UNIVERSITY OF CALIFORNIA, SAN FRANCISCO-FRESNO
CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

California law requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedure to be followed in the medical experiment and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

For questions about patient rights, contact the Chairman of the Institutional Review Board at Community Medical Centers at (559) 499-6553.

I have carefully read the information contained above and I understand fully my rights as a potential subject in a medical experiment involving people as subjects.

Participant Printed Name:	Participant Signature:	Date:	Time:

Witness Printed Name:	Witness Signature:	Date:	Time:

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

Study Title: DISulfiram for COvid-19 (DISCO) Trial: A Phase 2 Double-Blind, Randomized Placebo-Controlled Trial of Disulfiram Compared to Standard Care in Patients with Symptomatic COVID-19

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This is a medical research study. Dr. Mohamed Fayed or a member of the study staff will explain this study to you.

Introduction
We are asking you to take part in a research study being led by Dr. Sulggi Lee at University of California, San Francisco (Principal Investigator) and Dr. Mohamed Fayed at UCSF-Fresno (Local Principal Investigator) because you have tested positive for COVID-19. The first part of this form summarizes the study. We will give more details about the study later in the form. A study team member will also explain the study to you and answer your questions.

Research studies only include people who choose to take part. It is your choice whether or not you want to participate in this study. Please take your time to make your decision about participating and if you would like, discuss your decision with your family, friends and health care team.

Why is this study being done? This is a medical research study of the drug disulfiram. The drug is also called Antabuse. Disulfiram is a drug that is often used to prevent alcoholics from drinking alcohol. People who are taking this drug and who then drink alcohol develop flushing (suddenly feeling hot and reddening of the skin), headaches, nausea and vomiting. Disulfiram has been approved by the US Food and Drug Administration (FDA) for this purpose. The usual dose is between 250 and 500 milligrams once a day.

The use of disulfiram in the treatment of patients with COVID-19 is experimental. This study is being done to see if disulfiram may have a role in reducing the severity of Coronavirus Disease 2019 (COVID-19) disease. Patients who become very ill with COVID-19 have been shown to have high levels of inflammation, and it is thought that the excess inflammation is what leads to worsening disease and death in some patients. Recent data suggests that disulfiram may potentially reduce the severity of COVID-19 disease by (1) directly preventing the virus from making more copies of itself and (2) reducing the abnormal inflammation that may lead to more severe COVID-19 disease.

What will happen if I take part in the study?
If you choose to be in the study, you will sign this Informed Consent Form, the California Experimental Subject's Bill of Rights, a Use and Disclosure of Your Protected Health Information form, and a Release of Information for your medical provider (if you agree) so the researchers can review lab results or other relevant information in your medical record during the study. If you do not provide consent in person, you will complete a visit over the phone to provide consent and complete a questionnaire about your health. You will be asked to complete up to five in-person study visits during the next 31 days.

If you take part in the study, you will receive 5 days of study drug (disulfiram) or placebo (a pill that looks like disulfiram but contains no active ingredients); you are twice as likely to receive study drug than placebo since we will be randomly assigning 2 people to receive disulfiram for each person who is randomly assigned to placebo. Over the course of the study you will complete five additional visits over the phone to complete a questionnaire about your health. These visits will take place 1-2 days before each study visit that takes place in the clinic. You will also be asked to report your COVID-19 symptoms daily while on study treatment. During this period, you will be contacted by phone and asked about your symptoms. On in person visits, this information will be collected in person.

At each in-person study visit, you will be asked to complete a questionnaire and we will collect blood from your vein, collect nasal and throat swabs, and collect saliva. You will be in this study for a total of 31 days, or 1 month, with a total of approximately 11hours of participation.

Possible Risks: There are risks to taking part in any research study. The study medication disulfiram has limited information regarding its safety profile in patients with COVID-19. In addition, higher doses of disulfiram are associated with more frequent adverse events. The doses being evaluated in this study are higher than the doses prescribed for alcohol dependence disorder (approximately 250 mg to 500 mg daily). If you are randomized to receive disulfiram for this study, you will receive a total of 5 days of disulfiram at either 1000 mg or 2000 mg a day. These doses were found to be well tolerated without adverse events in a prior clinical trial when given for 3 days. **You must not drink alcohol while taking part in this study. You will also need to be very careful not to eat foods such as wine vinegars, or use products such as cough syrups and mouthwashes that contain alcohol.** The study medication disulfiram can

cause a reaction to alcohol. This reaction can include flushing (suddenly feeling hot and reddening of the skin), nausea, vomiting, low blood pressure, chest pain, headache, and anxiety. Rarely people have died from these reactions.

Less likely risks include slight drowsiness or tiredness, a skin rash, or a metallic or garlic-like taste in the mouth. More information about possible risks are listed in the main part of this consent form.

There are also risks of discomfort from blood draws and from providing specimens, and loss of privacy if there is a breach of data security.

Possible Benefits: Although there is a possibility that taking part in this study may reduce the severity of your illness, there may be no direct benefits to you from participating in this study.

Your Other Options: You do not have to participate in this study. Your other choices may include getting treatment or care for your condition without being in a study or taking part in another study. Please talk to your doctor about your choices before agreeing to participate in this study.

DETAILED STUDY INFORMATION

This part of the consent form gives a detailed description of the study and what it involves. Please review the description carefully and ask any questions to help you decide whether to join the study.

Why is this study being done?
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a newly identified coronavirus that causes an acute respiratory illness known as COVID-19. Early treatment of people with COVID-19, while their symptoms are still mild, may help reduce the number of people who become very ill from COVID-19. Reducing the number of people with severe COVID-19 disease may then help prevent the spread of the disease in the community as well as decrease the number of COVID-19 patients in the hospital.

How many people will take part in this study?
Up to 60 COVID-19 positive adults will be in this study.

You are being asked to take part in this study because:
1. You tested positive for COVID-19 by nasal or oral swab PCR test.
2. You are able to attend the five in-person study visits over an approximately 31-day period of time.

Where will the study take place?
The DISCO trial includes:
1. Either an initial telephone visit or clinic visit to complete a Baseline Survey;
2. Five in-person study visits for specimen collection;
3. Daily Phone calls between each in-person visit to ask you about your current COVID-19 symptoms while you are taking the study medication; and
4. Five days of taking study drug (disulfiram or placebo).

The in-person study visits will take place at East Medical Plaza Pulmonary Clinic located at 2335 East Kashian Lane, Suite 260, Fresno CA 93701. As the severity of the pandemic changes, and restrictions regarding COVID-19 change, you may be asked to come to the clinic at University of California, San Francisco-Fresno located at 155 N. Fresno Street Fresno CA 93701, if your illness is considered to be non-active (per the Centers for Disease Control guidelines), you have been cleared to return to work, and are no longer experiencing any symptoms.

Who is paying for this study?
This study is paid for by Dr. Sulggi Lee, UCSF, and Division of Acquired Immunodeficiency Syndrome (DAIDS). Dr. Fayed and the study coordinators are being paid by the sponsor for their work involved in the study procedures and the collection of study data. There is no financial conflict of interest concerning the Investigators or study staff at UCSF-Fresno.

What will happen if I am in the study?
If you decide you want to participate in this study and sign the Informed Consent Form and Use and Disclosure of Your Protected Health Information form, and a Release of Information for your medical provider (if you approve, and if applicable), the following things will happen:

Screening/Baseline Visit:
- You will first be asked to sign the informed consent. This may take place in the clinic, at the hospital if you were hospitalized, or over the phone using an electronic version of the consent form that you will sign electronically. After consent has been signed, you will be asked about any household members who have also been diagnosed with COVID-19, who may be interested in participating in the study. Family members who are interested will be invited to contact the study staff to discuss study participation.
- If you are consented electronically, a questionnaire about your health will be completed. You will be asked about your COVID-19 symptoms and exposures, any hospitalizations you have had due to COVID-19, how you feel emotionally, and about your use of tobacco, alcohol, and any drug use. If you are female, we will ask some questions about your reproductive health history. This telephone call will take up to 30 minutes. If you are consented in person, this questionnaire will be completed at the clinic.

At the first in-person baseline visit: This visit will take approximately one hour.

- If you did not first complete a visit over the phone, you will complete a baseline questionnaire to ask about your health, COVID-19 symptoms and exposures, hospitalizations, how you feel emotionally, and about your use of tobacco, alcohol, and other drugs. If you are female, we will ask you some questions about your reproductive health history.
- A study doctor will conduct a physical examination that is similar to those done for regular medical care.
- A study staff member will take your vital signs, including your blood pressure, pulse rate, temperature, respirations and oxygen saturation.
- A trained phlebotomist will draw approximately 68mL (about 1/3 of a cup) of blood by inserting a needle into a vein in your arm.
- We will collect a saliva (spit) sample (if you are able to provide one) to test for proteins that may be responding to COVID-19.
- If you are a female of child-bearing potential, you will be asked to provide a urine sample. Because being pregnant while you have COVID-19 could put you at higher risk of severe disease, some of your urine will be tested to see if you are pregnant. You will not be able to participate in this study if you are currently pregnant. The reason for this is because the amount of blood required for the research study exceeds the amount of blood that is considered safe for pregnant women.
- The study doctor can share the clinical lab results that may be important for your medical care with you, and/or your medical provider, if you give permission. Information about your primary care physician will be collected at the end of this form. However, some of the tests are exploratory or experimental, so the relevance and accuracy of the results are not known. You can indicate at the end of this consent form if you want to have this done.

Day 1, Day 15, and Day 31 visits: These visits will take approximately 1 hour each.

At these visits, the following will take place:

- You will complete a brief questionnaire about your current health.
- A study doctor will conduct a physical examination similar to those done for regular medical care.
- At your Day 1 visit, you will receive your first dose of study treatment (either disulfiram or placebo). If you are one of the first 30 people enrolled, you will get 1000 mg a day of disulfiram for 5 days or placebo for 5 days. If you are one of the second 30 people enrolled, you will get 2000 mg a day of disulfiram for 5 days or placebo for 5 days.
- We will collect some fluid from your nose using cotton swabs to test for the COVID-19 virus and to study your respiratory tract immune cells.
- A trained phlebotomist will draw approximately 65mL (about 1/3 of a cup) of blood by inserting a needle into a vein in your arm.
- We will collect saliva (spit) samples (if you are able to provide them) to test for proteins that may be responding to COVID-19).
- If you are female, because being pregnant while you have COVID-19 could put you at higher

risk of severe disease, some of your urine will be tested to see if you are pregnant. If you are currently pregnant, you will not be able to participate in this study. If you become pregnant during the course of the study, you will no longer be able to take part and no further research related procedures will be conducted.

Day 2:
Day 2 visit will take approximately 90 minutes.
At this visit, the following will take place:

- You will be asked not to take your study medication, and bring it with you to the study visit.
- You will be asked not to have anything to eat for at least 2 hours prior to the visit.
- You will complete a brief questionnaire about your current health.
- A study staff member will take your vital signs, including your blood pressure, pulse rate, temperature, respirations and oxygen saturation.
- You will be asked to take your study medication at the study visit.
- A trained phlebotomist will draw approximately 19 mL(about 4 teaspoons) of blood by inserting a needle into a vein in your arm. About 14 mL of the blood will be used to assess your current physical condition, and the rest will be stored for research.
- We will collect some fluid from your nose using cotton swabs to test for the COVID-19 virus and to study your respiratory tract immune cells.
- We will collect saliva (spit) samples (if you are able to provide them) to test for proteins that may be responding to COVID-19).

Day 5 visit: This visit will take approximately 6 hours.
At this visit, the following will take place:

- You will complete a brief questionnaire about your current health.
- A study doctor will conduct a physical examination similar to those done for regular medical care.
- At this Day 5 visit, you will receive your last dose of study treatment (either disulfiram or placebo).
- At this Day 5 visit, in addition to collecting blood at the beginning of the visit, we will also collect blood at 2 hours and 6 hours after your dose of study treatment. This is to measure the amount of the study treatment in your blood for us to determine how much of the study treatment is in your body. The total amount of blood that will be collected, by inserting a needle into your vein during this visit is 149 mL (2/3 cup of blood).
- We will collect some fluid from your nose and throat using cotton swabs to test for the COVID-19 virus and to study your respiratory tract immune cells.
- We will collect saliva (spit) to test for proteins that may be responding to COVID-19.

Telephone Visits: These visits will take approximately 30 minutes each.

You will be contacted by phone on days 3 and 4 while you are taking the study medication to complete a brief questionnaire about how you are feeling. After you complete your study treatment, you will be contacted to complete this questionnaire on Day 7, Day 9 and Day 11.

Participation in Future COVID-19-related research studies:

Additional studies may be conducted in relation to the DISCO study as researchers continue to learn about COVID-19. You will be asked for permission to contact you for future participation in DISCO-related research studies. This is voluntary and your decision will have no effect on your participation in this study. You will be asked for your consent in another area of this consent form.

How will my specimens and information be used?
Researchers will use your specimens and information to conduct this study. When the study is done using your specimens and information, we may share them with other researchers to use them 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 your permission to share this de-identified information.
Storage of de-identified blood and other specimens for future research studies
As part of this study, some of the blood and other samples that we collect from you will be stored at a UCSF specimen bank, at UCSF specialty labs, and with our research collaborators for future studies to learn about COVID-19. We may also collect and save information from your medical record such as diagnostic test results, medical questionnaires, diagnoses, treatments, and genetic test results. We do not know if your stored specimens or information will be used for future research. Only Dr. Fayed and his collaborators, including Dr. Lee from University of California, San Francisco, will have access to your specimens at this time. In the future, it is possible that external researchers from Harvard University, Cold Springs Harbor Lab, and Emory University may collaborate with University of California, San Francisco and may have access to your de-identified specimens.

All stored specimens will be coded with a unique ID number and will not include your name. We may label the specimens with a testing date, your age or your sex at birth, but we will not give them your name, address, phone number, date of birth or any other information that would identify you. Your identifiable personal health information cannot be used for additional research without additional approval from either you or a review committee.

Your specimens will be stored until they are used up or destroyed. Results from future research will not be given to you or your doctor. The research will not change the care you receive. Your stored specimens may be used to develop new discoveries, drugs, tests, treatments, or products.

In some instances, these may have potential commercial value. If this happens, you will not receive any payment or financial benefit from any products, tests, or discoveries. If you decide later that you do not want your specimens or information to be used for future research, you can notify Dr. Mohamed Fayed in writing at mohamed.fayed@ ucsf.edu or UCSF Fresno 155 N. Fresno Street, Suite 319 Fresno CA 93704, or by phone 559-793-3501 option 1 extension 7304), and any remaining identifiable specimens will be destroyed. We will not be able to eliminate data already collected.

Genetic Testing: Researchers would like to use some of your specimens (for example, blood, etc.) to look at your RNA (the genetic information that comes from your DNA) and may look at your DNA in later studies. This is called "RNA sequencing" or "DNA sequencing." DNA contain information that determines things like eye color, height, or disease risk that are passed on from parent to child. RNA can tell us which parts of the DNA are "active" and what cellular functions might be active in your body. You will be asked at the end of this consent form to indicate your willingness to participate in the genetic testing.

How will my genetic information be shared?
Genetic information (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in a coded form for future genetic research or analysis. Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health.

Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes. There will be no direct benefit to you from allowing your data to be kept and used for future research. However, we hope we will learn something that will contribute to the advancement of science and understanding of health and disease.

We may give certain medical information about you (e.g. diagnosis, blood pressure, age) to other scientists or companies not at UCSF, including to a public government health research database, but we will not give them your name, address, phone number, or any other identifiable information. Research results from these studies will not be returned to you, as they are exploratory in nature.

If the data or any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits. If you decide later that you do not want your information used for future genetic research, you can notify Dr. Mohamed Fayed in writing at mohamed.fayed@ucsf.edu or UCSF Fresno 155 N. Fresno Street, Suite 319 Fresno CA 93704, or by phone 559-793-3501 option 1 extension 7304) and any remaining samples will

be destroyed, and no further data will be collected. However, we cannot retract any data has been shared with other researchers.

What side effects or risks can I expect from being in the study?
Side effects associated with taking disulfiram: Disulfiram (Antabuse) usually produces no effect in a person who does not have any alcohol in their bloodstream.

It is not known what the risk is of taking disulfiram in the COVID-19 population. In patients without COVID-19, the following potential risks have been associated with disulfiram:

Likely (Greater than 20%)

Serious and more common effects (greater than 20%)(especially if you drink alcohol):

- You must not drink alcohol during this study and for 2 weeks afterward because disulfiram can cause a reaction to alcohol. This reaction can include:
- flushing (suddenly feeling hot and reddening of the skin)
- nausea
- vomiting,
- low blood pressure,
- chest pain,
- headache,
- anxiety.

Rarely people have died from these reactions.

This will not occur if you do not take alcohol or use alcohol-containing products (such as wine vinegars, salad dressing, mouthwash and cough syrup) while in this study and for at least 2 weeks afterward.

You should read labels and check ingredients of foods you eat and products you use to make sure that they do not contain alcohol while you take this medicine. We will provide you a list of commonly used medications to avoid, particularly over-the-counter medications (e.g., used for cough symptoms), that may interact with disulfiram and potentially cause adverse side effects. If you are in doubt about a product, call the study doctor who can advise you as to whether it is safe to use a product.

Less Likely side effects (less than 20%):

- Slight drowsiness or tiredness
- Skin rash,
- Metallic or garlic-like taste in the mouth can occur.

Other side effects have rarely been reported by people taking this medicine and they include:

- Pain and tingling in arms/hands and/or legs/feet (also called peripheral neuropathy),
- Inflammation of the liver
- Liver failure
- Seizures
- Vision problems due to inflammation in the eye nerve (also called optic neuritis)
- High blood pressure.
- The use of disulfiram while also using some tricyclic antidepressant medications, tuberculosis (TB) medication (isoniazid), or medications associated with acid reflux (Prilosec, Nexium and Protonix) could have unexpected side effects including drowsiness and confusion. We will closely monitor your health while you are taking part in this study.

Because the doses given in this study are higher than typically used or FDA approved, it is possible there will more side effects than expected or unusual side effects.

Rare but serious side effects:

- Although very rare, death from liver failure has been reported in retrospective population studies (1 in 32,000) for those who were on treatment for many weeks to months.
- In HIV-infected patients also taking another drug called vorinostat, with disulfiram 2000 mg for 28 days, led to some neurologic symptoms (paranoia, difficulty walking, lack of energy). These symptoms were reversed after stopping the drug, and levels of disulfiram drug in patients did not correlate with the symptoms.

We will be monitoring your response to these drugs very closely. In the event of a serious adverse event, we will provide you appropriate medical care immediately. Many side effects go away shortly after the drugs are stopped, but in some cases, side effects may be serious, long lasting, life threatening or result in death.

Reproductive risks

- The effects of disulfiram on an unborn baby are unknown. Women of childbearing potential are not excluded from these studies. Women will be tested for pregnancy in the medical workup for study entry and excluded from participation if pregnant. Women of childbearing potential must have a negative serum pregnancy test at screening and agree to use a double-barrier method of contraception throughout the study period. Women will be counseled not to breast-feed during this study. Both male and female participants will be asked to use two forms of birth control during the study.
- The use of the below mentioned birth control methods does not apply if the male partner has had a vasectomy at least two months prior to screening or if the female sexual partner has had a bilateral oophorectomy (surgical removal of both ovaries), a total hysterectomy (removal of the womb), a tubal ligation (commonly known as having tubes tied), other permanent birth control methods, or if she is post-menopausal (not

having monthly periods for at least 2 years).

- If you are a woman who is able to have children, you should not become pregnant or nurse your child during the study. You must agree to use 2 effective methods of contraception during the study, such as a barrier method that prevents transmission of fluids and a hormonal contraceptive like the pill, patch, or vaginal ring. Barrier contraception includes male condoms OR female condoms (not to be used both simultaneously as friction between the two can result in damage or breakage of either product) diaphragm with spermicidal jelly, or cervical cap with spermicidal jelly.
- If you are a man who has a female partner of child-bearing potential you must agree to use 2 effective methods of contraception. You and your female partner should use a male condom in combination with another effective method such as hormonal contraceptives (like the pill, patch or vaginal ring), intrauterine device, or diaphragm with spermicidal jelly or cervical cap with spermicidal jelly.
- You must agree to inform your sexual partner that you are participating in a research study which requires you and your partner to use 2 methods of contraception.

Blood Draw: Blood draws can cause some discomfort, bleeding or bruising where the needle enters the skin, and rarely, fainting or infection can occur. A total of 406 mL (about 1 3/4 cups) of blood will be drawn during the 31-day study period, which is within Red Cross Guidelines (which advise less than 500 mL every two months). Another risk of blood collection is anemia (low blood count). We will test you for anemia at each study visit. If investigators think you are at high risk for anemia, the amount of blood drawn at the next visits will be reduced. If you are currently anemic, the study doctor may exclude you from taking part in the study at his discretion.

Nasal/Throat Swab: The nasal and throat swabs may be uncomfortable or cause slight bleeding.

Pregnancy Testing (for females): You may worry about the results of a pregnancy test. We will give you the results as soon as possible and recommend you follow-up with your medical providers.

Confidentiality: Participation in research can involve a loss of privacy. We will handle your records as confidentially as possible. All study questionnaires and samples are coded with a study ID, and no personal identifiers such as your name or date of birth are used for any specimens. Dr. Fayed and the research staff as well as the study staff at University of California San Francisco, who are also working on this project will have access to your study records and test results. No individual identities will be used in any reports or publications that may result from this study.

Risk of genetic testing: Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To

further safeguard your privacy, genetic information in this study will not be placed in your medical record. Although we will do our best to protect your genetic information, we cannot guarantee complete protection from potential computer security breaches that are relevant to maintaining data in an electronic format.

Effect on participating in other studies: Every research study has different requirements for participation, which are known as eligibility criteria. If a participant agrees to take part in this study, the procedures required for this study may make him/her not eligible to participate in other studies for a period of time. How long that period of time is may be determined by the other study.

Risks of randomization: You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

Risks of placebo: If you are in the group that receives placebo, your condition will go without the active (study) treatment for 5 days.

Unknown Risks: Any research study may result in side effects that we do not yet know about. The researchers will let you know if they learn anything that could change your mind about participation.

Are there benefits to taking part in the study?
While there is a chance that taking part in this study may reduce the severity of your illness, it may not provide you with any direct benefit. It may also help us understand how individuals experience and recover from COVID-19, to guide future diagnosis, prevention, and treatment of COVID-19.

How long will I be in the study?
Each of the five in-person research visits will last approximately one hour, with the exception of the Day 5 visit, which will take approximately six hours.

Each of the five phone calls to complete Questionnaires will take anywhere from 10-30 minutes.

At the Day 5 visit, which is the last day of your study treatment (disulfiram or placebo), you will be monitored for 6 hours and your blood will be drawn at the beginning of the visit, and after 2 and 6 hours from taking your last dose of study treatment.

Your total time in the study visits will be approximately 11 hours, and your overall time in the study is for 31 days, or 1 month.

What does it cost to take part in this study?

There is no cost to you to take part in this research study. All study required lab tests and procedures that are not being ordered as part of your regular standard of care will be paid for by the study sponsor. Neither you nor your insurance company are responsible for any research-related costs.
You will not be charged for the following research-related tests and procedures:

- Saliva Collection and testing
- Research-related blood collection and testing
- Research-related physical exam
- Completion of Questionnaires and Surveys
- Research-related COVID-19 testing by throat or nose swabs
- Research-related urine pregnancy testing
- Study medication or placebo

There may be times that your study visit will coincide with a regularly scheduled standard of care visit, and in this case, study related procedures will be charged to the study and standard of care procedures such as lab work or other tests that are not part of the study will be billed to you or to your insurance. You will be responsible for co-pays, deductibles, and any other charges that your insurer will not pay. Before you take part in this study, you should call your health insurer to find out if the cost of these tests and/or procedures will be paid for by the plan. Some health insurers will not pay for these costs. You will have to pay for any costs not covered by your health insurer. Because there may be some costs which are not covered by the study sponsor or your health insurance, the study team can help you to determine if there are costs which may be billed directly to you.

Will I be paid for taking part in this study?
Yes. You will be paid $50.00 in cash for each regular single blood draw in-person study visit in return for your time and travel. There will be one pharmacokinetic (PK) day when we measure study treatment levels in your blood three times over a 6-hour period of time; you will paid $150.00 for this longer in-person study visit. This is a total of up to $400.00 for completion of all five visits that include the baseline visit, three regular in-person follow up visits, and one longer 6-hour in-person visit. You will not be paid for the telephone follow-up calls. You will receive your payment at the end of each visit.

What other choices do I have if I do not take part in this study?
The alternative to this study is not to participate and to receive your regular standard of care or enroll into another research study for COVID-19 if available to you. Please talk to your doctor about your choices before agreeing to participate in this study.

Can I stop being in the study?
Your participation in the study is completely voluntary and you can withdraw at any time by telling any study team member. Withdrawing will not affect your ability to receive care at the

COVID-19 clinic or at any other care center.

Additionally, the study team may end your participation at any time without your permission. This could be for your health or safety, because you have not followed instructions, or if for some reason your samples are no longer needed. If you leave the study before the last visit, you may be asked to attend a final visit for some of the end of study procedures.

Will my medical information be kept private?
We will do our best to make sure that personal information about you is kept private but cannot guarantee total privacy. In this study you will be asked about drug use and other possibly illegal activities. The researchers will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, research records have been subpoenaed by a court. The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifiers will not be used in any publication or teaching materials without your specific permission.

A research record is created when you participate in a clinical trial at UCSF Fresno. Some information from your medical records will be collected and used for this study. If you do not already have a medical record, one will be created for you because of your participation in this study. Your signed consent form and some of your research test results will be included in this 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.

Your personal information may be given out if required by law. For example, by California law, we are required to report

- New cases of HIV, tuberculosis, hepatitis B, and hepatitis C infection to the county public health department.
- New cases of COVID-19 disease are reportable to the county public health department.

Newly diagnosed COVID-19 cases using the research (i.e., not yet validated) assays used in this study may not be shared with you since these assays are not yet approved for clinical use. Only COVID-9 testing results from clinical (CLIA-approved) assays – such as those tests performed as part of your regular clinical care outside of research are reportable to the county public health department. The reports include the patient's name, social security number, and other identifying information. Additionally, identifiers might be removed from the identifiable private information or identifiable biospecimens and after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

Information about these new infections is used to track diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the study staff. No personally identifying information will be shared to other departments or agencies. If information

from this study is published or presented at scientific meetings, your name and other personal information will not be used. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The University of California
- Community Medical Centers
- Community Medical Centers Institutional Review board, involved in keeping research safe for people
- UCSF Institutional Review Board involved in keeping research safe for people
- The U.S. Food and Drug Administration (FDA)
- The Office for Human Research Protections (OHRP)
- Department of Health and Human Services (DHHS), and other government agencies involved in keeping research safe for people
- Safety Monitoring Committee

Research results: There may be times when researchers using your information and/or specimens may learn new information. The researchers may or may not share these results with you, depending on a number of factors. We can discuss those factors with you if you have questions. Your specimens may be used for commercial use. If this happens, you will not share in any profits.

What happens if I am injured because I took part in this study?
It is important that you tell the study doctor, Dr. Mohamed Fayed, if you feel you are injured because of taking part in this study. You can tell the doctor in person or at (559)793-3501 option 1 extension 7304.

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 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. Due to the coronavirus public health crisis, the federal government issued a Declaration under the public Readiness and Emergency Preparedness (PREP) Act. If the Declaration applies, it limits your right to sue and recover for losses from the researchers, healthcare providers, and study sponsor or manufacturer or distributor involved with the study, including the University of California, while participating in this COVID-19 clinical study. However, the federal government has a program that may provide compensation to you or your family for certain claims if you experience serious physical injuries or death and these costs are not covered by other payors. To find out more about this "Countermeasures Injury Compensation Program" go to https:///www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

ClinicalTrials.gov is a website that provides information about clinical trials. 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.

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, you may leave the study at any time. Whatever decision you make, there will be no penalty and you will not lose any of your regular benefits. Leaving the study will not affect your medical care, which you can still receive from our institution. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?
In the future, you may have questions about your study participation. You may have questions about your health, your test results, or about a research-related injury. If you have questions please contact Dr. Fayed at 559-793-3501 option 1 extension 7304.
or email: mohamed.fayed@ucsf.edu

For questions about your rights in this study, you can call the office of the Community Medical Centers Institutional Review Board (a group who reviews research to protect your rights) at (559) 499-6553.

INFORMED CONSENT

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline participation and can withdraw at any point without penalty or loss of benefits to which you are otherwise entitled. You will receive a copy of this Consent Form and an Experimental Subject's Bill of Rights. You will be asked to sign a separate form to authorize access, use, creation, or disclosure of health information.

By signing below, I affirm I have read this consent form, had a chance to ask questions, and have received satisfactory answers. I have been informed about the procedures, risks, and benefits and wish to participate.

Consent to Share Laboratory Results:
____ (initials) YES, I want to receive laboratory results that might be important to my care.
____ (initials) NO, I do not want to receive laboratory results that might be important to my care.

____(initials) YES, I would like my primary care doctor to be informed of and receive laboratory results that might be important to my care.

_____
Name and phone number of Primary Care Doctor

_____(initials) NO, I would NOT like my primary care doctor to be informed of and receive laboratory results that might be important to my care.

Consent for Genetic Testing:
_____(initials) YES, I agree to have genetic testing conducted on the samples collected for this study.
_____(initials) NO, I do not agree to genetic testing conducted on the samples collected for this study.

Consent for Nasopharyngeal (NP) and Oropharyngal (OP) Swab Collection:
_____(initials) YES, I agree to have NP/OP swabs collected for this study.
_____(initials) NO, I do not agree to have NP/OP swabs collected for this study.

Consent for Saliva Collection:
_____(initials) YES, I agree to have saliva collected for this study.
_____(initials) NO, I do not agree to have saliva collected for this study.

_____
Full Participant Name (Print)

_____ _____
Participant Signature Date/Time

_____
Medical Record Number

_____
Person Obtaining Consent Name (Print)

_____ _____
Person Obtaining Consent Signature Date/Time

_____
Investigator Name (Print)

_____ _____
Investigator Signature Date/Time

For remote/telephone/videoconference consent process:

_____	_____	_____
Print Name of Witness	Signature of Witness	Date/Time

CMC's Interpreter Statement:

<u>In the event that an interpreter is needed</u>:

I have accurately and completely read the foregoing document to:

_____
(patient or legal representative's name)
in _____ the patient's (or legal representatives) primary language.
(identify language used)

He/She understands all terminology/conditions, acknowledges his/her agreement by signing the document in my presence.

_____	_____
Signature of Interpreter	Date/Time

_____
Printed name of Interpreter

AUTHORIZATION FOR USE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

Protected Health Information is any personal health information through which you can be identified. A decision to participate in this research means that you agree to the use of your health information for the purposes explained in this consent form. By signing this form, you are authorizing the use and disclosure of your health information collected in connection with your participation in this research study. Your information will only be used in accordance with the provisions of this consent form and applicable law.

Your health information related to this study, including, demographics such as age, race, and sex, your health history, including chronic illnesses, illnesses related to COVID-19, information from hospital records if you were admitted to the hospital for COVID-19 including diagnosis, treatments, laboratory tests, imaging, medications, length-of-stay, physical examinations, and histories may be used or disclosed in connection with this research study. Study records that identify you will be kept confidential as required by law. Except when required by law, you will not be identified by name, SS#, date of birth, address, phone#, or any other direct personal identifier in study records disclosed outside of the Community Medical Centers (CMC). For records disclosed outside of CMC, you will be assigned a unique code number. The key to the code will be kept in a locked file in the office of the Principal Investigator, Dr. Mohamed Fayed.

Representatives of the following groups are authorized to use and/or disclose your health information in connection with this research study:
The Principal Investigator, Dr. Mohamed Fayed, the sub-investigator and the study coordinators working directly with this project.
University of California and their affiliates working directly with this project
Community Medical Centers
Community Medical Centers Institutional Review Board

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

The Office for Human Research Protections (OHRP)
Department of Health and Human Services (DHHS)
The U.S. Food and Drug Administration (FDA)

Safety Monitoring Committee

Your information may be re-disclosed if the recipients described above are not required by law to protect the privacy of the information.

EXPIRATION DATE OR EVENT FOR THE RETENTION OF RECORDS

The study results will be retained in your research record for at least six years after the completion of this study. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at Community Medical Centers. Any research information in your medical record will be kept indefinitely.

VOLUNTARY PARTICIPATION

Your participation is voluntary and you may choose not to participate in this research study or withdraw your consent or authorization for the use and disclosure of your health information at any time. Your choice will not at any time affect the commitment of your health care providers to administer care and there will be no penalty or loss of benefits to which you are otherwise entitled. If you decide to end your participation in the study, please notify the researcher(s) in writing.

If you have questions or concerns regarding your privacy and the use of your personal health information, please contact the CMC Privacy Office, at 559-724-4400.

_____

Signature (patient) Printed Name Date Time

_____

Signature (parent/legal guardian/conservator) Printed Name Date Time

_____

If signed by other than patient, indicate relationship

_____

Witness Signature Printed Name Date Time