Informed Consent for FLCCC COVID-19 Protocols
I-MASK+ | I-RECOVER

Medication and nutrient protocols to reduce the risks and severity of COVID-19 are continually being studied, evolving and are thus as yet considered "unproven" by state and Federal agencies. Public health agencies have approved limited therapies for patients requiring hospitalization and until recently, only one therapy for outpatient use, that of monoclonal antibodies which requires a health care facility to administer. The most recent FDA approvals, Paxlovid and Molnuparivir, may have limited availability and real world data but are important therapies that should be considered and discussed as part of this treatment decision.

The attached protocol was developed by the Frontline Covid-19 Critical Care Alliance ("FLCCC" or "Alliance"), a 501(c)(3) organization founded by highly respected and published physicians treating COVID-19 in their offices, hospitals and ICUs in major medical centers since the onset of the pandemic. (*See* extensive material at **https://covid19criticalcare.com)**. Protocols include the use of multiple prescription medicines including ivermectin as well as a number of nutraceuticals that have been shown to lead to improved COVID-19 outcomes in randomized controlled trials. Specific information about the treatments your physician has recommended are attached for your review and discussion with your physician.

Medical Controversies: This use of ivermectin in particular has been the subject of professional disagreement and substantial public misinformation. There are also differences of opinion about the significance of clinical evidence for the use of Fluoxetine, Nitazoxanide, Spironolactone and Nigella Sativa and of vitaminC, D3, quercetin, zinc and melatonin on COVID-19 which may be suggested by your physician. There has been a growing recognition that these nutrients have an important role in the course of a coronavirus infection, especially that vitamin D deficiency is correlated with poorer outcomes. The medical community has historically been skeptical of therapeutic uses for nutrients and public health officials have acknowledged that there is suggestive evidence but have not made these recommendations. There is evidence that the recommended viricidal mouthwash gargles can reduce viral load with some associated with reduced need for hospital when used.

*Public Health Measure*s: The prevention I-MASK+ prevention protocol is intended to supplement public health measures such as distancing, masks, self-isolation and vaccination as appropriate, particularly those with personal health or occupational risk factors. It can be used by vaccinated individuals to enhance protection, particularly where exposure is known or an occupational risk upon periods of waning efficacy. The I-RECOVER Protocol is intended to help treat the often disabling symptoms which recur or persist after recovery from the acute phase of COVID-19. Patients following these protocols, whether to reduce risk of contracting the disease or as treatment, cannot assume that they are therefore at any less risk of spreading the disease. All public health measures, including social distancing and wearing of masks along with vaccination should be strictly followed as appropriate.

Possible Drug Contraindications and Adverse Effects. Please review and sign the attached sheetsfor the prescribed recommended drugs and dietary supplements.

Additional Notices

Notice to Pregnant / Nursing Women: All female patients must alert their physicians if they know or suspect that they are pregnant or are breast feeding an infant.

No Guarantees: The optimal prevention and treatment of COVID-19 is still being determined, there are significant individual differences between patients and there can be no guarantees that a patient will gain any benefit or not suffer any adverse consequences.

Insurance Notice / Financial Responsibility: Patients are responsible for payment at the time of service. This prescription or related office visit may be considered non-covered or denied as "notmedically necessary" or as an "experimental" treatment. Medicare will not reimburse for ivermectin or related costs. Patients are responsible for understanding their medical and pharmaceutical coverage and are financially responsible without regard to any denial or other determination by their insurance.

Authorization and Informed Consent

I have discussed with my physician the use of the recommended protocol based upon the attached I-MASK+ or I-RECOVER+ protocol as modified for use in reducing risk of and/or treatment ofCOVID-19, including the medical controversies surrounding them, the view of public health agencies, potential adverse reactions, side effects and contraindications. I have also discussed any FDA-approved therapies for COVID-19 treatment. I have been able to review these materials and make my own choice. I understand there is no guarantee that this will prevent me from becoming infected with or transmitting the SARS-CoV-2 virus and that I need to continue to follow public health measures. I understand that there is no guarantee as to the outcome of any illness. I agree to assume the risks that could arise, including those which have been explained and which my physician could not have foreseen. I have requested that my physician prescribe /recommend these treatments. I have been adequately informed about the clinical and legal status of this therapy and questions I have asked have been satisfactorily answered. I understand and agree to the financial and other notices that have been provided.

I have read and signed the attached sheets for the specific treatments prescribed and/or recommended.

Dated:

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Signature of Patient or Legal Guardian Witness

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Patient's Printed Name Dated

PROTOCOL DRUG INFORMED CONSENT FORM ATTACHMENT: IVERMECTIN

Off-Label Use. Ivermectin is approved for and widely used for the treatment of parasites such asRiver Blindness. It has not been reviewed and approved by the US Food and Drug Administration (FDA) for use in COVID-19 or any other viral illness and its use is considered "off-label." FDA and CDC have cautioned about the possibility of potentially serious side effects at the dosing used for the treatment of COVID-19.

Medical Controversies. This use of ivermectin has been the subject ofprofessional disagreement and substantial public misinformation. The medical literature contains a significant number of clinical studies, meta-analyses, and reviews that analyze available studies, including epidemiological investigations following populations that have used ivermectin in the prevention or early treatment of COVID-19. Some meta-analyses have concluded that ivermectin is safe with moderate to strong, statistically significant effectiveness, particularly at early stages of the disease, while othersfound the evidence as yet inconclusive. Conclusions vary in part because of the level of dosing used and disagreements over the validity of study designs and rigor of some studies.

Part of a Protocol. The use of ivermectin is part of a protocol developed by FLCCC to addressCOVID-19 and works best when followed in its entirety rather than relying entirely on ivermectin.

There are some critical factors which appear to be clear from studies and clinical experience about which patients should be aware:

Timing. Ivermectin has the best chance to work against COVID-19 when taken early in the disease. It should be started as soon as possible.

Dosing. Concerns regarding Ivermectin arise in part because it requires higher dosing to achieve antiviraland therapeutic impacts than the doses originally approved for parasitic diseases. The potential for side effects is greater at higher doses; dose levels required vary by patient weight and the stage of disease. While

Delta/Omnicron Variants. Many of the studies done preceded the Delta and Omnicron variant of the coronavirus, which creates much higher viral loads than previous variants. Clinical experience of physicians treating with ivermectin is that it still has clinical effectiveness though it may be somewhat reduced in such cases and therefore may require higher doses or additional medications.

Veterinary Forms of Ivermectin. Patients should only take what is prescribed and obtainedfrom a pharmacy and not take veterinary ivermectin or purchase it on the internet, as theseforms may contain higher concentrations of impurities of unknown safety to humans and there are reports of serious side effects as a result of such use.

Public Health Measures. A patient taking ivermectin, whether to reduce risk of contracting

the disease or as treatment, cannot assume that they are therefore at any less risk of spreadingthe disease. All public health measures, including social distancing and wearing of masks and social isolation if indicated along with vaccination should be strictly followed as appropriate.

Ivermectin; Notice of Public Health Agency Positions. The view of public health agencies, asexpressed by the Centers for Disease Control and Prevention (CDC) is that:

> Clinical trials and observational studies to evaluate the use of ivermectin to prevent and treat COVID-19 in humans have yielded insufficient evidence for theNIH COVID-19 Treatment Guidelines Panel to recommend its use. Data from adequately sized, well-designed, and well-conducted clinical trials are needed to provide more specific, evidence-based guidance on the role of ivermectin in the treatment of COVID-19."
> https://emergency.cdc.gov/han/2021/han00449.asp.

The CDC has further issued a statement that adverse effects associated with ivermectin misuseand overdose are increasing, shown by a rise in calls to poison control centers reporting overdoses and more people experiencing adverse effects. The majority of such reported cases have resulted from the use of veterinary drugs and reports from human drugs are difficult to evaluate from available information.

The FDA has warned consumers not to use ivermectin to prevent or treat COVID-19, a warning initially based on the use of the animal version of the drug, which is highly inadvisable, and morerecently on the view that there is no evidence supporting its use in COVID-19. The FDA has not formally reviewed the evidence nor issued a guidance document but refers to the data at clinicaltrials.gov about which there is professional disagreement.

The National Institutes of Health ("NIH") reviewed the evidence in January of 2021 and elevated ivermectin from a "do not use" to a "neither recommend for or against" policy, the same status asconvalescent plasma and other treatments that are in use. NIH found that the evidence for or against was inconclusive, which, especially given the lack of well-demonstrated treatment alternatives, leaves the matter to the informed decision of physician and patient.

Potential Side Effects: Ivermectin has been administered in over 4 billion doses worldwide for parasitic disease and is generally considered to have an excellent safety profile. Most of the significant side effects resulting from such use are due to the die-off of the parasite. Dosing for parasitic diseases is based on weight up to a maximum of five 3 mg pills a day for 5 days. Dosingfor treatment of COVID-19 is higher in order to achieve therapeutic levels.

Clinical effects of ivermectin are generally mild and can include gastrointestinal symptoms suchas nausea, vomiting, and diarrhea; hypotension and neurologic effects such as low blood pressure, anemia, headache, blurred vision, dizziness, tachycardia, visual hallucinations, altered mental status, confusion, loss of coordination and balance, orthostatic hypotension,

central nervous system depression, and seizures. Cardiovascular side effects have included myocardial infarction and tachycardia but these are rare. EKG changes have been reported in rare cases including prolonged PR interval, flattened Twaves and peaked T waves. Significant overdoses are associated with effects such as decreased consciousness, confusion, hallucinations, seizures, coma, and death. Other adverse events that have been reported include acidosis, kidney injury, elevated liver enzymes. Patients should discuss any concerns about potential side effects with their physician before beginning treatment.

Get emergency medical help if you have signs of an allergic reaction to Ivermectin: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Drug interactions: Ivermectin has few major drug interaction, the most notable are with the anti-coagulant warfarin and immunosuppressive medications most often taken by organ transplant recipients. Some drugs can enhance or reduce the blood levels and effects of ivermectin. Makesure your physician has reviewed all of the other medicines that you are taking.

Date: _____

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Patient signature

PROTOCOL DRUG INFORMED CONSENT ATTACHMENT - NITAZOXANIDE

Nitazoxanide. Nitazoxanide is an antiprotozoal medicine usually used to treat infections caused by protozoa (single-cell parasites that live in moist places such as lakes, streams, and soil).

Possible contraindications: Be sure to tell your physician if you have liver or kidney disease; HIV or AIDS; or a weakened immune system.

Potential Adverse Effects: Nitazoxanide can cause abdominal pain, headache, abnormal urine color, nausea and diarrhea. It can also cause dizziness, heartburn, hives or welts, itching, or skin rash, redness of the skin, trouble breathing or vomiting. These generally do not require immediate medical attention unless they are particularly bothersome or persist.

Date: _____

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PROTOCOL DRUG INFORMED CONSENT ATTACHMENT - FLUOXETINE

Fluoxetine. Fluoxetine (Prozac) is a selective serotonin reuptake inhibitor (SSRI) antidepressant. There has been evidence suggesting that use is significantly and substantially associated with reduced risk of intubation or death due to antiviral effects. SSRIs are generally continued indefinitely and take up to 4 weeks to have an effect on mood. Use for COVID will likely be shorter-term and discontinued prior to obtaining psychiatric effects. Dosing and discontinuation should be done under medical supervision.

Contraindications: Inform your physician if you take any of these medications, as you should not use fluoxetine with thioridazine, linezolid, pimozide, or methylene blue injection. Patients already on an SSRI (such as Celexa, Lexapro, Paxil or Zoloft) or if you have used an MAO inhibitor in the past 14 days (such as Marplan, Nardil, Parnate, Emsam, Azilect or Eldepyrl) should not take fluoxetine. You must wait at least 14 days after stopping an MAO inhibitor before you take fluoxetine. You must wait 5 weeks after stopping fluoxetine before you can take thioridazine or an MAOI.

Potential Adverse Effects: Some people, especially the young, have acute anxiety or thoughts about suicide when first taking an antidepressant. Stay alert to changes in mood or symptoms. Fluoxetine could impair judgment, thinking, or motor skills. Use caution when operating machinery. Report any new or worsening symptoms to your doctor, such as: mood or behavior changes, anxiety, panic attacks, trouble sleeping, or if you feel impulsive, irritable, agitated, hostile, aggressive, restless, hyperactive (mentally or physically), more depressed, or have thoughts about suicide or hurting yourself.

Alert your doctor at once if you have blurred vision, tunnel vision, eye pain or swelling, or seeing halos around lights; fast or pounding heartbeats, fluttering in your chest, shortness of breath, and sudden dizziness (like you might pass out); low levels of sodium in the body - headache, confusion, slurred speech, severe weakness, vomiting, loss of coordination, feeling unsteady; or a severe nervous system reaction–very stiff (rigid) muscles, high fever, sweating, confusion, fast or uneven heartbeats, tremors, feeling like you might pass out.

Seek medical attention right away if you have symptoms of serotonin syndrome, such as: agitation, hallucinations, fever, sweating, shivering, fast heart rate, muscle stiffness, twitching, loss of coordination, nausea, vomiting, or diarrhea.

Common fluoxetine side effects, which do not require immediate medical care may include: sleep problems (insomnia), strange dreams; headache, dizziness, drowsiness, vision changes; tremors or shaking, feeling anxious or nervous; pain, weakness, yawning, tired feeling; upset stomach, loss of appetite, nausea, vomiting, diarrhea; dry mouth, sweating, hot flashes; changes in weight or appetite; stuffy nose, sinus pain, sore throat, flu symptoms; or decreased sex drive, impotence, or difficulty having an orgasm.

Date: _____

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PROTOCOL DRUG INFORMED CONSENT ATTACHMENT - SPIRONOLACTONE

Spironolactone. Spironolactone is a potassium-sparing diuretic (water pill) that prevents your body from absorbing too much salt and keeps your potassium levels from getting too low. It is used to treat heart failure, high blood pressure (hypertension) or hypokalemia (low potassium levels in the blood).

Contraindications: Patients should use spironolactone with caution with kidney, liver or heart disease, high levels of potassium or any other electrolyte imbalance (such as low levels of calcium, magnesium, or sodium in your blood), Addison's disease, difficulty urinating or if taking eplerenone.

Tell your doctor if you are pregnant or plan to become pregnant. Having congestive heart failure, cirrhosis, or uncontrolled high blood pressure during pregnancy may lead to medical problems in the mother or the baby. Your doctor should decide whether you take spironolactone if you are pregnant.

Possible Adverse Events: Common spironolactone side effects may include breast swelling or tenderness. Call your doctor at once if you have: a light-headed feeling, like you might pass out; little or no urination; symptoms of high potassium level such as nausea, weakness, tingly feeling, chest pain, irregular heartbeats, loss of movement or signs of other electrolyte imbalances such as increased thirst or urination, confusion, vomiting, muscle pain, slurred speech, severe weakness, numbness, loss of coordination, feeling unsteady.

Date: _____

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PROTOCOL DRUG INFORMED CONSENT ATTACHMENT - NIGELLA SATIVA

Nigella Sativa: Nigella sativa is a widely used medicinal plant for a variety of conditions including as an antihypertensive, liver tonic, diuretic, digestive aide, anti-diarrheal, appetite stimulant, analgesics, anti-bacterial and in skin disorders.

Possible Contraindications and Adverse Effects: Patients with kidney or liver disease should review the use of this herb with their physician. It may lower blood pressure and should be used with caution in patients with hypotension. It may slow blood clotting and increase the risk of bleeding disorders interviews and caution in patients on blood thinners and should be discontinued before surgery. In some patients it may cause stomach upset, vomiting or constipation.

Date: _____

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