UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: *Intensive Outpatient Management of Moderate to Severe Ulcerative Colitis: A Treatment Approach for the COVID-19 Era*

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This is a research study about management of moderate to severe ulcerative colitis requiring intravenous corticosteroids outside the hospital compared to in the hospital. The study researcher, Sara Lewin, MD, will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you have ulcerative colitis and are a candidate for outpatient intravenous corticosteroids to treat your current flare.

Why is this study being done?

The purpose of this study is to learn more about how patients do when they are treated for moderate to severe ulcerative colitis with outpatient intravenous corticosteroids compared to being admitted to the hospital for the same treatment.

How many people will take part in this study?

About 140 people will take part in this study.

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

If you agree, the following procedures will occur:

You will agree to answer a questionnaire daily for 14 days, followed by a weekly questionnaire for an additional 12 weeks. The questionnaires will be administered electronically. The first questionnaire will take 15 minutes to complete. The following questionnaires will take 10 minutes to complete.

The overall time commitment is approximately 5 hours over the course of 14 weeks.

During the study, you will receive care for acute severe ulcerative colitis either in the hospital or as an outpatient. You will receive methylprednisolone intravenously either in the hospital or in an infusion center. Regardless of inpatient or outpatient treatment setting, you may also require blood and stool laboratory testing, abdominal x-ray imaging, COVID-19 testing, and flexible sigmoidoscopy as part of routine clinical care. Your participation in the study does not affect the setting or type of clinical care that you receive.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

How long will I be in the study?

After 14 weeks, the study will be completed. We may review your medical records after the 14 weeks, but you will not be contacted beyond 14 weeks of enrollment in the study.

What side effects or risks can I expect from being in the study?

- You will need to spend approximately 10 minutes each day completing the questionnaire, which is time you could spend doing something else.
- We will ask you about your eating habits, which may be triggering if you have a history of disordered eating
- We will confidentially ask you about access to food and transportation, which may be difficult for some participants to answer.
- We will ask you about your daily digestive tract symptoms, including information bowel movements, which may be embarrassing to some.
- The risks of outpatient treatment vs inpatient treatment should be discussed with your medical provider.
- For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

- You will have the opportunity to track your symptoms and food intake during a flare daily to have quantitative information about your progress during treatment.
- The information that you provide may help health professionals better understand/learn more about managing ulcerative colitis that requires IV steroids.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still

get your care from our institution the way you usually do. If you do not choose to take part in this study, you can still opt to receive outpatient or inpatient care for acute severe ulcerative colitis, as long as your healthcare provider agrees.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share your information with other researchers so they can use your information for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. Your signed consent form will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records and may be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California

Are there any costs to me for taking part in this study?

You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.

If you have questions about what costs you will be responsible for, please talk with the study investigator before deciding to enroll in the study.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. Lewin, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at 415-502-4444.

Treatment and Compensation for Injury Statement (standard)

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the researcher Dr. Sara Lewin at 415-502-4444.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

CONSENT

You have been given a copy of this consent form to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.