Title of Study: Effect of oral hygiene products on reducing expelled/exhaled SARS-CoV-2

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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Effect of oral hygiene products on reducing expelled/exhaled SARS-CoV-2
Principal Investigators: Yingda L. Xie, MD (Contact Principal Investigator); David Alland, MD; and Padmapriya Banada, PhD

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to evaluate the effect of common mouthwashes in reducing amount of COVID-19 virus that is expelled or breathed out into the air. From this study, we hope to learn whether mouthwashes would be an effective quick and low-risk intervention, on top of mask wearing and distancing, to potentially reduce infectiousness of someone with COVID-19. If you take part in the research, you will be asked to speak while wearing a face mask, for several 15-minute intervals, provide saliva samples, and rinse your mouth with water and/or a mouthwash. Your time in the study will take about 2 - 3 hours.

Possible harms or burdens of taking part in the study may be discomfort and/or burden of repeated mask wearing while speaking or oral irritation from using a mouthwash. Possible temporary benefit may be a transient reduction of the amount of COVID-19 virus in your mouth if the mouthwash is successful in reducing the virus. However, it is possible that you might not receive any direct personal benefit from taking part in this study.

An alternative to taking part in the research study Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Drs Yingda Xie, David Alland, and Padmapriya Banada are the Principal Investigators of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr Yingda (Linda) Xie (contact Principal Investigator) may be reached at 973-972-2246; 225 Warren Street, E250D, Newark, NJ 07103; yingda.xie@rutgers.edu

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

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Sponsor of the Study: Colgate-Palmolive

Why is this study being done?
This study is being done to evaluate the effect of common over-the-counter mouthwashes on reducing the amount of SARS-CoV-2 virus that is breathed or expelled into the air. This will help us understand if mouthwashes can be useful, in addition to masks and distancing, to reduce infectiousness and risk of transmitting COVID.

Who may take part in this study and who may not?

COVID + Participants (Control and Evaluation Phase):

Inclusion Criteria
- Age greater than 18
- Able to provide consent
- Confirmed to have COVID-19 virus (by a polymerase chain reaction [PCR] or antigen test) within the previous 72 hours.

Exclusion Criteria
- Clinical contraindication or poor feasibility to complete study procedures
- Unwilling or unable to produce saliva or face mask samples
- Unable to produce at least 500 microliters of saliva.
- Eaten within past 30 minutes
- Known allergy to mouthwash products

Healthy Volunteer Cohort: We will also look for 10 or fewer healthy volunteers to ensure that the mouthwashes don't interfere with the accuracy of laboratory tests used in this study. If you are asked to be a healthy volunteer for the study, the criteria for health volunteers are adults able to provide consent who are willing and able to provide at least 2mL of saliva, have not eaten within the past 30 minutes, do not have possible symptoms of COVID, do not have any known allergy to mouthwash products, and have not tested positive for the COVID-19 virus by a PCR or antigen test within the past 30 days.

Why have I been asked to take part in this study?
You have been asked to take part in this study because you tested positive for COVID-19 by PCR within the previous 72 hours and your participation will help further our COVID research.

How long will the study take and how many subjects will take part?
The overall study will take about 6 months and you will be one of about a total of 90 participants in the study. For each participant, the study procedures will take about 2-3 hours, plus a break of at least 30 minutes in the middle. If the sequence of procedures are interrupted, it can be repeated at some point over the next 24 hours.

What will I be asked to do if I take part in this study?

Healthy Volunteers: You will sign the informed consent to take part in the study. You will then be asked to rinse your mouth with water and provide a saliva sample, and after 60 minutes or more, rinse your mouth with a Colgate mouthwash product, and provide a 2nd saliva sample.

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COVID + Participants (Control Phase): You will sign the informed consent to take part in the study. You will then be asked to provide 1 swab sample of both nostrils, up to 6 saliva samples and wear a face mask for 15 minutes (with or without speaking), up to 4 times. If an interruption occurs during the sequence, you may be asked to provide additional saliva and/or face mask samples. Between each round of providing saliva and/or wearing the face mask, you will be asked to perform one of the following: to pause for about 30 seconds, rinse your mouth with water and spit (in a collection cup), or rinse your mouth with a Colgate mouthwash for 30-60 seconds and spit (following the usual package instructions). There may also be breaks of at least 30 minutes before you rinse your mouth with water and/or the Colgate mouthwash. The total sequence from start to end will be around 2-3.5 hours. If the sequence is interrupted, it may be repeated if you are willing, starting with repeating the last saliva and face mask sample collected. Other than sips of water, you will not be able to eat or drink anything 30 minutes prior to and during the mask wearing, saliva collection, and mouth-rinsing sequence.

COVID + Participants (Evaluation Phase): You will sign the informed consent to take part in the study. You will be asked to provide 1 swab sample of both nostrils, up to 3 saliva samples, and wear a face mask for 15 minutes with or without speaking, up to 4 times. After the first round of providing saliva and/or wearing the face mask, you will be asked to rinse your mouth with a Colgate mouthwash for 30-60 seconds and spit (following the usual package instructions), followed by wearing facemask in 3 fifteen minute intervals and providing saliva on the last 2 intervals. This total sequence from start to end will be around 1.5 hours. If the sequence is interrupted, it may be repeated if you are willing, starting with repeating the last saliva and face mask sample collected. Other than sips of water, you will not be able to eat or drink anything 30 minutes prior to and during the mask wearing, saliva collection, and mouth-rinsing sequence

Audiotaping (sound) may be made to record you during the procedure. The recording will be used to confirm the times of the various steps on the procedure and to verify how the procedure was conducted.

What are the risks of harm or discomforts I might experience if I take part in this study?
Discomforts may include feeling claustrophobic when wearing the mask (similar to an N95 mask) or weariness of repeating the same text for four 15-minute sequences while wearing the mask. These are non-serious effects which can prompt discontinuation of the mask wearing and study procedures if you are unable to tolerate.
Risks associated with mouthwash products, which are common over-the-counter Colgate mouthwashes, include rare oral irritation and allergy-type symptoms. Long term use with some of the mouthwash products can lead to staining of the teeth, though would be very unusual after a single use. As the mouthwashes used in this study are all alcohol-free, there should be no burning or discomfort with rinsing. Some of the mouthwashes may foam during the mouth rinse. This study poses no known reproductive risks of harm for pregnant women or their fetuses.

Are there any benefits to me if I choose to take part in this study?
This study will help generate important information about how to potentially reduce the risk of COVID-19 transmission with an easy mouth-rinse intervention. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
There are no alternative treatments available. Your alternative is not to take part in this study.

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How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
Because the results of the saliva, water rinse, and face mask samples are investigational (for research purposes) and not FDA approved, you will not receive the results
In general, we will not give you any individual results from the study because the tests performed in this study are not approved for clinical use. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Will there be any cost to me to take Part in this study?
There will be no costs to you to take part in this study

Will I be paid to take part in this study?
You will receive **$100.00** for taking part in this study according to the following schedule:

- $25.00 if you complete the procedures through the second face mask sample
- $50.00 if you complete the procedures through the third face mask sample
- $100.00 if you complete all of the procedures (through the fourth face mask and saliva samples)

If you travel to our clinic for the study visit, you will additionally receive a stipend of $ 75 for travel and possible loss of time at work.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Your identifiable information (for example, your name) will not be shared with anyone outside the study team. Other information about you and your sample will be identified by a code number. Only this code number, and not your name, will be used on the samples collected in this study. Files that link your name to the code number will be stored in access-restricted file located within a high-security, password protected data platform. We will only release confidential study information if it is ordered by the court of law. You will not be identified by name in any publication or presentation from this study. There are many safeguards in place to protect your information while it is stored in repositories and used for research.

A description of this clinical trial will be available on 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.

What will happen to my information or biospecimens collected for this research after the study is over?
Your samples and information that could identify you will be discarded by 6 years after study completion. However your de-identified data, which can no longer be traced to you, will be retained for at least 6 years after study completion and may be used by or distributed to investigators to complete research limited to this current study.

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What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to: Yingda Xie, MD; 225 Warren Street, E250D, Newark, NJ 07103; or yingda.xie@rutgers.edu

Any data that has already been sent to Colgate-Palmolive (Sponsor) or to the Data Coordinating Center cannot be withdrawn because there may not be any identifiers with the data.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I contact if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Yingda Xie, Department of Medicine; yingda.xie@rutgers.edu; (973)-972-2246

If you have questions about your rights as a research subject, you can contact the Rutgers IRB Director at: Newark HealthSci IRB, 65 Bergen St., SSB 511, Newark, NJ 07107, (973)-972-3608; or the Rutgers Human Subjects Protection Program at (973) 972-1149, email us at humansubjects@ored.rutgers.edu., or write us at 65 Bergen St., Suite 507, Newark, NJ 07107.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?
- Symptoms, medical history, and treatment
- Oral intake
- Medications

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- Consultations
- Laboratory/diagnostic tests or imaging
- Dental records
- Physician and nursing reports
- Hospital discharge summaries
- Radiology records or images (CXR, CT scans)

Who May Use, Share or Receive My Information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved In The Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Non-Rutgers Investigators on the Study Team: Professor Michael Barer, University of Leicester, UK is a consultant in this study. Dr Barer's team developed the face mask sampling procedure and will work with us to optimize the mask sampling procedures used in this study.
- **Persons or organizations not affiliated with Rutgers:** Colgate-Palmolive

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Is there anything else I should know?
Dr. David Alland, one of the Principal Investigators in this study receives licensing fees and research support from Cepheid, Inc. Cepheid, Inc makes and manufacturers tests for the COVID-19 virus. There are currently no plans to use any Cepheid tests in this study, though it may be possible in the future.

Will I Be Able To Review My Research Record While The Research Is Ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Yingda Xie, MD; 225 Warren Street, E250D, Newark, NJ 07103.

How Long Will My Permission Last?

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There is no set date when your permission will end. Your de-identified health information collected in this study will be kept for at least 6 years after study completion and may be studied for many years.

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____