University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants: Rapid, onsite COVID-19 detection

Formal Study Title: Rapid, onsite COVID-19 detection

Lead Researcher: David O'Connor, 608-890-0845

Where Lead Researcher works: University of Wisconsin – Madison, Department of Pathology and Laboratory Medicine

Invitation

We invite you to take part in a research study about an experimental COVID-19 test that gives results fast, and that does not need to be done in a laboratory. We are inviting you because you have shown interest in participating in this study.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and for other research in the future and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

Why are researchers doing this study?

The purpose of this research study is to see whether a rapid COVID-19 test can be performed in a large number of people, at multiple testing locations. The test is designed to identify people who are possibly contagious and likely to spread the virus to others. The rapid COVID-19 test is experimental. This means that the rapid COVID-19 is not a diagnostic test and the results won't go into your medical record.

A 'positive' test result is, however, a potential finding of clinical significance that should be followed-up with conventional diagnostic testing. We are doing this research because if it is successful, we will use the data and lessons learned to determine whether a larger, more ambitious testing program based on the same principles is warranted and could be used as a Point-of-Care test in locations such as schools and nursing homes.

This study is being conducted with oversight from the University of Wisconsin-Madison (UW-Madison). We are hoping that a total of at least 1000 people will participate in this study from multiple sites in the Madison area.

Funding for this study is provided by WARF (Wisconsin Alumni Research Foundation) and the NIH (National Institutes of Health) through a grant administered to WNPRC (Wisconsin National Primate Research Center).

A member of this research team has a personal interest in or might profit financially from the results of this study. This is called a "conflict of interest." The University of Wisconsin-Madison manages conflicts of interest so that they do not affect study participants or the quality of the data collected. Researchers with a conflict are not allowed to obtain informed consent or recruit potential subjects. We are telling you about the conflict of interest in case it affects whether you want to take part in this study.

What will happen in this study?

If you decide to participate in this research study, the researchers will ask you to donate approximately 1 ml (~1/4 teaspoon) of saliva by spitting into a vessel (i.e tube or cup). You may donate your saliva as many times as you want for the duration of the study by either visiting a testing location or by using a home collection kit provided by our team.

Results from this study could be shared with the scientific community and the public in various ways such in publications and presentations or via online databases, open research portals and dashboards. When it is shared in public like this, it will include the date of collection as well as where the sample was collected.

Advanced Molecular Testing

We will also perform advanced molecular testing, such as viral load or viral sequencing, on your saliva. This includes the genetic sequence of the virus. (It does not include information that is specific to the DNA in your body or human genomic data.) We will also perform tests like polymerase chain reaction (PCR) to make many copies of the viral DNA so that we can look for the virus or certain proteins on the surface of the virus. This will be done to help optimize the assay and learn more about the virus.

One of the online databases we will share your data with is GISAID, which is being used to collect all SARS-CoV-2 and other coronavirus sequences to track the spread of the virus globally and when they are appearing in communities. The viral sequences that we create from your saliva sample can help researchers estimate the number of times the virus was independently introduced into Wisconsin, as well as track community-level transmission of the virus.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Your name, the date and location of the sample collection/drop off and the county where the sample was collected.

- A phone number to contact you if you have a potential finding of clinical significance.
- Results of the test (if potentially significant) will be linked to the ID listed on your consent form.

How long will I be in this study?

Your participation in this study will be done either when the testing has stopped for this study or when you have determined you are done providing saliva samples. Once you have signed the consent form, there is no limit to the number of samples you can donate (typically 1 per day) so you will determine when you are done with the study.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study.

Let the researchers know if you change your mind and choose to leave the study or do not want your sample to be banked for future research.

If you decide not to take part in the study, or if you choose to not allow your samples to be banked for future research, your choice will not affect any healthcare treatment relationship, employment, or class standing you might have with the University of Wisconsin-Madison, UW Health, any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by contacting the Lead Researcher, David O'Connor, at dhoconno@wisc.edu or by a written letter to UW AIDS Vaccine Research Laboratory, ATTN: David O'Connor, Science Drive, Madison, WI 53711.

What are my other choices if I do not take part in this study?

You do not have to be in this research study to get a test for COVID-19. If you decide not take part in the study, you have other choices. For example:

- you could get a test for COVID-19 through your healthcare provider
- you could get a test for COVID-19 at a free community testing site run by the National Guard, if one is available

The tests performed at these other options are not experimental, unlike the test being performed in this research study.

Will being in this study help me in any way?

Being in this study will not help you directly. Your participation in the study may benefit other people in the future because if this research project is successful, we will be able to show that a larger, more ambitious testing program based on the same principles is warranted and could be used as a Point-of-Care test in locations such as schools and nursing homes.

Will I receive the results of research tests?

The rapid COVID-19 test is looking at whether you have COVID-19 right now, at the time of the test. It cannot tell us if you have had COVID-19 in the past.

Receiving results is optional. If you choose to receive results and the results of the rapid COVID-19 test are of potential clinical significance, a physician with appropriate expertise will contact you and strongly encourage you to obtain a clinical diagnostic test and self-isolate until the results of that test are known.

The rapid COVID-19 test is experimental and not allowed to be used by your healthcare provider. You will need to get a clinical diagnostic test to confirm any results.

Also, even if the test is accurate, we do not know yet if it means you are immune or protected from getting COVID-19 again.

This means that you will not hear from us at all if the test is negative. A negative result does not mean that you do not have COVID-19 or the infection that causes it: you could; therefore, continue to adhere to all local guidelines until a diagnostic test is performed. Because of this, it is optional to receive results.

☐ Yes, I want to be contacted if my experimental test result is potentially clinically significant.

If checking yes, please provide your telephone number: _____

☐ No, I do not want to be contacted if my experimental test result is potentially clinically significant.

No matter what the results of this experimental research test are, you should not assume that you can relax the prevention measures you have been doing, such as frequent hand washing, , wearing a face mask in indoor spaces that are not your home,

covering your coughs and sneezes, physical distancing, and staying home as much as possible.

If you have questions about the test results or concerns about your health and whether you have COVID-19, you should contact your primary care provider. You (or your insurance company) will be responsible for costs related to any follow-up care.

What are the risks?

There is a risk that your information could become known to someone not involved in this study.

When we give your data and saliva to other investigators or online databases, we will not include your name or phone number. However, we may include the collection date, location and county. Including this information will let researchers understand how COVID-19 has spread in Wisconsin and how the virus has changed over time. It is possible someone could use this information to figure out that positive samples came from you, and that you have COVID-19. We think this is unlikely but it is possible, especially if you live in a county where very few people have tested positive.

There is also the risk that the test may not detect enough virus in your sample to give a clinically significant result but you could still have COVID-19. If your test result is clinically significant, there may be additional stress associated with self-isolating and obtaining a diagnostic test.

Will being in this study cost me anything?

There will be no cost to you for providing a saliva sample as part of this research study. You may have to pay for basic expenses like any childcare, food, parking, or transportation related to study activities.

Will I be paid or receive anything for being in this study?

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.

Researchers may develop products from the samples and information you provide for this study. Some of these products may have commercial value. If the research team or others use your samples or information to develop products of commercial value, you will not receive any profits from products created from your samples or information.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name and other identifiers. We will also store this information securely. The study has a Certificate of Confidentiality from the National Institutes of Health for this study. A Certificate of Confidentiality prohibits researchers from disclosing information or biospecimens that may identify you in a legal proceeding or in response to a legal request without your consent. We may

publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring the safety of this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information and biospecimens that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team
- Other researchers at UW-Madison
- Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The U.S. Food and Drug Administration (FDA)
- Other researchers at universities, private companies, or other kinds of organizations.
- The data will also be shared with the public via publications and open research portals such as openresarch.labkey.com portal.

When we give your data to other investigators or online databases for research projects, we will not include your name or phone number. However, we may include the result, date, location and/or county of where we collected your sample.

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.

Will information from this study go in my medical record?

None of the information we collect for this study will go in your medical record.

What if I have questions?

If you have questions about this research or you feel you have been harmed by participating in this study, please contact the Lead Researcher, David O'Connor, at 608-890-0845. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

Optional study activities

This part of the consent form is about additional research activities that you can choose to take part in. Things to know about these activities:

- They are optional. You can still take part in the main study even if you say "no" to any or all of these activities.
- These activities will not help you directly. The results will help researchers track the spread of the virus globally and improve the assay.
- We will not tell you the results of these optional activities, and we will not put the results in your medical records.
- Taking part in the optional activities will not cost you anything

Banking for Future research

We would like to keep your data and leftover saliva for an indefinite period of time, meaning we have no plans of ever destroying the data or the sample. Keeping data and biospecimens like this for future research is called "banking." The banked data and saliva will be kept in a secure location for use by researchers.

This is what will happen with your banked data and saliva:

We will use your data and saliva samples in future research projects about COVID-19 and coronaviruses. We may also use them for other types of research.

- We may share your data and saliva sample with other researchers at the University of Wisconsin-Madison and outside the University. Other researchers could work at universities, private companies, or other kinds of organizations.

- The research team will maintain a link between your information and saliva samples and your identifiable information.
  You can request to have your data and saliva sample removed from the bank at UW-Madison by contacting the research team at any time. However,

    - Once we have shared your data, there is a chance that it will not be able to be removed or that it has already been downloaded by other researchers and cannot be retrieved.

Indicate your choice by checking the appropriate box.

☐ Yes, you may bank my data and saliva sample for future research.

☐ No, you may not bank my data or saliva sample for future research.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

____
Printed Name

______________________________________ ________________
Signature Date

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______________________________________ ________________
Signature of Person Obtaining Consent and Authorization (Study Team Member) Date