Any pre-enrollment steps that have time limits must be finished on time for you to continue in the study. If the study fills before you finish pre-enrollment steps, there is a chance you might not be able to take part in the study. Weekly surveys must be completed within 3 days of becoming available. Daily questionnaires must be answered by 11:59 PM in the time zone corresponding to your mailing address on the day that it becomes available.

Evidation will pay you for the study activities you complete as instructed. We will not pay you for study activities completed late or left incomplete. If you decide to withdraw from the study, you will receive

the payment you earned before withdrawing.

You will receive payment electronically. You will be sent an email with instructions for how to redeem your payment once we have processed it.

The research that takes place during this study may lead to new tests, technologies, or other commercial products. Evidation may receive additional payment for analyzing the study data or doing other research. You will only receive the payment described in this consent form. No other financial payment or benefits are being offered to you.

What are the potential risks and benefits of this study?
Risks associated with nasal swab samples: Self-collecting nose samples (using the provided swab in the kit) has the potential to cause discomfort, nasal irritation and/or rarely may cause a minor nosebleed. It is normal to observe a small amount of blood on the nasal swab. However, if you experience a nosebleed that does not stop on its own after a few minutes of applying pressure by pinching your nose, please contact your healthcare provider for further assistance.

Incorrect use of at-home sample collection kits can cause harm if, for example, the liquid solutions in the test touch a person's skin or eyes or if the parts of the test such as small vials containing the liquid solutions are swallowed. The liquid solution in some tests may contain chemicals which may cause harm if swallowed or if it comes in contact with skin, nose, mouth, or eyes. The following are recommendations to promote the safe use of at-home sample collection kits:

- Keep all parts of at-home sample collection kits out of reach from children and pets before and after use.
- Store the at-home sample collection kits in its box until you are ready to use it.
- Follow the manufacturer's step by step test instructions exactly.
    - Read the Warning, Precautions, And Safety Information in the test instructions for a description of chemical ingredients and recommendations for safe handling and what to do if they accidentally touch your skin or eyes.
    - Keep the liquid solution away from the skin, nose, mouth, and eyes. Do not swallow the liquid solution.
    - Use only the swab in the test kit to collect a nasal sample.
- After you perform the test:
    - Follow all instructions for how to throw away the used parts. (Please dispose of any extra materials and packaging by placing them in the trash.)
    - Wash your hands thoroughly with soap and water.
- If you spill any of the liquid solution
    - Blot up spills with paper towels or similar materials.
    - Clean the affected area with warm water and detergent or similar.
    - **DO NOT CLEAN WITH BLEACH** or other acid-based products.

Get medical help right away by contacting your local poison control or health care provider if:
Skin or eye irritation does not go away after exposure.

A person or animal swallows the liquid solution.

In addition, this study does not replace the care you currently receive from your doctor. You should seek care from your doctor with any health concerns.

Privacy and confidentiality risks: Your privacy is very important to us. The Evidation study team will make all reasonable efforts to protect the confidentiality and privacy of your data. But, there is still a risk of unauthorized access or sharing of your personally identifiable information (PII). PII is information that can be used to identify who you are, like your name or email. If there is reason to believe that your privacy has been compromised, we will contact you as required by law.

If you decide to take part we will email you a PDF copy of this signed and dated consent form. Risk of loss of privacy and confidentiality may occur if this PDF, study activities, or messages with study staff are viewed or stored on a personal electronic device (PED). The risk is higher if that PED is shared with others, lost, hacked, or subject to a search warrant or court order.

This study requires the shipment of nasal swab kits and a Fitbit, if applicable. As with any shipped package, there is a risk that the package may be lost or damaged. This could impact your receipt of the package or receipt of your package by the vendor. If the package is lost in the mail there may be risk to your privacy because your name and address will be on the package. Neither Evidation nor the vendor has control over any materials lost in the mail.

> Read more: Potential Study Risks

This minimal risk study does not involve the testing of any new or experimental drugs or wearables. You will not be provided with medical advice. You may choose to leave the study at any time.

The potential study risks are associated with the self-collection of nose samples using the nose swabs that are provided in the kit. Insertion of foreign objects (e.g. nose swab) into the nasal cavity has the potential to cause nasal irritation and/or a nosebleed. This is usually a minor nosebleed but if you experience a nosebleed that does not stop after a few minutes of applying pressure by pinching your nose, please contact your healthcare provider for further assistance. Incorrect use of at-home sample collection kits can cause harm if, for example, the liquid solutions in the test touch a person's skin or eyes or if the parts of the test such as small vials containing the liquid solutions are swallowed. The liquid solution in some tests may contain chemicals which may cause harm if swallowed or if it comes in contact with skin, nose, mouth, or eyes. Keep all parts of at-home sample collection kits out of reach from children and pets before and after use. Keep the liquid solution away from the skin, nose, mouth, and eyes. Do not swallow the liquid solution. If you spill any of the liquid solution clean with paper towels and with warm water. **DO NOT CLEAN WITH BLEACH** or other acid-based products to clean up any spills. Please dispose of any extra materials and packaging by placing them in the trash. In addition to these risks, taking part in this research may harm you in unknown ways.

All information collected from you as part of this study will be protected and treated as confidential. However, total confidentiality cannot be guaranteed. There is a risk that your study information could

be subject to unauthorized access or linked to you. Your privacy is very important to us. The study team will make every effort to protect the privacy of your data.

The research team will **not** monitor any of your Study Data for specific values such as test results, activity data, survey responses, etc. during the study. If you experience any concerning changes to your health, you should reach out to your doctor. However, the research team will review the data quality at various times and they may contact you if they have a question about your data.

You are not expected to receive any direct benefit from being in this study. If you take part in this study, the results may help the investigators understand the relationship between respiratory illness and daily behaviors and activity.

What other choices do I have besides taking part in this research?
This is not a treatment study. Your alternative is to not take part in this research study.

Compensation for study-related injury

Seek care from your physician if you are injured as a result of participating in this research.

Due to the coronavirus public health emergency, the federal government issued a Declaration under the Public Readiness and Emergency Preparedness (PREP) Act. If the Declaration applies, it limits your right to sue and recover for losses from the researchers, healthcare providers, any study sponsor or manufacturer or distributor involved with the study, including Evidation and BARDA, while participating in this COVID-19 clinical study.

However, the U.S. government has a program that may provide compensation to you or your family if you experience serious physical injuries or death related to procedures or other actions taken in this study. For more information, or If you would like to make a claim related to this study, please consult the Health Research Service & Administration's Countermeasure Injury Compensation Program: https://www.hrsa.gov/cicp or call 1-855-266-2427.

Except as outlined above, you will not lose any of your legal rights to which you are otherwise entitled by signing and submitting this consent form.

Can I be removed from the study?
The Investigator, Sponsor, or the Funder may stop your participation at any time. This may happen for the following reasons:

- If it appears to be medically harmful to you;
- If you do not follow directions, including the instructions for submitting nasal swab samples;
- If it is discovered that you do not meet the study requirements;
- If suspicious activity or abuse is identified, including falsifying information to receive a Fitbit or other compensation;
- If the study is canceled; or
- For administrative reasons such as:
    - Already having enough people for the study

- The enrollment period ending

If you are removed from the study, we may ask you to return the study Fitbit device if you were provided one.

What if I have questions or want to stop taking part in the study?
You can ask questions about this consent form or the study at any time. Evidation is here to help. Once you are enrolled in the research study you can withdraw from the study at any time.

If you decide to withdraw from the study, survey data collection will end when you withdraw and activity data collected on the Evidation platform after you withdraw will not be used as part of Study Data. However, any data already collected will still be used as described above. If we receive nasal samples that you collected and shipped before you withdrew or if you shipped nasal samples after you withdrew, we may still process and test them. You may still receive automated study messages unless you withdraw using your Study Dashboard.

> Read more: If you want to withdraw from study
Once you are enrolled in the research study, you can withdraw from the study at any time before completing the study. Just go to the Settings section of your Study Dashboard and click the "Withdraw from Study" button. You can click the "Contact Us" button within the Study Dashboard or email wavestudy@evidation.com at any time.

> Read more: Who to contact about study related questions:
For any questions about the study, concerns, or complaints, contact the Evidation Study Team at wavestudy@evidation.com or 415-650-4741, or the study staff listed below. The email address will be available and monitored for 6 months after study completion.

This study has been reviewed by the WCG Institutional Review Board ("WCG IRB"). WCG IRB is a group of people who independently review research. WCG IRB reviewed this study to make sure that your rights and welfare are protected and that this study is done ethically.

> Read more: Who to contact about your rights as study participant:
Contact WCG Institutional Review Board (WCG IRB)
Please reach out to WCG IRB for questions about your rights as a research participant or for questions, concerns, or complaints about the research.

Address: 1019 39th Avenue SE Suite 120, Puyallup, Washington 98374-2115
Phone Number: 1 855-818-2289
Email address: clientcare@wcgclinical.com

> Read more: If you want to contact the researchers in charge of this study:
Principal Investigator: Ernesto Ramirez, PhD
Address:
Evidation Health
63 Bovet Rd #146

San Mateo, CA 94402

I have read all of these study materials. I understand the consent form. I fully understand the contents of this research study as it relates to my participation.

By completing the fields below, I give my consent to take part in this research study. I also consent to receiving standard email communication, texts, and phone calls, from the research team. Standard text message rates apply.

[checkbox] I give my consent to take part in this research study and allow my personal information to be collected and used as described above.

[checkbox] I certify that I am completing this consent on my own behalf and that my electronic signature, as documented by completing the fields below, is a true and binding legal equivalent of my handwritten signature on this consent form.

Electronic Signature (please type name below)
[Electronic Signature Date - Auto Populated]

First Name:
Last Name:

Place of birth (security question):

Phone number:

In order for the system to locate your address, please make sure to enter your information in the following format: 1234 Main Street, Apt 1, San Francisco, CA 94111. Once you begin typing in your address, you'll be able to select from options displayed in the dropdown. Note that office addresses may not be supported by this verification tool.

Current residential address (you will need to be sent research materials for the study) [P.O. Boxes are not accepted for this study]:
Address (include apt / suite #):

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

1. What is the purpose of this section?

This section is required by the Health Insurance Portability and Accountability Act of 1996. Specifically, the privacy regulation (HIPAA) permits the research investigators listed above to use and disclose health information about you for the research study identified above which has been approved by WCG Institutional Review Board. If you agree to the terms of this Informed Consent, you are authorizing Molecular Testing Labs (MTL) to release your Protected Health Information ("PHI") as specified below to Evidation Health, and the study investigators for the purposes of this research. Once it is disclosed to Evidation Health, and the study investigators your PHI will no longer be protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and may be re-disclosed pursuant to the terms of this Informed Consent.

2. What protected health information will be used in this research?

If you provide your consent, the researchers will be able to access certain portions of your PHI, which, combined with information that could be used to identify you, may include the following:

- Laboratory results associated with the nasal swab samples and date of collection
- Laboratory results associated with saliva samples - if you provide them

3. Why do the researchers want my protected health information?

Your lab results will help researchers confirm respiratory viral infections to help researchers explore illness and illness onset using behavioral data.

4. Who will be able to use my protected health information?

Only authorized researchers will have access to your PHI, and will only be able to use it for research purposes pursuant to the terms of this Informed Consent.

5. How will information about me be kept private?

The researchers will keep all patient information private to the extent possible. Only researchers working with the study will have access to your information. The researchers will not release personal health information about you to others except as authorized or required by law.

6. What happens if I do not sign this Informed Consent form?
Participation in this research is voluntary. If you do not sign this Informed Consent form, you will not be able to take part in the research study for which you are being considered. Your treatment, payment, enrollment in a health plan, or eligibility for benefits will not be affected if you do not sign this Informed Consent.

7. What happens if I want to withdraw my permission?
You can change your mind at any time about participating in this study and can withdraw your consent to allow your protected health information to be used in the research. Beginning on the date you withdraw your consent, no new protected health information will be used for research. However, researchers may continue to use the protected health information that was provided before you withdrew your consent. If you sign this form and enter the research study, but later change your mind and withdraw your consent, you will be removed from the research study at that time.

To withdraw from the study, just go to the Settings section of your Evidation study dashboard and click the “Withdraw from Study” button. You can also click the “Contact Us” button within the dashboard or email wavestudy@evidation.com at any time. We will ensure that you are removed from the research population.

8. How long will this permission last?
If you agree by signing this form that researchers can use your protected health information, this permission will last 10 years. However, as stated above, you can change your mind and withdraw your consent at any time.

9. What are my rights regarding access to my personal health information?
You have the right to refuse to sign this consent form. You have the right to review and/or copy records of your protected health information kept by the researcher. You do not have the right to review and/or copy records kept by the researchers associated with the research study.

I have read these study materials in their entirety, understand the consent form, and fully understand the contents of this research study as it relates to my participation.

By clicking the “I agree” box and completing the fields below, I give my consent to take part in this research study and allow my personal information to be collected and used as described above. I also consent to receiving standard email communication from the research team.

[checkbox] I agree:

First Name:
Last Name:

I certify that my electronic signature is the legal equivalent of my manual signature on this consent form.

Electronic signature (please type name below):

[Electronic Signature Date - Auto Populated]

CONSENT ADDENDUM TO PARTICIPATE IN THIS CLINICAL RESEARCH STUDY
Optional Saliva Sample Collection

What do I need to know?
As part of the WAVE study, you can decide to also participate in an **optional** study activity that involves collecting a one-time saliva sample. The Biomedical Advanced Research and Development Authority (BARDA), which is part of the U.S. Department of Health and Human Services, plans to store and use these saliva samples and your coded survey information from the WAVE study (identified only by ID codes) for secondary research, or may choose to not use it. Secondary research is research that is not part of this study, and the research is not planned yet; it will be performed in the future. Types of future research may include exploring how antibodies might be associated with the risk for SARS-CoV-2 (COVID) infection. You will not be told about the future research.

By agreeing to this **informed consent**, you are expressing your willingness to complete this optional activity if selected. Taking part in this **optional** study activity is voluntary. You can also agree to participate in this activity and change your mind later. There is a chance you will not be invited to provide a saliva sample even if you agree to this informed consent.

You can choose not to take part in this study activity. If you do not agree to this informed consent, you will still be able to enroll in the main WAVE study.

The saliva sample kits are for research use only. You and your healthcare provider will not receive the results of any tests completed as part of this research study. No diagnosis or treatments will be provided as part of this optional study activity. If you need any medical advice, please contact your healthcare provider.

You may change your mind about secondary research and withdraw consent for the storage and future use of your coded saliva sample or information at any time until the WAVE study is complete. You will need to contact the study team at wavestudy@evidation.com. Your samples will be removed from future use when the WAVE study is completed. Only stored samples with an ID code and not used in this research can be removed or destroyed. Research that has already begun using your sample cannot be withdrawn. For example, if some research with your saliva sample and data have already been completed, the information from that research may still be used. Also, for example, if the saliva sample and data have been shared already with other researchers, it might not be possible to withdraw the sample and data.

How many people will take part in the optional study activity?
Around 2,000 people enrolled in the WAVE study will be contacted and invited to take part.

What will you be asked to do?
If you are invited, you will be asked to complete the following steps:

- Receive one saliva sample collection kit. We may ask you to complete this step once you enroll in the WAVE study or some time during the 10-week study period.
- Follow the instructions for collecting and shipping your saliva sample when you are asked to do so.
    - Use the saliva swab to collect your sample and screw down the cap to release a stabilizing solution.
    - Tilt the tube to mix the solution and use the provided shipping material to return the sample within 24 hours of saliva collection.

How will my Study Data be used?
We will need your name and address to send you the saliva sample collection kit. Your saliva sample will be stored at a BARDA-designated lab until it is processed. Samples will be identified by a code and will not include any of your identifying information like your name or address. Lab results may be combined with Coded Study Data from surveys collected in the WAVE study, including your self-reported COVID infection and vaccination history.

Saliva samples will be stored indefinitely at a secure location determined by the United States Government or BARDA. Samples will be labeled only with a barcode and a unique tracking number (ID code). These samples will not be labeled with your name or initials, or any other information that could readily identify you, and will be kept confidential to the best of Evidation and BARDA's ability within state and federal law. Staff at the storage facility and future research testing laboratories will not know your identity, or even the study identifier you were assigned. However, the Evidation study staff who enrolled you will keep a list in a secure area with your name, contact information, and the ID code (called a code key) that links the samples to you. Access to the ID code is limited to study staff at Evidation.

If saliva samples are tested in the future, the results may be published. You will not be identified in such publication. In other words, the publication will not contain any information about you that would enable someone to determine your identity.

The results of any future research testing will be kept confidential in the same way as the results of other testing done for this study. The results of any future research, or any test results related to these samples, will not be available to you or your healthcare provider.

This research will not have an effect on your care. The saliva sample kits are investigational and will be used for research purposes only. Neither you nor your doctor will receive the results from the saliva samples.

Who will have access to my Study Data?
The lab that processes your saliva samples will send your Coded Study Data (your antibody levels) to BARDA. BARDA may share summary or coded study results with research partners, vendors, or other third-parties. BARDA may also share these results and data with its employees and representatives, including affiliated companies.

At any time during this study or after this study is over, saliva samples may be shared with other study doctors/institutions and used for future research.

Will I be paid for participating?
Yes, you will receive up to a total of $15 for completing this activity. You will only earn payment if you are selected to participate in this portion of the study and follow the instructions provided.

Are there any risks to being in this optional study activity?
There is a risk of loss of personal information. Your personal information will be protected to the greatest extent possible.

Are there any benefits to you being in this optional study activity?
There are no benefits to you in the collection, storage, and future research use of your saliva sample. Future research tests may benefit others by leading to new approaches in the development of vaccines or treatments for COVID infection.

Although the results of any future research may be patentable or have commercial profit, you will not receive payment if this happens. You will have no legal or financial interest in any commercial development resulting from any future research.

PARTICIPANT'S CONSENT

I have read the **optional** study activity materials in its entirety, understand the consent form, and fully understand the contents of this research study as it relates to my participation.

By clicking the "I agree" box and completing the fields below, I give my consent to take part in this optional study activity (if selected).

I also consent to allow researchers to use my saliva sample as described in the main consent form and in this optional consent form.

You also can **choose NOT** to consent by not signing this form. If you do not consent, we will **NOT** invite you to provide a saliva sample. You will still be able to participate in the main study activities.

- I Agree
- I Do Not Agree

First Name:
Last Name:

Electronic signature (please type name below):
Timestamp of Electronic Signature

I certify that my electronic signature is the legal equivalent of my manual signature on this consent form.