Cooper University Hospital

INFORMED CONSENT AND HIPAA AUTHORIZATION TO PERMIT THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH PURPOSES

TITLE OF STUDY: Health Care Hotspotting: A Randomized Controlled Trial

PRINCIPAL INVESTIGATOR: Jeffrey Brenner[1], MD

DEPARTMENT(S):
1. Urban Health Institute, Cooper Health System

SPONSOR: Massachusetts Institute of Technology

CO-INVESTIGATOR(S):
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Introduction

You are being invited to take part in a research study. This form is part of an informed consent process. It will give you information to help you decide if you want to volunteer for this research study. Volunteer means you choose to take part. You do not have to take part in this study to receive treatment at Cooper Hospital. This study is conducted by the Camden Coalition of Health Providers (CCHP). A CCHP recruiter will discuss with you what is involved in this research study. If you decide to take part, you and the CCHP recruiter will sign this consent form. You will receive a copy of this consent form to keep. If you have questions at any time during the research study, you should feel free to call any of the researchers listed above and ask your questions until you receive answers that satisfy you.

What is the purpose of this research study?

You are being asked to take part in a research study that measures how CCHP's Comprehensive Care Program ("Program") affects health and healthcare use. CCHP's Program gives extra support to patients who have multiple chronic conditions, seek medical care from multiple providers, and are admitted to a hospital often.

What is involved in the study?

If you decide to take part, then you will be asked to complete a survey today. This survey should take about 30 minutes to complete. You will then be randomly picked for either a control or intervention group. There is a 50/50 chance of being put into either group. We expect to enroll 800 subjects in total.

The intervention group will have the option to enroll in CCHP's Program. This program is described in more detail below. The control group will not be able to enroll in CCHP's program. The control group will receive the standard of care, which is a written discharge plan from the hospital.

Control Group:

You will be informed today if you are picked for the control group. Members of the control group will not be able to take part in any CCHP intervention for 12 months.

Intervention Group:

You will be informed today if you are picked for the intervention group. Members of the intervention group will be able to enroll in CCHP's Program. The Program consists of care management and coordination for a 1 to 3 month period, but could be longer or shorter depending on your needs. As part of the Program, you will be given a care team that includes:

- a registered nurse,
- licensed practical nurse,
- social worker,
- intervention specialist,
- community health worker, and
- health coaches.

A member of the care team will sign you up for the Program during your hospital stay today. As part of the program, the care team will visit your home and help you to schedule medical appointments. They will also go with you to these office visits and, if needed, help you interact with social service agencies. The care team will work to schedule a home visit within 3 days of your discharge. The care team will also schedule a primary care visit within 7 days of your discharge. At the first home visit, the care team will:

- organize your medications
- set goals, and
- assess the following:
    - your thoughts about your discharge from the hospital and medical care,
    - medical/health needs,
    - activity/mobility,
    - service needs, and
    - stage of readiness to change.

At the next home visits, the team will check the progress you make toward meeting the set goals. Your progress will determine how long it takes you to finish the program. Your care team will consider things like your hospital use, health education, and level of support to decide when you should end the program.

This is different from the usual standard of care, which includes a printed discharge plan for you to follow.

Both Control and Intervention Group:

If you chose to sign up, we will collect identification and health information from you. This does not depend on whether you are picked for to the control or intervention group. The identification information we will collect are:

- name,
- address,
- social security number,
- Medicare Health Insurance Claim Number (HICN) (if applicable),
- Medicaid Statistical Information System ID (if applicable), and
- date of birth.

This information will be used to access official records of your health care use and experiences for the next 3 years. These data will be used to measure your healthcare use (e.g. how many

times you visit Camden hospitals) and health outcomes (e.g. whether you are diagnosed with diabetes) over the next three years.

What risks are there?
There is only minimal risk in taking part in this research. There is always a small risk when sharing your Protected Health Information (PHI). However, the researchers are making sure to keep this information private. This risk applied to both the control and intervention groups.

What benefits are there?
Participating in this study can generate information that can help improve care for patients in the future. This information can improve how patients interact with healthcare and social services providers. If you are assigned to the intervention group, the Program should improve your experience with the healthcare and social services systems. For both groups, you will be paid $20.00 to compensate you for the time it takes you to complete the survey.

What are your alternatives (other choices) if you do not take part in this study?

The alternative is to not take part in this study.

When can your participation be terminated by the investigator?

The study doctor may decide to stop your participating without your permission. This will happen if the study doctor thinks that being in the study may cause you harm, or for any other reason.

Are there any other costs?
There are no costs to you from participating in this study.

Will you be paid for participation?
If you choose to sign up for this study, you will be asked to complete a short survey. To compensate you for the time it takes you to complete the survey, you will be paid $20.00.

What will happen if you withdraw?
If you leave this study, you will still receive your normal medical care. The only care that you will lose is the help managing your medical care you are getting if you are part of the Program. You might be able to get that same kind of care outside of the study. Ask your doctor.

Will you be told about new information that might affect your decision to take part in this research?
There is a chance that researchers will find new information that might affect your decision to take part in this research. If this happens, you will be notified by a member of CCHP's care team.

USE AND DISCLOSURE
OF PROTECTED HEALTH INFORMATION (PHI)
FOR RESEARCH PURPOSES

Will your information be kept confidential?

The privacy rules of a law passed by Congress became active on April 14, 2003. The law is called the Health Insurance Portability and Accountability Act, HIPAA for short. The law gives people who take part in research studies certain rights about their protected health information (PHI). Anything about medical records or payment that can be linked to a specific person is protected health information. If you sign this form you give permission for certain people to use your protected health information for a research study. Researchers, their staff, and other people listed on this form will be able to see the information.

Protected health information will be collected from people in the control and intervention groups. The PHI collected will be:

- your name,
- date of birth,
- social security number,
- address,
- Medicare Health Insurance Claim Number (HICN) (if applicable),
- Medicaid Statistical Information System ID (if applicable),
- information about your healthcare use and health outcomes, and
- information about your interactions with various state agencies.

This information may include things like your medical history or hospital records. Public insurance claims, state welfare participation, wage reports, and other official records may also be collected. If you take part in Medicare or Medicaid, researchers of this study plan to use your ID numbers from these programs to study your public health insurance claims. These IDs include your Medicare Health Insurance Claim Number (HNIC) or your Medicaid Statistical Information System ID. By signing this form, you are giving the researchers of this study permission to use your HICN or MSIS ID for this research purpose. Researchers will also use your wage report data (including quarterly wages and employer IDs) for research purposes. This information will allow the researchers of this study to track the impact of the CCHP's Program.

All of the information listed above is collected about you even if you are not in the study. None of this information is created due to taking part in the study. Taking part in the study means that researchers are able to use the information for research purposes.

The only new information that will be collected as part of this study will be about members of the intervention group who enroll in the Program. CCHP will collect information about these subjects' experience with the intervention. Examples of this information include enrollment date, home visit dates and graduation dates. This data will be stored in a secure database operated by CCHP.

Information about you will also be collected from your medical records and other administrative data sources. These records are stored at 1 Cooper Plaza in Cooper University Hospital's medical records department. Researchers will use this information to answer the questions about the program. For example, the number of hospital visits can be compared between the intervention and control groups.

To help maintain the privacy of your study records, you will be assigned a subject number. All of your information from the study will be kept with only your subject number. Your information from the study will not be kept with things like your name and address that could identify you.

Your study documents will be stored in a locked file cabinet. Findings from this study may be published in scientific journals, meetings or public data sets. However, no one will be able to identify you in any of these publications..

By signing this form, you are allowing the following people or groups to have access to the information described above (your PHI).

The research team, which includes the researchers listed on this form and other people who will study the data.

Cooper's Institutional Review Board (IRB), a committee that reviews, approves, and monitors research involving human subjects may look at your study records.

All of these people and groups are required to protect your PHI.

You are also allowing your PHI to be shared with other people or groups listed below:
- Camden Coalition of Healthcare Providers (CCHP)
- Massachusetts Institute of Technology (MIT)
- National Bureau of Economic Research (NBER)
- Harvard University

The groups listed above have their own privacy procedures to protect your PHI. They are not covered by the same federal privacy rule (HIPAA) that governs healthcare providers. This means that they do not need to follow those regulations.

You have the right to limit who gets to use and share your PHI. You also have the right to see your research study records and know who else is seeing them. You will not be allowed to see the health information that is created or collected during the research. After the research is finished, however, you may see this information.

You are authorizing us to use and disclose your PHI until the end of the research study. You may cancel this authorization at any time by contacting the principal investigator, in writing, at the address on the front of this form. If you decide not to authorize the investigator to use and disclose your PHI or you cancel this authorization, you will no longer be able to participate in this research study, and the use or sharing of future PHI will be stopped. However, the PHI that has already been collected may still be used.

<u>Whom can you contact if you have a question?</u>
If you have any questions about this research, you can contact the researcher carrying out this study: Jeffrey Brenner. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Brenner at (856) 365-9510x2021. You will be given a copy of this form to keep.

You should call the Chief Medical Officer or his representative at (856-968-7858) (a) if you have any questions about your rights as a research subject or your rights related to the research use of your PHI, (b) if you believe that you have not been told about all the risks, benefits, and alternative treatments, (c) if you believe that you are being forced to stay in this study when you do not want to, or (d) you have any complaints about the research.

CONSENT STATEMENT

Your participation and your decision to allow the use of your PHI are entirely voluntary. You do not have to participate or let us use your PHI. If you decide not to participate or not to let us use your PHI or you decide to stop participating or to stop letting us use your PHI, it will not affect your treatment at Cooper University Hospital. Your doctors will continue to treat you the way they always have.

All of the above has been explained to me. All of my questions have been answered. I can ask questions that I have about the research or about the use and disclosure of my PHI at any time. My questions will be answered by one of the investigators listed on the first page of this form.

By signing this form I agree to participate in this study and I agree to the use and disclosure of my PHI for the purposes described above. A copy of this form will be given to me.

Signature Block for Adult Subjects

Printed Name of Subject: _____

Signature: _____ Date: _____ Time: _____

I have discussed the study described above with the subject.

Printed Name of Person Obtaining Consent: _____

Signature: _____ Date: _____ Time: _____