

Informed Consent Form

Network-Targeted Strategies for Efficient Community SARS-CoV-2
(COVID-19) Sampling (Snowball)

NCT04437706

17 May 2022



Consent to Participate in a Research Study

ADULT

Duke RDS²: Respondent-Driven Sampling for Respiratory Disease Surveillance, the Snowball Sampling Study

CONCISE SUMMARY

The purpose of this research study is to learn about how COVID-19, the illness caused by SARS-CoV-2 or “coronavirus,” spreads in the community. The information we learn may help us to understand how the virus spreads so that we can target testing resources to key groups in the community.

Participants in this study will answer an online questionnaire and receive a coupon for a convenient appointment for a free coronavirus test. The test involves a health provider inserting two testing sticks (nasopharyngeal swabs) into your nose that will tell if you currently have the virus. You will also be asked to provide a blood sample from a vein in your arm that will tell if you have been exposed to the virus in the past via antibody testing. Your active participation will last a total of approximately 1 hour and 15 minutes. Your test result will be provided to you within 48 hours.

The greatest risks of this study involve temporary discomfort from the tests.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study called “Snowball” because you have either tested positive or may have been exposed to the coronavirus. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As you read this consent form, please let us know if there are any words or information that you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you choose to not participate we would like to ask you why you choose so but you are under no obligation to provide an answer.

WHO IS CONDUCTING THIS STUDY?

This study is being conducted at Duke University by Dr. Dana Pasquale, Dr. Christopher W. Woods, and Dr. James Moody .

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn about how the coronavirus is spreading in our community through “network sampling.” Some people who are infected with the coronavirus become very ill with fever, headache, body aches, coughing, and trouble breathing, but others do not appear or feel sick. Even though these people seem to be healthy, they may be able to pass the virus on to other people. We want to be able to identify people who have been exposed and infected with the virus to find out how the coronavirus is spreading through the community.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 1,000 people will take part in this study at Duke.



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WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will go to a web link where you will be asked to sign and date this consent form. You will answer a brief online questionnaire where you will answer some questions about yourself and your contact network. If you received a coupon to participate from another person then the Snowball study team will contact you by telephone after you finish the survey to schedule an appointment for convenient coronavirus testing at a Duke study Site or at your home. We will access your medical record at Duke to verify the results of your tests and obtain information about your health history.

For people who received a coupon from another person and make the appointment for a coronavirus test as a part of the Snowball Study:

After you receive your appointment and take your convenient coronavirus test, you will receive your test results within 48 hours. One of the following will happen:

- If your coronavirus rapid or acute swab test (the ones taken from your nose or throat) is negative, you will know that you do not have the coronavirus and should continue to keep yourself healthy through social distancing. You may receive up to 10 coupons to give a family member, co-worker and other person in your social network with whom you have been in contact. Each coupon contains a special code which can be used one time that will allow that person to participate in this study and receive their own, free coronavirus tests. After you give out any coupons that you receive, your participation in this research study is over, but you will have the opportunity to enter another study, CovIdentify, where you may be given a smartwatch to monitor you for signals that you might have gotten a virus. If you already own a smartwatch, you may also choose to enroll in that study on your own. If you choose to enroll in CovIdentify then we will share your information with that study so that you don't have to answer the same questions twice.
- If your coronavirus rapid or acute swab test is positive, it means that you have the coronavirus right now and you should isolate yourself for 5 full days from the date that your symptoms started or from your positive test if asymptomatic, wear a mask for 10 days from the date that your symptoms started or from your positive test if asymptomatic, and take actions to not spread the infection. You may receive up to 10 coupons to give a family member, co-worker and other person in your social network with whom you have been in contact. Each coupon contains a special code that can be used one time that will allow that person to participate in this study and receive their own coronavirus tests. After you give out any coupons that you receive, your participation in this research study is over. You will also have the opportunity to join another study, called CovIdentify, which will ask you to share any smartwatch data that you might have. If you choose to enroll in CovIdentify then we will share your information with that study so that you don't have to answer the same questions twice.
- We will not test the blood right away. We will contact you with those results, probably in 3-6 months. If your blood test is negative, you will know that you have probably not had the



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coronavirus in the past and should continue to keep yourself healthy through social distancing. Your participation in this research study is over, but you will have the opportunity to enter another study, CovIdentify, where you may be given a smartwatch to monitor you for signals that you might have gotten a virus. If your blood test is positive, you have probably been exposed to the coronavirus in the past.

If possible, you should isolate yourself and limit your contact with others while waiting for your coronavirus nasal swab test result.

Your participation in this research study is voluntary and you can end your participation at any time. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you receive a coupon and decide that you do not want to participate, you can either give the coupon to someone else or throw it away. If you sign this consent form and complete the survey but decide that you do not want to take the test, you can either cancel your test appointment or not show up for the test.

You do not have to reveal the result of your coronavirus test to people who receive a coupon from you. You can simply tell them that we are inviting contacts of some study participants to also participate in this research study and receive a convenient coronavirus test and that you would like to give a coupon to them.

HOW LONG WILL I BE IN THIS STUDY?

This study will require approximately 1 hour and 15 minutes of your time. It will take about 45 minutes to read and sign this consent form and to answer the online survey. Since you will have an appointment for your convenient coronavirus test, your test may require about 30 minutes of your time.

WHAT ARE THE RISKS OF THE STUDY?

There are minimal physical risks associated with this study. The coronavirus test may cause momentary discomfort while the stick or swab is in your nose. You will also have blood drawn (about 2 teaspoons) from your arm to see if you have been exposed to coronavirus in the past via antibody testing. Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to you. You will know whether or not you currently have or have been exposed to the coronavirus. If your test results are negative, you can continue social distancing which has been effective for you up to the time that you



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took your test. If you do not have active coronavirus but have antibodies in your blood, you have been exposed to coronavirus but did not feel sick. At this time, we do not know if having antibodies in your blood will prevent you from getting coronavirus again in the future.

If you receive a positive coronavirus swab test (the ones taken from your nose or throat) result, this means that you do have the coronavirus and should take extra care to isolate yourself for 5 full days by not leaving your home. You should social distance from others in your home and wash your hands frequently, wear a high quality mask around your nose and mouth, use a separate bathroom, and sleep in a separate room, where possible. We hope that the information learned from this study will help us understand how the coronavirus spreads in a community.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

If you joined this research study after receiving a coupon from someone you know, please be aware that the person who gave you the coupon will know how many of their coupons were used. Based on that information, they may be able to figure out if you do, or do not, participate in the survey. They will not be given information regarding the results of your coronavirus test or the answers to your survey questions.

As part of this study, you will be asked to have coronavirus tests. The test results will be recorded in your medical record and will be reported to the research data office at Duke and to the local health department. By law, all positive results will be reported to the State of North Carolina public health department. The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private.



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If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2. you have consented to the disclosure, including for your medical treatment; or
3. the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

WHAT ARE THE COSTS TO YOU?

There are no direct, financial costs to you for participating in this research. The coronavirus tests are being provided to you free of charge. Participation will require your time to complete this consent form and the online survey, and also the time that it takes you to participate in the convenient coronavirus test.

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles, or medical care related to COVID-19, which occurs during or after your participation in this study. Routine medical care services are those that you would have received for your health if you were not participating in this research study. Not all services are covered by insurance.



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WHAT ABOUT COMPENSATION?

You will be paid for participating in this research study. The amount of payment depends on completing required research activities in a certain time period.

- You will receive \$15 for completing the survey before your invitation (coupon) expires.
- If you received a coupon from another person to participate then you will receive \$25 for the coronavirus testing (nasal swab, nasopharyngeal swab, and blood collection), If you were contacted to participate by Duke after your positive coronavirus test result, you are not eligible for this \$25 payment.
- If you are diagnosed with active coronavirus (on a nose or throat swab) or if you are believed to be part of a Durham community at risk, you may be given up to 10 “coupons” with unique codes to enroll some of your close contacts into the study. Each coupon is good for 1 person. You will receive additional compensation if any of the people that you gave a coupon to enroll in the study and take the survey before their coupon expires (the expiration date will be on the coupon).
 - You will receive \$5 for any person who enrolls in the study and takes the survey before their survey expires.
 - We will make recommendations for the people that you could give coupons to. You don’t have to follow our recommendations, but you will receive an additional \$5 (up to \$10 per person or coupon) if the person that takes the survey is one of the people that we recommended.
- If you are diagnosed with coronavirus, or if you were already diagnosed with coronavirus before your participation in the study, and own a smartwatch you could receive \$25 if you agree to enroll in the CovIdentify study and share some of your monitoring data, such as heart rate, temperature, blood pressure, or pulse oximetry (blood oxygen level).
- If you do not have and have not previously had coronavirus then you may have the opportunity to enroll in the CovIdentify study in exchange for a Garmin smartwatch.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Dana Pasquale at 919-681-6801 during regular business hours and at 919-681-6801 after hours and on weekends and holidays.



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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Dana Pasquale in writing and let her know that you are withdrawing from the study. Her mailing address is Duke University, Box 104023, Durham NC 27710.

If you received a coupon from another person and get tested: If you agree to allow your blood or nasopharyngeal swab to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time. We ask that you contact Dr. Dana Pasquale in writing and let her know you are withdrawing your permission for your identifiable blood to be used for future research. Her mailing address Duke University, Box 104023, Durham NC 27710.. At that time, we will ask you to indicate in writing if you want the unused identifiable blood destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

I allow my samples to be used for future research. YES NO Initials: _____

If you choose for your samples to be stored in a COVID-19 biorepository (place to store biological samples such as blood) then you will be asked to sign a separate consent form.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Dana Pasquale at 919-681-6801 during regular business hours and at 919-681-6801 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and

