September 27, 2026

The informed consent document below refers to study "UCSD RELINK: Connecting Adults To Supportive Services", for NCT number NCT05605054. The document was last approved by the IRB with an expiration date of September 27, 2027.

University of California, San Diego
Consent to Act as a Research Subject

UCSD RELINK: An RCT Testing a Health Literacy Intervention to Reduce Disparities in Access to Care Among Minority Justice-Involved Adults

OVERVIEW

Dr. Victoria Ojeda from the University of California, San Diego (UCSD) is conducting a research study and asking for your consent to participate. This section provides an overview of key information. The rest of the form provides more details.

- Research is voluntary. Whether or not you join is your decision. You can discuss your decision with others, such as family or friends.
- You can say yes, and change your mind later.
- If you say no, we will not hold your decision against you.
- Your decision will not affect any benefits you may be entitled to.
- You can say no even if the person inviting you is part of your healthcare or case management team.
- Please ask questions or mention concerns before, during or after the research.

The UCSD RELINK Program is designed to improve health-related knowledge, skills, and behaviors among adults who were recently impacted by the justice system. The purpose of this study is to collect data that will help us to understand how *well* the UCSD RELINK Program works. Your participation in the study may or may not benefit you directly, or it may result in new knowledge that can help improve future programs that support justice-impacted adults.

If you agree to enroll in this study, your participation will last about 20 hours over 12 months. You will be asked to participate in service navigation sessions and a health literacy course. You will also be asked to complete three surveys, and you may be asked to participate in 2 optional interviews. This is explained in more detail later on. If you choose to participate, you will be randomly assigned to one of two study groups- either a group that meets with the study staff to review the material OR a group that will complete the program by studying the materials on their own time.

The most commonly expected risk of the study is emotional discomfort when answering some of the survey and interview questions. There may also be some topics covered in Health Literacy course and in Service Navigation that may make you feel uncomfortable. If you feel uncomfortable, you do not have to discuss these topics or answer those questions.

The most serious risk of the study is the potential risk of loss of privacy of information. However, the research team will make every effort to keep all personal identifying information confidential. All information collected will be kept confidential and stored in locked cabinets or on password protected study computers and secure servers. Only study team members will be able to access this information. Identifiable information such as your name is not included in your survey responses and all information is stored securely. Additionally, we have a Certificate of Confidentiality from the National Institutes of Health (NIH), which protects you and is explained in more detail in the confidentiality section of this consent form.

Detailed information about this research is provided below. Please feel free to ask questions before signing this consent.

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DETAILED CONSENT FORM

Why have you been asked to participate, how you were selected, and what is the approximate number of participants in the study?

You have been asked to participate in this study because you:

- Are age 18 or older.
- Were on probation, parole, or a court-ordered diversion program within the past 3 years.
- Have access to a cell phone, and
- Live in the Central/Southeast/South area of San Diego County.

A total of 300 participants will be enrolled in this study.

What will happen to you in this study?

If you choose to participate, you will be randomly assigned to one of two study groups.

Health Literacy Course & Service Navigation: Participants in both groups will complete a 12-session Health Literacy course and receive tailored Service Navigation referrals to health and social service providers. You will be "randomized" into one of the two study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin.

- If you are randomly assigned to **Group A**, you will meet in person or by phone with your Health Coach for about 1 hour per week for 12 weeks to complete the Health Literacy course, and with your Service Navigator for 30 minutes per week for 12 weeks to support your health and social service needs.
- If you are randomly assigned to **Group B**, you will complete a self-guided printed or online version of the Health Literacy course (about 1 hour per week for 12 weeks) and receive a detailed Service Navigation report with recommended referrals to services, providers, and contact information for service providers so that you can access these resources independently (i.e., without Navigator assistance).

All participants will be asked to complete the following as part of the study:

- **Orientation Appointment(s) (2 hours):** Your first study activities will take about 2 hours. These activities may take place over 2-3 meetings if needed, and will include:
  - **Consent Form Review** (15 minutes, this form)
  - **Needs Assessment Research Survey (60 minutes)**: You will be asked to answer survey questions about your physical and mental health and health behaviors, your use of healthcare and social services, and your education, housing, and employment status. Your Service Navigator will enter your responses into a computer, and we will use this information to help connect you to health and social service providers.
  - **Individualized Service Plan Review (ISP, 45 minutes):** After you complete the enrollment survey, you will receive a personalized list of recommended referrals based on your health and social service needs. Your Service Navigator will review this list with you, ask you about which needs have higher priority for you, and answer any questions you may have.
- **Health Literacy Course (9 hours total; about 45 minutes for each session):**
  - Group A: 12 coach-guided (in-person or by phone); or

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  - Group B: Self-guided sessions.
- **Service Navigation (6 hours total; about 30 minutes for each session):**
  - Group A: 12 navigator-guided (in-person or by phone); or
  - Group B: Self-guided sessions.
- **2 Follow-Up Research Surveys (1.5 hours total, 45 minutes each, 6 and 12 months after enrollment)**: Study staff will ask you to answer survey questions similar to the questions in the enrollment survey again in 6 months and in 12 months to see if anything has changed. We will use this information to understand how well the UCSD RELINK Program is working and to improve the program for future clients.
- **Monthly check-ins from month 7 to month 12 (six check-ins that are 5 minutes each, 30 minutes total):** Someone from our study team will reach out to you by phone, text message, or email each month from month 7 to month 12 to make sure we have the latest contact information for you and to just keep in touch before the final 12-month survey.
- **Optional Individual Interviews:** About 40 participants (20 from Group A and 20 from Group B) will be invited to participate in individual interviews at 6 and 12 months after enrollment so we can learn more about their experiences with the UCSD RELINK program. To be considered for the individual interview, participants must have one or more of the following situations at enrollment: be uninsured, lack a regular source of care, or have had no recent doctor visit in the past 6 months. They also must have completed their 6-month research survey. Interviews will last about 30 minutes each and be audio recorded. If you do not wish to be audio taped, it will not be possible for you to participate in the individual interview. These interviews are optional- if you are invited and choose not to give an interview, it will not impact your study participation.

What risks are associated with this study?

Participation in this study may involve some added risks or discomforts. These include emotional discomfort, being dissatisfied with the study group you are randomized to, and loss of confidentiality. Here is more information about each of these risks:

- **Risk of Emotional Discomfort:** There may be some topics covered in Health Literacy course and in Service Navigation that may make you feel uncomfortable, or survey/interview questions you do not wish to answer. If you feel uncomfortable, you do not have to discuss these topics or answer those questions. However, you must participate in the three surveys to be in the Health Literary Course/Service Navigation part of the study.
- **Randomization**: You will be assigned to a study group at random (by chance). Your assignment is based on chance rather than a decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. Your assigned study group might also prove to be less effective than the other study group, or other programs available.
- **Risk of Loss of Confidentiality:** There is also a risk that information about you could be released to an unauthorized party. To minimize this risk, we will use a code on any information we collect and we will keep a link between the code and your identity in a different location.

What benefits can be reasonably expected?

In addition to the benefits listed at the beginning of this form the researchers may also learn more

about how to improve health-related knowledge, skills, and behaviors to ultimately help formerly justice-involved adults access needed healthcare services and be more satisfied with the care they receive.

Are there any costs associated with participating in this study?
There will be no cost to you for participating in this study.

What are the alternatives to participating in this study?
The alternative to study participation is to not participate.

What happens if you change your mind about participating?
Participation in research is voluntary. You may refuse to participate or withdraw at any time and it will not be held against you. However, if you do so, you will no longer have access to online or in-person/phone support from Health Coaches or Service Navigators. You will be able to continue to seek or receive services from any community organizations or providers that study staff have referred you to as part of service navigation. If you decide that you no longer wish to continue in this study, you will be asked to notify study staff of your decision.

If you are invited to participate in the optional individual interviews but do not wish to participate, you do not have to. You can decline and it will not affect any other aspect of your study participation.

You will be told if any important new information is found during this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study if:

1. Dr. Ojeda believes that continuing to participate is not in your best interest,
2. If you are unable to participate in the UCSD RELINK program or we are unable to contact you for more than 6 weeks, or
3. If you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?

- **Research Surveys:** To thank you for your time and travel to complete the research surveys, you will receive a $20 gift card for the survey at enrollment, a $30 gift card for the 6-month survey, and a $50 gift card for the 12-month survey. If you complete all three research surveys, you will receive a total of $100 in gift cards
- **Check-Ins:** You may also receive up to six $5 gift cards if you respond to monthly check-ins from study staff from month 7 to month 12. These quick check-ins will be by phone or text message, and you must respond to them to receive a gift card.
- **Optional Interviews:** The 40 participants who are selected to complete individual interviews will receive a $30 gift card for their interview at 6 months and a $50 for their interview at 12 months, for a total of $80 in gift cards if both interviews are completed.

You can choose to receive your gift cards in person or by mail. If you choose to receive gift cards by mail, we will not be able to replace any gift cards that are lost in the mail.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research

Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?

Research records will be kept confidential to the extent allowed by law. Any records that contain identifying information about you or your participation in the UCSD RELINK Program will be kept in a locked filing cabinet in a locked office in a secure building *or* in password protected, encrypted electronic files on a secure server available to study personnel only. Upon enrollment, you will receive an ID number to which your personal data will be linked. Personal/identifying information, including consent forms and survey responses, will be stored separately from your data. All data that could identify you will be destroyed within 7 years of the close of the study.

Research records may be reviewed by the UCSD Institutional Review Board and the National Institutes of Health (NIH). As part of UCSD RELINK Service Navigation part of the UCSD RELINK program, Service Navigators may share relevant information about your needs and basic contact information (e.g., name, phone number, email) with community organizations to support your access to needed health and social services. These communications will only occur with your knowledge and agreement, may occur in-person, over email or via phone, and will involve the minimum amount of information necessary.

This research is covered by a Certificate of Confidentiality from NIH. Researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence unless you have consented for this use. Information and documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research *unless* there is a federal, state, or local law that requires disclosure (such as to report child abuse, elder abuse, intent to hurt self or others, or communicable diseases), you have consented to the disclosure, including for your medical treatment; or it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding the project. You should also understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the research to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, such as the disclosure of relevant information about your needs or how to contact you that the UCSD RELINK Service Navigators may provide to community organizations with your knowledge and agreement to support you in accessing health and social services.

Personal identifiers might be removed from the information collected as part of the research. After such removal, the information could be used for future research studies or distributed to another researcher for future studies without your additional informed consent.

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.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any researcher, Service Navigator, Health Coach, or other study staff member has or is given such information, he or she may be required to report such information to the appropriate authorities.

Who can you call if you have questions?
If you have other questions or research-related problems, you may reach Dr. Victoria Ojeda at 858-822-6165.

If before or during your participation in the study you have questions about your rights as a research participant, or you want to talk to someone outside the research team, please contact:
• UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu

Your Signature and Consent
You will receive a copy of this consent document to keep.

If you agree to participate, please write your full name below to sign this consent form.

If this informed consent is being administered over the phone, a member of the study staff will record your agreement to participate by filling in your name.

Today's Date:_____

Subject's Name:

_____

Study Staff Name:

_____

(If consent is administered by phone)

☐ I agree to be contacted at month 6 – 12 to be considered for the extra individual interviews. (Note: Checking this box does not mean that you will automatically be included in the extra interview group.)

Would you like to learn about other programs and/or studies in the future?

○ Yes, I give my permission to be told about other programs and/or studies.

○ No, I do not give my permission to be told about other programs and/or studies.

Would you like to receive text message reminders for upcoming RELINK appointments?

○ Yes, I want to receive text message reminders.

○ No, I do not want to receive text message reminders.