Title: Evaluation of Self-Collected Saliva Samples Without Viral Transport Media For SARS-CoV-2 Testing via RT-PCR

NCT number: NCT04604145

Date: 6 April 2021

FORM D – INFORMED CONSENT DOCUMENT

Volunteer Name:	

60TH MEDICAL GROUP
INFORMED CONSENT DOCUMENT

Title of Protocol/Project:	**EVALUATION OF SELF-COLLECTED SALIVA SAMPLES WITHOUT VIRAL TRANSPORT MEDIA FOR SARS-COV-2 TESTING VIA RT-PCR**
FWH #:	FWH20200198H

KEY INFORMATION ABOUT STUDY PARTICIPATION:
Currently, there is an urgent need for widespread COVID-19 testing. Shortages in testing supplies, make it hard to meet this demand so new methods, including saliva (spit) sampling, are needed. The majority of testing currently uses a nasopharyngeal (nose) swab which is both invasive and uncomfortable for patients. We desire to make testing more comfortable and practical. Therefore, we are studying the use of saliva for COVID-19 testing. In order to prove testing is reliable, samples from people who get COVID-19 testing with a nose swab will be asked to provide a saliva sample within 72 hours. The saliva will be tested and both results will be compared. In order to compare, we will need your approval to see your COVID-19 nose swab results in your medical record.

The saliva results will not be in put into your medical record. Participation is voluntary. It should take no more than 30 minutes to complete paperwork and one saliva sample of approximately half a teaspoon (2ml).

INFORMATION ABOUT THIS CONSENT FORM:
You may be eligible to take part in a research study. This form gives you important information about the study. You may be asked to initial in more than one place in this document, as needed. Please take time to review this information carefully. You should talk to the researchers and ask any questions you may have about the study. You may also wish to talk to your friends, family, or a health care provider about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand the purpose and procedures of the study, including risks and possible benefits to you. If you are taking part in another research study, please tell the researchers or study staff.

VOLUNTARY PARTICIPATION:
Your participation in this study is completely voluntary. If you choose not to participate in this research study or leave before the study is completed, your decision will not affect your eligibility for care or any other benefits to which you are entitled as a DoD beneficiary. If significant new findings develop during the course of this study that may relate to your decision to continue to participate in the study, you will be informed.

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PRINCIPAL INVESTIGATOR:

The Principal Investigator (PI) is the researcher directing this study and is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is:

PI Name and Degrees:	Rank:	Branch:	Department and Base:
N. Ryan Hudson	CIV	USAF	Clinical Investigation Facility, Travis AFB

PURPOSE OF THIS STUDY (Why is this study being done?)**:**

The purpose of this study is to prove that saliva collection and testing is an effective way for the military to detect COVID-19. Using this method for COVID-19 testing would avoid the current supply chain back-up which significantly effects military medicine and public health. Another collection method would also allow more flexibility when providing patient care in settings that have limited resources, thus, enhancing mission readiness.

The Air Force Medical Readiness Agency is aiming to approve widespread testing of up to 1,000 individuals a month. The saliva method would make it easier to reach this goal. Additionally, the results of this study could be generalized to the civilian population, allowing us to assess and monitor infection rates in the community. This could potentially have a major impact on schools, large businesses, and other environments.

You have been selected to participate in this study because you are getting a COVID-19 test or was told your COVID-19 test was positive. Your sample may be used to see if the saliva method for COVID-19 is effective. This study will enroll approximately 60 individuals tested for COVID-19. From that group, the results of approximately 30 COVID-19 positive and 30 COVID-19 negative participants will have their nose swab and saliva sample results compared. The remaining portion of samples collected, if allowed and saliva testing was done, will be stored for future testing.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, a publicly available Federal website, 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. Additionally, an IRB-approved copy of the clinical trial template consent form will be posted with no subject information included on the form. You can search this website at any time.

PROCEDURES:

If you decide to take part in this research study, you will be asked to sign this consent form.

You will make contact with study staff to see if you meet study criteria, review and sign study documents, collect additional information, then provide a saliva sample. The total time to complete the visit should be no more than 30 minutes. For the saliva sample, you will be asked to spit into a small tube. You cannot smoke, eat or drink 10 minutes before collecting the saliva sample. After it is collected, it may be tested for COVID-19.

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The research team will check your medical record for the nose swab results and compare it to the saliva sample results.

As a research participant, you will undergo the following procedures:

- You will meet with the study staff to review and sign this consent and HIPAA Authorization form
- Study staff will obtain contact (name, date of birth, email address if you desire future contact) and demographic (age, race, ethnicity, sex) information to record on study forms
- You will be asked to provide a 2 ml saliva sample.
- You will not have to do anything else related to this study. You will NOT be notified of your saliva test results.
- If you indicate your consent, the remaining portion of your sample may be placed into special storage for lab samples where they will be available for use in future studies.

RISKS OR DISCOMFORTS:

Although very unlikely

- Your private information could be released by mistake

For more information about risks and side effects, ask one of the researchers or study staff. There may also be unforeseen risks associated with this or any research study.

WITHDRAWAL FROM THE STUDY:

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and you will not be penalized or lose any benefits to which you would otherwise be entitled if you are a DoD beneficiary.

BENEFITS:

There is no guarantee or promise that you will receive any personal benefit from this study. We hope the information learned from this study may offer another effective collection and testing method for COVID-19 in the future.

COSTS: Will taking part in this study cost anything?

The investigators have designed this study so that there is no cost to you to participate other than what it will cost you to travel to the research site. You will not be reimbursed for these costs.

The extent of medical care provided on this research protocol is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. Your entitlement to medical and dental care is governed by Federal laws and regulations.

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PAYMENT (COMPENSATION):

You will not receive any compensation (payment) for participating in this study.

POTENTIALLY BENEFICIAL ALTERNATIVES TO STUDY PROCEDURES OR INTERVENTIONS:

There are no appropriate alternative procedures or courses of treatment that might be advantageous to the subject for the specific medical condition being researched. However, choosing not to participate in this study is an alternative.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:

Records of your participation in this study may only be disclosed in accordance with Federal law, including the Federal Privacy Act, 5 U.S.C. § 552a, the Health Insurance Portability & Accountability Act of 1996, Public Law 104-109 (also known as HIPAA), and their implementing regulations. DD Form 2005, *Privacy Act Statement-Military Health Records*, contains the Privacy Act Statement for the records.

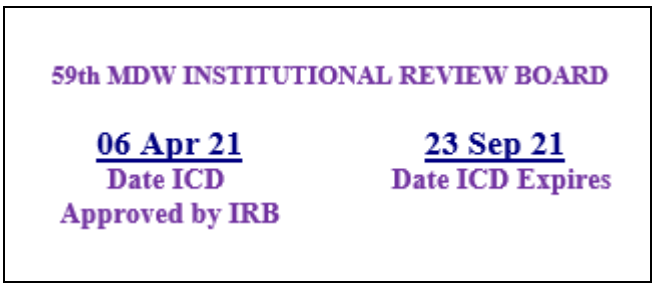
By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further the generalizable knowledge of the medical science community. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), the Air Force, the DoD, other government agencies that oversee human research, the 59 MDW Institutional Review Board, and by authorized 60 MDG personnel. These reviews will help ensure research subjects are being protected and the confidentiality of their records will also be protected to the extent possible under existing regulations and Federal, State and local laws.

This consent will be stored by the investigator in a locked cabinet in a locked room, as part of your research record. Saliva samples used for testing will be labeled with a code generated by a randomizer to create a coded record set for study use which only study staff will be able to decode. None of the information collected during this will be placed in your medical record as it is being collected for research use only.

Information about you collected on this study will be kept in an electronic database, which will be password-protected and access-restricted to people involved in this study. With your consent, after removal of information from your bio-specimens, the de-identified bio-specimens could be used for future research. If you do not authorize the storage of your saliva specimen for future studies or it was not tested, the link between your personal identifying information and your study bio-specimens will be destroyed no later than at the closure of the study. The research information and bio-specimens collected about you for this study will not be used for any additional research activity beyond what you have approved by signing this consent.

The study staff advises that you protect your copy of the informed consent document. A breach of



confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to assist you in contacting the 59 MDW Privacy Office for assistance.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential UCMJ violations or concerns regarding fitness for duty may be reported to appropriate medical, law enforcement, or command authorities.

ENTITLEMENT TO CARE:

If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctors. If you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may also contact the 60 MDG Authorized Institutional Official (AIO), 707-423-7829 or the 59 MDW Authorized Institutional Official (AIO), 210-292-3355.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

BLOOD, TISSUE & BIOLOGICAL SAMPLES:

Before we process your study results, your name will be removed from the identifiable private information and saliva bio-specimen and will be replaced with a six-digit study code. After being re-coded by a Data/Bio-Specimen Repository honest broker, the information and bio-specimens could be used for future research studies or distributed to another investigator for future research studies, without additional informed consent from you.

All bio-specimens kept at the 60 MDG will be handled and disposed of in accordance with Federal regulations and local laboratory procedures. Unless you specifically authorize it in the manner described below, no laboratory or other investigator, whether inside or outside of the 60 MDG, will have permission to use the identifiable or coded samples or research data for any additional research. If you decide to withdraw from the study, any remaining portion of your identifiable or coded specimen (and/or biological sample) will be destroyed. However, any de-identified data already obtained by researchers from your sample will continue to be used for data analysis, as discussed in this protocol.

REPOSITORY BLOOD, TISSUE & BIOLOGICAL SAMPLES:

It is possible that, after this study, your bio-specimens may be used for research generating commercial profit. If so, you will not be entitled to share in this commercial profit.

It is possible that, after this study, your bio-specimens may be used for research involving whole genome sequencing.

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The investigators are asking for your permission to store your data and biological specimens for future use in research studies. (Examples of biological specimens are blood, saliva, tissue specimens obtained from biopsies, and tissues or organs removed during surgery.) These research studies will likely relate to infectious disease treatment and surveillance, but could involve other types of research too. Your samples will be stored with information, such as your age, sex, race, current duty station and research test results. This information will be linked to your sample using an anonymous code. Only the Data/Bio-Specimen Repository manager and/or a designated Data/Bio-Specimen Repository investigator will have the key to link your identity to this code. This information and your sample will be stored in the 60 MDG Clinical Investigation Facility for use in future research. Although this code can be linked to you, it is kept separate from the data and we have control mechanisms to maintain the anonymity of your data and specimens. Because the code exists, and we maintain the ability to trace back to you, this is considered identifying information and can be traced back to you as the donor.

The data and bio-specimen storage repository area is maintained at 60 MDG Clinical Investigation Facility. The Manager, Mr. N. Ryan Hudson, is responsible for the tissue storage bank.

Your samples will be frozen and entered into the bank by associating your COVID-19 status, age, sex, race and sample type with a coded identifier by the Data/Bio-Specimen Repository honest broker. The key to this code will differ from the code used for the research study and will be maintained by a member of the repository team to enable you to have your specimens and data withdrawn from the Data/Bio-Specimen Repository in the future should you choose. Other research investigators requesting portions of saliva samples from the bank will not have access to the key. Other research investigators requesting portions of saliva samples from the bank must have the approval of the Data/Bio-Specimen Repository Manager and must also have a research protocol for this newly proposed study that has been reviewed and approved by an Institutional Review Board (IRB), a committee responsible for protecting research subjects.

Some research studies may include genetic testing of your samples. Since storage (banking) of tissues, organs and other biologic specimens for future genetic testing is still undergoing development, the risks of genetic testing are unknown. It is believed that the risks are very low. However, using new technology(ies) that involve whole genome sequencing of a bio-specimen, it is possible that detailed information about your DNA structure (genetic information) may be obtained and used to indicate your risk or your children's risk for developing certain diseases. This genetic information is unique to you and may indicate changes in your future health status or life expectancy, or that of your children and other relatives. These discoveries could be stressful and could cause psychological difficulties or family problems. It is also possible that during this research, people of your ethnic background may be found to be more at-risk for certain diseases. This could stigmatize your ethnic or cultural group. Release of this information may pose a possible risk of discrimination or increased difficulty in obtaining health insurance, life insurance, or employment. A possible risk of not knowing the test results includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

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A Federal law, the *Genetic Information Non-discrimination Act* of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information. However, GINA does not apply to employers with fewer than 15 employees. GINA's protections in employment do not extend to the US military. Nor does it apply to health insurance through the TRICARE military health system, the Indian Health Service, the Veterans Health Administration, or the Federal Employees Health Benefits Program. Lastly, the law does not cover long term care insurance, life insurance or disability insurance.

The risks currently associated with genetic research would occur most frequently if the confidentiality of data is breached. Because of the consequences of a breach of confidentiality, every effort will be made to protect your privacy. Procedures to protect the confidentiality of the samples and the data stored with the samples include:

Regarding the possibility of informing you of your genetic test results, you should understand the meaning of the following outcomes:

- The information may be too limited to give you particular details or consequences
- You may be determined to carry a gene for a particular disease that can be treated
- You may be determined to carry a gene for a particular disease for which there is no current treatment
- You may be determined to carry a gene for a disease and might consider informing relatives that they, too, might carry the gene

Any tissues you have donated which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the investigators, sponsors and/or others. However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, test or discoveries.

Choose one: (please initial by your choice)

_____ I do not authorize the storage of my data and biological specimens for future use in research studies.
_____ I authorize the storage of my data and biological specimens for future use in research studies.

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With regard to future research studies done on my biological specimens kept at the storage bank:
Choose one: (please initial by your choice)

_____ I do not wish to be notified by investigators in the event of research findings with potential clinical consequence to my family members or myself.
_____ I wish to be notified by investigators in the event of research findings with potential clinical consequence to my family members or myself.

Generally, you (and your provider) will not be provided with the results of the studies using your tissue from this bank. Any results from stored specimens would be of unclear value and unknown clinical meaning.

You may request that your identifiable or coded data and specimens be withdrawn from the tissue bank at any time if you decide you no longer want to participate. This can be done by calling the Tissue Bank Manager listed above at 60 MDG Clinical Investigation Facility Data/Bio-Specimen Repository Administrator/SGSE, 101 Bodin Circle, Travis AFB CA 94535, (707) 423-7272. However, any data or specimens already released to other authorized researchers may be used to maintain the integrity or reliability of their current research.

The following options apply to future contact with you regarding the possibility of gathering additional information for the bank, additional research opportunities, informing you of test results from future research and any other related communication:

Choose one: (please initial by your choice)

_____ I do not wish to be contacted in the future.
_____ I wish to be contacted in the future.

CONTACT INFORMATION:

****In the event of an emergency, dial "911" or immediately seek assistance at your nearest emergency room.****

Principal Investigator (PI):
The principal investigator and an alternate member of the research staff will be available to answer any questions concerning procedures throughout this study.

Principal Investigator: Mr. N. Ryan Hudson Duty Phone: (707) 423 -7272 After-Hours Phone: (707) 628-4163

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Alternate Contact:

Co-Investigator: Maj Benjamin Ramos Duty Phone: (707) 423-3080 After-Hours Phone: (707) 624-6593

Institutional Review Board (IRB):

The 59 MDW Institutional Review Board (IRB), the 59 MDW committee that reviews research on human subjects, will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer at 210-292-4683. You can contact the IRB by calling the Alternate Chairperson of the 59 MDW IRB at 210-292-7363, or by mail to IRB at 59 MDW/STC, 1100 Wilford Hall Loop, Bldg 4430, JBSA Lackland, Texas 78236. If you have any questions about your rights as a research subject, research-related injuries or any other concerns that cannot be addressed by the PI, you can also or call the Research Hotline at 210-292-5146 or 59 MDW Authorized Institutional Official (AIO) at 210-292-3355.

The following options apply to future contact to participate in DGMC COVID-19 research:

Choose one: (please initial by your choice)

_____ I do not wish to be contacted to participate in future research.
_____ I wish to be contacted to participate in future research.

All oral and written information and discussions about this study have been in English, a language in which you are fluent. If you agree to participate in this research study, please sign this section. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction.
- Your consent to participate in this study is given on a voluntary basis.

A signed copy of this form will be given to you for your records.

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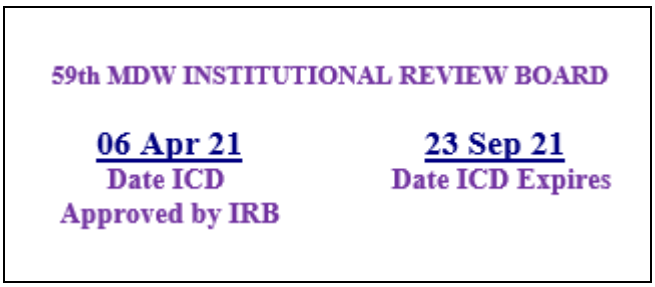

_____ _____

VOLUNTEER'S SIGNATURE **DATE**

_____

PRINTED NAME OF VOLUNTEER

If you desire notifications or future contact, please provide at least one of the methods below:

EMAIL address: _____

PHONE number: _____

_____ _____

ADVISING INVESTIGATOR'S/RESEARCH COORDINATOR'S SIGNATURE **DATE**

_____

PRINTED NAME OF ADVISING INVESTIGATOR/RESEARCH COORDINATOR

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