RESEARCH SUBJECT CONSENT FORM

TITLE Assessing methadone dose taken using electrochemistry

PROTOCOL NO.: 003
WCG IRB Protocol #20233500

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888-539-0282 (24 hours)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether or not you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Dr. Foster Carr received employee compensation as Chief Medical Officer from the study sponsor in the past 12 months and owns private equity in the sponsor company. He may be the physician that will perform the procedure for obtaining fluid from your skin. He is certified in this procedure and has previously performed it on other patients. He will not have access to your confidential patient records and will only know you by your assigned participant number. He will have access to the de-

identified data but not to any personally identifiable information. Please feel free to ask any further questions you might have about this matter.

How long will I be in this research?
The amount of time that you will participate in this research will depend on whether you are assigned to participate in the 3 hours, 6 hours, 12 hours, and/or 3 day part of the study. If you are assigned to be monitored for 3 hours, the whole process may take up to 4-5 hours. If you are assigned to be monitored for 6 hours, the whole process may take up to 7-8 hours. If you are assigned to be monitored for 12 hours, the whole process may take up to 13-14 hours. If you are assigned to be monitored for 3 full days, the whole process may take 3 full 24-hour days. This does not include travel to and from the study site.

Why is this research being done?
The purpose of this study is to evaluate the early safety and feasibility of detecting and continuously monitoring methadone in the fluid under the surface of the skin, known as interstitial fluid, of patients taking prescribed daily doses of methadone by using a minimally-invasive remote medication monitor.

Once it is confirmed that methadone can be detected in the fluid underneath the skin it will be possible to create a wearable product that will enable patients to prove that they have taken their medication as prescribed without having to physically visit the clinic.

You have been invited to participate in this study because you have indicated that you do or do not have a prescription for methadone to treat an opioid use disorder or treat pain.

What is interstitial fluid sampling?

a. Interstitial fluid sampling is a procedure where very small needles are placed in the skin to make tiny openings from which fluid under the skin can come out. There are 3 methods that can be used for collecting the interstitial fluid as described in detail in the next section of this consent form. All of these methods have been used in humans before. Briefly, the following 3 methods may be used if you participate in this study include:
    - Collecting fluid with a single microneedle attached to paper for absorption.
    - Collecting fluid from the surface of your skin after about 10 pokes from a microneedle device followed by a suction device.
    - Collecting fluid with the Kiffik device which places small holes in the surface of the skin using electrical currents and then suctions fluid from those holes with a device that is worn on the skin for multiple hours.
b. The ultimate reason we are collecting the interstitial fluid is to develop a sensor so patients can prove that they have taken a dose of methadone without having to visit the clinic.

What happens to me if I agree to take part in this research?
If you have a prescription for methadone, there are two parts to this study. If you decide to participate in part 1 of this research study, the general procedures include a questionnaire (up to 15-30 minutes), an in-person a physical exam (up to 30 minutes), a first blood collection (up to 10 minutes), interstitial fluid sample collections (up to 6 hours), a second blood collection (up to 10

minutes), and a follow-up call 2 days after your in-person visit (up to 15 minutes). This whole process on visit 1 may take up to 7-8 hours.

If you have a prescription for methadone and you decide to participate in part 2 of this research study, you will repeat the steps above with the addition of a continuous sensor application for up to 12 hours and/or 3 full 24-hour days. This means that you will wear the sensor at the study site for a total of 12 hours and/or 3 full days while being monitored by a healthcare provider and study staff. If you are assigned to be monitored for 12 hours, the whole process may take up to 13-14 hours. If you are assigned to be monitored for 3 full days, the whole process may take 3 full 24-hour days. If spaces are available, you will have the option to participate in as many visit days as you wish.

If you do not have a prescription for methadone the general procedures include a questionnaire (up to 15-30 minutes), an in-person a physical exam (up to 30 minutes), a blood collection (up to 10 minutes), interstitial fluid sample collections (up to 3 hours), and a follow-up call 2 days after your in-person visit (up to 15 minutes). This whole process may take up to 4-5 hours.

By signing this consent, you agree to participate in at least one of the research visit days.

Could being in this research hurt me?
The most important risks or discomforts that you may expect from taking part in this research include mild allergic reaction to adhesives, bleeding, bruising, infection, pain or discomfort, scarring or skin discoloration, skin inflammation, thinning, discoloration and/or redness. Although unlikely, hospitalization due to infection is possible.

Will being in this research benefit me?
It is not expected that you will personally benefit from this research. However, possible benefits to others include helping patients who are prescribed methadone for pain by providing medication adherence reminders and personalizing their dose.

What else should I know about this research?
Other information that may be important for you to consider so you can decide whether to take part in this research is you will be asked to abstain from alcohol and non-prescribed substances at least 24 hours before your in-person clinical assessment. You will be compensated for your participation. Any participants who enroll in the study can stop participating at any time.

DETAILED RESEARCH CONSENT

A person who takes part in a research study is called a research subject, or research participant.

You are being invited to take part in a research study because you are age 18-70, you do not have a condition preventing or complicating interstitial fluid collection such as dermatological (skin) condition, bleeding, immunodeficiency, recent blood donation, anemia, end stage renal disease, liver cirrhosis, cancer, congestive heart failure, bleeding diathesis, tuberculosis, active severe depression (e.g., suicidal ideation), mania symptoms, any severe forearm skin injury, tattoo or piercing close to the sampling area, or under a conservatorship. You also have not consumed/used alcohol or illicit

substances (e.g., barbiturates, benzodiazepines, amphetamine, methamphetamines, cocaine, heroin) in the past 24 hours before intestinal fluid collection. If you are a woman, pregnant, lactating, or intending to become pregnant during the course of the study.

In addition to the eligibility criteria listed above, the following eligibility criteria also applies to the following group of participants:

> **If you have a prescription for methadone**: You have had that prescription at a dose of 10mg or more for at least 7 days and you have been taking that prescribed dose during the last 4 days before the study visit. You have also been prescribed at least 3 days of take-home doses.

If you do not have a prescription for methadone: You have not taken an opioid in the last 7 days (prescribed or not prescribed). You do not have a substance use disorder.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to evaluate the early safety and feasibility of detecting and monitoring methadone in the fluid under the surface of the skin interstitial fluid of patients taking prescribed daily doses of methadone by using an investigational minimally-invasive remote medication monitor and software.

Once it is confirmed that these common medications can be detected and monitored in the fluid right underneath the skin it will be possible to create a wearable product that will enable patients to prove that they have taken their medication as prescribed without having to physically visit the clinic.

You have been invited to participate in this study because you have indicated that you do or do not have a prescription for methadone for an opioid use disorder or pain and you meet the eligibility criteria.

What is interstitial fluid sampling?

1. Interstitial fluid sampling is a procedure where very small needles are placed in the skin to make tiny openings from which fluid under the skin can come out. There are 3 methods that can be used for collecting the interstitial fluid.
    - Collecting fluid with a single microneedle attached to paper for absorption.

- Collecting fluid from the surface of your skin with 10 controlled pokes from a microneedle device followed by use of a suction device to help the fluid under the skin come out. An operator will then remove the fluid from your skin with a pipette.
- Collecting fluid with the Kiffik device which places small holes in the surface of the skin using electrical currents and then suctions fluid from those holes with a device that is worn on the skin for multiple hours.

2. The ultimate reason we are collecting the interstitial fluid is to develop a sensor so patients can prove that they have taken a dose of methadone without having to visit the clinic.

How long will I be in this research?
The amount of time that you will participate in this research will depend on whether you are assigned to participate in the 3-hour, 6-hour, 12-hour, and/or 3 day part of the study. If you are assigned to be monitored for 3-hours, the whole process may take up to 4-5 hours. If you are assigned to be monitored for 6-hours, the whole process may take up to 7-8 hours. If you are assigned to be monitored for 12-hours, the whole process may take up to 13-14 hours. If you are assigned to be monitored for 3 full days, the whole process may take 3 full 24-hour days. This does not include travel to the study site.

What happens to me if I agree to take part in this research?
If you have a prescription for methadone, there are two parts to this study. If you decide to participate in part 1 of this research study, the general procedures include a questionnaire (up to 15-30 minutes), an in-person a physical exam (up to 30 minutes), a first blood collection (up to 10 minutes), interstitial fluid sample collections (up to 6 hours), a second blood collection (up to 10 minutes), and a follow-up call 2 days after your in-person visit (up to 15 minutes). This whole process on visit 1 may take up to 7-8 hours.

If you decide to participate in part 2 of this research study, you will repeat the steps above with the addition of a continuous sensor application for up to 12 hours and/or 3 full 24-hour days. This means that you will wear the sensor at the study set for a total of 12 or 72 hours while being monitored by a healthcare provider and study staff. If you are assigned to be monitored for 12 hours, the whole process may take up to 13-14 hours. If you are assigned to be monitored for 3 full days, the whole process may take 3 full 24-hour days.

If you do not have a prescription for methadone, the general procedures include a questionnaire (up to 15-30 minutes), an in-person a physical exam (up to 30 minutes), a blood collection (up to 10 minutes), interstitial fluid sample collections (up to 3 hours), and a follow-up call 2 days after your in-person visit (up to 15 minutes). This whole process may take up to 4-5 hours.

By signing this consent, you agree to participate in at least one of the research study days. If spaces are available and you are eligible, you will have the option to participate in as many visit days as you wish.

Initial questionnaire (up to 15-30 minutes):

a. If you agree to participate as indicated by your signature on this consent, you will be assigned a computer-generated Participant ID code. You will then be asked to complete a baseline assessment. The questionnaire will include the following:
   i. Demographics (e.g., age, sex, race, ethnicity)
   ii. Past and current diseases or medical conditions
   iii. Previous operations or medical procedures
   iv. Any medicines, vitamins, minerals, and herbal remedies that the person is currently taking
   v. Diet and exercise habits
   vi. Tobacco, alcohol and other substance use history
   vii. Previous pregnancy history (if female)

b. Once the assessment has been completed, the Clinical Research Coordinator will schedule in-person clinical visit for you if needed. If you have a methadone prescription, you will be instructed to take your methadone as prescribed by your physician (e.g., dose, dosing times). As such, the in-person visit will be scheduled around your usual dosing time. You will also be asked to abstain from alcohol, tobacco, and non-prescribed substances at least 24 hours before your in-person assessment.

2. In-person study visits:

a. **Physical assessment (up to 30 minutes)**
   i. If you have a methadone prescription, you will be instructed to take your methadone as prescribed. As such, in-person assessments will be scheduled around your typical methadone administration time.
   ii. The in-person assessment for all participants with or without a prescription for methadone may include the following:
      1. Limited physical exam:
         - Height and weight measurements
         - Feeling for the pulse
         - Listening to the heart and lungs with a stethoscope
         - Measuring blood pressure using a sphygmomanometer
      2. Report of changes in medications in the past week
      3. Urine pregnancy test for premenopausal women. If you test positive, you will be discharged, paid $50, and referred to your primary care doctor or OBGYN
      4. Urine test to confirm no alcohol, barbiturates, benzodiazepines, amphetamine, methamphetamines, cocaine, heroin, oxycodone, or other opiates

b. **In-person first blood sample collection (10 minutes)**
   i. Before the interstitial fluid collection, a standard venipuncture blood sample will be collected (about ½ teaspoon) by a certified clinician. These samples will be used for comparative analysis with the interstitial fluid. The blood draw may cause mild discomfort.

c. **Interstitial fluid samples collected by 1 of 3 potential methods (up to 3-6 hours)**
    1. Non-invasive episodic measurements of methadone and its metabolites in the interstitial fluid will be carried out using a microneedle electrode sensor and differential pulse voltammetry for up to 3 or 6 hours using one or more of three extraction methods (described below). The interstitial fluid collection methods will be applied by a clinician to the surface of the upper-back right or left arm (your preference). If more than one of the three interstitial fluid collection methods are applied then it will be applied on the same upper arm or forearm areas by the physician at least 10 cm apart. You will have the opportunity to decide whether you are willing to have more than one of the extraction methods administered.
        1. **Method 1:** (microneedle patch and applicator):
            - The interstitial fluid under your skin will be collected by a board-certified physician with procedural skills, training, and familiarity with interstitial fluid collection.
            - Interstitial fluid will be collected from the surface of your right or left arm (your preference) 1 hour prior to taking your prescribed methadone and continued every 20-40 minutes until about 4 hours after taking your methadone (up to 5 hours).
            - You will be prepared for the interstitial fluid collection using standard clean working techniques (e.g., prepped and draped).
            - The procedure will involve covering the skin with a transparent film skin dressing containing a 1-cm-diameter opening where microneedle treatment will be performed.
            - A minimally invasive microneedle patch will be used in conjunction with a standard vacuum pump. The microneedles patch will be inserted to collect greater than or equal to 1 µ1 of interstitial fluid. A standard vacuum pump will then be administered for 20 min to draw out the interstitial fluid. Skin appearance should remain largely unchanged and result in a swift recovery as seen in a previous study. This approach has been well tolerated with minimal visual evidence of damage to the skin in previous studies.
            - Gauze will then be used to collect the interstitial fluid from the surface of the skin.
        2. **Method 2** (manual microneedle application): Similar to the method described above, a minimally invasive microneedle array will be used in conjunction with a standard vacuum pump by a board-certified physician. Controlled cycles of suction and release will be performed to allow for about 10 insertions (approximately 0.3 mm into the skin) and removal of the microneedles followed by controlled low level suction on the mechanically created skin pores. The interstitial fluid on the skin will be subsequently removed for its collection after 10 minutes to 3 hours.

3. **Method 3** (microneedle patch and applicator)**:** A board-certified physician will place the Kiffik device on your preferred arm. Interstitial fluid collection will start 2 hours prior to taking your prescribed methadone dose and will end prior to dosing with repeat collections after dosing every 2 hours until 6 hours of collection time has ended. Thus, a total of 3 samples will be collected from you.

ii. After the application is complete, the microneedles will be removed and a sterile bandage covering will be supplied to the area.

iii. You will be monitored before, during, and 15 minutes after the application to report your tolerability, pain, and experience. Your responses will be documented on a secured google drive spreadsheet, which will be encrypted with a password that adheres to secure Good Clinical Practice certified online storage medium requirements.

d. **Interstitial fluid samples collected by 1 of 3 potential methods (up to 12 hours or 3 24-hour days).**

i. Participants with a methadone prescription assigned to this part of the study will repeat the steps listed above, however, instead of only having periodic applications of one the three aforementioned devices, you will also continuously wear up to 3 remote medication monitor device(s) for either 12 hours or 3 24-hour days.

ii. The remote medication monitor is a microneedle sensor wired to a PalmSens or CHI Device and bluetooth connected to a cell phone application or computer program that is used to measure methadone and its metabolite levels in the fluid beneath your skin surface. A digital signal, known as a digital pulse voltammogram, will be translated into data and sent via a secure web server to the lead research staff. This will allow the researcher to identify evidence of the methadone dose you took.

iii. After the application is complete, the microneedles will be removed and a sterile bandage covering will be supplied to the area.

iv. You will be monitored before, during, and 15 minutes after the application to report their tolerability, pain, and experience. Their responses will be documented on a secured google drive spreadsheet, which will be encrypted with a password that adheres to secure Good Clinical Practice certified online storage medium requirements.

e. **In-person second blood sample collection (10 minutes)**

i. Those participating in the 6-hours, 12-hours, or 3 day visits will have a standard venipuncture blood sample collected (about ½ teaspoon) by a certified clinician after interstitial fluid collection. These samples will be used for comparative analysis with the interstitial fluid. The blood draw may cause mild discomfort.

3. **Follow-up call/visit (15 minutes)**
    a. Approximately 2 days after each study day, you will be contacted by the Clinical Research Coordinator via phone. You will be asked to report your tolerability, pain, and experience. Your responses will be documented in a secure online storage medium provided by the research site.

Your interstitial fluid and blood will be tested for methadone, the medication metabolites described in this consent. Your interstitial fluid may also be tested for other substances such as other opioids, alcohol, medications, etc. Your urine sample will be tested for alcohol and other drugs to confirm there are no other drugs in your system.

What are my responsibilities if I take part in this research?
As mentioned, if you decide to participate in part 1 of this research study, the general procedures include a questionnaire (up to 15-30 minutes), an in-person a physical exam (up to 30 minutes), a first blood collection (up to 10 minutes), interstitial fluid sample collections (up to 3-6 hours), a second blood collection (up to 10 minutes- those in the 6-hour visit only), and a follow-up call 2 days after your in-person visit (up to 15 minutes). This whole process may take up to 4-5 hours if you are assigned to the 3-hours assessment (participants without a prescription for methadone) or 7-8 hours if you are assigned to the 6-hour assessment (participants with a prescription for methadone).

If you decide to participate in part 2 of this research study, you will repeat the steps above with the addition of a continuous sensor application for up to 12-hours or 3 24-hour days. This means that you will wear the sensor at the study set for a total of 12 or 72 hours while being monitored by a healthcare provider and study staff. If you are assigned to be monitored for 12-hours, the whole process may take up to 13-14 hours. If you are assigned to be monitored for 3 full days, the whole process may take 3 full 24-hour days.

By signing this consent, you agree to participate in at least one of the research study days. If spaces are available and you meet the eligibility criteria, you will have the option to participate in as many visit days as you wish.

Could being in this research hurt me?
The most important risks or discomforts that you may expect from taking part in this research include:

- Mild allergic reaction to adhesives
- Mild bleeding
- Mild bruising
- Mild or moderated infection
- Mild or moderate pain, dizziness or discomfort
- Mild scarring or skin discoloration
- Mild skin inflammation, thinning, discoloration and/or redness.
- Although unlikely, hospitalization due to infection is possible.

Even though we will keep information collected in this study private, there is a possible risk of loss of confidentiality or privacy.

In addition to these risks, taking part in this research may harm you in unknown ways.

As a participant in this study, you always have the right of suit to recover compensation for damages directly caused by research procedures.

Will it cost me money to take part in this research?
Taking part in this research will not lead to added costs to you.

Will being in this research benefit me?
It is not expected that you will personally benefit from this research. However, possible benefits to others include helping patients who are prescribed methadone for an opioid use disorder or pain by providing medication adherence reminders and personalizing their dose. The information learned could also be used to help patients in the future.

What other choices do I have besides taking part in this research?
You can decide to participate or not participate in this research study. This research is not designed to diagnose, treat or prevent any disease. Any participant who enrolls in the study can stop participating at any time.

What happens to the information collected for this research?
Your private information and your medical record may be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor (CARI Health, Inc.)
- People who work with the research sponsor
- Government agencies, such as the Department of Health and Human Services (DHHS), National Institute of Health (NIH), National Institute of Drug Abuse (NIDA), and U.S. Food and Drug Administration (FDA)
- Research Advisory Panel of California (RAPC)
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your

information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data or specimens collected in this research will not be used to identify you. However, data or specimens (e.g., intestinal fluid, blood, urine) collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent. For example, your specimens may be used for additional analyses that may include whole genome sequencing (determining the order of DNA building blocks (nucleotides) in your genetic code). Reports about research done with your samples will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Interstitial fluid, blood, and urine taken from you may be used to establish products that could be patented and licensed. There are no plans to provide you with financial compensation should this occur. Your biological samples and their derivatives may have significant therapeutic or commercial value. You consent to such uses.

1. There will be use restrictions on how biological samples are used in "further testing," by this study or by any other researchers and entities with whom the samples may be shared;
2. Biological samples or test results will not be placed in publicly available biobanks;
3. Your present and/or future medical record can be accessed for 7 years and will then be destroyed.

Who can answer my questions about this research?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Website at any time.

What if I am injured because of taking part in this research?
If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

Can I be removed from this research without my approval?
The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- The urine pregnancy test on admission suggests that you are pregnant
- Urine toxicology tests include the following substances: barbiturates, benzodiazepines, amphetamine, methamphetamines, cocaine, heroin, oxycodone, or other opiates. You will be discharged from the study if these tests positive for any of the listed non-prescribed medications tested and you will be paid a total of $50.
- The research is canceled by the sponsor
- You are unable to have your interstitial fluid collected
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?
If you decide to leave this research, contact the research team so that the investigator can:

- Take you off the study schedule.
- Provide you with your compensation for the steps you completed.

If you do not participate in the follow-up phone call assessment, there may be risks with this decision. These may include: Un-identified adverse events associated with the interstitial fluid collection procedure.

Will I be paid for taking part in this research?
For taking part in this research, you may be paid with a visa gift card up to a total of $200 for the 3-hour visit, $250 for the 6-hour visit, $380 for the 12-hour visit, and/or $1,500 for the 3 day visit. You may have the opportunity to participate in more than one visit if you are eligible. The researchers

will inform you of that option as spots become available. Participating in more than one visit is optional. Your compensation will be broken down as follows:

3-hour visit: 3 hours of sensor measurement, total $200:

- $25 for the initial assessment (up to 15-30 minutes)
- $25 for the in-person physical exam and data collection (up to 30 minutes)
- $25 for the first blood collection (up to 10 minutes)
- $105 for interstitial fluid collections and remote medication monitor monitoring up to 3 hours
  $20 for the follow-up call (up to 15 minutes)

6-hour visit: 6 hours of continuous sensor measurement, total $250:

- $25 for the initial assessment (up to 15-30 minutes)
- $25 for the in-person physical exam and data collection (up to 30 minutes)
- $25 for the first blood collection (up to 10 minutes)
- $130 for interstitial fluid collections and remote medication monitor monitoring up to 6 hours
- $25 for the second blood collection (up to 10 minutes)
- $20 for the follow-up call (up to 15 minutes)

12-hour visit: 12 hours of continuous sensor measurement, total $380:

- $25 for the initial assessment (up to 15-30 minutes)
- $25 for the in-person physical exam and data collection (up to 30 minutes)
- $25 for the first blood collection (up to 10 minutes)
- $260 for interstitial fluid collections and remote medication monitor monitoring up to 12 hours
- $25 for the second blood collection (up to 10 minutes)
- $20 for the follow-up call (up to 15 minutes)

3 day visit: 3 24-hour days of continuous sensor measurement, total $1,500 or $500 per day. This will include an initial assessment (up to 15-30 minutes), an in-person physical exam and data collection (up to 30 minutes, a first blood collection (up to 10 minutes), interstitial fluid collections and remote medication monitor monitoring up to 12 hours, a second blood collection (up to 10 minutes) and a follow-up call (up to 15 minutes). If you withdraw from the 3 day study before it is complete you will be compensated for the following items that you complete:

- $25 for the initial assessment (up to 15-30 minutes)
- $25 for the in-person physical exam and data collection (up to 30 minutes)
- $25 for the first blood collection (up to 10 minutes)
- $1,380 for interstitial fluid collections and remote medication monitoring for every 6 hours
- $25 for the second blood collection (up to 10 minutes)
- $20 for the follow-up call (up to 15 minutes)

You will be paid in full after your follow-up call for each visit separately. If you drop out before the follow-up call for either day, you will be compensated for the steps you have completed. As mentioned, participating in one of the visits does not guarantee that you will be invited to participate in the other visits.

Your specimens (even if identifiers are removed) may be used for commercial profit. You will not share in this commercial profit.

Statement of Consent:
I have read this information, which is printed in English. This is a language that I read and understand. Your signature documents your consent to take part in this research. You will receive a copy of this signed informed consent form as well as a copy of the Experimental Subject's Bill of Rights.

_____
Name of adult subject capable of consent

_____ _____
Signature of adult subject capable of consent Date

_____
Name of person obtaining consent

_____ _____
Signature of person obtaining consent Date

CA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:
- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. They may also share the research information with Synergy Research Center, an agent for the study doctor.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:
- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:
- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Research Advisory Panel of California (RAPC)
- The institution where the research is being done
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- WCG IRB.

Why will this information be used and/or given to others?
- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

AUTHORIZATION SIGNATURE:

_____ _____

Signature of Subject **Date**