Department of Mental Health & Substance Abuse Services

TO: Prospective Researchers/Investigators

FROM: TDMHSAS IRB

DATE: January 21, 2019

SUBJECT: Sample Informed Consent Template

The Tennessee Department of Mental Health and Substance Abuse Services Institutional Review Board (TDMHSAS IRB) obtained permission to share this Sample Informed Consent Template to help researchers/investigators include the new elements required by the 2018 Common Rule. The template was developed by the University of California, Davis Campus, Office of Research.

We hope that our researchers/investigators find the template useful. For questions about the TDMHSAS IRB, please call Dr. Chappell at (615) 741-9476 or email Edwina.Chappell@tn.gov.

Consent Form

Title of research study: [insert title of research study here with protocol number, if applicable]

Investigator: [insert name of principal investigator]

[Include the section below titled "California Experimental Subjects Bill of Rights" when the research procedures include any of the following: (Otherwise the section "California Experimental Subjects Bill of Rights" can be deleted.)

- ***Severance or penetration or damaging of tissues of a human subject***
- ***The use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.***
- ***Investigational use of a drug or device***
- ***Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject]***

California Experimental Subjects Bill of Rights

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used. ***[Delete if there are no drugs and devices used.]***
- Any common or important discomforts and risks.
- Any benefits you might expect.
- Other procedures, drugs, or devices that might be helpful, and their risks and benefits compared to this study. ***[Delete for research involving no alternatives.]***
  - Medical treatment, if any, that is available for complications. [***Delete for research involving no more than minimal risk.]***
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document. ***[Delete if the consent process will not include obtaining signatures on the consent document.]***
- If you agree to take part, you will be given a copy of this document. ***[Delete if the consent process includes obtaining signatures on the consent document.]***

Key Information about This Research Study

[The 2018 Common Rule requires a brief and concise set of statements at the beginning of the consent document that explains what a "reasonable person" would want to know about the study. This section is intended to fulfill that requirement.]

You are invited to participate in a research study. The purpose of this research is ***[brief explanation of why the study is being done]***. You are invited to be in this study because ***[briefly explain why the person is being asked to participate in the study, (e.g. have been diagnosed with a certain condition or meeting***

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certain eligibility requirements)]. Your participation in this research will involve _____ visits and will last about ***[expected duration in hours, days, months, years]***. We expect about [number] people at UC Davis will join and about ***[number]*** people ***[around the U.S./worldwide]*** to participate in this research.

Participation in this study will involve ***[briefly provide a description of any procedures, drugs, and/or devices that the participant will experience as a part of this study]***. All research studies involve some risk. Risks of this study are ***[significant/minimal]***. These risks are described in detail later in this document. There ***[is/is not]*** the possibility that you may benefit from participation in this study.

Here are some reasons you may not want to participate in this research: ***[List the reasons a reasonable person might not want to enroll such as a requirement for frequent visits to the research site, likelihood of receiving placebo, risks of the study, compliance with study requirements (e.g. completion of diaries, only being allowed to eat certain foods, etc.)]***.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include ***[briefly describe any alternatives the participant will have aside from participating in this study]***. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions you need to help decide whether or not to join this study.

Information to help you understand research is online at http://www.research.ucdavis.edu/policiescompliance/irb-admin/for-research-participants.

What if I have Questions?

The person in charge of this study is [local PI name]. If you have questions or concerns about this study, please contact the Lead Researcher, at ***[local PI phone number]***.

[Clinical studies involving more than minimal risk will need to provide a 24-hour number] For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to ***[the Internal Med Resident on-call, etc.]***. In the case of an emergency, dial 911 from any phone.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, you may talk to a team member at the Institutional Review Board (IRB) at (916) 703-9151, hs-irbadmin@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817. The IRB is a group of people who oversee research.

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How is this research funded? [Include for sponsored research. Otherwise, delete.]

This research is being funded by ***[sponsor name]*** also called the sponsor. Sponsors may change or be added.

[Include for sponsored research if no one on the research team has received direct income from the sponsor. Otherwise, delete.] UC Davis is being paid to conduct this study, but the study doctor and research staff have not received any direct income from the sponsor.

[Include the following Conflict of Interest Language if a member of the research team has a related financial interest or if the University of California has an institutional conflict:]
[Name of Conflicted Party], a researcher on the study team, has a financial interest in ***[Sponsor]***, the company paying for this study. The company is paying ***[Name of Conflicted Party]*** for ***[describe the interest; or payment, e.g., consulting fee, salary].*** The ***[type of interest]*** income ***[Name]*** receives is in addition to their salary from the University of California. If you have questions, tell the study coordinator and they will put you in touch with someone to talk to.

Why is this research being done?

[Include this section if more information is needed on the purpose of the research. If the information was explained completely at the beginning of this document, delete this section. Briefly tell the subject the purpose of the research and explain the background of the research problem in lay language.]

What happens if I say yes, I want to be in this research?

If you decide to participate in this research study, the researchers will ask you to

[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:

- ***Describe procedures, activities, and treatments that subjects will undergo because they are in the research study.***
  - ***Organize this information in a logical, intuitive way, such as in order of occurrence.***
  - ***Standard treatments/procedures should be included only when they are part of the research (i.e., they must be administered/performed as specified by the protocol rather than per local clinical practice).***
  - ***Clearly identify any procedures, devices, drugs, etc. that are experimental.***
  - ***Describe as briefly as possible those study activities that will be familiar to your subject population based on their everyday experience or routine health care.***
  - ***Describe in detail those study activities that are risky and/or unfamiliar (e.g. randomization, investigational drugs/devices, imaging procedures).***
- ***Optional sub-studies should usually be described in a separate area at the end of the consent form. See the*** Optional Studies section ***at the end of this consent template.***
- ***Describe where study activities will take place (e.g. in a clinic, in a subjects' homes).***
- ***If subjects will be divided into different groups, explain how this will be done and any group-specific differences in procedures.***
- ***Describe the information you are collecting or using for study purposes, where this information will come from, and how it will be collected (e.g. directly from subjects, from medical records,***

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from tests or procedures done as part of the research). Particularly note the following in the consent form if they apply to your study:

- ***Collection or use of sensitive information (e.g. illicit or stigmatizing behavior, HIV/STI history, drug/alcohol abuse, some psychiatric diagnoses).***
- ***Collection of information about potentially distressing topics.***

- ***Describe how specimens and/or data will be used.***
- ***Use active verbs and clearly identify who is doing what.***
- ***Avoid dense, lengthy narrative descriptions. Use headings, bullets, white space and formatting to enhance the readability for better subject understanding.***
- ***Avoid unnecessary repetition. Describe each study activity in detail ONLY once.***
- ***If there are multiple study visits, create a table or flow chart illustrating the study visit schedule and activities.]***

[Include for a clinical trial that includes a placebo. Otherwise, delete.] You may be assigned to receive a placebo if you participate in this study. A placebo is a substance that has no active ingredients.

[Include for a clinical trial that includes randomization. Otherwise, delete.] The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an _____ ***[equal/one in three/etc.]*** chance of being given each treatment. ***[For double-blinded research add]*** Neither you nor the study doctor will know which treatment you are getting. ***[For single blinded research add]*** You will not be told which treatment you are getting, however, your study doctor will know.

How is being in this study different from my regular health care?

[Include this section for studies involving a patient population. Delete this section if your study does not include patients as subjects. For treatment studies, use the language below that best reflects the relationship between the study and standard care. *DELETE* ***language that does not apply:]***

People with ***[specify the disease/condition]*** usually don't have any treatment until their disease gets worse. If you take part in this study, you would be taking ***[study drug]*** sooner than it is usually given to treat ***[disease/condition].***

People with ***[specify the disease/condition]*** usually ***[describe standard care, e.g. have surgery/take drug]***. People in this study will have ***[study treatment]*** instead.

People with ***[specify the disease/condition]*** usually ***[describe standard care, e.g. have surgery/take drug X]***. In this study, some people will get this standard treatment, and others will get ***[study treatment]*** instead.

People with ***[specify the disease/condition]*** usually ***[describe standard care, e.g. have surgery/ take drug X]***. In this study, some people will get this standard treatment, and others will get standard treatment plus ***[study treatment]***.

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There is no single standard treatment for ***[specify the disease/condition]***. As part of their regular health care, people might get ***[treatment X, treatment Y, or treatment Z,]*** or no treatment at all. People who take part in this study will all get ***[study treatment]***.

[For studies that involve research conducted concurrently with standard care, include one of the following statements. DELETE language that does not apply:]

If you take part in this study, the main difference between your regular care and the study is ***[describe.]***

[Include if true] This study is not part of your health care.

[You can delete the following section if the research is not a clinical trial.]

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for: ***[Describe any responsibilities of the subject.]***

Do I have to be in this study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide not to take part, you can choose to leave the study at any time.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UC Davis Health or any services you receive from them. No matter what you decide, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

[Add the following for studies involving multiple visits and/or collection of information over a period of time:]

Please let the researchers know if you choose to leave the study. ***[If there are any risks associated with stopping study procedures, add either:]*** We will tell you how to leave the study safely. ***[OR]*** We will ask you to come in for a final study visit to check your health.

[Include if there are alternatives other than participating. Otherwise, delete.] Instead of being in this research study, your choices may include: ***[List alternative procedures. For student subject pools describe alternatives for course credit. For clinical trials describe the options that you would normally offer the patient. If applicable, include supportive care as an option.]***

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise, delete.] If you decide to leave the research, contact the study team so the investigator can work with

you to create a safe plan for your withdrawal. ***[Describe the procedures for orderly termination by the subject, if any.]***

[Include for FDA-regulated research. Otherwise, you may delete.] If you stop being in the research, data and specimens that have already been collected will not be removed from the study database. You will be asked whether the investigator can collect data from your future routine medical care. ***[Note: The consent document cannot give the subject the option of having data removed.]*** If you agree, this data will be handled the same as research data. ***[Note: If a subject withdraws from the study, the investigator must not access the subject's medical record or other confidential records without first obtaining the subject's consent and authorization. The investigator may continue to use data that were collected before the withdrawal.]***

[For research that is not FDA-regulated, describe what will happen to data and specimens collected up to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects but may agree to undergo follow-up procedures and data collection.]

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

[Describe any alternative treatment choices that the subject has outside of participation. If study treatment uses therapies available outside the study (e.g. approved drugs), make this clear. Delete this section if the only alternative is not to participate.]

You do not have to be in this research study to get care for your ***[disease/condition]***. If you decide not to take part in this study, you have other choices. For example:

[Select relevant options from the list below, and add other available alternatives.]

You may decide not to get treatment, but receive comfort care to help you stay as active and comfortable as possible.
You may choose to get the regular care described above for ***[disease/condition]***.
You may choose to take part in a different study if one is available.
These options may have risks. Discuss the possible risks and benefits with your study doctor.

[Include for research where this is a possibility. Otherwise, delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

[Delete the following section if not applicable.]

Can I be removed from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if:

- your health changes and staying on the study is no longer in your best interest;

- you do not follow the study rules or you no longer meet the requirements to be in the study; or
- the study is stopped by the sponsor or researchers.

Is there anyway being in this study could be bad for me?

There are risks to participating in this research. The study doctor and study team will monitor you to see if you are experiencing any harm related to your participation. If you experience any pain or discomfort, you must inform the study team as soon as possible.

[For clinical trials, the lists itemized in this consent form should be consistent with the Expected Adverse Event Table from the Investigator Brochure. We highly recommend risks be formatted as a table or bulleted list. Include the ratio of subjects who experience the risk (example 1 in 10) or list the risks as Very Common, Less Common, or Rare. Include the risks of other drugs and procedures required by the protocol. This may include standard of care drugs and procedures that are required by the protocol.]

[Describe each of the following risks, if appropriate.

- ***Physical Risks***
- ***Psychological risks***
- ***Privacy risks***
- ***Legal risks***
- ***Social risks***
- ***Economic risks***

[Include for clinical trials and research that involves procedures whose risk profile is not well known. Otherwise, delete.] In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

[If this research involves genetic testing, insert] Genetic Research Model Language ***[If you are not using the suggested language, please remove the language at the end of the document]***

[If this research involves genomic data sharing with NIH, insert] Genomic Data Sharing Model Language ***[If you are not using the suggested language, please remove the language at the end of the document]***

[Include for studies involving only non-sensitive data.] There is a risk that your information could become known to someone not involved in this study.

[For studies that collect data with psychosocial risks, such as information on genetic predisposition to diseases, drug or alcohol abuse, illicit behaviors, etc.] There is a risk that your information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

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What about Birth Control?

Include the language below when the study could adversely affect an embryo, fetus or a breastfeeding baby or if it is unknown whether such harm could occur. Check the protocol to see if there are specific requirements for contraception.

Note: When the study drug/device is known to harm an embryo or fetus or if it is unknown whether the study drug or device could cause such harm, the UC Davis IRB will usually require at least one of the methods included in the list below.

Contraception Requirements for Women

The study ***drug(s)/device(s)/procedure(s)*** may harm a fetus or a breastfeeding baby. If you are pregnant or breastfeeding, you cannot take part in this study. If you think you may be pregnant, you should not volunteer for this study. If you are able to become pregnant, you must have a pregnancy test before you begin the study ***[if tests are repeated, add:] and while you are in the study***. You must not get pregnant or breastfeed while you are in this study. If you are a woman who can become pregnant, you must take measures to avoid becoming pregnant while you are in this study. The following are acceptable measures to avoid becoming pregnant:

One of the following forms of birth control should be used:

- Abstinence (not having sexual relations with a person of the opposite sex)
- Implantable hormone (e.g. Norplant)
- Intrauterine Device
- Male partner must have a vasectomy
- Female sterilization
- Hormonal injection
- Oral contraceptives

You must use contraception, at least ***[include the timeframe]*** before starting study treatment unless you abstain from sexual intercourse. You must use contraception during study treatment and for at least ***[include the timeframe]*** after stopping study treatment.

Contraception Requirements for Men

There may be risks to the embryo/fetus if your sexual partner is pregnant or becomes pregnant while you are in this study. If your partner is a woman of child bearing potential, you and your partner must either practice total abstinence or use effective contraception while participating in this study. One of the following forms of contraception should be used by you or your partner:

- Abstinence (not having sexual relations with a person of the opposite sex)
- Implantable hormone (e.g. Norplant)
- Intrauterine Device

- Vasectomy
- Female sterilization
- Hormonal injection
- Oral contraceptives

You must use contraception during study treatment and for at least ***[include the timeframe]*** after stopping study treatment. You should also refrain from donating semen during therapy and for ***[include the timeframe]*** after stopping the therapy.

There is theoretical concern that study treatment can result in sperm abnormalities and/or can transmit harmful substances in their semen during sex. Therefore, if you are a male, you must remain abstinent or use a condom, even if you have undergone a vasectomy.

If your partner becomes pregnant or suspects becoming pregnant during study treatment or within ***[include the timeframe]*** after completing study treatment, you must inform the Study Doctor immediately. Your Study Doctor may want to follow the pregnancy and may ask your partner to sign a consent form so they can collect information about the outcome of the pregnancy.

Will being in this study help me in any way?

[Describe any tangible benefits to subjects. Avoid vague statements such as "you may or may not benefit." State specifically if subjects are not expected to benefit directly. Note that Phase I clinical trials typically involve no expectation of direct benefit to subjects. Do not include monetary reimbursement, free clinic visits, or other incentives in this section. Place such language in its own section, such as "Will I Be Paid or Receive Anything for Participating?" The following are examples. Delete the examples that do not apply:]

Being in this study may ***[specify how the subject may benefit, such as: relieve your symptoms, help you feel better]***. The study treatment may work better than the standard of care for your condition, but we cannot promise this will happen. The study treatment might not work at all, or it might have bad side effects. Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about ***[describe potential scientific/societal benefits]***.

Being in this study will not help you directly. But your participation in the study may benefit other people in the future by helping us learn more about ***[describe the potential scientific/societal benefits]***.

[Include the following text if medical procedures or tests are being performed in the study solely for research purposes and will not be used for clinical care:] This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

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Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

[Include only for research involving prisoners] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

Will being in this study cost me anything?

Choose the option(s) most appropriate for your study. DELETE options that do not apply:

There will be no cost to you for any of the study activities or procedures.

There will be no cost to you for the ***[describe types of activities covered by the study, e.g. lab tests, diagnostic tests, drugs, clinic visits]*** that are done for research purposes only and are not part of your regular care. ***[If subjects have to pay for any of the drugs or treatments required in the protocol, include information about the costs of those drugs and treatments.]***

You will have to pay for basic expenses like any childcare, food, parking, or transportation related to study activities.

You or your insurance company will have to pay for all costs for medical care related to participation in this study, including co-payments and deductibles. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have to pay, you should contact your insurance company. If you do not have health insurance, you will have to pay all the costs for your medical care just as you would if you did not take part in this study.

If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

[Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise, delete.] If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

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Will I be paid or receive anything for being in this study?

[Choose the option(s) most appropriate for your study. DELETE options that do not apply:]

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.

We will pay you ***[dollar amount]*** for participating in this study. Payment will be provided at the end of the study visit in the form of ***[a gift card, cash, check, etc.]***. If you choose to leave or we take you off the study before you complete the study visit, you will receive ***[describe pro-rated payment]***.

We will pay you ***[dollar amount]*** for ***[Visit 1, intervention x, each study visit, etc., dollar amount for Visit 2, intervention, etc.]***. Payment will be provided ***[at the end of: each visit, every 3 months, the study, etc.]*** in the form of ***[a gift card, cash, check, etc.]***. If you complete all the study visits, you will receive ***[dollar amount]*** for being in this study. If you choose to leave or we take you off the study for any reason, you will receive ***[describe pro-rated payment]***.

You may be asked for your social security number for payment purposes. It will not be used for any other purpose without your permission.

If you receive $600 or more during a calendar year from the University for participating in research, you may receive a 1099 for tax reporting purposes. Reimbursements for travel and other expenses are not included in this amount.

[Always include:] Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

[Include for Department of Defense (DOD) research that targets military personnel where subjects will be compensated. Otherwise, delete.] Military personnel should check with their supervisor before accepting payment for participation in this research. You may be asked for your social security number for payment purposes. It will not be used for any other purpose without your permission.

What happens if I am injured or get sick because of this study?

[For all studies involving greater than minimal risk, include:]

If you are injured or get sick because of this study, medical care is available to you through UC Davis Health, your local provider, or emergency services.

- If it is an emergency, call 911 right away or go to the emergency room.

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Investigator: ***[insert name of principal investigator]***

- For non-emergency issues, you can call the UC Davis Health Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to ***[the Internal Med Resident on-call, etc.]***.

If you are injured as a result of being in this study, the University of California will provide the necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by the University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may contact the IRB Administration at (916) 703-9151 or HS-IRBAdmin@ucdavis.edu.

[Include if applicable, otherwise delete.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

What happens to the information collected for the research?

We will do our best to limit the use or disclosure of your personal information, including information from this research study and from your medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information including the IRB and other University of California representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. ***[Include any/all of the following three statements as appropriate, deleting those which do not apply. Add in any other steps which will be taken to protect the subject's confidentiality.]*** We will remove identifiable information from the data we collect about you. After we remove all of the identifiers, we will place a code on the information. The code will be linked to your identity but the link will be kept in a location that is separate from your study data. ***AND/OR*** We will maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need the access to properly conduct the study. ***AND/OR*** The information we send to the sponsor will not include information that directly identifies you. Instead, a code will be applied to the data and link between the code and your identity will be kept at the research site.

We may publish and present what we learn from this study, but none of this information will identify you directly without your permission. Information which can identify you may be removed from the data or samples we collect, and after such removal, the data or samples could be used for future research studies or provided to another researcher for future research without additional informed consent.

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Investigator: ***[insert name of principal investigator]***

However, we cannot promise complete confidentiality. If you agree to be in this study, Federal or state laws may permit or require us to show information to university or government officials ***[Delete if not applicable:] and to study sponsors*** responsible for monitoring this study. ***[If ICH-GCP guidelines apply and the investigator has agreed to comply with broader access to subjects' medical records, add:]*** We may also show your medical records to study monitors, auditors, the IRB, and the FDA. These groups are obligated to maintain your confidentiality. The following is a list of individuals who may access your records:

- Members of the research team
- Offices and committees responsible for the oversight of research
- ***[Include if applicable:]*** Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study
- ***[For federally funded studies only, include:]*** U.S. Office for Human Research Protections
- ***[For FDA-regulated studies only, include:]*** The U.S. Food and Drug Administration (FDA)
- ***[Include if applicable:]*** The study sponsor, ***[name of sponsor]***
- Collaborating researchers outside of UC Davis, including researchers at ***[name collaborating institutions]***
- Companies or groups performing services for the research team, such as ***[add examples of services, e.g.: laboratories outside of UC Davis Health]***
- ***[Include any other individual or entity who may access study records.]***

[Include for all studies that include, as part of their protocol, any clinical intervention, including the invasion of any research participant (control or subject) body cavity (e.g. blood draw) when such an intervention takes place within a UC Davis Medical Center (UCDMC) licensed facility. Otherwise, delete.] If you agree to participate in this research study, a signed copy of this consent document will be filed in your electronic medical record (EMR) to ensure people caring for you at UC Davis Health will have the information they need about this research study when they provide care for you. **[If the study is NIH funded or has a CoC, include the following:]** Placing a copy of this consent form in the EMR is intended only to give information to caregivers providing treatment for you while you are on this study.

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

[Include if registration on clinicaltrials.gov is required. For assistance determining if registration on clinicaltrials.gov is required, visit the clinicaltrials.gov section of the HRP-503 General Template.] 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 website will include a summary of the results. You can search this web site at any time.

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

[Include if a HIPAA authorization for research is required. If required, ensure that you provide a copy of the HIPAA authorization form to the subject. Otherwise, delete.] If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. ***[If applicable, include the following sentences.]*** Your medical records may become part of the research record. If that happens, your research records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/legal/privacy/) and in an attached document.

[Certificate of Confidentiality: If this research is funded by the NIH, you must include this language. If you have submitted or plan to submit an application for a Certificate of Confidentially, you must include this language.] This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. For example, the information collected in this research cannot be used as evidence in a proceeding unless you consent to this use. Information, documents, or biospecimens protected by this CoC cannot be disclosed to anyone else who is not connected with the research, except:

- To a federal agency sponsoring this research when information is needed for auditing or program evaluations;
- To meet the requirements of the U.S. FDA;
- If a federal, state or local law requires disclosure such as a requirement to report a communicable disease;
- If information about you must be disclosed to prevent serious harm to yourself or others such as child abuse, elder abuse or spousal abuse;
- If you consent to the disclosure, including for your medical treatment, to an insurer or employer to obtain information about you; or
- If it is used for other scientific research, as allowed by federal regulations protecting research subjects.

This CoC also does not prevent you or a family member from voluntarily releasing information about yourself and your involvement in this research.

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

[Include for research involving prisoners. Otherwise, delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

Will I receive any results from this research?

Use this section to inform subjects whether they will receive any study results. Caution: if results of testing are experimental or are not performed at a CLIA certified lab, you cannot provide results to subjects.

Will information or leftover specimens be used for other research?

During this research, the study team will obtain information about you. They will also collect biological specimens from you such as blood or urine. The information and specimens will be used for this research and may also be used for other research studies here at UC Davis. We may also share the information and specimens with other institutions for research. Before using the information and specimens for other research, the study team will remove information that identifies you so the individuals performing the research will not know who the information and specimens came from. We will not ask for additional consent from you to use your information and specimens for the additional research.

Are there any optional parts of the study?

[Include this section in the consent form if the research includes optional components, such as sample collection for correlative research, or banking of data or specimens for future unspecified research. Delete if there are no optional study components. Use the language below to introduce the optional activities, followed by specific information about the optional study component(s):

- ***Purpose of the optional study***
- ***Procedures specific to the optional study (e.g. completing a questionnaire)***
- ***Who will use information from the optional study, and how confidentiality will be protected***
- ***How to withdraw from the optional study if the subject chooses to stop participating***
- ***Include yes/no initial boxes for each optional study component. Clearly, state what yes and no mean for each optional study.]***

This part of the consent form is about additional optional parts of the study that you can choose to take part in. Things to know about these optional parts of the study:

- They are optional. You can still take part in the main study even if you say “no” to any or all of these parts of the study.

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

- These parts of the study will not help you directly. We hope the results from these optional parts of the study will ***[describe the potential scientific/social benefits, e.g.: help other people with your disease in the future]***.
- We will not tell you the results of these optional parts of the study, and we will not put the results in your medical records.
- Taking part in the optional parts of the study will not cost you anything. ***[If optional research requires additional time or additional study visits, explain any related costs that are not covered by the study, e.g.:]*** You will have to pay for basic expenses like any childcare, food, parking, or transportation needed for optional study visits.
- Initial your choice of "yes" or "no" for each of the following optional parts of the study.

Include the following information for each study:

- ***Name of study (if applicable)***
- ***Study purpose***
- ***Description***
- ***The reason why subject might want to participate***
- ***The reason why subject might not want to participate***

May we contact you by e-mail?

[If the research team is planning to use email to communicate with study participants, please include this language.]

We are requesting your email address so we can ***[describe how email will be used in the study]***. Email is generally not a secure way to communicate about your health, as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact ***[Name, Title, Phone Number for appropriate contact person, such as the lead investigator or physician on call]***. You do not have to provide your email address to participate in this study. Please initial one of the lines below.

_____ Yes, may use email to contact me for this study. My email address is: _____

_____ No, I do not want to be contacted by email.

Are there other research opportunities?

[Delete this section if there are no additional research opportunities.]

If you are interested in being contacted for future research, please provide your phone number and/or email. <u>This is completely optional.</u>

Do not write below this line. For IRB stamp and version date only.

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

_____(Initials) Yes, I am willing to be contacted for future research opportunities. My phone number and/or email is: _____

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

[***Insert Electronic Consent Language if an electronic signature is obtained for consent***
Omit the signature page if there is no written documentation of consent.]

[Include GDPR language if the data collected through this research are subject to the GDPR.]

Do not write below this line. For IRB stamp and version date only.

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	

Do not write below this line. For IRB stamp and version date only.

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

Signature Block for Adult Unable to Consent

Your signature documents your permission for the named subject to take part in this research.

Printed name of subject

Signature of legally authorized representative | Date

Printed name of legally authorized representative

Signature of person obtaining consent | Date

Printed name of person obtaining consent

[Add the following block if you will document assent of the subject.]

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process | Date

Printed name of person witnessing consent process

Do not write below this line. For IRB stamp and version date only.

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

Signature Block for Children

Your signature documents your permission for the named child to take part in this research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

❑ Parent
❑ Individual legally authorized to consent to the child's general medical care (See note below)

Printed name of parent or individual legally authorized to consent to the child's general medical care

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Signature of parent

Date

Printed name of parent

If signature of second parent not obtained, indicate why: (select one)

❑ The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]***
❑ Second parent is deceased
❑ Second parent is unknown
❑ Second parent is incompetent
❑ Second parent is not reasonably available
❑ Only one parent has legal responsibility for the care and custody of the child

[Add the following block if you will document assent of children]

Assent

❑ Obtained
❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
❑ Waived by the IRB because the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.

[Add the following block to all consents]

Signature of person obtaining consent and assent

Date

Printed name of person obtaining consent

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the

Do not write below this line. For IRB stamp and version date only.

subject.

Signature of witness to consent process	Date

Printed name of person witnessing consent process

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

When the document is complete, delete all text after the signature section, i.e. this line onward.

Model Optional Data/Specimen Banking Language:

Will information or leftover specimens be used for other research?

We will keep the data we collect about you and we ***[will OR would like to (if optional)]*** keep your data and samples for ***[period of time OR:]*** an indefinite period of time.

Keeping data or samples for future research is called "banking." The banked data and samples will be kept in a secure location for use by researchers.

This is what will happen with your banked data and samples:

- We will use the data and samples in other research projects ***[if there are limits to potential future uses, add:]*** about ***[describe any restrictions on the use of the data/samples, such as limiting future use to a specific disease category]***.
- ***[If you may share the data/samples outside your research team, add:]*** The data and samples may be shared with other researchers at UC Davis and with researchers outside of UC Davis.

[Include if banked data/samples are coded; DELETE if not applicable:]

- The banked data and samples will be labeled with a code instead of your name.
- When we give your data and samples to other investigators for research projects, they will not be able to use the code to figure out which data and samples are yours.
- The research team will maintain a link between your data and samples and your identifiable information kept by the study team.
- You can request to have your data and samples removed from the bank by contacting the research team at any time.

[Include if data/samples will be anonymized for purposes of banking; DELETE if not applicable:]

- The banked data and samples will be labeled in a way so that no one can identify which data and samples came from you.
- This means that if you decide at a later time that you do not want your data and samples used for other research, we will not be able to remove your data and samples from the bank.
- You will not be given the results of any of the studies done using your banked data and samples. Also, banked data and samples will not be shared with your health care providers or used in your treatment outside this study.

[Include if banking is optional. Include additional yes/no options if data and samples are banked separately:]

Please initial one of the lines below to indicate whether or not you agree to the optional data and samples banking:

____ Yes, I agree to have my data and samples banked for future research purposes.

Do not write below this line. For IRB stamp and version date only.

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

____ No, I DO NOT agree to have my data and samples banked for future research purposes.

Will genetic research be done as a part of this study?

[Add this language to the main body of the consent form when genetic research is part of the main study. Add this language to the Optional Studies portion of the consent document when the genetic research may be done as part of optional sub-studies or in future research using banked specimens. Include the statement about whole genome testing if the research will (or might) include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Model Language:]

Some of the tests we will perform on your ***[blood/tissue/etc.]*** will be genetic testing, which is done on your DNA. DNA, or deoxyribonucleic acid, carries the genetic instructions for the cells that make up your body. Genes tell your body how to do things like form your spine, or what color your eyes should be.

[Include the following for whole genome testing:]
We will do whole genome testing for this study. Your "genome" is the complete DNA instruction book. "Whole genome testing" means making a list of the entire order, or sequence, of the DNA in your genome.

[Include in the consent form risk section for any study involving genetic testing in families:]
You should be aware that we might find instances of non-paternity. For example, if a person you believe is one of your parents is actually not your biological parent, the testing may reveal this. If this occurs, we will not tell you about it, but there is always a chance that someone outside of the study could find out about the results and you could still find out.

[Include in the consent form risk section if the study involves the release of samples to other researchers for what could include genetic testing:]
The DNA samples and information sent to other researchers will not include personal information like your name or your birthdate. However, even without your name or other identifiers, your genetic information is unique to you, like a fingerprint. Scientists expect that over the next few years, researchers will be able to look at your genetic information and be able to trace the data back to you (and potentially also to your blood relatives).

[Include in the consent form risk section for studies enrolling hundreds of subjects, and involving genetic testing looking at the incidence of disease:]
Research has already shown that some populations are more likely to develop certain diseases than others. For example, sickle cell anemia is more common in people of African, African American, or Mediterranean heritage. By participating in this research, your genetic information could help

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

researchers find out if members of a specific population are at greater risk for specific diseases. Some people have been concerned that this information could be used to stereotype all members of a population group, even if not everyone in that group is at risk for the disease common in their racial or ethnic heritage.

[Include in the consent form risk section for any study that is banking specimens for future unspecified or genetic research:]

There may be other risks related to genetic testing that we don't know about right now. This is because the field of genetics is moving forward very quickly.

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

Will My Genetic/Genomic Data Be Shared With Repositories?

[Include the language below if genetic data may be shared, now or at some time in the future, with public data repositories under the NIH Genomic Data Sharing (GDS) Policy. This includes:

- ***NIH-funded studies***
- ***Studies likely to receive NIH funding in the future***
- ***Collaborative research with someone who has NIH funding***
- ***Studies that will voluntarily share data with public repositories***

Model Language:]

At some point in the future, we ***[are/may be]*** required to share genetic data with federal repositories. Because this research receives funding from the National Institutes of Health (NIH), we will submit your genomic information to a public repository approved by NIH. NIH is a national research agency and is part of the federal government. The NIH and other central repositories have developed special data (information) banks that collect the results of genetic studies, especially when the research looks at all or large sections of individual's genetic code. This is often called whole genome sequencing. Genomic information relates to the structure and function of all of the genetic material in the body.

These central banks will store your genetic information and give them to other qualified and approved researchers to do more studies. The data that we share with federal repositories will be coded in such a way that you would not be able to be identified. We will not share your name, birth date, or any other information that could directly identify you. The link to the code would be kept securely at UCD. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people from trying to identify individuals whose genomic information is in an NIH-designated repository.

We do not think that there will be further risks to your privacy and confidentiality by sharing your genetic information with these banks. However, we cannot predict how genetic information will be used in the future. The genetic data could be used to study a wide variety of diseases.

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

[Insert if the consent process will be electronic.]

What are my rights when providing electronic consent?

- California law provides specific rights when you are asked to provide electronic consent:
  - You have the right to obtain a copy of the consent document in a non-electronic format.
  - You have the right to provide consent in a non-electronic format.
  - If you change your mind about electronic consent, you have the right to request your electronic consent to be withdrawn and you can then provide consent in a non-electronic format; however, a copy of your electronic consent will be maintained for regulatory purposes. If you wish to withdraw your electronic consent please tell the study team.
- This agreement for electronic consent applies only to your consent to participate in this research study.

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

[Instructions: This GDPR Notice and Consent is required when the research collects or creates Personal Data[1] from subjects located in the EU or EEA. If the research is obtaining "Sensitive Data[2]," explicit consent is required. Delete all language in red type before submitting this Notice for review.]

Notification/Consent for Collection and Use of Study Data

This research will collect data about you that can identify you, referred to as Study Data. The General Data Protection Regulation ("GDPR") requires researchers to provide this Notice to you when we collect and use Study Data about people who are located in the European Union or in the European Economic Area.

We will obtain and create Study Data directly from you or from ***[insert the data sources, including repositories, collaborators, publicly available sources, etc.]*** so we can properly conduct this research. As we conduct research procedures with your Study Data, new Study Data may be created.

The Research Team will collect and use the following types of Study Data for this research:

[Delete any categories of information that you will not collect or create.]

- Contact Information
- Health information
- Your racial or ethnic origin
- Your political opinions
- Your religious or philosophical beliefs
- Your sexual orientation or beliefs
- Genetic data
- Information about your response to the research procedures

[Insert the categories of any additional data that you will collect.]

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1 Article 4 of the GDPR states "'personal data' means any information relating to an identified or identifiable natural person ('data subject')"

2Per Article 9 of the GDPR, processing Personal Data about racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation is prohibited unless additional requirements are met such as informed consent from the data subject.

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

[Include, if applicable, otherwise delete.] The Research Team will enter data about you and your health into a computer and a computer program will help the study team decide if you meet requirements to be in this study.

[Include, if applicable, otherwise delete.] The research protocol requires the Research team to enter data about you and your health into a computer. A computer program will be used to assign you to one of the following specific study treatments: ***[list study treatments]***. If you sign this consent form, you are consenting to the use of this automated process to determine the treatment you receive. ***[Describe any other procedures that use an automated process to make decisions about the subject.]***

Please initial one of the boxes below to indicate whether you consent to use of the automated processes described above.

I agree _____	I do not agree_____

This research will keep your Study Data for ***[insert the time the data will be maintained by the research – UC Davis requires the data to be maintained for at least 10 years following completion of the research]*** after this research ends.

The following categories of individuals may receive Study Data collected or created about you: ***[Delete any category that is not applicable.]***

- Members of the research team so they properly conduct the research
- UC Davis staff will oversee the research to see if it is conducted correctly and to protect your safety and rights
- The research Sponsor who will monitor the study and analyze the data
- Agents of the Sponsor who will assist the sponsor with data monitoring and analysis
- Representatives of the U.S. Office of Human Research Protections (OHRP) who oversee the research
- Representatives of the FDA who will use the data to determine whether a marketing application for the investigational ***[drug/device]*** can be approved
- Other researchers, so they can perform procedures required by this research
- Other researchers, including researchers in other countries, so they can conduct additional research on ***[condition]*** and other, unrelated diseases and problems

Consent Form

Title of research study: ***[insert title of research study here with protocol number, if applicable]***

Investigator: ***[insert name of principal investigator]***

[List the additional categories of individuals who may receive access to Personal Data and describe the reason for the disclosure.]

[Include, if applicable, otherwise delete.] The research team will transfer your Study Data to our research site in the United States. The United States does not have the same laws to protect your Study Data as States in the EU/EEA. However, the research team is committed to protecting the confidentiality of your Study Data. Additional information about the protections we will use is included in this consent document.

The GDPR gives you rights relating to your Study Data, including the right to:

- Access, correct or withdraw your Study Data; however, the research team may need to keep Study Data as long as it is necessary to achieve the purpose of this research
- Restrict the types of activities the research team can do with your Study Data
- Object to using your Study Data for specific types of activities
- Withdraw your consent to use your Study Data for the purposes outlined in this consent form (Please understand that you may withdraw your consent to use new Study Data but Study Data already collected will continue to be used as outlined in this consent document and in this Notice)

The Regents of the University of California, on behalf of UC Davis, is responsible for the use of your Study Data for this research. ***[Include the appropriate contact information depending on which campus the research is conducted:]*** The UC Davis Health Privacy Officer is Sharalyn Rasmussen. You can contact Ms. Rasmussen by phone at (916) 734-8808 or by email at smreed@ucdavis.edu. ***OR*** The UC Davis Privacy Officer is Cheryl Washington. You can contact Ms. Washington by phone at (530) 754-6484 or by email at cwashington@ucdavis.edu. You can contact the Privacy Officer if you have:

- Questions about this Notice,
- Complaints about the use of your Study Data, or
- If you want to make a request relating to the rights listed above.

[If the data will be used for sponsored research or research authored by another research institution, where a non-UC researcher or non-UC institution is determining the data to be collected and scope of research, and UC is acting at the direction of the non-UC researcher or non-UC institution: name and contact information of sponsor/institution; sponsor/institution's Data Protection Officer (DPO) and Representative, if any, and their contact information. If there is no DPO or Representative, provide name and contact information of sponsor/institution privacy official.]

Do not write below this line. For IRB stamp and version date only.