

Study Title: Specialized Community Disease Management to Reduce Substance Use and Hospital Readmissions

NCT Number: NCT02059005

Document Date: June 7, 2016

PATIENT CONSENT FORM (COC Version)
Project RISE

PURPOSE: The Treatment Research Institute (TRI) is doing a study at Temple University Hospital. The purpose of this study is to look at different ways to help people manage their health after discharge from the hospital. TRI is an independent research group and is not connected with Temple. About 222 patients will take part in this study.

INVITATION TO PARTICIPATE: We are asking you to be in this study because:

- You are a patient at this hospital diagnosed with one of the following conditions: congestive heart failure, pneumonia, acute myocardial infarction, chronic obstructive pulmonary disease, diabetes mellitus, or end-stage renal disease; OR you have had a previous hospitalization within the past six months.
- Your answers to some questions showed that you may benefit from changing your health habits.

You cannot be in this study if:

- You are under 18 years of age.
- You plan to leave the Philadelphia area in the next six months.
- You were admitted to Temple University Hospital directly from an inpatient drug and alcohol rehabilitation facility.
- You are currently homeless.
- You have had an organ transplant, are being discharged on a ventilator, or have a ventricular assist device or artificial heart.
- You cannot understand this consent form.

PROCEDURES: Your part in this study will take about six months. If you agree to be in this study, we will ask you to:

- **Complete interviews and surveys** that ask about your health, mental health, education, family, drug and alcohol use, risky behaviors, personality traits, social support, quality of life, and use of other services. We will ask you to complete these today. It will take you about 1 hour and 30 minutes to do this. You will also be asked to complete these interviews and surveys again 3 months and 6 months from now. These follow-up interviews will take about 1 hour to complete. Overall, you will be asked to complete these interviews and surveys 3 times. These interviews will take place either at Temple Hospital or at a mutually agreed upon location in the community. Additionally, we will ask you to complete a brief check-in call 1 month, 2 months, 4 months, and 5 months from now. These calls will take approximately 5-10 minutes. On these check-in calls, we will ask you to update your contact information and will also ask you a few questions about your health and substance use. If you are incarcerated in the next 6 months, we will not ask you to complete any interviews or check-in calls while you are still incarcerated. Additionally, the screening surveys you completed to determine your eligibility for this study will become part of your research record.
- **Give our research staff your contact information.** We will ask for your addresses, phone numbers, and the contact information of family and friends who know how to find you. We will use this information to schedule follow-up interviews, send you reminders about appointments, and conduct a home

TRI IRB

Approval Date: 06/09/2016

Expiration Date: 03/19/2017

outreach visit if we are unable to reach you. Additionally, we may use contact information from your TUH medical chart to get in contact with you. You may also receive a phone call from research staff who will check in on your experience participating in the study and ask if you have any questions or concerns. Providing this contact information will take about 10 minutes to complete today.

- **Allow Temple University Hospital (TUH) to share information from your medical chart** with the research team. This information includes your name, health insurance status, hospitalizations, emergency room visits, diagnoses, medications, and results of urine drug tests at TUH. We will collect this information beginning on the date two years prior to your study enrollment date and ending on the date three years after your study enrollment date. We may also access contact information in your medical chart during the six months that you are enrolled in this study in order to reach you to schedule follow-up interviews.
- **Provide urine samples** that will be tested for various drugs like stimulants, sedatives, marijuana, and opiates. It will take about 5 minutes. We will ask you to give us a sample at the 3-month and 6-month interviews. We may also ask you to give us a urine sample today if we cannot get the results from your medical chart. Overall, you will be asked to provide 2 or 3 urine samples.
- **Agree to be assigned to one of two brief programs:** either the Advantage Program, or the Prime Program. These two programs are designed to help you manage your health condition after you are discharged. The way you are assigned to a program is by chance, like flipping a coin. You have the same chance of getting into either program. Neither you nor TRI study staff will be able to change which program you are assigned to. If you agree to be in this study, we will ask you to follow the procedures for one of the two programs that are explained below.

Advantage Program

- If you are in this program, you will be enrolled in the Temple Advantage Program. This program helps people manage their condition after they leave the hospital. This program lasts for 90 days.
- Before you leave the hospital, you will meet with a nurse navigator or community health worker. The nurse navigator or community health worker will ask you some questions about your home environment. They will also teach you the best ways to take care of yourself for your condition. If you are discharged from the hospital before the nurse navigator or community health worker meets with you, they will contact you after you leave the hospital.
- Before you leave the hospital, you will also meet with a health counselor one time. This meeting will take 20 to 40 minutes. In this meeting, the health counselor will talk to you about your drug and alcohol use. The counselor may also give you a referral to self-help meetings or to other services. You do not have to attend any of these other services in order to be in the study. If you are discharged from the hospital before the health counselor meets with you, s/he may contact you up to one week after you are discharged to complete this meeting.
- After you leave the hospital, the nurse navigator or community health worker will call you 1 or 2 times each week to check in and see how you are doing. They will ask you some questions to make sure you are getting better, and will answer any questions that you have. You will receive these calls for 90 days after you leave the hospital.
- Also after you leave the hospital, a home nurse or community health worker may visit you to see how you are doing. They will teach you about living with your condition. They will also make

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Approval Date: 06/09/2016

Expiration Date: 03/19/2017

sure you are taking your medications, will help you set up visits with your doctors, and will help you get to your doctors' appointments.

- The nurse navigator or community health worker may continue to provide additional help after 90 days, if requested.

Prime Program

- If you are in this program, you will be enrolled in TRI's Prime Program. This program helps people manage their substance use and health condition after they leave the hospital. This program lasts for 90 days.
- Before you leave the hospital, you will meet 1 to 2 times with a health counselor. These meetings will last 20 to 40 minutes each. In these meetings, the health counselor will talk to you about your drug and alcohol use. The counselor may also talk to you about things that you can do to cut back or stop your drug or alcohol use. He or she will also give you referrals to self-help meetings or other services. You do not have to attend any of these services in order to be in the study. If you are discharged from the hospital before the health counselor meets with you, s/he may contact you up to one week after you are discharged to complete your first meeting.
- After you leave the hospital, the health counselor will call you 1 or 2 times each week to see how you are doing. The counselor will ask you some questions to see if you are getting better. He or she will also ask you about your drug and alcohol use and your attendance to treatment or self-help meetings. The counselor may also give you more referrals to other treatment programs or resources. The health counselor will call you for 90 days after you leave the hospital.
- A nurse navigator may also call you to ask you some questions about your health status to see if you are getting better. The nurse navigator will also answer any questions you have about managing your condition.
- Also after you leave the hospital, a peer specialist will visit you to see how you are doing. The peer specialist will help teach you ways to cut back on or stop your drug or alcohol use. He or she may also help you get to 12-Step meetings or treatment appointments. The peer specialist will also check in to see if you are taking your medications, will help you set up visits with your doctors, and will help you get to your doctors' appointments. The peer specialist will visit you about once a month for 90 days after you leave the hospital.
- The health counselor or peer specialist may continue to provide additional help after 90 days, if requested.
- If you are in this program, you will be eligible to receive rewards for staying in contact with the health counselor and peer specialist. You will receive weekly gift cards for completing at least one phone call per week with either the health counselor or peer specialist. You will be eligible to receive a \$10 gift card for each of the first two weeks, and you will be eligible to receive a \$5 gift card for each of the next ten weeks. The gift cards will be for a retailer in the community (e.g., Rite Aid, CVS).

COMPENSATION: You will receive a \$50 gift card each time you complete a full interview with TRI staff. If you choose to finish the first interview on another day, then you will receive \$25 today and another \$25 when you complete it. You can also receive gift cards to a retailer in the community for providing contact information for family or friends who know how to find you. You will get paid for up to three contacts (\$5

each, maximum of \$15 total), and you will only get paid for contacts with whom TRI research staff are able to establish contact. You will also receive \$10 (in the form of a check or money order) each time you complete a check-in call with TRI staff. The total amount that you can earn for completing interviews and check-in calls with TRI staff is \$205. If you are assigned to the Prime Program you can also earn gift cards up to an additional \$70 for staying in contact with the Program.

BENEFITS: The two programs being offered in this study may help you manage your health condition after you leave the hospital. If you are in the Prime Program, it may also help you to stop or cut down your drug and alcohol use. The Prime Program may also help you to learn about and use other services.

RISKS/DISCOMFORTS: This is considered a minimal risk study. There are three potential risks that might happen to you.

- 1) **You may feel like you have to be in this study because someone at this hospital told you about it.** To make sure you only agree to take part in the study if you want to, you should know that:
 - Temple staff responsible for your care, such as nurses, doctors, and social workers, will be notified that you are participating in the study and will also be notified which program you are assigned to. However, there is no benefit to TRI research staff or to your nurses, doctors, or social workers whether or not you are in the study.
 - If at any point you feel any pressure to take part in this study, you can tell TRI research staff. You can also tell the Principal Investigator, Dr. Adam Brooks, at 1-800-355-9874.
 - If you decide not to be in the study, you will still receive the standard services and treatment at this hospital. This is true even if you decide to drop out of this study later.
- 2) **Certain parts of this study may make you feel uncomfortable. You may feel uncomfortable or experience distress:**
 - a) **during the program sessions**
 - b) **providing urine samples, or**
 - c) **during some of the interviews and surveys.**
 - The nurses, health counselors and research staff are trained to assist in dealing with difficult feelings. If you feel uncomfortable at any time, please let us know and we will talk to you about it.
 - If you feel uncomfortable when answering questions, you can ask to take a break. You can also choose to not answer any question.
 - You may also drop out of the study at any time and not affect your care at this hospital.
- 3) **Breach of Confidentiality.** We keep the information that we collect from you in this study private. However, it is possible that others may learn that you are in this study or about information you tell us. We will take the following steps to reduce any chance that this would happen:
 - The interviews and surveys that you complete with TRI staff will not have anything on them that can identify you. Instead, we will use a research number for all of these. All study materials are kept in locked filing cabinets or are stored on a secure computer system. Only TRI research staff will be able to access these forms and use this system. What you say in the interviews and on the surveys will not be shared with your nurse, doctor or health counselor, or anyone else at the hospital.

- If you are in the Prime Program, your answers to questions that your health counselor asks you over the phone will be entered into a secure computer system. The computer system is password protected. Only your health counselor and TRI research staff will be able to use this system.
- Any information that includes your name (like this form and your contact form) will be kept in a locked cabinet separate from your interviews and surveys. Only staff working with TRI on this study will have access to these forms. These forms will be destroyed three years after the study is over.
- We will also protect your privacy when we try to contact you to schedule follow-up interviews. On the phone, we state that we are from a health survey. TRI staff will not mention this study until we know that it is you on the telephone. If a health counselor calls you as part of the study, he or she will also follow this procedure.

COSTS AND FINANCIAL RISKS: You will be responsible for the cost of your travel to any follow-up appointments. You will also be responsible for any missed time from work and the cost of any childcare services.

VOLUNTARY PARTICIPATION: You do not have to be in this study. If you choose to be in the study today, you may still drop out at any time. If you drop out of this study, you will still receive standard services and treatment at this hospital. To drop out of the study you can tell the TRI research staff. You can also contact the Principal Investigator, Dr. Adam Brooks at 1-800-335-9874 or abrooks@tresearch.org.

REASONS FOR REMOVAL FROM STUDY: TRI research staff may remove you from the study for the following reasons:

- In order to enroll in this study, you must complete the following steps before leaving the hospital: 1) sign this consent form, and 2) complete the first section of your first interview with TRI staff. TRI research staff will remove you from the study if you leave the hospital before completing these two items.
- You must also meet with the health counselor in order to fully enroll in this study. This meeting must occur while you are in the hospital or within one week after you are discharged. TRI research staff will remove you from the study if you do not meet with the health counselor within one week after you are discharged from the hospital.
- If you are in jail or prison, TRI research staff will not contact you.
- If you begin having medical or mental health issues that prevent you from being in the study, TRI research staff will remove you from the study.
- If the study is stopped for any reason.

CONFIDENTIALITY: The information that you share with us will be kept private.

- The interviews and surveys you complete will not include any information that can identify you.
- Only research staff for this study will have access to your research forms. We will not include your name or anything else that can identify you in any publication, presentation, or grant application.
- This research study has a Certificate of Confidentiality from the U.S. Government. This helps so that researchers with this study do not have to give out information that says who you are (even under a court order). The research staff will do everything possible to protect your identity.

- You can tell others that you are in this study if you want. If you give someone written consent to receive your research information, then we cannot use the Certificate to refuse to give this information.

Exceptions to Confidentiality. There are certain times when we will break our privacy agreement. The Certificate does not prevent us from voluntarily disclosing these things without your consent.

- If you tell us that you have been abusing a minor or an elder, then we will report this to the appropriate authorities.
- We will also break your privacy if TRI study staff determines (or you tell us) that you present a serious threat of harm to yourself or someone else. We will also break our privacy agreement if you have a medical emergency. Finally, if we think that your safety is at risk, we will break your privacy and talk to your nurse or health counselor.
- The meetings you have with the nurse navigator and health counselor as a part of this study are also a part of the standard care you receive here at the hospital. Therefore, the content of these sessions, including any substance use intervention that you receive from Temple staff while you are in the hospital, may become part of your medical record.

YOUR RIGHTS: You may contact Dr. George Woody at 1-800-730-7636 if you would like more information about your rights as a study participant. Dr. Woody is the Chair of the TRI Institutional Review Board. This review board oversees the safety and ethics of this study. If you have any questions about being in this study, you may contact the Principal Investigator, Dr. Adam Brooks. Dr. Brooks' phone number and email address is at the top of this form.

CONCLUSION: You have read, or been read, this consent form. Any questions you had have been answered to your satisfaction. If you understand the reasons and procedures in this study, **and** you agree to take part in this study, please sign the consent form in the space below. Once you sign, you will receive a copy of this consent form.

Participant's Name (Please Print)

Participant's Signature

Date

Staff Obtaining Informed Consent

Staff's Signature

Date