# CONSENT FORM AND HIPAA AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

**INVESTIGATOR'S NAME:** SYED NAQVI, MD
**PROJECT IRB #:** 2035652

**STUDY TITLE:** EVALUATION OF ZINC AND GREEN TEA EXTRACT SUPPLEMENTATION ON REDUCTION IN SYMPTOM DURATION AND SEVERITY ASSOCIATED WITH COMMUNITY RESPIRATORY VIRAL INFECTIONS: A RANDOMIZED CONTROL TRIAL (ZIPHENOL STUDY)

We invite you to take part in this research study. This consent form tells you why we are doing the study, what will happen if you join the study, and other important information about the study.

Please take as much time as you need to read this consent form. You can discuss it with your family, friends, or personal doctor. If there is anything you do not understand, please ask us to explain. Then you can decide if you want to take part in the study or not.

The Principal Investigator (also called the study doctor) is Dr. Syed Naqvi. The people working with Dr. Syed Naqvi on this study are called the study team.

*University of Missouri School of Medicine* (called the sponsor in this form) is paying for this study.

## WHAT SHOULD I KNOW BEFORE I DECIDE WHETHER TO TAKE PART IN THIS STUDY?

- Research studies help us to learn new things and test new ideas about treating certain conditions/diseases.
- Taking part in a research study is voluntary. You decide if you want to take part, and you can stop taking part at any time. Your regular medical care at the University of Missouri Hospitals and Clinics will not be affected now or in the future if you decide you do not want to be in this study.



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- We hope to learn if taking a dietary supplement can speed up the recovery from cold and flu like symptoms, including those caused by COVID-19. Other potential benefits such as fewer missed days from work or school will also be studied.
- We invite you to take part in this study because you came to the Emergency Department for concerns about a viral respiratory infection.
- About 100 people will take part in this study at the University of Missouri.
- If you take part in this study, you will be discharged from your Emergency Department Visit with a supplement to take twice a day. We will be calling you every day to check on your symptoms for seven days. We will explain these procedures in this form.
- If you join this study, you will have to stop any supplements or products that contain zinc, green tea, or ascorbic acid (vitamin C) for as long as you are in the study.
- The total amount of time you could be in this study is about 8 days (including today).
- Taking part in this study may or may not make your health better. We hope that the information we learn from this study will help in the future treatment of people with cold and flu like illness including COVID-19. **There is no guarantee that taking part in this research will result in any improvement in your condition.**
- As with any research study, there are risks that we know about and there may be some we don't know about. We will explain these risks in this form.
- We will only include you in this study if you give us your permission first by signing this consent form.

## Why Are The Researchers Doing This Study?

In this study, we want to find out if a dietary supplement containing Zinc, Vitamin C, and Green Tea extract (also called the study drug in this form), works better than a placebo. A placebo is something that looks like the study drug, but does not contain any active dietary supplements. To do this, we will compare study drug and the placebo in people with viral respiratory illness and see which one is more effective at reducing the time it takes to feel better. The dietary supplement is not approved by the U.S. Food and Drug Administration (FDA), but these ingredients are commonly used by people as over the counter supplements.



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We don't know if this study will help you. Your condition may get better, but it could stay the same or even get worse. We hope the information we get from this study will help us to develop better treatment for respiratory illness in the future.

## What will happen if I take part in this study?

**Screening Tests**

If you decide to join this study, you will sign this form and then you will have some screening tests to see if you qualify to be in the study. These are the screening tests:

- Physical Exam: You will have a physical exam, similar to what happens during regular doctor visits.
- Medical Chart Review: The study doctors will review your medical chart.

If the results of these tests show that you can be in the study, you will start in the study today**.** If you do not qualify to be in the study, the study doctor will discuss other options with you and/or refer you back to your regular doctor.

**Research Study Groups**

To find out if study drug works better than placebo for cold and flu like illness including COVID-19, this study has 2 groups. One group will take study drug, and the other group will take placebo. A placebo is a pill that looks like study drug but does not contain any real medicine. We will check the symptoms of everyone in the groups in 1 day and every day thereafter for 6 days and compare the results.

Because we don't know which of the supplements is best, we will "randomize" you into one of the 2 study groups. "Randomize" means putting you into a group by chance. It is like flipping a coin or pulling a number from a hat. You will have an equal chance of being placed in either group. A computer program chooses which group you go in. You and the study doctor cannot choose which group you go into.



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This study is "blinded", which means that you and the study team will not know which study drug you are getting until the end of the study. This way, no one's expectations of what will happen in the study will affect the results.
In an emergency, the study doctor can find out which study drug you are getting.

**Study Tests and Procedures**

If you take part in this study, you will have the following tests and procedures for study purposes only:

- At discharge from your Emergency Department visit, you will receive enough supplement or placebo to take for five days with the following directions:
    - Take three (3) capsules by mouth two (2) hours following a meal twice daily for five (5) days
- You will need to be available for one telephone visit lasting 15-20 minutes in duration from University of Missouri Healthcare Emergency Department personnel anytime during the hours of 8:00am – 8:00pm every day starting tomorrow and everyday thereafter for six days. Please inform study personnel of a preferred time of day (e.g. morning or afternoon) to be contacted. During each telephone visit you will be asked the following questions:
    - You will be asked to rate the severity of 12 different symptoms using a simple scale ranging from 0 to 3 points.
    - You be asked if you are experiencing any side effects such as nausea or skin rash
    - You will be asked how many days you may have missed from work or school due to being sick
    - You will be asked if you required any medical treatment such as going to your doctor or being admitted to the hospital
    - You will be asked about any missed doses of study drug or placebo
    - You will be asked about taking any over-the-counter (OTC) products including product name(s) and number of doses taken. If may be helpful to use a diary to record use of these products, but it is not required.


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We will keep the information we collect from you for this study without asking for your consent again. Information that could identify you will be removed from your research data so no one will know that they belong to you.

Your information may be used by the investigator to develop new treatments that may be sold commercially for profit. You will not share in these profits.

Results of research testing will be given to your doctor only if it is needed to treat you for an unexpected side effect suspected to be due from taking study drug.

## How Long Will I Be in the Study?

You will be in this study for about 8 days (including today).
You will take the study drug or placebo for 5 days.
A study team member will call you every day for seven days starting tomorrow to check on your symptoms and other study related events of interest.

## CAN I STOP BEING IN THE STUDY?

**You can stop being in the study at any time without giving a reason**. If you stop being in the study, your regular medical care will not change. Leaving the study will not affect your future medical care at the University of Missouri.

**There is no penalty to you if you do not join the study or if you leave it early**. You will not lose any benefits you are entitled to if you leave the study.

If you decide to stop participating in the study, you should discuss your decision with the study doctor. If you still want to stop participating in the study after talking to the study doctor then you can bring back any remaining study drug or placebo to the University of Missouri Healthcare Emergency Department for disposal or you can place your study drug or placebo


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bottle with unused capsules in a sealed container such as a Ziplock bag and dispose in the trash in an area away from children or pets.

The study doctor may decide to take you off this study at any time, even if you want to stay in the study. The study doctor will tell you the reason why you need to stop being in the study. These reasons may be:

- If it is in your best medical interest
- Your condition gets worse
- You are hospitalized for any reason
- You become pregnant
- You do not follow the study rules
- The whole study is stopped

If necessary, the study doctor will arrange for you to continue your medical care with your regular doctor.

## What health risks or problems can I expect from the Study?

There are risks to taking part in any research study. There is a risk that you may get a study drug that does not help your condition or makes it worse. There may also be problems (also called side effects) we do not know about yet. If we learn about new important risks and side effects, we will tell you. We will tell you about any new information we learn that may affect your decision to continue taking part in the study.

Dietary supplements can affect people in different ways. Not everyone gets the same side effects. Side effects may be mild or very serious. Many go away soon after you stop taking the drug. Some side effects can last a long time or never go away. You may receive other drugs to make side effects less severe and uncomfortable. Complications of some of the side effects listed below may lead to life-threatening events such as liver injury or a severe allergic reaction.

We will closely watch everyone in the study for side effects. You need to tell the study doctor immediately if you have any problems, side effects, or changes in your health. Dr. Syed Naqvi, MD telephone number is 573-884-9066.



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In other studies, the side effects that other people have experienced so far with study drug are:

- Nausea
    - This can occur in up to 10-15% of patients.
    - Taking study drug two (2) hours after a meal can help reduce the risk of nausea.
    - **Do not take study drug on an empty stomach.**
- Skin rash
    - This can occur in up to 3.4% of patients.
- Elevations in liver function tests such as ALT, which could indicate liver injury
    - This can occur in up to 6.7% of patients.
    - Severe elevations of ALT that may require medical treatment can occur in up to 1.3% of patients.
    - In patients for which ALT elevations occurred all recovered an average of one month after stopping treatment.

- **Randomization risks**: You will be put into a group by chance. The supplement you receive may turn out to be less effective or have more side effects than that in the other groups. It may also be less effective and have more side effects than other supplements taken for respiratory illness. While you are in this study, we will not know which supplement you are getting. If your condition gets worse during the study and we need to know which you are getting, there will be a way for us to find out.
- **Placebo risks**: If you are in the placebo group, you will go without study treatment for your condition for 5 days, however, use of over-the-counter medications to treat cold and flu-like symptoms will be permitted so long as they do not contain any of the ingredients of the study drug.

- **Unknown risks**: The experimental supplement in this study may have side effects that no one knows about yet. The study team will tell you if they learn anything that might make you change your mind about being in the study.

## Are There Benefits to Taking Part in the Study?



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We don't know if this study will help you. Your condition may get better, but it could stay the same or even get worse. We hope that this study will help us to learn more about the study drug, and to develop new treatments for cold and flu like illness including COVID-19 in the future.

## What Other Choices Do I Have?

**You do not have to take part in this study**. You are free to say yes or no. If you do not want to join this study, your doctor will discuss other choices with you. The study doctor can discuss the possible benefits and risks of the other options available to you.

## What about Privacy And Confidentiality?

The study team needs to use some of your health/personal information. This information comes from questions we ask you, forms you fill out, and your medical record. One risk of taking part in a research study is that more people will handle your personal health information. We are committed to respecting your privacy and to keeping your personal information confidential. The study team will make every effort to protect your information and keep it confidential to the extent allowed by law. However, it is possible that an unauthorized person will see it.

State and federal privacy laws (HIPAA) protect the use and release of your health information. If you decide to take part in this study, you also give us your permission to use your private health information, including the health information in your medical records and information that can identify you.
You have the right to refuse to give us your permission for us to use your health information. However, doing so would mean that you could not take part in this study.

The following identifiers will be obtained from your health records:

| | |
|---|---|
| ☒ Name | ☐ Address |
| ☒ Dates related to you | ☒ Telephone number(s) |
| ☐ Fax Number | ☐ Email Address |
| ☐ Social Security Number | ☒ Medical Record Number |
| ☐ Health Plan Beneficiary Number | ☐ Account Numbers |
| ☐ Certificate or License Numbers | ☐ Any vehicle or device serial number |
| ☐ Web Address (URL) | ☐ Internet Protocol (IP) Address(es) |



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☐Biometric Identifiers (finger/voice print)
☐Photographic images
☒Any other characteristic that could identify you

The following is the type of protected health information that will be used in the study:

☒Radiology Images
☒Discharge Summaries
☒Radiology Reports
☐Health Care Billing or Financial Records
☒EKG Recordings/Reports
☒Consultations
☒Progress Notes
☒Medications
☒History and Physical Exams
☒Emergency Medicine Reports
☐Operative Reports
☐Dental Records
☒Pathology Reports
☒Demographics (age, race, etc.)
☒Laboratory Reports
☒Questionnaires, Surveys, Diaries
☐Photographs/Video Recordings
☐Audio Recordings
☐Social Security Number (This is only collected for billing/payment purposes and will not be shared with the study sponsor)
☐Other

We may share any of this information with the following:

- Authorized members and staff of the University of Missouri Institutional Review Board (IRB).
- Laboratories and other individuals and organizations that may need to see your health information in connection with this study.
- Study monitors and auditors who make sure that the study is being done properly.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), and the Office for Human Research Protections (OHRP)

Any research information shared with outside entities will not contain your name, address, telephone or social security number, or any other personal identifier unless it is necessary for review or required by law.


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We will keep the information we collect from you for this study to use in future research/to share with other investigators to use in future studies without asking for your consent again. Information that could identify you will be removed from your research data so no one will know that they belong to you.

The people who get your health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

Your permission for us to use and/or release your information will last until the end of the study unless you cancel your permission.

You can cancel your permission at any time by writing to:
Investigator's Name: Syed Naqvi, MD
Institution: University of Missouri Health Care
Department: Medicine
Address: One Hospital Drive, DC043.00
Columbia, MO 65212

The information we have already collected may still be used for this research study, but we will not collect any more information after we receive your letter.

You will not be allowed to access your protected health information that is obtained or created during this research project until the end of the study.

If you have not already received a copy of the University of Missouri Healthcare Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights, you may contact the Privacy Officer at 573-882-9054.

We will scan a copy of this consent form into your medical record. We may also record your research information, including the results of tests and procedures, in your medical record. The


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medical information produced by this study will become part of your hospital medical record, and people allowed to look at your medical records may see this research information.

Information that does not become part of your medical record will be stored in the investigator's electronic/computer or paper files. Computer files are protected with a password and the computer is in a locked office that only study team members can open. Paper files are kept in a locked drawer in a locked office that only study team members can open.

Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location. Information that may identify you may not be given to anyone who is not working on this study without your written consent, or if required by law.

The people who may use and/or release your research information include:

- Those working on the study team at University of Missouri Health Care
- The members of the University of Missouri Institutional Review Board (IRB)
- Those who check on research activities to make sure it is being done correctly and safely
- The FDA
- Other government or inspection agencies

We may present the results of this study in public talks or written articles, but we will not use information that can identify you.

## CAN I SEE MY RESEARCH RECORDS?

If you join this study, you will be given one of the study supplements without knowing exactly which one. This is called a "blinded" study. This is a way of doing research when we want to compare drugs and we don't want people's feelings about the drug to affect the results.

If you ask to see your health records during this blinded study, the study team cannot tell you which study drug you are getting. This is because the study team is also blinded to which study drug you are getting. You would have to wait until **all participants have completed the study**.



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If we need the blinded information to treat you for an emergency, the study doctor will be able to find out.

## Are There Any Costs To Being In The Study?

There is no cost to you for taking part in this study.

The sponsor will provide the study drug to you free of charge while you are in this study.

Some tests and procedures are done for your routine health care, and you would get them even if you weren't in this study. You and/or your health plan/insurance will be billed for the tests and procedures you need for your routine health care while you are in this study.

Some health plans/insurance companies will not pay for these costs for people who are in research studies. Check with your health plan/insurance company to find out what they will pay for. If you have any questions about which tests/procedures will be billed to you and/or your health plan/insurance, please ask us.

## Will I be Paid for Taking Part in this Study?

There is no payment to you for taking part in this study.

## What Happens If I am Injured During The Study?

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff.
The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri.

In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information.
This statement is not to be construed as an admission of liability.

## What Are My Rights as a Study Participant?

**Taking part in this study is voluntary. You do not have to take part.** Your present or future medical care will not be affected if you decide not to take part.

If you do decide to take part, you can change your mind and drop out of the study at any time. This will not affect your current or future care at the University of Missouri Hospitals and Clinics. There is no penalty for leaving the study and you will not lose any benefits that you are entitled to receive.

If the study investigator decides to take you off the study, he will explain the reasons and help arrange for your continued care by your own doctor, if needed.

An Independent Safety Monitor, an independent group of experts, will review the data collected during this study. We will tell you about any new information discovered during this study that might affect your health, welfare, or change your mind about taking part.

## Where Can I Get More Information About This Study?

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## Who Can Answer My Questions About The Study?

If you have more questions about this study at any time, you can call Dr. Syed Naqvi at 573-884-9066.
You may also contact the University of Missouri Institutional Review Board (IRB) if you:

- Have any questions about your rights as a study participant;


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- Want to report any problems or complaints; or
- Feel under any pressure to take part or stay in this study.

The IRB is a group of people who review research studies to make sure the rights of participants are protected. Their phone number is 573- 882-3181, and email is muresearchirb@missouri.edu.

If you want to talk privately about your rights or any issues related to your participation in this study, you can contact University of Missouri Research Participant Advocacy by calling 888-280-5002 (a free call), or emailing MUResearchRPA@missouri.edu.

We will give you a copy of this consent form. Please keep it where you can find it easily. It will help you to remember what we discussed today.

## SIGNATURE OF STUDY PARTICIPANT

**Consent to Participate in Research**

By signing my name below, I confirm the following:

- I have read/had read to me this entire consent form.
- All of my questions were answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits were explained to me.
- I voluntarily agree to take part in this research study. I have been told that I can stop at any time.

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| | |
| **Subject's Signature** | **Date** |

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| | |
| **Signature of Witness (if applicable)*** | **Date** |

**A witness is required when a participant is competent to provide consent but is blind, or cannot read or write.*

## SIGNATURE OF PERSON AUTHORIZED TO OBTAIN CONSENT*

I have explained the purpose of the research, the study procedures (identifying those that are investigational), the possible risks and discomforts and potential benefits of the study, and have answered questions regarding the study to the best of my ability.

| | |
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| | |
| **Signature of Person Authorized to Obtain Consent** | **Date** |

***This signature is required for FDA regulated research and/or research that involves any medical procedure or surgical treatment.*



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