Date: 08/30/2022

National Clinical Trials #: NCT04559893

Study Title: Collaboration Leading to Addiction Treatment and Recovery From Other Stresses (CLARO)

CLARO SUPPLEMENT
CONSENT FORM – CALIFORNIA

PURPOSE OF THE PROJECT

CLARO is a research project being conducted by the University of New Mexico and the RAND Corporation in collaboration with several clinics in New Mexco and California, including [FILL CA health system]. The goal of this project is to learn whether a care coordinator can help primary care patients who use opioids and have mental health concerns get better care for their mental health and substance use issues. The project is funded by the National Institute of Mental Health (NIMH) through the Helping to End Addiction Long-term (HEAL) Initiative.

HOW WE SELECTED YOU

We are asking you to take part in the project because based on the answers you gave during your screening, you are eligible and have expressed interest in participating in the project.

WHAT WE WILL ASK YOU TO DO

If you agree to be in the project, you will be in the project for 18 months. During this time we will ask you to:

- Complete three interviews. You will be paid for each interview. The first interview will be today and the next two will be by telephone in the future.
    - The interviews will include questions about things related to substance use, mental health, use of services, and general well-being. It will also ask about your experience with getting care for your substance use and mental health concerns.
    - We will ask you to provide some personal and contact information, such as your full legal name, your date of birth, phone number, and where you were born. This information will only be used for CLARO research purposes, and to help us get in touch with you for the two telephone interviews. If we cannot reach you, we might search public records for new phone numbers or ways to get in touch with you. We also plan to keep this information for up to five years after the study ends in order to contact you about other research opportunities that might arise. If we contact you in the future it will be up to you if you decide to take part at that time.

- You will be paid $100 after you complete the interview today. **You need to complete the interview to be paid, so if you don't finish it today, we will pay you on the day you finish. This first interview will last about 45-60 minutes.** We are offering an additional $25 bonus to anyone who either A) completes the first research interview the same day as they complete the eligibility screener or B) calls us back later to complete the first research interview. If you are eligible to receive the bonus, you will be paid $125 after you complete the interview. We will pay you pay you in cash if it is allowed by your clinic. Otherwise, all payments will be made in the form of a gift card.
- We also will contact you by phone in about 3 months and then again in 6 months to ask you to participate in similar interviews that will each take about 45 minutes. **You will be paid $40 if you complete the interview in 3 months and $40 if you complete the interview in 6 months.** These payments will be made in the form of a gift card.

- After the first interview, half of participants will be assigned a care coordinator at the clinic that will work to help them with things like getting treatments and services and reminding them about appointments. The other half of participants will continue to get their usual treatment at the clinic. **Either way, you can continue to get all services you would normally at the clinic.** You will have a 50/50 chance of being randomly assigned (like a coin toss) to a CLARO care coordinator.
- If you are assigned to the CLARO care coordinator, we will share with them two pieces of information from the interview we do with you today. First, during the interview we will ask you about experiences you might have had with a past traumatic event. If you have had a traumatic event, we'll pass this information on to your care coordinator so he/she can better link you to services. Second, we will pass along contact information you give us like your phone number, address, or email so the care coordinator can get in touch with you and set up an appointment.

- We will ask you to allow the project to obtain some information from your clinic medical records including:
    - The dates you visited medical providers and therapists during the project;
    - Dates of visits that were scheduled but you did not attend;
    - Medical diagnoses, including any diagnoses related to a mental health or substance use disorder;
    - Medical procedures conducted by your providers during the course of the project, such as testing or treatment, including any procedures related to a mental health or substance use disorder;
    - Prescriptions for medications that are provided to you by your medical provider during the course of the project, including medications for mental health or substance use disorders;
    - Information you report on your mental health symptoms and how much and how often you use substances between your visits and any problems you might be having.
    - Results of any drug screens the clinic might do;
    - Any clinical information your care coordinator is using to keep track of your care, services you need, and your participation in CLARO;
    - Any updated phone number or contact information you might have so we can get in touch for the telephone interviews.
- We ask all participants to allow the project to obtain mortality data from your state's vital records office.
- If you are randomly assigned to work with a care coordinator, we may ask if you would like to include a support person (e.g., family member, partner, or friend) in a meeting with the care coordinator. The care coordinator will give your support person more information about opioid use, medications to help cut back on using opioids, and ways they can help you stay safe. Your support person will also learn how to use Naloxone, an emergency medication that can be used for someone who is overdosing on opioids. You do not have to agree to involve a support person in order to participate in the project, and the care coordinator will not contact the support person without first getting permission from you. If the support person contacts

the care coordinator or other study staff with questions about your treatment or health, the staff member will state that they cannot discuss the treatment or health of a patient, but they can provide general health resources if helpful.

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (HIPAA)

As a part of this project, we will be collecting health information about you. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI): By signing this consent document, you are allowing the researchers and other authorized personnel to use your protected health information for the purposes of this research project. By signing the medical release form, you are authorizing the CLARO project staff to contact your healthcare providers to collect the information detailed above about your appointments, use of services, diagnoses, prescribed medications, and contact information. This information will be used **only** for research purposes.

Right to Withdraw Your Authorization: Your authorization for the use of your health information for this research project shall not expire unless you cancel this authorization. Your health information will be used as long as it is needed for this research project. However, you may withdraw your authorization at any time if you notify the research team verbally or in writing. Please know that the research team will not have to destroy or retrieve any of your health information that has already been collected before your withdrawal is received.

Refusal to Sign

If you choose not to sign this consent form and authorization for the use and disclosure of your PHI, you will not be allowed to take part in the CLARO research project. **You will still be able to receive your usual care at the clinic.**

CONFIDENTIALITY

We will keep all of your responses and information completely confidential. We will not share or tell your name or anything that may identify you to anyone outside of the research staff, except for the information we told you we would share with your care coordinator. Your name will never appear in any project reports or presentations.

Information in these reports or presentations will be grouped together with all of the people in the project so no person can be identified.

Information about your participation in the project and any treatment you receive will be documented in your medical record as part of routine clinical care. This information is covered by confidentiality regulations and state and federal laws.

Your information is also protected by a Certificate of Confidentiality (CoC) from the National Institute of Mental Health. This protects researchers from being forced, even by court order or subpoena, to identify you. You should understand, though, that a CoC does not prevent you or a member of your support system from voluntarily releasing information about yourself or your involvement in this research.

Additionally, if at any time during the project, you share that you plan to harm yourself or others or we hear about or suspect child abuse, or we hear about or suspect elder/ dependent adult abuse, the Certificate does not protect that information from being released to the proper authorities. We will not share your answers with anyone outside the project without your permission, with the following exceptions. If I observe or if you tell me that a child or elderly person is being abused, I must report this to my supervisor, who may report it to the appropriate authorities. If you tell me that you might harm yourself or others, I may give information about you to people who could help provide protection from that harm.

DATA STORAGE

Deidentified data (meaning it cannot be used to identify you) from this research project will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified data from many NIMH studies is stored and managed.

During and after the study, the researchers will send deidentified data from the CLARO project to the NDA. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified research data helps researchers learn new and important things about mental health and substance use more quickly than before.

Researchers may request from the NDA your deidentified study data for other research. Every researcher who requests the deidentified study data must promise to keep your data safe and promise

not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you do not want your data in the NDA, please tell the study researcher now or before we finish speaking today. If you decide any time after today that you do not want your data to be added to the NDA, please call or email the study staff, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, you can find it at http://nda.nih.gov.

PARTICIPATION IS VOLUNTARY

Your participation in this research project is completely voluntary. This means it is up to you whether to take part in the project activities. You may refuse to take part, or you may stop being in the project at any time and for any reason, without any penalty. If at any time you no longer wish to participate in the research project, let the research team know verbally or in writing and your participation will be discontinued.

RISKS OF PARTICIPATION

There could be a possible risk of unintentional disclosure of information like someone finding out you are participating in a substance use and mental health project. Sharing your study data with NDA does have some risks. Your study data could accidentally be shared with an unauthorized person who may attempt to learn your identity. However, these risks are minimal because we take many steps to protect your identity and the information you provide.

During the interview we do today and the ones in three and six months, we will ask you some questions about your substance use, your health, and your mental health. These questions might make you feel nervous, embarrassed, or upset. But you are allowed to refuse to answer any question if it makes you uncomfortable, or to stop participating at any time.

COSTS OF PARTICIPATION

If you pay for your phone use by the minute and complete any CLARO interviews or meetings with a care coordinator on your cell phone, you may be charged for those minutes. If you are unable to afford this cost we may be able to pay for those additional minutes.

BENEFITS OF PARTICIPATION

This research may benefit you personally by helping you access treatment for substance use and mental health. It also may help future patients of the clinic. The study data provided to NDA may also help researchers around the world learn more about mental health and substance use and how to better help others who have problems with mental health and opioid use. We hope the research will benefit you, your whole community and other communities by finding better ways to access opioid and mental health treatment in health clinics.

WHO TO CONTACT ABOUT THE STUDY

If you have any questions about the project, collection of data, data storage, or confidentiality, please contact Kirsten Becker at 310-393-0411 ext. 6480 or becker@rand.org.

WHO TO CONTACT ABOUT YOUR RIGHTS AS A PARTICIPANT

If you have questions about your rights as a research participant or need to report a research-related injury or concern, you can contact RAND's Human Subjects Protection Committee toll-free at (866) 697-5620 or by emailing hspcinfo@rand.org. When you contact the Committee, please reference Project # 2019-0509.

☐ **I agree to let my de-identified data be shared with the National Data Archive (NDA).**

_____

Research Participant (Print Name)

_____

Signature Date

_____

Consent Administrator

PATIENT AUTHORIZATION FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION

Patient Name _____
Medical Record # _____ Date of Birth _____
Phone # _____
Patient Address _____

I authorize [FILL CLINIC NAME EG. **Providence Saint John's Health Center**] to DISCLOSE my patient information.

_____

I authorize the following organizations TO RECEIVE my patient information:

Name: RAND
Address: 1776 Main Street, Santa Monica, CA 90407
Phone #: 310-393-0411 Fax #: [FILL]

For the purpose of: Participation in the CLARO project

Information to be disclosed includes:

- Service encounters – for example, dates of visits and appointments, type of visit (in person or phone), provider name, reason for visit, services received
- Prescriptions – for example, dates ordered and filled, prescribing provider, associated diagnoses, name and amount of medications
- Drug screening – for example, dates tested, provider name, results
- Substance Use – for example, substances and use you report, treatments, impacts on your health
- Mental Health - for example, symptoms you report, treatments, impacts on your health

Covering the period(s) of healthcare: from [6 MO PRIOR TO ENROLLMENT] to 5/21/2025

I authorize the release of information relating to (initial if applicable):

[ ] yes [ ] no	Behavioral health services/psychiatric care	initial [ ] yes [ ] no
_____	Treatment for alcohol and/or drug abuse	initial

I understand that I have a right to revoke this authorization at any time. I understand that if I revoke this authorization I must do so verbally or in writing and inform the [FILL CLINIC MANAGER] of my revocation. I understand that the revocation will not apply to information that has already been released in response to this authorization. I understand that the revocation will not apply to my insurance company when the law provides my insurer with the right to contest a claim under my policy.

Unless otherwise revoked, this authorization will expire on the following date, event, or condition: [FILL DATE 1 YEAR AFTER END OF STUDY]. I understand that authorizing the disclosure of this health information is voluntary. I can refuse to sign this authorization. I need not sign this form in order to obtain healthcare treatment, but understand that if I do not sign, I may not participate in the CLARO research project.

Signature, Patient, or legal representative (Relationship to patient) (Date)

Signature of Witness (Date)

PATIENT AUTHORIZATION FOR DISCLOSURE OF INFORMATION FROM CONTROLLED SUBSTANCE UTILIZATION REVIEW AND EVALUATION SYSTEM (CURES)

(CALIFORNIA'S PRESCRIPTION DRUG MONITORING PROGRAM)

WHAT IS CONTROLLED SUBSTANCE UTILIZATION REVIEW AND EVALUATION SYSTEM (CURES)?

Controlled Substance Utilization Review and Evaluation System (CURES) is a database that aids in the collection and reporting of dispensed controlled prescription drugs in California. The purpose of CURES is to collect and store information about prescription drug use. CURES has given the CLARO research project permission to access data regarding drug prescriptions.

WHAT WILL CLARO PROJECT COLLECT FROM CURES?

The CLARO research project will access CURES database for research purposes only to collect and store data on drugs you have been prescribed by any provider. For example, we will request data from CURES about buprenorphine prescriptions, or other drugs such as benzodiazepines. Having CURES data from CLARO participants will allow researchers to assess trends and discover better ways to diagnose, prevent and treat some conditions.

HOW WILL THE DATA BE COLLECTED AND STORED AND FOR HOW LONG?

The information we get from CURES will be sent to the RAND Survey Research Group. They will remove all identifying information from the data and will link the data to our CLARO research record. The data we get from CURES will be stored on the RAND SRG's secure segment and encrypted when not in use. It will only be accessible to designated CLARO research staff. This data will be destroyed 7 years after the study ends. We will not reveal your identity to anyone outside of the research project.

PERMISSION TO COLLECT CURES DATA.

We would like to have your permission to access CURES data about prescriptions you might have had for controlled substances. You may withdraw consent to access this data by oral or written communication with the CLARO team. If you withdraw consent, we will not destroy any data that has already been collected, however we will stop collecting any further CURES data.

RISKS

The main risk of allowing us to access this data is a breach of confidentiality. However, the project will follow precautions to prevent against this.

WHAT IF YOU CHOOSE NOT TO ALLOW US TO ACCESS YOUR CURES DATA, OR YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR CONSENT?

It is your choice if you will allow us to access CURES data and is completely voluntary. Choosing not to allow access will not affect your care or cause you to lose benefits to which you are entitled. Choosing not to allow will not affect your participation in the CLARO research project.

You may withdraw your permission to continue taking part in the registry at any time. To do so, you must send a verbal or written withdraw request to RAND Survey Research Group, CLARO Project c/o Kirsten Becker. The mailing address for the RAND Survey Research Group is 1776 Main Street, Santa Monica CA 90407. They will remove any information regarding future data collection from CURES and destroy any code that links you to CURES. However, the information that has already been shared with other researchers or placed in shared databases cannot be withdrawn.

WHAT IF YOU WANT TO ACCESS YOUR CURES DATA THAT THE CLARO PROJECT ACQUIRED?

You have the right, under the Information Practices Act (IPA), to access your CURES data. If you would like to obtain your CURES data that RAND acquired for the CLARO project, please write to the RAND Survey Research Group, CLARO Project c/o Kirsten Becker at 1776 Main Street, Santa Monica CA 90407. In order to release any information, you must provide a written request, an original signature, and proof of identification.

CURES DATA COLLECTION – PERMISSION

The request will cover the period of CURES data: from [DATE 6 MONTHS PRIOR TO ENROLLMENT] to 5/21/25

☐Yes, I choose to allow the CLARO research project to access data about my prescriptions from the CURES.

☐No, I choose not to allow the CLARO research project to access data about my prescriptions from CURES.

Signature, Patient, or legal representative (Relationship to patient) (Date)

Signature of Witness (Date)

CLARO
SUPPLEMENT CONSENT FORM – NEW MEXICO

PURPOSE OF THE PROJECT

CLARO is a research project being conducted by the University of New Mexico and the RAND Corporation in collaboration with UNM Southeast Heights Clinic, UNM Southwest Mesa Clinic, UNM North Valley Clinic, First Choice Community Healthcare, and Hidalgo Medical Services. The goal of this project is to learn whether a care coordinator can help primary care patients who use opioids and have mental health concerns get better care for their mental health and substance use issues. The project is funded by the National Institute of Mental Health (NIMH) through the Helping to End Addiction Long-term (HEAL) Initiative.

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We are asking you to take part in the project because based on the answers you gave during your screening, you are eligible and have expressed interest in participating in the project.

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    - The interviews will include questions about things related to substance use, mental health, use of services, and general well-being. It will also ask about your experience with getting care for your substance use and mental health concerns.
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- We will ask you to allow the project to obtain some information from your clinic medical records including:
    - The dates you visited medical providers and therapists during the project;
    - Dates of visits that were scheduled but you did not attend;
    - Medical diagnoses, including any diagnoses related to a mental health or substance use disorder;
    - Medical procedures conducted by your providers during the course of the project, such as testing or treatment, including any procedures related to a mental health or substance use disorder;
    - Prescriptions for medications that are provided to you by your medical provider during the course of the project, including medications for mental health or substance use disorders;
    - Information you report on your mental health symptoms and how much and how often you use substances between your visits and any problems you might be having;
    - Results of any drug screens the clinic might do;
    - Any clinical information your care coordinator is using to keep track of your care, services you need, and your participation in CLARO;
    - Any updated phone number or contact information you might have so we can get in touch for the telephone interviews.
- We ask all participants to allow the project to obtain mortality data from your state's vital records office.
- If you are randomly assigned to work with a care coordinator, we may ask if you would like to include a support person (e.g., family member, partner, or friend) in a meeting with the care coordinator. The care coordinator will give your support person more information about opioid use, medications to help cut back on using opioids, and ways they can help you stay safe. Your support person will also learn how to use Naloxone, an emergency medication that can be used for someone who is overdosing on opioids. You do not have to agree to involve a support person in order to participate in the project, and the care coordinator will not contact the support person

without first getting permission from you. If the support person contacts the care coordinator or other study staff with questions about your treatment or health, the staff member will state that they cannot discuss the treatment or health of a patient, but they can provide general health resources if helpful.

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (HIPAA)

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Right to Withdraw Your Authorization: Your authorization for the use of your health information for this research project shall not expire unless you cancel this authorization. Your health information will be used as long as it is needed for this research project. However, you may withdraw your authorization at any time if you notify the research team verbally or in writing. Please know that the research team will not have to destroy or retrieve any of your health information that has already been collected before your withdrawal is received.

Refusal to Sign

If you choose not to sign this consent form and authorization for the use and disclosure of your PHI, you will not be allowed to take part in the CLARO research project. **You will still be able to receive your usual care at the clinic.**

CONFIDENTIALITY

We will keep all of your responses and information completely confidential. We will not share or tell your name or anything that may identify you to anyone outside of the research staff, except for the information we told you we would share with your care coordinator. Your name will never appear in any project reports or presentations.

Information in these reports or presentations will be grouped together with all of the people in the project so no person can be identified.

Information about your participation in the project and any treatment you receive will be documented in your medical record as part of routine clinical care. This information is covered by confidentiality regulations and state and federal laws.

Your information is also protected by a Certificate of Confidentiality (CoC) from the National Institute of Mental Health. This protects researchers from being forced, even by court order or subpoena, to identify you. You should understand, though, that a CoC does not prevent you or a member of your support system from voluntarily releasing information about yourself or your involvement in this research.

Additionally, if at any time during the project, you share that you plan to harm yourself or others or we hear about or suspect child abuse, or we hear about or suspect elder/dependent adult abuse, the Certificate does not protect that information from being released to the proper authorities. We will not share your answers with anyone outside the project without your permission, with the following exceptions. If I observe or if you tell me that a child or elderly person is being abused, I must report this to my supervisor, who may report it to the appropriate authorities. If you tell me that you might harm yourself or others, I may give information about you to people who could help provide protection from that harm.

DATA STORAGE

Deidentified data (meaning it cannot be used to identify you) from this research project will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified data from many NIMH studies is stored and managed.

During and after the study, the researchers will send deidentified data from the CLARO project to the NDA. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified research data helps researchers learn new and important things about mental health and substance use more quickly than before.

Researchers may request from the NDA your deidentified study data for other research. Every researcher who requests the deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you do not want your data in the NDA, please tell the study researcher now or before we finish speaking today. If you decide any time after today that you do not want your data to be added to the NDA, please call or email the study staff, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, you can find it at http://nda.nih.gov.

PARTICIPATION IS VOLUNTARY

Your participation in this research project is completely voluntary. This means it is up to you whether to take part in the project activities. You may refuse to take part, or you may stop being in the project at any time and for any reason, without any penalty. If at any time you no longer wish to participate in the research project, let the research team know verbally or in writing and your participation will be discontinued.

RISKS OF PARTICIPATION

There could be a possible risk of unintentional disclosure of information like someone finding out you are participating in a substance use and mental health project. Sharing your study data with NDA does have some risks. Your study data could accidentally be shared with an unauthorized person who may attempt to learn your identity. However, these risks are minimal because we take many steps to protect your identity and the information you provide.

During the interview we do today and the ones in three and six months, we will ask you some questions about your substance use, your health, and your mental health. These questions might make you feel nervous, embarrassed, or upset. But you are allowed to refuse to answer any question if it makes you uncomfortable, or to stop participating at any time.

COSTS OF PARTICIPATION

If you pay for your phone use by the minute and complete any CLARO interviews or meetings with a care coordinator on your cell phone, you may be charged for those minutes. If you are unable to afford this cost we may be able to pay for those additional minutes.

BENEFITS OF PARTICIPATION

This research may benefit you personally by helping you access treatment for substance use and mental health. It also may help future patients of the clinic. The study data provided to NDA may also help researchers around the world learn more about mental health and substance use and how to better help others who have problems with mental health and opioid use. We hope the research will benefit you, your whole community and other communities by finding better ways to access opioid and mental health treatment in health clinics.

WHO TO CONTACT ABOUT THE STUDY

If you have any questions about the project, collection of data, data storage, or confidentiality, please contact [BEFORE 8/15/22 FILL: the study project director at 505-272-1817, BEGINNING ON 8/15/22 FILL: Kirsten Becker at 310-393-0411 ext. 6480 or becker@rand.org].

WHO TO CONTACT ABOUT YOUR RIGHTS AS A PARTICIPANT

If you have questions about your rights as a research participant or need to report a research-related injury or concern, you can contact RAND's Human Subjects Protection Committee toll-free at (866) 697-5620 or by emailing hspcinfo@rand.org. When you contact the Committee, please reference Project # 2019-0509.

☐ **I agree to let my de-identified data be shared with the National Data Archive (NDA).**

_____

Research Participant (Print Name)

_____

Signature Date

_____

PATIENT AUTHORIZATION FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION

Patient Name
Medical Record # Date of Birth
Phone #
Patient Address

I authorize the following health care provider/facility to DISCLOSE my patient information: (CIRCLE ONE)

University of New Mexico (UNM) Health System

First Choice Community Healthcare Hidalgo Medical Services

For UNM patients only: UNM sometimes partners with Healthy Families of Albuquerque LLC, a counseling agency in Albuquerque, to offer mental health counseling to patients. I authorize Healthy Families of Albuquerque LLC to DISCLOSE my patient information. (CIRCLE ONE)

Yes No

I authorize the following organizations TO RECEIVE my patient information:

Name: University of New Mexico Statistics and Data Coordinating Center (SDCC) Address: University of New Mexico Health Sciences Center, MSC10 5550, 1 University of New Mexico, Albuquerque, NM 87131-0001 Phone #: 505-272-3205 Fax #: 505-272-2570	Name: RAND Address: 1776 Main Street, Santa Monica, CA 90407 Phone #: 310-393-0411 Fax #: [FILL]

For the purpose of: Participation in the CLARO project

Information to be disclosed includes:

- Service encounters – for example, dates of visits and appointments, type of visit (in person or phone), provider name, reason for visit, services received
- Prescriptions – for example, dates ordered and filled, prescribing provider, associated diagnoses, name and amount of medications
- Drug screening – for example, dates tested, provider name, results
- Substance Use – for example, substances and use you report, treatments, impacts on your health
- Mental Health - for example, symptoms you report, treatments, impacts on your health

Covering the period(s) of healthcare: from [DATE 6 MONTHS PRIOR TO ENROLLMENT] to 5/21/25

I authorize the release of information relating to (initial if applicable):

[ ] yes [ ] no	Acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV) infection, or other sexually transmitted diseases	initial
[ ] yes [ ] no	Behavioral health services/psychiatric care	initial [ ] yes [ ] no
	Treatment for alcohol and/or drug abuse	initial

I understand that I have a right to revoke this authorization at any time. I understand that if I revoke this authorization I must do so verbally or in writing and inform the [FILL CLINIC MANAGER] of my revocation. I understand that the revocation will not apply to information that has already been released in response to this authorization. I understand that the revocation will not apply to my insurance company when the law provides my insurer with the right to contest a claim under my policy.

Unless otherwise revoked, this authorization will expire on the following date, event, or condition: [FILL DATE 1 YEAR AFTER END OF STUDY]. I understand that authorizing the disclosure of this health information is voluntary. I can refuse to sign this authorization. I need not sign this form in order to obtain healthcare treatment, but understand that if I do not sign, I may not participate in the CLARO research project.

_____

Signature, Patient, or legal representative (Relationship to patient) (Date)

_____

Signature of Witness (Date)

PATIENT AUTHORIZATION FOR DISCLOSURE OF INFORMATION FROM THE NEW MEXICO PRESCRIPTION MONITORING PROGRAM

WHAT IS THE NEW MEXICO PRESCRIPTION MONITORING PROGRAM (PMP)?

The New Mexico Prescription Monitoring Program (PMP) is a database that aids in the collection and reporting of dispensed controlled prescription drugs in New Mexico. The purpose of the PMP is to collect and store information about prescription drug use. The New Mexico PMP has given the CLARO research project permission to access data regarding drug prescriptions.

WHAT WILL CLARO PROJECT COLLECT FROM THE NEW MEXICO PMP?

The CLARO research project will access the PMP database for research purposes only to collect and store data on drugs you have been prescribed by any provider . For example, we will request data from the PMP about buprenorphine prescriptions, or other drugs such as benzodiazepines. Having PMP data from CLARO participants will allow researchers to assess trends and discover better ways to diagnose, prevent and treat some conditions.

HOW WILL THE DATA BE COLLECTED AND STORED AND FOR HOW LONG?

The information we get from the PMP will be sent to UNM. The research team will remove all identifying information from the data and will link the data to our CLARO research record. The data we get from PMP will be stored on UNM's secured and encrypted server behind the UNM firewall and will only be accessible to designated CLARO research staff. This data will be destroyed 7 years after the study ends.

PERMISSION TO COLLECT PMP DATA.

We would like to have your permission to access PMP data about prescriptions you might have had for controlled substances. You may withdraw consent to access this data by oral or written communication with the CLARO team. If you withdraw consent, we will not destroy any data that has already been collected, however we will stop collecting any further PMP data.

RISKS

The main risk of allowing us to access this data is a breach of confidentiality. However, the project will follow precautions to prevent against this.

WHAT IF YOU CHOOSE NOT TO ALLOW US TO ACCESS YOUR PMP DATA, OR YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR CONSENT?

It is your choice if you will allow us to access New Mexico PMP data and is completely voluntary. Choosing not to allow access will not affect your care or cause you to lose benefits to which you are entitled. Choosing not to allow will not affect your participation in the CLARO research project.

You may withdraw your permission to continue taking part in the registry at any time. To do so, you must send a verbal or written withdraw request to the research team. You can contact the research team at [BEFORE 8/15/22 FILL: UNM-SDCC@salud.unm.edu, BEGINNING ON 8/15/22 FILL: CLARO SRG ALIAS]. They will remove any information regarding future data collection from the PMP and destroy any code that links you to the PMP. However, the information that has already been shared with other researchers or placed in shared databases cannot be withdrawn.

PMP DATA COLLECTION – PERMISSION

The request will cover the period of PMP data: from [DATE 6 MONTHS PRIOR TO ENROLLMENT] to 5/21/25

☐Yes, I choose to allow the CLARO research project to access data about my prescriptions from the New Mexico PMP.

☐No, I choose not to allow the CLARO research project to access data about my prescriptions from the New Mexico PMP.

Signature, Patient, or legal representative (Relationship to patient) (Date)

Signature of Witness (Date)