Consent Form: Whole Health Study: Collaborative Care for OUD and Mental Health Conditions

NCT: NCT04245423

Approval: 11/8/2022

University of Pennsylvania
Informed Consent and HIPAA Authorization Form

Title of the Research Study: The Whole Health Study: Collaborative Care for OUD and Mental Health Conditions: Randomized Trial

Protocol Number: 834490

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Research Study Summary for Potential Subjects
You are being asked to join a research study. Your participation is voluntary. This means you should only join if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after joining, please contact the Institutional Review Board (IRB) at (215) 898-2614 for help.

The research study is being done to compare 3 care conditions to find out which is most effective in helping people with an opioid use disorder (OUD) and a mental health condition. You have been asked to join because you have been diagnosed with an opioid use disorder(e.g., addiction to heroin, oxycodone, fentanyl) or have taken medication for opioid use disorder (MOUD) in the last year and have a mental health condition (e.g. depression, anxiety, or post-traumatic stress disorder (PTSD). If you agree, you will be asked to answer survey questions. If you receive one of the two experimental care conditions you will also meet with a care manager who will help you with your OUD and mental health concerns. Your participation will last for 6 months. The most common risk of participation is a small risk of violating your privacy. However, we will take every precaution to make sure this does not happen.

Please note that there are other factors to consider before agreeing to participate. These include additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being asked to join a research study because you have been diagnosed with an opioid use disorder or have received medications for opioid use disorder MOUD) such as buprenorphine in the past year. You also have a mental health condition.

Your participation is voluntary. This means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you decide, you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if you decide to join. The research team is going to talk with you about the study and give you this consent form to read. You do not have to decide now; you can take the consent form home and share it with friends, your family doctor and family.

If you decide to join, you will be asked to sign this consent form and a copy will be given to you. If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. Keep this form; in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

If you sign this form, you are agreeing to participate in this research study. You should not sign this form until you are sure you wish to join, and all your questions about this study have been answered.

What is the purpose of the study?

We are interested in comparing 3 care conditions to determine which condition is best to help people with opioid use disorder (OUD) and mental illness reduce their drug use and improve their psychiatric symptoms. The model we are testing is called collaborative care. This model uses a team-based approach in which a primary care physician (PCP) and a care manager coordinate care. Care managers are hired in primary care practices to work as part of the health care team. As part of this study, care managers will keep their role and continue to provide care monitoring of patients with mental health conditions in the primary care practice. As part of this study, care managers in the experimental conditions will also receive training in treating patients with OUD. You will be offered medication for opioid use disorders (MOUD) such as buprenorphine. Buprenorphine, in combination with counseling, provides a whole-patient approach to the treatment of OUD. When taken as prescribed, buprenorphine is safe and effective. Buprenorphine lowers your risk for misuse and reduces withdrawal symptoms and cravings. It also helps reduce the chances of overdose.

Why was I asked to participate in the study?

You are being asked to join this study because you are 18 years of age or older. You also have been diagnosed with an opioid use disorder (e.g., addiction to heroin, oxycodone, and fentanyl) or have received MOUD such as buprenorphine in the past year. You also agree to receive medications for OUD at this primary care site. In addition, you have a mental illness (e.g. depression, anxiety, or PTSD). You were referred to the study by your PCP.

How long will I be in the study? How many other people will be in the study?

Your participation in the study will last for 6 months. This means for the next 6 months you will participate in answering survey questions that last from 45 minutes to 2 hours. If you are assigned to

one of the two experimental care conditions, you may have more visits which will range from one time per week at the beginning to monthly. Many of the visits will be done over the phone. You will be one of 1,185 people in the study.

Where will the study take place?

The screening part of the first or baseline interview and consent will take place at your PCP's office in a private area of the clinic where you usually see your doctor. The remaining part of the baseline interview will be done over the phone. We may also conduct the interview at our offices at 3535 Market in Philadelphia if that works for you. Due to COVID-19 we will be conducting all follow-up interviews for this study over the phone. An exception is that at the 3 and-6 month follow-ups we may ask you to come to our offices at 3535 Market to provide a urine drug screen if none is available in your electronic health record (EHR). Please note that once COVID-19 restrictions have been removed, we will continue the study with both in-person and phone visits. We will let you know when this takes place and which interviews will be done over the phone versus in-person. We will ask you to review this consent form again with the updated changes. Research staff will contact you to complete the interviews at times that are good for you.

What will I be asked to do?

By answering questions about your drug use and any psychiatric symptoms you may be having (depression, anxiety, PTSD, mania, psychosis, suicidal thoughts) you completed the screening or first part of the baseline interview. Based on these findings it appears that you are eligible for the study. If you agree to join the study, the remaining part of the baseline interview will be done over the phone. We will ask you about treatment services that you have received and questions about other factors that may affect your health such as stable housing. We will ask about your sleep patterns and tobacco use. We will also collect demographic information (e.g., age, gender, and race). Your EHR will also be reviewed to see if you have any other health conditions such as high blood pressure or diabetes.

If you agree to join the study, you will be randomly assigned to one of 3 groups. You are not able to pick which group you are in. Random assignment is like flipping a coin. You will have an equal chance of being assigned to one of the three groups. The first group is called Augmented Usual Care (AUC). This group receives the support which is normally provided at your PCP's office. This group will also receive an addiction psychiatrist who will serve as a consultant to your PCP regarding your treatment for OUD. AUC will include routine collection of urine drug screens which is part of standard practice.

The second group is called Collaborative Care (CC). If you are assigned to the CC group, you will receive a care manager. The care manager is trained in evidence-based treatments for people with OUD and psychiatric disorders. The care manager provides care in the primary care practice as part of the collaborative care team. During COVID restrictions, all of these visits will be over the phone. After COVID restrictions are removed these visits may be in-person or may continue by phone. We will let you know of any changes. These visits will consist of the care manager carrying out treatment activities. Treatment activities cover 6 months. After reviewing your psychiatric history, medical history, and medication and drug use, the care manager will work with your PCP to suggest treatment according to the treatment guidelines. You will also receive counseling using treatments that have shown to be effective in helping people with mental illnesses in primary care. Visits with the care manager are at baseline (60-minute intake appointment), and then weekly. When you are stable they will occur once a month. There will be a final visit at 6 months. You will be reminded by phone about upcoming visits with the care manager. The treatment will include routine collection of urine

drug screens which is part of standard practice.

The third group is called Collaborative Care Plus (CC+). If you are assigned to CC+, you will receive the CC described above, plus you will receive a Certified Recovery Specialist (CRS). A CRS is a person in the community who is in recovery. They may share the same experiences and barriers that you have faced. They will work with you as a peer to help you manage information and needs with your providers. They serve as a link between you and your care team to make sure that you are receiving the right care and that your needs are met. The CRS may take you to your PCP visits and any other visits that you may have. This will help you engage and stay in care to remain healthy. They will also provide education and help you work on your recovery goals. They will identify and support linkages to community resources. Some examples are communities of recovery, medication for opioid use disorders (MOUD), educational, vocational, social, cultural, spiritual resources, self-help groups, and professional services. They will help you identify barriers to your recovery and/or community resources and develop plans to remove those barriers. Due to COVID-19, many of these visits may also occur by phone.

Individuals in all 3 groups will complete interviews with research staff on Dr. Mandell's (Principal Investigator) study. There will be a total of 7 research interviews over 6 months. The first is the baseline interview described above. After the baseline you will complete phone follow-up interviews; the phone interviews are at months 1, 2, 3, 4, 5 and 6. During the 1,2, 4 and 5 month phone interviews we will ask you about your substance use and any psychiatric symptoms you are having. At the month 1 interview we will also ask you about your drug and alcohol use history and any pain you may be having. At the 3 and 6 month interviews you will be asked about your substance use, mental health, treatment services you received and other factors that affect your health like housing. We will also collect a urine drug screen at months 3 and 6 unless you provided one at the clinic. At all the follow-up interviews we will ask you about side effects that you may be having and whether you are taking your medication as prescribed. The baseline interview will take about 1 ½ to 2 hours. The 1, 2, 4, and 5 month interviews will take about 45 minutes. The 3 and 6-month interviews will take about 1 to 1 1/2 hours to complete. Standard practice for MOUD is the collection of urine drug screens. In addition to the research interviews, we will obtain urine drug screens from your PCP's practice for people in all 3 groups.

Please know that even if you receive the AUC condition you will be receiving additional care. This will be more care than you would otherwise receive as part of usual care for OUD from your PCP. Your PCP will receive help from an addiction psychiatrist regarding your treatment for OUD.

We will want to get in touch with you again for follow-up interviews. We will need to get information to you about your next appointment and the study in general. To be able to locate you, we ask for a lot of locator information - names, addresses, and phone numbers. This will help us find you. As we try to contact you, we will send letters, texts or leave phone messages. We also can get in touch with you through myPennMedicine if that is something you have access to and would like. However, we will not reveal details about the study or why you are in it. We will just say that we are calling or writing from the University of Pennsylvania and will ask to speak with you. If you are not home, we will leave a message. The message will ask you to call us at the University, and the study staff member will leave his/her first name along with our phone number. If asked, we will not disclose any more information. If you would prefer us to say or write something other than what is described above, please let us know and we will note it in our records. We will also ask you to provide contact information from family and/or friends. These are people who would know of your whereabouts if we are unable to contact you directly. We will just say that we are calling or writing from the University of Pennsylvania and that you have been listed as a contact. We will not tell them that you are part of a research study or tell

them anything about the study. We will just ask them for information to contact you, or if we could leave a message for them to have you call us.

What are the risks?

One risk of being a part of this study is that you may be asked questions which you may think are personal or embarrassing. You do not have to answer a question if you do not want to do so.

If you become uncomfortable or upset during the study, you may ask to speak with a counselor. If you tell the research staff that you are thinking about killing yourself or you answer yes to a question about having thoughts about suicide and have a plan, you will receive an assessment for safety by a licensed clinician right away. If your thoughts are intense, we will work with you on a plan. This plan may include getting you to a hospital for safety. Your primary care physician will be informed of this plan by the clinician performing the safety assessment.

Also, because the information we take from you will identify you by name, there is some small risk of violating your privacy. However, we will take every precaution to make sure that this does not happen. The exception is that if you express harm to yourself or others, or if you report child or elder abuse or neglect. These will be reported to the authorities, as required by law.

If you show signs of a more severe mental illness such as psychosis or mania (extremely high energy levels, racing thoughts, very high irritability), we will ask you to speak with a psychiatrist on our study. We will also notify your PCP. We will do this so you may receive the right kind of referrals or any treatment that you need.

Please know that if you are pregnant or become pregnant during the study, it is suggested that pregnant women with OUD receive MOUD such as buprenorphine as standard practice. You and your unborn child will not be exposed to any more risks over and above the risks involved in the treatment of OUD with buprenorphine. Of course, you will be provided with options for treatment including care outside of the research study.

How will I benefit from the study?

We cannot promise that you will get any direct benefit from joining the study. However, you could benefit from talking about your substance use and psychological issues with your health care providers. You may learn about how you can improve your understandings of treatments available for you. Your participation may benefit others in the future. By providing information to help improve the way that PCPs can help people with OUD and mental illness, you may be helping people in the future. If you are pregnant or become pregnant during the study, your participation may provide a benefit to you and your unborn child. This is because the benefits of treatment outweigh the risk of continued use of heroin or other illicit opioids.

Will I receive the results of research testing?

Most tests done in research studies are only for research and have no clear meaning for participants. Research results from this study will not be returned to you because they will only be used for research purposes.

What other choices do I have?

Your alternative to being in the study is to not be in the study. You may refuse to participate in this study at any time. If you agree to join now and then change your mind, you may drop out of the study at any time. Dropping out will not hurt your standing with the University of Pennsylvania. In addition, you need to know that any services you receive from doctors, care managers, therapists, or social workers will not change if you choose not to participate. Your decisions about whether you join will not affect your receipt of care and services from any other agency or clinic. You should also discuss any futures alternatives with your personal PCP.

After you are enrolled in the study, you may later decide that you would like to receive care outside of the research study. If this is the case, we would still like to follow you to complete research interviews.

What happens if I do not choose to join the research study?

You may choose to join the study, or you may choose not to join the study. Your participation is voluntary.

There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you or would come to you in the future. Your doctor, nurse, or social worker will not be upset with your decision. If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

If you decide not to be in the study, you will be referred to appropriate services that you may need.

When is the study over? Can I leave the study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. The study may be stopped without your consent for the following reasons:

- The Principal Investigator (PI) feels it is best for your safety and/or health. You will be told the reasons why.
- You have not followed the study instructions.
- The PI, the sponsor or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime.

If you decide to participate, you have the right to drop out of the research study at any time. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with any future care.

If you no longer wish to be in the research study, please contact David Mandell, ScD, at David.Mandell@pennmedicine.upenn.edu, or (215) 573-7494. You should inform him you no longer wish to be enrolled. There are no consequences to dropping out of the study.

All collected data will be kept for 7 years and will then be destroyed.

How will my personal information be protected during the study?

Being in a research study involves some loss of privacy. This study will collect personal data like your name, date of birth, address, and health related information.

We know that your information is personal. We are committed to protecting your privacy. We will do our best to keep your information private. However, we cannot guarantee total privacy.

Personal information we collect may be seen by other people involved in this research. This includes those working with funding, and regulating the study. This may include people who are not part of the University of Pennsylvania.

We will only share information needed for us to do research. Personal information may also have to be shared if required by law.

Your study information might be reported to the National Institute of Mental Healthy (NIMH) and its partners. Also, your records may be reviewed in order to meet federal or state regulations.

Reviewers might include people at NIMH, the University of Pennsylvania IRB**,** and others as appropriate. If any of these groups review your record, they may also need to review your medical record.

We will maintain your privacy by making sure that:

- No individual information collected after eligibility and consent will be shared with clinic staff.
- Information will be reported by combining all data from all participants; no individual agencies or people will be identified.
- The only individuals at Penn who will see your information are researchers involved in this study.
- All interview files will be kept in password-protected files on a password-protected encrypted server.
- Subject identity will be masked using numeric codes in all files used for analysis. Paper consent forms will be locked in a confidential filing cabinet at the Center for Mental Health at the University of Pennsylvania. Electronic consent forms will be stored in a password-protected database on a secured server.
- Files kept on the computer for analysis will only be identified with subject numbers. The files will not contain identifying information.
- If information from this study is published or presented at scientific meetings, your name and other personal data will never be used.

An exception to confidentiality is if you report child or elder abuse or neglect. Another exception is if you report suicidal or homicidal ideation or intent to the research team. Any information about child or elder abuse or intent to harm yourself or others will be reported to the authorities, as required by law.

Also, if you show signs of a more severe mental illness such as psychosis or mania (extremely high energy levels, racing thoughts, very high irritability), we will ask you to speak with a psychiatrist on our study. We will also notify your PCP. We will do this so you may receive the right kind of referrals or any treatment that you need.

What may happen to my information collected on this study?

Future Use of Data

Your information will be de-identified. De-identified means that all identifiers like name, address, and birthdate have been removed. The information could be stored and shared for future research in this de-identified fashion. Future researchers will not be able to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

NIMH Data Sharing

Data from this study will be sent to the NIMH Database (NDA) at the National Institutes of Health (NIH). NDA is a large database of de-identified study data from many NIMH studies. De-identified study data means that all personal information about you (like name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your de-identified study data helps researchers learn new and important things about mental health and substance use more quickly.

During and after the study, the researchers will send de-identified study data to the NDA. Other researchers across the world can then request your de-identified study data for their research. Every researcher (and institutions to which they belong) who requests your de-identified 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. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with the NDA. The study data provided to the NDA may help researchers around the world learn more about mental health and substance use. It will also show how to help others who have problems with mental health and substance use. NIMH will also report to Congress and on its website about the different studies using NDA data. You will never be contacted directly about the study data you provided to the NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still join this research study even if you decide that you do not want your data to be sent to the NDA. If you know now that you do not want your data in the NDA, please tell the study researcher before leaving the clinic today.

If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study. They will tell the 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 told that you changed your mind. If you would like more information about the NDA, visit http://nda.nih.gov.

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you

get for the injury. However, you may also be responsible for some of them. You may also visit the emergency room, your PCP, or your therapist for injuries sustained while part of the study.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, please tell the PI Dr. Mandell as soon as possible. Dr. Mandell can be reached at 215-573-7494.

Will I have to pay for anything?

You will not have to pay anything to join this study.

Will I be paid for being in this study?

If you are eligible for the study and agree to participate, you will sign a consent form and we will enroll you. We will pay you $50 for the baseline interview, $60 for the 3-month follow-up and $70 for the 6-month follow-up interview. You will also receive $20 for the 1, 2, 4 and 5-month interviews. If you complete all 7 interviews you would receive a total of $260.

Payment for the baseline interview is divided into two parts. We will pay you $25 for the screening and consent part of the baseline interview that is completed in your PCP's office. We will pay you another $25 when you complete the remaining part of the baseline interview that may be done over the phone, for a total of $50. If you complete just part of the baseline interview for any reason, you will not receive the second $25.

The 3 and 6-month follow-ups each require a urine drug screen. This screen can be one you provide as part of your regular doctor's visits. If the urine drug screen is available through your health record, you will receive $60 for completing the 3-month interview and $70 for completing the 6-month interview.

If a recent urine drug screen result is not available in your health record, we will ask you to provide a urine sample at our research office at 3535 Market. In this case, the 3 and 6-month interview payments will be split into 2 payments. At 3 months you will receive $30 for completing the phone interview. You will receive another $30 once you provide a urine sample at 3535 Market. Similarly, at the 6-month visit, if you have a recent urine in your health record at the time of the interview you will receive $70 ($40 for the phone interview and $30 for the urine). If you do not have a urine in your health record, you will receive $40 for the phone interview and another $30 once you provide a urine sample at 3535 Market.

You will be paid using the Greenphire ClinCard. The Greenphire ClinCard is a reloadable prepaid card**.** Please note: In order to be paid for your participation in this study, you must provide your Social Security Number. Also, please note that the University of Pennsylvania is required to report to the IRS any total payments for participation in research studies that exceed a total of $600 in a calendar year. Information about the ClinCard amount you received and the last 4 digits of your social security number will be stored in a password protected RedCap database on a secured server.

What information about me may be collected, used or shared with others?

- Name, address, telephone number, date of birth
- Email address

- Social Security number
- Medical record number
- Personal medical history
- Results from urine drug screening tests

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

To better understand your use of services in this study, we would like to link additional data from Medicaid claims. The Medicaid claims will be from either the PA Medicaid claims database from the Department of Public Welfare (DPW) or the Philadelphia Medicaid claims database from the Community Behavioral Health (CBH) managed care program. These Medicaid claims data will be linked to your answers to interview questions. These data will provide more detailed information that cannot be obtained from your interview answers. We will also collect data from your electronic heath records (EHR). This will help us understand the treatment services and medications you received.

Medicaid claims records will be accessed and linked to your interview responses. The information from these records may include:

- Medicaid claims number
- Date of birth, gender, ethnicity, provider of service
- Medication name and amount you received
- Date and type of Medicaid services you received

Is this research study part of your electronic health record (EHR)?

An electronic health record (EHR) is an electronic version of the record of your care within a health system. An EHR is simply a computerized version of a paper medical record. If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient), an EHR is created for you. Our research study will be included as part of your EHR. Results of research-related procedures (i.e. clinic visits, urine results) are placed in your existing EHR maintained by UPHS.

Once placed in your EHR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EHR may also be shared with others who are determined by UPHS to be appropriate to have access to your EHR (e.g. health insurance company, disability provider, etc.).

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Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of the School of Medicine, might receive my information?

- Those working under the direction of the investigator for the study, (e.g. under subcontracts).
- All research centers taking part in the study, even if they are not part of the School of Medicine
- The funding sponsor, NIMH and organizations supporting the sponsor
- If at any point you are provided transportation related to your care, such as Lyft, we would disclose information such as your name, phone number and address to the company

Oversight organizations

- The Office of Human Research Protections
- The study data and safety monitoring board

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The PI or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's IRB grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

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

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

By signing this form, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding taking part in this research study or if you have any questions about your rights as a research subject, please contact David Mandell, ScD. Dr. Mandell can be reached at David.Mandell@pennmedicine.upenn.edu, (215) 573-7494. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB with any questions, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

Please also note that you will be informed if any new significant information becomes available regarding the results of the study or the study itself.

INTERVIEWER: **ASK THESE QUESTIONS OF ALL PARTICIPANTS AFTER REVIEWING THE INFORMED CONSENT FORM BUT PRIOR TO SIGNING**

Now I'm going to ask you a few questions about the consent form to make sure that everything I described was clear.

1. The purpose of this study is to:
   a. compare different models of collaborative care
   b. understand how medications work
   c. understand how people get along with their family members

2. If I agree to participate, I am agreeing to:
   a. participate in ten research interviews
   b. participate in seven research interviews
   c. participate in one in-depth interview.

3. I can refuse to answer any questions that make me feel uncomfortable:
   a. True
   b. False

4. I can pick which treatment I will get:
   a. True
   b. False

5. Each interview will take:
   a. 10-15 minutes
   b. 45 minutes to 2 hours
   c. 5 hours

6. Since I am assigned randomly to the treatment conditions, there is a chance that I will NOT be assigned to receive either of the two experimental collaborative care conditions such as the care manager who is trained in opioid use disorders or the care manager and certified recovery specialist provided by the study:
   a. True
   b. False

SCORING:

Question Number	Correct Initially? (Y/N)	Number of times re-explained? (0-2) **	Competent? (Y/N) **
1			
2			
3			
4			
5			
6			

** *Interviewer*: If on any question the content is re-explained two (2) times and the respondent still does not answer correctly then the respondent is incompetent to proceed and should not be interviewed at this time.

When you sign this form, you are agreeing to join this study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

I consent to allow my study data to be sent to the NDA.

{Please initial your selection below}

Yes_____ No _____