INFORMED CONSENT DOCUMENT

Project Title: **Contact Network Transmission Modeling of Healthcare Associated Infections**

Principal Investigator: Alberto Segre

Research Team Contact: Shelby Francis, 319-775-0689

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you have been diagnosed with COVID-19.

The purpose of this research study is track symptoms and temperatures for 10 days in patients who have been diagnosed with COVID-19.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 500 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 10 days. Information will be collected from you virtually via online surveys. There will be no in-person visits for this study. The baseline survey is expected to take approximately 5 minutes. The twice daily text message surveys are expected to take approximately 5 minutes each.

WHAT WILL HAPPEN DURING THIS STUDY?

First, you will be asked to complete an online survey. This survey will ask for your cell phone number so that we can send you text message reminders to take your temperature (a thermometer will be dropped off outside your home if you do not already have one) and a link to the twice daily symptom surveys. It will also ask for a convenient morning and evening time to send these text message reminders. Finally, the survey will ask for demographic information about you (e.g., sex, race, ethnicity, and other health conditions). We anticipate that this survey will take approximately 5 minutes to

complete.

For the 10 days following enrollment in the study, you will be sent a morning and evening text message. This message will ask you to take and report your temperature as well as report any additional symptoms that you are currently experiencing. We anticipate that each response will take approximately 5 minutes. There is no additional participation in the study once the 10 days are complete.

We will also obtain the following from your medical record: date of birth, date of COVID test, type of COVID test, and COVID test number.

Data Storage for Future Use

As part of this study, we are obtaining data from you. We would like to study your data in the future, after this study is over without further consent. Your data may be placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, it may be stripped of identifiers (such as name, date of birth, address, etc). Other qualified researchers who obtain proper permission may gain access to your sample and/or data for use in approved research studies that may or may not be related to in the purpose of this study.

The tests we might want to use to study your data may not exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding COVID-19 but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products tests, or discoveries that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of data do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you should this occur.

Your data will be stored *with a code which may be linked to your name* that would enable us to identify which data are yours. If you agree now to future use of your data but decide in the future that you would like to have it removed from future research, you should contact Alberto Segre at 319-335-1713. However, if some research with your data has already been completed, the information from that research may still be used.

We are keeping your contact information and may contact you regarding participation in future studies about COVID-19. Agreeing to participate in this study does not obligate you to participate in any future studies; you will need to sign a separate Consent Document for any future studies.

WILL I BE NOTIFIED IF MY DATA RESULT(S) IN AN UNEXPECTED FINDING?

The results from the data we collect in this research study are not the same quality as what you would receive as part of your routine health care. The data results will not be reviewed by a physician who normally reads such results. Thus, you will not be informed of any unexpected findings. The results of your data will not be placed in your medical record with your primary care physician or otherwise. If you believe you are having symptoms that may require care, you should contact your primary care

physician.

WHAT ARE THE RISKS OF THIS STUDY?

The main foreseeable risk of this study is loss of confidentiality. In addition to this, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because of the knowledge gained about the symptoms of COVID-19.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study above those associated with receiving text messages on your normal cell phone plan.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your address so a check can be mailed to you.

You will be paid $5 for completing the baseline survey plus $1.50 for every response you submit to the text message surveys (i.e, $35 total if the baseline survey and both responses are submitted for all 10 days).

WHO IS FUNDING THIS STUDY?

The US Department of Health & Human Services, Centers for Disease Control & Prevention is funding this research study. This means that the University of Iowa is receiving payments from the CDC to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the CDC for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will store all of your data on password-protected, secure servers that are only available to members of the research team. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once University of Iowa Health Care has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Alberto M. Segre, 2 W Washington St., Iowa City, IA 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we will ask you to notify the research team by responding to the text messages that you receive. We will stop all future text messages.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Shelby Francis, 319-775-0689**.** If you experience a research-related injury, please contact: Alberto M. Segre, 319-335-1713.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

_____	_____
(Signature of Subject)	(Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____	_____
(Signature of Person who Obtained Consent)	(Date)