Official Title:	NIDA CTN Protocol 0139: Collaborative Care for Polysubstance Use in Primary Care Settings (Co-Care)
NCT Number:	NCT06116266
Study Number:	23-01169
Document Type:	Informed Consent Form
Date of the Document:	• August 14, 2024

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK
[INSERT NAME OF SITE]

PATIENT PARTICIPANT INFORMATION AND INFORMED CONSENT FORM

Protocol Title: Collaborative Care for Polysubstance use in Primary Care Settings (Co-Care)

Protocol #: CTN-0139

Sponsor: National Institute on Drug Abuse (NIDA)

Lead Investigator: Jennifer McNeely, MD, MS
NYU Grossman School of Medicine
550 1st Avenue
New York, NY 10016
(646) 501-3551

Site Principal Investigator: [INSERT NAME OF SITE PI]
[INSERT NAME OF PARTICIPATING INSTITUTION]
[INSERT ADDRESS OF PARTICIPATING INSTITUTION]
[INSERT PHONE NUMBER OF SITE PI]

KEY STUDY INFORMATION

You are being asked to participate in the *Collaborative Care for Polysubstance use in Primary Care Settings (Co-Care)* study that [INSERT CLINIC NAME] is taking part in. This study seeks to understand whether a team made up of a primary care physician, a nurse care manager, an addiction specialist, and a health coach can help patients reduce their substance use. Approximately 350 patient participants will be enrolled in this study at multiple primary care sites across the country.

The following table contains key information to assist you in understanding why you may or may not want to participate in the research study.

Purpose	The purpose of this study is to understand whether a team-based approach in primary care is effective at helping patients to reduce their substance use.
Voluntary Participation	Your decision to be in this study is your choice. You may decide not to participate, or you may discontinue your participation at any time during the study, without penalty or loss of benefits or medical care to which you are otherwise entitled.
Withdrawal	If you decide to participate in this study and then change your mind, you can leave the study at any time without penalty and without giving a reason.
Length of Participation	Your participation will last approximately 12 months.
Procedures	The procedures in the study will depend on which group you are assigned. All participants will: • Complete questionnaires about your substance use and health when you enroll in the study (by computer, phone, and/or in person), and at

	approximately 3, 6 and 12 months afterwards (by computer and/or phone). • Provide a urine sample when you enroll in the study, and at approximately 3, 6 and 12 months, either remotely or in person. • Respond to a brief survey about your substance use that you will receive via email or text message once a month. You may complete this survey on any internet enabled device. Depending on your group assignment, some participants may also: • Participate in 4 to 12 health coaching sessions (appx. 30-45 minutes each) via telephone or video chat, approximately weekly after enrollment. • Meet with a study nurse for up to 6 months for care management.
Risks	Risks associated with participation are minimal. It is not anticipated that there will be any injury or adverse reactions caused by the study intervention.
Benefit	As a result of your participation in this study, you could potentially benefit, but there is no guarantee. However, what is learned may help people in the future with reducing substance use.
Alternative to Study Participation	The alternative to participating is to not participate. If you do not want to be in this study, your eligibility for the medical care and services at this clinic will not be affected. You can still see your primary care provider and can still get the services to which you have access and are otherwise entitled.
Costs	There will be no costs for you to participate.
Confidentiality	To the extent allowed by law, every effort will be made to keep your personal health information and study information confidential.

INFORMED CONSENT AND AUTHORIZATION

INTRODUCTION
You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the research staff to explain anything in this form or about the study that is unclear. Please take time to read this information carefully. Feel free to discuss it with your relatives, friends, and your primary care physician. If you agree to take part in the research study, you must sign this consent form. If you enter the study, you can stop participating at any time. The research study is explained in this consent form.

This is a multi-site study supported by the National Institute on Drug Abuse (NIDA). Dr. Jennifer McNeely at New York University Grossman School of Medicine and Dr. Jane Liebschutz at University of Pittsburgh are the national Lead Investigators of this study. [NAME OF SITE PI] is the Principal Investigator for this study at [NAME OF SITE].

DISCLOSURE OF FINANCIAL INTERESTS
The National Institute on Drug Abuse (NIDA) is providing funds to the [INSERT NAME OF SITE] to conduct this study.

PURPOSE OF THE STUDY
This clinic and your primary care provider are taking part in the Co-Care study, which seeks to understand whether a team involving a primary care physician, a nurse, an addiction specialist, and a health coach can work together to help patients reduce their substance use.

NUMBER OF PARTICIPANTS AND LENGTH OF STUDY
Your participation in the study will last approximately 12 months. Approximately 350 patient participants will be enrolled in this study at research sites across the country, with about 70 patient participants from this site.

STUDY PROCEDURES
If you choose to be in the study, you will be asked to sign this consent form before you begin the study. Your first meeting with the research staff (by computer, phone, and/or in person) will last approximately 1 hour. After that, you will be asked to participate in additional activities, detailed below, over the course of approximately 12 months.

Primary care providers have been randomly assigned to one of two groups (Group A: Collaborative Care and Group B: Enhance Usual Care, as described below). The providers are assigned to their group by chance, like flipping a coin. The study activities you participate in will depend on the group to which your provider is assigned. You are not able to choose which group you are in. You will not know ahead of time the group assignment of your primary care provider.

No one outside of the research staff will see your answers to any surveys or interviews, or the results of your urine tests, with the following exception:

- For Group A participants, results of some questionnaires that you completed as part of screening for this study will be shared with your primary care provider, nurse care manager and health coach. No other survey data or results will be shared with clinical staff during the study.

The following is the schedule of study activities and what will be done for each group.

Study Activity	Group A: Collaborative Care	Group B: Enhanced Usual Care
First meeting with research staff, approximately 1 hour	Complete questionnaires about your substance use and health. Provide a urine sample. Receive educational materials.	Complete questionnaires about your substance use and health. Provide a urine sample. Receive educational materials.
Meet with the Nurse Care Manager (approximately 6 months of contact)	Meet with the study Nurse (in-person or via phone or video call) for care management.	Not applicable.
Health Coaching, approximately 30-45 minutes per session	4 to 12 sessions with a health coach, scheduled approximately weekly after you enroll in the study. During these calls, you will address issues related to your health, including substance use, symptom management, behavior change, and quality of life.	Not applicable.
Monthly Survey, approximately 10 minutes each	Complete one survey per month (text message or online) asking you about substance use and health behaviors.	Complete one survey per month (text message or online) asking you about substance use and health behaviors.
3, 6 and 12-month surveys, approximately 45 minutes to 1 hour each	Complete questionnaires online and/or by telephone.	Complete questionnaires online and/or by telephone.
Urine Screening	You will be asked to provide a urine sample when you enroll in the study, and at 3, 6 and 12 months. Your provider will not see the results of the tests.	You will be asked to provide a urine sample when you enroll in the study, and at 3, 6 and 12 months. Your provider will not see the results of the tests.

After you have provided your consent, study staff will ask for a list of ways to contact you, such as your e-mail address and phone number, as well as the contact information for relatives or friends who know how to reach you. The study staff will also not tell your relatives or friends anything about this study, your participation in the study, or any other information unless you give permission. Your contact information will be used to remind you about upcoming study surveys and health coaching sessions. The follow-up surveys are very important to the study, and the research team will make every effort to contact you to remind you about these surveys. If research staff has difficulty getting in touch with you for your follow-up surveys, they may search public databases in an effort to try and locate you.

Urine Screening: Any urine specimen collected and/or used for the purposes of this research will not be used or distributed for future research studies. To ensure participants are able to provide the sample in the most convenient manner, sites have the option of collecting samples in the following ways:

1) In the clinic conducted by research staff.
2) At home, conducted by you.

Samples will be collected when you enroll in the study, and at approximately 3, 6 and 12 months. The results of these urine tests will be used for research purposes only. They will not affect your eligibility for this study and will not be shared with any clinical providers or clinical staff.

Health and administrative records: Additional information on your health will be recorded from your medical records by the research team. We will review your medical records for the period of 12 months before your enrollment in the study and for the 12-month period during the study, for a total review period of 24 months. We will look for information about the care that your primary care provider delivered, as well as your prior and current health conditions, medications, and use of health services.

Audio recording: For participants receiving health coaching, we would like to digitally audio record these coaching sessions. The purpose of this is to confirm that the health coaches are conducting the sessions in accordance with study policies and procedures. If calls are conducted via video chat, only audio (and not video) will be recorded. If you agree to participate in this study, your initials below give the researchers permission to make and retain the audio recordings for this study. You have the right to request that all or any portion of the recording be erased.

- Recordings will be accessed only by members of the research team who are trained and assigned to review recordings. This may include experts located at other research facilities also involved in this research.
- Recordings will be identified by a number to protect your identity and to ensure that your study information remains confidential. Recordings are labeled with a participant study ID number, session number and session date. Randomly selected session recordings will be reviewed for quality monitoring.
- Your name will not be recorded. Your name will only be linked to your study ID number in a secure and locked file cabinet and/or on password-protected computer. If you wish to not reveal who you are on the recording, do not say your name during sessions.
- At any time, you may choose to stop being recorded. If you choose to not be recorded, you can still be in this study, and your care will not be affected in any way. Recordings of an ongoing session can be destroyed, but once a recording has been submitted for quality monitoring it cannot be recalled.
- All study recordings will be kept in locked file cabinets and/or on password-protected computers. Only study staff will have access to them. All recordings will be destroyed after completion of the study.

I **agree** to have coaching sessions audio-recorded. _____
Initial here

I **decline** to have coaching sessions audio-recorded. _____
Initial here

RISKS AND DISCOMFORTS

Risks associated with participation are minimal. It is not anticipated that there will be any injury or adverse reactions caused by the study intervention.

Discomfort: You may feel uncomfortable or embarrassed by providing information about your health behaviors, substance use, quality of life, or other information while answering surveys or speaking with research staff. You are free to provide as little or as much information as you like during the study. If any of the survey topics make you uncomfortable or if you find something upsetting, you can stop at any time. You may stop participation at any time, without any consequences towards your care at the clinic.

Violation of privacy: Some personal and sensitive information will be requested from you during the course of this research study. There is some potential risk of disclosure of your personal information. The study team will ensure to the best of their ability that your information is kept safe, by storing all data and records on password-protected computers and/or in locked cabinets that are only accessible by research staff.

NEW INFORMATION

During the course of this study, we may learn more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

Clinically Relevant Individual Research Results

As the results obtained during this study are for research purposes only and are not for medical diagnosis, you will not receive individual results.

BENEFITS

You may benefit from your participation in this study, but there is no guarantee. Your participation may help future patients who may benefit from what we learn in this study.

ALTERNATIVES TO STUDY PARTICIPATION

Your decision to participate is voluntary (which means you can choose whether or not you want to take part in this study). If you decide to participate, you are still free to withdraw at any time without giving a reason, and without penalty or loss of benefits to which you are otherwise entitled. Should you choose not to participate, your medical care at [NAME OF CLINIC] will not be affected. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

COSTS OF PARTICIPATION

You will not have to pay for anything that is done in this study. If you need medical care while enrolled in the study, you or your third-party payer (i.e., health insurance company, Medicaid, etc.) will be responsible for costs related to any standard treatment or other services received that are not part of the study.

REIMBURSEMENT

You will receive reimbursement to offset costs of time for completing study activities. You will be reimbursed by [INSERT FORM OF PAYMENT] [INSERT WHEN PAYMENT WILL BE GIVEN].The table below details the payment for each study activity:

Study Activity	Amount
First Study Surveys and Urine Screening	Your choices for compensation include: $95 total (no cell phone) - $20 after completing study enrollment and providing contact information for yourself and a locator - $40 after completing additional surveys with research staff - $35 after completing self-administered surveys OR $55 total (plus cell phone) - $20 after completing study enrollment and providing contact information for yourself and a locator

	- A cell phone (approximately $40 value) with a pre-paid plan for up to 13 months after completing additional surveys with research staff. *Note that cell phones will not be replaced if lost, damaged, or stolen.* - $35 after completing self-administered surveys
Follow-up Surveys (3, 6 and 12 months)	$50 for each survey
Follow-up Urine Screenings (3, 6 and 12 months)	$20 for each sample
Monthly Surveys via email/text message	$25 for each month
Bonus payments for completing consecutive Monthly Surveys	$10 bonus payments for participants who complete consecutive monthly surveys (available in months 2, 3, 4, 5 and 6)

Group A: Collaborative Care participants who take part in health coaching sessions will receive a payment of $3 per session to offset any costs they may incur from the telephone and/or video call (total of $12 to $36, depending on number of sessions completed).

Additionally, should your contact information change during the study, you will receive a $5 incentive if you contact the research team and provide the updated information. Participants will be able to receive payment for updating their contact information up to four times but are encouraged to inform study staff any time it changes over the course of the study.

If you choose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be reimbursed for each completed activity prior to withdrawal.

If you become a prisoner (including being in jail or prison, being on probation or parole, or being under house arrest or electronic monitoring), you will still be able to receive reimbursement for your continued participation if your institution approves the amount and method of reimbursement.[THIS LANGUAGE MAY BE TAILORED TO MEET LOCAL LAWS AND REGULATIONS]

Tax law may require the payer (e.g., research institution or third party) to report the amount of payment you receive from that payer to the Internal Revenue Service (IRS) or other agencies, as applicable. You would be responsible for paying the taxes on the payment you received from the study. Generally, this reporting would take place if you receive $600 or more from the payer in a calendar year.

You will not receive payment of any kind for your information or specimens (even if identifiers are removed) or for any tests, treatments, products or other things of value that may result from this research study.

COMPENSATION FOR INJURY

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the Site Principal Investigator as soon as possible. The Site Principal Investigator's name and phone number are listed at the top of page 1 of this consent form. No financial compensation will be offered by the sponsor or [Insert name of Site] or the Biomedical Research Alliance of New York. You do not give up your legal rights by signing this form.

INFORMATION ABOUT INCARCERATION

If you become a prisoner (including being in jail or prison, being on probation or parole, or being under house arrest or electronic monitoring), we would still like to find out how you are doing and if you completed the study questionnaires. If necessary, we will make an effort to collect follow-up data from you over the phone or in

person. Please note that your continued participation in the study will have no effect on your criminal case, or release or parole from jail or prison, or probation case. In addition, knowledge of your participation in this research study will not be shared with prison staff, parole officers or probation officers, in any manner, to affect your conditions at the institution where you are held. Details of the nature of the research will not be shared with staff at the jail or prison, and study activities, whether in person or by phone, and will only take place if your confidentiality can be maintained and no audiotaping occurs. If you stop participating in this study, your sentence, probation, or parole will not be affected in any manner.

CONFIDENTIALITY AND AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

To the extent allowed by law, every effort will be made to keep your personal and medical information confidential. You will be assigned a unique study ID number, and your name will not appear on the questionnaires that you submit for this study. However, total confidentiality cannot be guaranteed.

The study staff will use your medical information collected or created as part of the study, such as medical records, test results and research records. Some of this information may identify you by name or in another way. The following information may be used or shared with others in connection with this study:

- Your name, demographic information, and contact information
- Your responses to interviews and surveys, including responses collected during the screening phase of this study that you provided before giving consent to join the study.
  Information from your medical record about the care you received from your medical providers, prior and current health conditions, medications, and use of health services. Note that this information may be accessed for the purpose of locating you, should research staff have difficulty getting in touch with you throughout the study.

The study staff may use and share information about you and your health with other professionals involved in the study, including:

- the Biomedical Research Alliance of New York;
- New York University Grossman School of Medicine's Institutional Review Board;
- the members and staff of [INSERT NAME OF SITE'S] Institutional Review Board;
- [NAME OF SITE PI] and members of the research team who are responsible for the support or oversight of the study;
- the following research sponsors and the people and companies they use to oversee, administer, or conduct the research: The National Institute on Drug Abuse; researchers at New York University Grossman School of Medicine, University of Pittsburgh, University of California at Los Angeles, Kaiser Permanente Washington Health Research Institute, Oregon Health & Science University and Boston Medical Center who are leading this study, United States research regulatory agencies, the Patient Advocate or Research Ombudsman, Members of the [NAME OF UNIVERSITY AND/OR SITE] Clinical Trials Office/Office of Research and Sponsored Programs (if applicable), Clinical Coordinating Center (Contract Research Organization): Emmes, Data and Statistics Center (Contract Research Organization): Emmes, and the Data Safety Monitoring Board, Vink Software (developers of Nurse Care Manager Data Registry) .

Additionally, if you are in Group A: Collaborative Care, your primary care provider, nurse care manager and health coach will receive the results of some questionnaires that you completed as part of screening for this study. They are all members of your health care team, and they may discuss among themselves ways of coordinating care to better assist you. However, they will not receive results of any other surveys, interviews, or urine tests that are collected for the study.

Please be aware that the individuals or groups receiving your health information may not be required to keep it private if they are not covered by the Federal Medical Privacy Rule. They may pass it on to other persons or

organizations not named here if permitted by their governing laws. The purposes for using and sharing your medical information include: to carry out the research study and evaluate its results and to meet government reporting requirements. Results of this research may be presented at meetings or in publications. Your name will not be used in any study reports or presentations. You have the right to review and copy your health information, but you may not be allowed to do so until after the research is completed.

This authorization does not have an expiration date. You have the right to cancel your consent at any time by giving written notice to [NAME OF SITE PI] at [ADDRESS OF SITE PI]. If you withdraw your permission, you will not be able to continue in this study, but you will not lose access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information about you will be gathered after that date. Information that has already been collected may still be used and given to others.

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 website at any time.

De-identified data (which cannot be used to identify you) from this study will be available to researchers on another website, https://datashare.nida.nih.gov/ after the study is complete and the data analyzed. The primary outcome(s) publication for the full study will also be included along with study underlying primary data in the data share repository, and it will also be deposited in PubMed Central http://www.pubmedcentral.nih.gov/. These websites will not include information that can identify you. You can view these websites at any time.

After identifiers are removed from your information (making it anonymous), the information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. However, any urine specimens collected and/or used for the purposes of this research will not be used or distributed for future research studies.

Certificate of Confidentiality

To help us further protect your confidentiality, the National Institutes of Health (NIH) has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data or documents) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information 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, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse). The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. You should also understand that even with a Certificate of Confidentiality, if we learn about abuse of a child or elderly person, or that you intend to harm someone else, the investigators have certain obligations to report that information to the proper authorities or parties in order to reduce the chances that serious harm will occur to either you or others. Should we learn that you intend to harm yourself, the investigators may be obligated to disclose your intent to other providers in order to reduce the chances that serious harm will come to you. Federal regulations may also allow for the use or sharing of information for other scientific research.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your participation in this study is voluntary. The study is expected to end after all participants have completed all study activities, and all information has been collected. This study may also be stopped, or your participation may be terminated at any time by your physician, the study investigator, or study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study, has decided to stop the study.
- You've exhibited unacceptable behavior including, but not limited to, harassment of study or site staff or other participants, disrespecting the research environment, making threats, or sharing private information about other participants.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your standing as a patient of this clinic. If you do decide to withdraw your consent, we ask that you contact [NAME OF SITE PI] and let him/her know that you are withdrawing from the study. His/her mailing address is [ADDRESS OF SITE PI].

Permission to Contact You about Future Research

In the future, if there are additional research studies that we think you may be eligible for, can we contact you regarding these other study opportunities? Please note that participation in any additional study is entirely voluntary and refusing to volunteer for an additional study will not affect your participation in the study.

I **agree** to be contacted for future research studies. _____
Initial here

I **decline** to be contacted for future research studies. _____
Initial here

QUESTIONS/COMPLAINTS/CONCERNS

If you have any questions relating to this research study or your participation in it, if you want to voice a complaint or concern about this research, or if you experience a research-related injury, you may contact [INSERT NAME OF SITE PI] at [INSERT SITE PI PHONE NUMBER].

If you have any questions about your rights as a research participant or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board (BRANY) at 516-318-6877. Questions, concerns, or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research. The IRB is a committee that reviews research studies to help protect the rights and welfare of study subjects.

STATEMENT OF CONSENT

I have read this consent form. I have been informed of the risks, discomforts, and benefits involved. All of my questions have been answered to my satisfaction. The study staff will answer any future questions I may have. I will be given a copy of this signed consent form.

By signing this consent form I voluntarily agree to participate in this study and agree to provide my Authorization for the uses and disclosures of my protected health information as described above.

_____
Participant's Name
(Printed)

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Consent and Authorization
(Printed)

_____ _____
Signature of Person Obtaining Consent and Authorization Date

[INSERT ADDITIONAL SIGNATURE LINES IF LOCAL PARTICIPATING SITE REQUIRES]