Rutgers Corona Cohort Study

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RUTGERS
Robert Wood Johnson
Medical School

Department of Medicine
Division of General Internal Medicine

Title of Study: Rutgers Corona Cohort Study
Principal Investigators: Jeffrey L Carson, M.D. and Reynold A. Panettieri, Jr., M.D.

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: determine the reasons why some people might become infected and get sick from the novel coronavirus (COVID-19). If you take part in this study, you will be asked to answer questions about yourself and your health in questionnaires. You will allow us to take blood samples and get saliva and swabs of your nose or throat to check for signs of the virus. Your first visit will take about 30 minutes (10-15 minute questionnaire and 15 minutes to draw your blood and get saliva and swab your nose or throat). Later visits will be about 20 minutes (5 minute questionnaire and 15 minutes to draw your blood and get saliva and swabs your nose or throat). Over the 6 months you are in the study, you will complete 17 questionnaires total and have your blood and nasal samples collected 6 times.

Possible harms or burdens of taking part in the study may be discomfort with giving samples, and possible benefits of taking part may be early detection of COVID-19 infection.

An alternative to taking part in the research 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?
Jeffrey L. Carson, M.D. and Reynold A. Panettieri, Jr., M.D. 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.

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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. If you complete the consent by e-mail, you will be provided with a signed copy that you can download.

Sponsor of the Study: Rutgers University

Rutgers University is the sponsor of this research study. They are providing the support for study doctors to conduct this study according to a budget that will cover the costs of collecting all of the information and samples required by the study.

Why is this study being done?

The coronavirus disease-2019 (COVID-19) is starting to spread around the United States. We are trying to learn the reasons why some people might become infected and get sick from this virus. These reasons could include the kind of work you do (for example, in the hospital with patients), possible exposures outside of work, and genes (portions of your DNA) related to the infection or the response of your immune system.

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

People age 20 or older who work at least 20 hours/week at Robert Wood Johnson University Hospital in New Brunswick, New Jersey, at University Hospital in Newark, or at Rutgers University (Newark, New Brunswick, or Piscataway campuses) can be in this study. Research staff with direct in-person contact with research participants can also participate in the study. People who have previously been diagnosed with COVID-19 cannot participate.

You cannot be in the study if you are pregnant or if you have diagnosed with a new medical condition in the past 30 days or if the medications that you usually take have been changed in the past 30 days. You cannot be in the study if in the past 30 days you have been hospitalized, had an emergency room or urgent care visit, or if you have had surgery. You cannot be in the study if you have a fever on the day of your first visit to the study site (for consent, biospecimen collection, etc.).

Why have I been asked to take part in this study?

You are being asked to take part in this study because there is a lot we do not yet understand about the coronavirus in health care workers compared with non health care workers who are affiliated with Rutgers. Working together as a community, we can help scientists learn about what puts certain people at risk for getting sick from the virus.

How long will the study take and how many subjects will take part?

There will be a total of 500 participants (age 20 and older) who are health care workers and 250 people who are not health care workers in the study. Your participation in this study will last 6 months. Your time in the study will take about 30 minutes for the first visit and 20 minutes each for the 5 subsequent visits. In between visits you will be asked to complete 16 additional questionnaires online on or in person. Each one takes about 5 minutes.

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

If you take part in this study, you will be asked to complete questionnaires and to provide saliva, swabs from your nose or throat, and 4-6 teaspoons of blood at a number of time points across a six month period. You will also be asked to take your temperature.

Questionnaire: At the time you enroll in the study, you will complete an initial approximately 15 minute questionnaire about yourself, including items on your age, where you live, your role at work (example:

faculty or staff), whether you have contact with patients, and how you get to work. You will also be asked questions about your lifestyle and health, including what medical problems you have, what medicines you take, and whether you have come in contact with anyone diagnosed with the coronavirus. You will also provide your contact information and the names and contact information of 2 individuals who know you well to use if you have missed a study activity and we are not able to reach you. Sixteen additional 5 minute questionnaires over the next six months including items about symptoms you may have and whether you have had contact with others who are ill. You will be able to complete the 16 questionnaires on a secure website online or in person at our study locations.

If your questionnaire indicates that you are having new symptoms, we may ask that you have blood specimens, saliva, and nose or throat swabs taken for testing at that time, even it is not when you were normally scheduled to come in for blood, saliva, and nose or throat swab collections. If you have completed the survey online, a study nurse or doctor will call you to ask that you come in to one of our testing sites (Clinical Research Units and in patient study stations) for testing as soon as possible.

Blood, saliva, and nose or throat swabs: We will ask you to come to one of our study locations where trained members of our research team will draw about 4-6.5 teaspoons (20-32.5 ml) of blood, have you spit into a container, and take a swab from your nose or throat. If you weigh less than 110 pounds we will reduce the amount of blood that is taken. These samples will then be sent to the study research laboratory at Rutgers University RUCDR, Piscataway, New Jersey where they will be stored and analyzed for infection.

You will take your temperature every day for the next 2 months and record the results on the same secure website as your questionnaire responses.

If you develop symptoms that you believe could be consistent with coronavirus infection, we will also ask you to call one of our study nurses or doctors at 973-972-3173 (Newark) or 732-235-6402 (New Brunswick/Piscataway) or email COVID-HCW@rbhs.rutgers.edu

Below is the schedule of study activities for participants:

Activity	Baseline	Daily for 2 months	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Months 3 to 6	Months 4 and 6
10-15 minute questionnaire	x											
Blood specimen, saliva, and nasopharyngeal/throat swab	x			x		x				x		x
Temperature	x	x										
5-minute questionnaire			x	x	x	x	x	x	x	x	x*	

*Twice per month

If the study tests indicate that you have become infected with the coronavirus during this study, you will be directly contacted by one of the study nurses or doctors who will provide you names of local clinicians with expertise on COVID-19, but the choice of care will be yours. We also will suggest what actions you should take based on the results but will not provide direct medical care. We will instruct you to stop working, and we will inform the appropriate personnel at your place of work (e.g., hospital infection control, occupational health, student health, human resources) that you have tested positive for COVID-19.

If you agree, we will have you sign a form that, should you develop an infection, gives the study doctors permission to review all of your medical records related to the infection for the 6 months that you are in the study, or until the infection clears.

We may ask that you talk with your household members about participating in a related study about exposures and illness in people who live with study participants.

What are the risks of harm or discomforts I might experience if I take part in this study?

Questionnaire: We will ask for certain information that you may not want others to know, such as how much you smoke. We will also ask you about stress in your life which may make you uncomfortable. You are free to not answer the questions if you choose.

Samples:

- Blood: When blood is drawn, there may be a bruise, or bleeding, or infection, at the place where the blood is drawn. However, infection is rare.
- Swabs: You may experience brief discomfort from getting a swab of your nostril or throat.

Psychological or Social Risks Associated with Loss of Privacy:
Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. Further, patterns of genetic variation also can be used by agencies to identify a person or his/her blood relatives (for example, to establish relationships between parents and their children).

Economic Risks of Harm:
Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Therefore, your genetic information potentially could be used in ways that could cause you or your family economic distress.

There is a federal law call the Genetic Information Nondiscrimination Act (GINA) that helps protect against genetic discrimination. In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Are There Any Benefits To Me If I Choose To Take Part In This Study?

The benefits of taking part in this study may be early detection of coronavirus infection, and knowledge that you are antibody positive with immunity from the disease. You will also receive a free new thermometer (depending on availability) to use for this study which you may keep for your personal use.

By working together as a community, we can learn more about the spread of the coronavirus and the reasons why some people get sick. We hope that this information helps other people affected by COVID-19 in the future. In time, as new treatments become available for COVID-19, such as medicines or vaccines, people who take part in this study may be eligible to take part in early studies to test those treatments.

What Are My Alternatives If I Do Not Want To Take Part In This Study?

Your alternative is not to take part in this study.

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?

If the study tests indicate that you have become infected with the coronavirus a study nurse, or doctor will contact you immediately by telephone and provide you with guidance as to what medical attention you should seek. We will also share the results with your place of work so that they can decide how best to alert those with whom you may have had contact.

Will There Be Any Cost To Me To Take Part In This Study?

There will be no costs to you for participating in this study.

Will I Be Paid To Take Part In This Study?

We will provide $25.00 for each regularly scheduled sample collection visit that is completed. This compensation for your time will be via a ClinCard, which is a specially designed debit card for clinical research.

Greenphire, the company which developed the ClinCard, will act as an agent of Rutgers University to manage the payment. You will be given a Greenphire ClinCard, which is a debit card that your study payments are loaded onto following completion of study visits. When a study visit is completed, the payment will be approved and loaded onto your card. The funds will be available within one hour of the completed visit, unless the study coordinator advises you that it may take a little longer. You may use the ClinCard as you choose. You will be issued one ClinCard for the duration of your study participation. If your card is lost or stolen, you can contact ClinCard support at (866) 952-3795. This phone number is also on the back of the card. If you do need a replacement card and you obtain it directly through the ClinCard customer support service, it will be mailed to your address. In that event, the balance from your lost card will be loaded onto your replacement card, minus a $7 replacement fee charged by the customer support service. Or, you may request a replacement card during your next visit with your study coordinator, who will provide you with a replacement card for a fee of $3.50, which will be subtracted from your ClinCard balance.

How Will Information About Me Be Kept Private Or Confidential?

Rutgers will make every effort to keep the information collected from you private. In order to do so, we will assign all of your study materials (including your stored biological samples) a study number and remove all identifying information. All documents with your name on them will be kept in a locked file or encrypted (made impossible to read) on a computer. Only the study team will have access to this information. All staff associated with the project will be trained in procedures for maintaining confidentiality. Results of the research may be presented at meetings or in publications, but your name and identity will never be disclosed. Sometimes, however, researchers need to share information that may identify you with people that work for the University, government regulators, or study sponsor.

If you do become infected during this study, you will be directly contacted by one of the study nurses or doctors. We will also inform human resources at your place of work about this infection.

What Will Happen To My Biospecimens or Information Collected For This Research After The Study Is Over?

After information that could identify you has been removed, de-identified information and biospecimens collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you. Personal details that identify you, such as your name and date of birth, will not be shared in the future without your additional permission.

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.

Beginning on the date that you withdraw your approval, no new personal health information will be used for research. However, the study doctor/investigator may continue to use the health information that was provided before you withdrew your approval. To withdrawal your approval you must do this in writing to Jeffrey L Carson, M.D. Rutgers, Robert Wood Johnson Medical School, 125 Paterson Street, New Brunswick, New Jersey 08901

Who Can I Contact If I Have Questions?
If you have questions about taking part in this study you can contact the Principal Investigator: Jeffrey L Carson, M.D. Rutgers, Robert Wood Johnson Medical School, 125 Paterson Street, New Brunswick, New Jersey 08901, Telephone: 732-235-7122 email: jeffrey.carson@rutgers.edu or Reynold A. Panettieri, Jr., M.D. Child Health Institute of New Jersey, Rutgers, The State University of New Jersey, 89 French Street, New Brunswick, NJ 08901. Telephone: 732-235-6404, email: rp856@rbhs.rutgers.edu

If you have questions about your rights as a research subject, you can contact the Rutgers IRB Director at: New Brunswick/Piscataway HealthSci IRB 335 George St., Liberty Plaza Ste. 3100, New Brunswick, NJ 08901, (732)235-9806 or the Rutgers Human Subjects Protection Program at (973) 972-1149, email 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?
If you become infected by the coronavirus, we will request copies of medical records up to 6 months after enrolling in the study.

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
- The National Institutes of Health
- Other institutions and scientists who are studying COVID-19 and the coronavirus.

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.

We may share your health and genetic information through the National Institutes of Health (NIH) database of Genotypes and Phenotypes (dbGaP) study. By sharing this information, the hope is to maximize the chance for researchers to use and learn from your information to better understand COVID-19. The NIH dgGaP study team will work with Drs. Carson, Panettieri, and the study team from Rutgers to coordinate the secure transfer, storage, and access of your information. The NIH dbGaP study team will make sure that this information cannot be used to identify you and that it remains password-protected and available only to qualified researchers studying COVID-19.

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 from the time you withdraw (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: Jeffrey L Carson, M.D. Rutgers, Robert Wood Johnson Medical School, 125 Paterson Street, New Brunswick, New Jersey 08901, Telephone: 732-235-7122 email: COVID-HCW@rutgers.edu or Reynold A. Panettieri, Jr., M.D. Child Health Institute of New Jersey, Rutgers, The State University of New Jersey, 89 French Street, New Brunswick, NJ 08901. Telephone: 732-235-6404, email: COVID-HCW@rutgers.edu.

How Long Will My Permission Last?
There is no set date when your permission will end. Your health information may be studied for many years.

AGREEMENT TO PARTICIPATE IN BASELINE QUESTIONNAIRE ONLINE

Subject Consent:

I acknowledge that I am 20 years of age or older and have read and understand the information. I agree to take part in the research, with the knowledge that I am free to withdraw my participation without penalty. I understand that after completing the baseline questionnaire online, I will be asked to meet with a study coordinator at one of the study locations (Clinical Research Units and inpatient floors). At that time, I will be able to ask questions about the study and should I choose to continue, I will be asked to sign informed consent for all additional study activities in person.

Subject Name (e-signature):_____

Subject e-mail:_____ Subject phone number:_____

Date: Time:

AGREEMENT TO PARTICIPATE IN ALL STUDY ACTIVITES TO BE COMPLETED IN THE PRESENCE OF STUDY STAFF

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:_____

Optional:

I prefer not to allow my genetic information to be used for this research. Initials:_____

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 Name (Print):_____

Signature:_____ Date: _____