Protocol Title: Surveillance of individuals following SARS-CoV-2 exposure

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PRINCIPAL INVESTIGATOR: Steven M Holland, MD

STUDY TITLE: Surveillance of individuals following SARS-CoV-2 infection

STUDY SITE: NIH Clinical Center

Cohort: Standard

Consent Version: 5 January 2021

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal investigator: Steven M Holland, MD, 301-402-7684, Smh@nih.gov

Study coordinator: Lisa Barnhart, RN, MSN, 301-496-5270, lbarnhart@niaid.nih.gov

KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you make a decision can be found in other sections of the document. Taking part in research at the NIH is your choice.

We are asking you to join this research study because you have a confirmed or probable SARS-CoV-2 infection. SARS-CoV-2 is the name of the coronavirus that has been circulating and causing the 2020 pandemic. The disease this virus causes has been named COVID-19. If you decide to take part in this study, you will be asked to come to the NIH Clinical Center for at least 1 study visit if you have a probable infection. You will be asked to attend at least 2 study visits if you have a confirmed infection. We may ask you to attend additional visits depending on the test results from your first visit(s). The additional visits will be within 7 to 21 days after the previous visit until you have 2 negative tests in a row for SARS-CoV-2. At each visit, we will take your temperature, collect a nasopharyngeal (NP) swab, midturbinate swab(s), saliva sample(s), and a blood sample, and ask you to complete a short questionnaire to collect information about possible COVID-19 symptoms. At the first visit, we will also ask you to complete an online questionnaire about your recent social contacts. We will collect the NP swab by inserting a swab deep into the back of your nose. Most people feel pressure and discomfort during this procedure, and it can cause a nosebleed. For the midturbinate swab, we will swab inside your nose to the middle, but not as far as an NP swab. This may tickle and be uncomfortable. Collecting the blood sample can cause pain, bruising, fainting, and, rarely, infection where the blood was drawn. As part of this study, we may request some of your medical records from outside of NIH to review. If you work at NIH, we may check your OMS record for your SARS-CoV-2 screening results only.

We will use your swabs and saliva samples to test for the SARS-CoV-2 virus and your blood samples to do research tests for SARS-CoV-2 antibodies. We will give you the results of these

tests. This will be helpful to you because it will tell you whether you have developed a SARS-CoV-2 infection. Knowing if or when you develop an infection may help you look for care and treatment options earlier than would be possible under the current recommendations for testing. These test results may be especially helpful because some people never develop symptoms even if they have an infection. People who do not feel sick may not be as careful about following social distancing, and may be more likely to spread the virus. Therefore, knowing you have the virus even if you do not have symptoms may help you be more careful about preventing virus spread.

The information we collect in this study will help us evaluate different ways of testing for SARS-CoV-2. The results of this study could be used to help improve public health guidelines for quarantines and social distancing, including when people can return to work after having contact with an infected person, and could help determine how long a person with an infection might be able to spread the virus.

The remaining document will now describe more about the research study. This information should be considered before you make your choice. Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want toparticipate. Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

The main purpose of this research study is to compare different laboratory tests for SARS-CoV-2 in people who have a confirmed or probable infection.

The results of this study could be used to help improve public health guidelines for quarantines, social distancing, and returning to work after virus exposure.

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this study, you will be asked to come to the NIH Clinical Center for study visits. We will discuss with you where study visits will take place at the Clinical Center and whether any infection control precautions will need to be taken. At each visit, we will take your temperature and ask you to complete a short questionnaire to collect information about possible COVID-19 symptoms. At the first visit only, you will also complete an online questionnaire that includes questions about your recent social contacts. We will collect an NP swab, 1 or 2 midturbinate swabs, 1 or 2 saliva samples, and about 10 mL of blood at each visit. The NP swab is collected by inserting a swab deep into the back of your nose. The midturbinate swab is taken by inserting a swab inside your nose to the middle. For the saliva sample, you will

spit into a tube. We will test the swabs and saliva sample for the SARS-CoV-2 virus using a laboratory test called RT-PCR (reverse transcription-polymerase chain reaction). We may also use these samples for viral culture (trying to grow the virus in a laboratory dish). We will use your blood sample to test for SARS-CoV-2 antibodies. As part of this study, we will check your recent positive SARS-CoV-2 results or ask you for the documentation of those results, if applicable.

HOW LONG WILL THE STUDY TAKE?

If you have a probable SARS-CoV-2 infection and you have a positive RT-PCR test result at the first study visit, we will ask you to continue with additional study visits within 7 to 21 days after the previous visit until you have 2 negative test results in a row. If you have a negative result at the first visit, then you will be finished with the study.

If you have a confirmed SARS-CoV-2 infection and have positive RT-PCR results at study visits 1 or 2 (or both), we will ask you to continue with additional study visits within 7 to 21 days after the previous visit until you have 2 negative test results in a row.

Additional study visits could continue for months or even a year or longer. These additional visits are optional, and you can refuse to attend them at any time.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have approximately 1,000 people participate in this study at the NIH.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

Blood draw: Drawing blood can cause pain, bruising, fainting, and, rarely, infection where the blood was drawn.

NP swab: Most people feel pressure and discomfort during this swabbing procedure, and it can cause a nosebleed.

Midturbinate swab: This swabbing procedure may tickle and be slightly uncomfortable.

Saliva collection: There are no risks associated with this procedure.

What are the risks related to pregnancy?

There are no additional risks for pregnant women, other than those described above.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study.

However, we will tell you the results of your SARS-CoV-2 RT-PCR and antibody tests. This information can help you practice appropriate quarantine and social distancing measures. It may also help us refer you to appropriate care or treatment, if needed, or other research studies.

Are there any potential benefits to others that might result from the study?

In the future, other people might benefit from this study because better laboratory tools for detecting infection may allow for more optimal guidelines for self-quarantining and returning to work. In addition, following people who shed virus for long periods of time to find out whether or not they may be shedding infectious virus will also inform public health and these guidelines.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could look for other studies of SARS-CoV-2. You could also not join any study and continue to follow current guidelines for testing.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

We will tell you the results of the SARS-CoV-2 RT-PCR tests done on your NP and midturbinate swabs and saliva samples, and the results of your antibody test done on your blood samples. These are the same as the clinical tests done at the NIH. These tests are experimental (investigational tests) and have not been approved by the FDA. However, the FDA has allowed these tests to be used under its emergency use authorization.

The viral cultures are for research only and not approved as clinical SARS-CoV-2 tests. Therefore, the results should not be used to make any decisions about your health, and we will not share the results of the viral cultures with you.

EARLY WITHDRAWAL FROM THE STUDY

You may be removed from the study by the investigator for any of the following reasons:

- You do not or cannot follow study requirements.
- If you lose the ability to provide consent for study procedures.

If your participation in this study ends early for any reason, we will still store and use your samples and data unless you ask us not to.

STORAGE, SHARING, AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

Will your specimens or data be saved for use in other research studies?

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding coronaviruses, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices that may lead to development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this

happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

Will your specimens or data be shared for use in other research studies?

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. These researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number, and your data will be labeled with only a code. We cannot offer you a choice of whether your data will be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

How long will your specimens and data be stored by the NIH?

Your specimens and data may be stored by the NIH indefinitely.

Risks of storage and sharing of specimens and data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known; someone could still gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

PAYMENT

Will you receive any type of payment for taking part in this study?

You will receive $10 for each blood draw, $40 for each NP swab, $10 for each saliva collection, $10 for each midturbinate swab, and $20 for each study visit, for a total of $90 for each visit. These total amounts could be slightly higher if you have 2 midturbinate swabs or saliva collections at a visit.

If you are unable to finish the study, you will receive payment for the parts you completed. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically reduced to repay that debt on your behalf.

With few exceptions, study compensation is considered taxable income that is reportable to the Internal Revenue Service (IRS). A "Form 1099-Other Income" will be sent to you if your total payments for research participation are $600 or more in a calendar year.

REIMBURSEMENT

Will you receive reimbursement or direct payment by NIH as part of your participation?

This study does not offer reimbursement for, or payment of, hotel, travel, or meals.

COSTS

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center. The costs for any other medical care provided outside the NIH during this period will not be covered.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

To receive compensation and/or reimbursement, you will be asked to provide your Social Security Number. If you do not provide one, you can still participate in the study, but you may not be able to receive compensation and/or reimbursement.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board.

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might

affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care will be provided by the NIH, the NIH Clinical Center, or the Federal Government.

A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 10, 2020. This Declaration limits the legal rights of a subject participating in clinical studies utilizing COVID-19 countermeasures. Because this study is covered by the Prep Act Declaration, the manufacturers, study sponsor, researchers, healthcare providers and others have liability immunity (that is, they cannot be sued by you or your family).

If you believe that you may have been harmed as a result of this research study, certain claims for serious injury or death caused by the countermeasure may be eligible for compensation through the Countermeasures Injury Compensation Program. This is a program set up by the United States Government. Information about this program can be found at https://www.hrsa.gov/cicp/about/index.html or by calling 1-855-266-2427.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Steven M Holland, MD, 301-402-7684, Smh@nih.gov. Another researcher you may call is: Lisa Barnhart, at 301-496-5270. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process with a non-English speaking subject and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.