Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: The STOP-COVID trial: a double-blind, placebo-controlled clinical trial of fluvoxamine for symptomatic individuals with COVID-19 infection

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Research Team Contact: **Angela Stevens (314)362-6291**
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This consent form describes the research study and helps you decide if you want to participate. It 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 and responsibilities as a research participant.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- 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 invite you to participate in this research study because you are 18 or older, have tested positive for the COVID-19 infection, and are currently exhibiting symptoms of the infection.

The purpose of this research study is to determine if a widely used drug called fluvoxamine can be used early in the course of the COVID-19 infection to prevent more serious complications like shortness of breath. Fluvoxamine is an anti-depressant drug approved by the U.S. Food and Drug Administration (FDA) for the treatment of obsessive-compulsive disorder. The use of fluvoxamine for the treatment of COVID-19 is considered investigational, which means the U.S. Food and Drug Administration has not approved it for this use.

WHAT WILL HAPPEN DURING THIS STUDY?

Screening

For your safety and the safety of others, all interactions for this study will be conducted remotely with you by videoconferencing, phone, and email. Once we have determined from a short pre-screen that you may be eligible, study staff will contact you to go over this informed consent. You will then be asked to complete brief screening assessments to determine if you meet criteria for the study. If you qualify after completing the screening assessments, the study team send you the study medication. You will also use self-monitoring equipment to record your oxygen level (a monitor goes on your fingertip), blood

pressure and pulse, and temperature. If you are a female of childbearing age and are not using contraception, you will also take a pregnancy test. If you do not have the equipment needed to measure your blood pressure and pulse, temperature, or oxygen levels daily, we can help you obtain the proper equipment. Once the study team has finalized the screening process, you will begin taking the study medication.

Randomized Controlled Trial (Fluvoxamine vs. Placebo)
You will be randomly assigned (like flipping a coin) to take either fluvoxamine or a placebo (a sugar pill without active medication). Your assignment is completely random; therefore, you will not have a choice in this study decision. This phase of the study will last approximately 15 days and is double-blinded, meaning neither you nor the investigators will know if you are receiving fluvoxamine or placebo. You will take up to 100mg of fluvoxamine or placebo by mouth three times a day for a daily total of 300mg. You will continue this dose for approximately 15 days. Depending on how you tolerate the medication, we may adjust the dose. You will also complete short 10-15 minute assessments daily to assess your symptoms, results of self-monitoring your illness (including your oxygen level, blood pressure and pulse, and temperature) and any adverse events. Daily surveys are for data collection purposes only and are not monitored in real time. If you experience a worsening of symptoms, please contact your physician or go to the nearest emergency room.

Open-label Fluvoxamine Phase
After completing the randomization phase, you will then participate in an open-label phase (meaning you will definitely receive fluvoxamine) that will last up to 15 days. If you were randomized to placebo, you will have the opportunity to try fluvoxamine during this time. If you were randomized to fluvoxamine, you will continue this medication while slowly decreasing the drug. You may opt out of this phase per your preference.

Follow-up Phase (approximately 30 days after the randomized phase)
Once you have discontinued the study drug, we will follow you for approximately 30 days. You will complete one short survey at the end. If needed, we will review your medical records to determine your clinical course (for example, what happened if you were hospitalized).

Will you save my research information to use in future research studies?
Identifiers may be removed from your private information and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 152 people from the community will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 45 days. This includes:

- Randomized phase, lasting approximately 15 days
- Open-label phase, lasting up to 15 days

- Follow-up, lasting approximately 30 days after the randomized phase

Your involvement will also include 10-15 minute daily assessments, which will be conducted either by videoconferencing, email, or phone.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Risks of stopping SSRI:
If you are currently taking a selective serotonin reuptake inhibitor, you will need to stop this medication for participation in this trial. There is a 50% chance that you will be randomized to placebo or fluvoxamine. Your mood could change as a result of stopping your prescribed SSRI.

Study Assessments
There are no risks associated with any of the assessments.

Fluvoxamine

Likely/common >10%	**Less likely/less common (1-10%)**	**Rare (<1%)**
none	Dizziness	Painful joints
	Weight loss or loss of appetite	Hallucinations or confusion
	Agitation, nervousness, or anxiety	Stiff muscles
	Yawning	Drop in blood pressure while standing
	Trouble sleeping or excessive sleepiness	Rash or itchy skin
	Tremor	Mania (elevated mood)
	Headache	Seizures
	Palpitations (feeling your heart beating)	Abnormal liver function
	High heart rate	Becoming sensitive to light
	Diarrhea or constipation	Breast milk unrelated to pregnancy or breast feeding
	Sweating	
	Weakness or feeling of malaise	
	Dry mouth	
	Sexual dysfunction (delayed orgasm or reduced libido)	

If you are a woman capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. Although there are no known risks of fluvoxamine to an unborn child, here may be long-term effects of this medication that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are

on the study medication. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. You do not need to wait before becoming pregnant after completing the medication in this study.

Potential risk associated with Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because the results will provide more knowledge on the effectiveness of fluvoxamine in the treatment for COVID-19.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether to be in this study, you may discuss with your doctor the other options that are available to you. Instead of being in this study, you could take a different experimental treatment for COVID-19. However, at this time there is no known effective treatment for COVID-19.

If your condition worsens, you may or may not be able to participate in other COVID trials.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at 314-362-1671 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University**.** If you need to seek medical care for a research-related

injury, please notify the investigator as soon as possible.

The federal government has issued a declaration under a law known as the Public Readiness and Emergency Preparedness (PREP) Act to address the coronavirus (COVID-19) public health emergency. If you are injured or harmed as a result of participating in this study, that federal government declaration may limit your ability to obtain damages by filing a lawsuit against the study's researchers, health care providers, study site, study sponsor, and/or manufacturer or distributer of the drug. However, if you are injured or harmed as a result of participating in this study, the federal government has established a program that may provide compensation to you or your family. To find out more about this program, known as the "Countermeasures Injury Compensation Program" (CICP), go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427. The CICP is the payer of last resort, meaning that the CICP would generally only reimburse or pay for items or services to the extent such items or services are not covered by other third-party payers, such as your health insurance or workers' compensation you receive.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

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. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, all electronic records will be password-protected.

A description of this clinical trial will be available on http://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.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - **!** The research team may only use and share information already collected for the study.
      - **!** Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - **!** You will not be allowed to continue to participate in the study.

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- We may use emails to schedule remote visits, communicate about your medications, follow-up to your questions or to an adverse event, send links to surveys and/or assessments, and patient education.

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

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. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

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 withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be safe for you to continue.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Angela Stevens, 314-324-6291 or Marissa Rhea, 314-362-3797.** If you experience a research-related injury, please contact: Eric Lenze at the 24/7 exchange number at 314-388-5205 (local)/800-909-4903 (toll free) and tell the operator you are a participant in Eric Lenze's research study.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form 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 agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

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 signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 04/07/21.

~~(Signature of Participant)~~ _____ ~~(Date)~~ _____

~~(Participant's name – printed)~~ _____

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

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

_____
(Name of Person who Obtained Consent - printed)