COVID-19 anti-CD14 CaTT Treatment Trial

STUDY SITE INFORMATION

Study Title: **Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of the Effect of Anti-CD14 Treatment in Patients with SARS-CoV-2 (COVID-19)**

Version Date: January 14, 2021

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

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

There are no costs to you or your insurer for any costs that are directly related to this study. Costs related to usual clinical care of your COVID-19 illness or other medical problems will be billed to you and/or your insurer in the normal manner.

Will I be paid for taking part in this study?

You will receive a payment of $30.00 for each virtual visit that we schedule with you and $50.00 for coming back to the clinic 28 days and 60 days after you began treatment with the study drug.

How will information about me be kept confidential?

We will do our best to make sure that information about you is kept confidential. However, it is possible that others could learn that you are part of this study and learn information about you as a result of a breach of confidentiality. The information and samples we collect will be labelled with a code rather than your name. We will keep your name and other information that could identify you separate from the samples and information.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Government, hospital, or university staff sometimes review studies like this to make sure they are being done safely and legally. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm. Your study records may be viewed by:

- The University of Washington in Seattle, WA
- Offices at the hospital or university where you are being treated
- The U.S. Food and Drug Administration (FDA)
- The Vanderbilt Coordinating Center at Vanderbilt University in Nashville, TN
- Other federal or state agencies

We have a Certificate of Confidentiality from the National Institutes of Health (NIH). This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We cannot use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about you or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it to audit or evaluate the research
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly
- the FDA if they require it
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form

The Certificate of Confidentiality expires when the NIH funding for this study ends. Data collected prior to expiration will continue to be protected, but any data collected after expiration is not protected as described above.

What happens if I am injured because I took part in this study?
It is important that you tell study doctors if you feel that you have been injured because of taking part in this study. The study doctor will treat you or refer you for treatment.

(NOTE TO SITES: add site-specific information about resources available to help pay for costs of study-related injuries).

Whom can I contact about the study?
NOTE TO SITES: Lines in the following Table should not be deleted, but may be added to or amended depending on site specific contact information.

If you are having an emergency	**[add site-specific contact information]**
Any questions, concerns, or complaints you have about this study, or if you think you have been injured.	**[add site-specific contact information]**
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, complaints or concerns you may have about the study	**The Office that oversees this research** The University of Washington (UW) IRB oversees this research at all sites. 206.543.0098 or collect at 206.221.5940 or hsdinfo@uw.edu
If you want to learn about the results of the study	A description of this clinical trial will be available on https://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.

ADMINISTRATIVE INFORMATION
PRINCIPAL INVESTIGATORS FOR THE STUDY: Mark M. Wurfel M.D., Ph.D.

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Professor of Medicine, Division of Pulmonary and Critical Care Medicine, Department of Medicine, University of Washington, Seattle, WA

Thomas R. Martin M.D.
Emeritus Professor of Medicine, Division of Pulmonary and Critical Care Medicine, Department of Medicine, University of Washington, Seattle, WA

NOTE TO SITES: Fill in the information below with information that is specific for your site.

Site Name:	
Site Principal Investigator:	
Site Principal Investigator Contact:	
Site Study Coordinator:	
Site Study Coordinator Contact:	

Optional Consent for Sample Storage for Future Research
Do you agree to the storage and sharing of your samples and information for future research? You can still be a part of the main study even if you say "no" to this.

☐ Yes ☐ No

PARTICIPANT'S SIGNATURE

I volunteer to take part in this research.

Printed name of study participant Signature of participant Date

LEGALLY AUTHORIZED REPRESENTATIVE'S SIGNATURE

Printed name of legally authorized Signature of legally authorized

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Representative Representative Date

SIGNATURE OF PERSON EXPLAINING AND OBTAINING CONSENT

Printed name Signature Date