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COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 4 (2016-2)
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: Understanding Recovery After Cardiac Surgery

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Best Contact Number: 475-201-8349

Funding Source: None

What is this study about?

You are invited to take part in a research study to understand how you recover after heart surgery. We use an app to centralize your healthcare information from multiple sources so it is easy for you and researchers to understand your health status and how you are doing after the surgery. You have been asked to take part in this study because you are planned to undergo or have undergone cardiac surgery at Yale New Haven Hospital (YNHH). If you agree to take part in this study, you will be asked to answer questionnaire through a mobile application platform called Hugo. Through Hugo, you will be asked to answer short questionnaires on your smartphone or email for up to 90 days.

This research study will examine the ability of the mobile health application, Hugo, to quickly and securely obtain healthcare information from multiple sources to monitor your outcomes after a procedure. Among the advantages of this system are that, with your permission, we will be able to access your records at multiple health systems. The risks for this study are similar to the risks associated with traditional research methods: you are sharing your personal health information with researchers and there is a risk to your privacy. However, researchers will only be able to view the heath data that you sync with the Hugo platform. There will also be audit logs of who has accessed your data via Hugo and other safeguards that do not exist with paper and faxed records. Researchers will also access your records within the YNHH electronic medical record (EMR) system. This access is to allow the researchers to confirm that your data has fully come into the Hugo, and that there are no major missing data points.

In order to decide whether you would like to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion should review all aspects of this research, especially the confidentiality risks of you having personal health information on your mobile device.

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How is this study conducted?

Setup process

The initial set up process will take about 30 minutes in total and entails the following:

1. Using your own mobile device, a research associate (RA) will help you with the registration process for the mobile platform Hugo. Hugo will be downloaded from Google Play Store or Apple app store. Registration for Hugo will ask for basic information including first name, last name, email address, and to choose a password. You will then be prompted to accept standard terms and conditions and a privacy notice for the Hugo platform.

2. You will check your email and click the confirmation link to activate your new Hugo account.

3. The Hugo mobile application will prompt you to link your patient portal accounts by presenting a list of participating health systems. You can select the systems where you have received care and enter your patient portal credentials (all of these are password-protected).

4. You will be asked to agree to share data from Hugo. The medical record data being shared may include Medications, Problems, Allergies, Procedures, Encounters, Lab Results, Diagnoses, Vital Signs, Notes, and possibly other data that becomes available.

5. The questionnaires will be delivered to you via email or text, whichever you prefer.

6. We are asking your permission at the end of this consent form to give the researchers permission to see health information that you sync and share via the Hugo app along with your YNHH medical record.

Please note: The investigators of this study will not be watching or evaluating your symptoms as part of this study, including those that you reply to on the questionnaires. If at any point you begin to experience new symptoms or any medical issues arise, **please contact your doctor or call 911 immediately.**

Continuous Study Process

After the initial in office set up is complete you will be asked to answer questionnaires periodically until the study completion. If you have any questions or experience technical issues at any time, please reach out to the study team via email at **makoto.mori@yale.edu**:

- An RA will follow up in-person with you the day after you are transferred out of the intensive care unit to make sure your accounts and applications are working correctly, and to answer any additional questions you may have.

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- Short questionnaires will be sent to your email or text, depending on your preference, initially every 3 days and eventually every 2 weeks up to 90 days following the surgery. This questionnaire should take around 4 minutes on average to complete. The RA may also call you or reach out via email to check in about any technical issues.

- You will receive reminder emails from the Hugo application 1 and 2 days after your questionnaires are sent, reminding you to complete them. These are automated messages and will be sent even if you have completed the surveys. You will also receive reminder messages to use & sync your provided devices.

New Information

You will be informed of anything that happens during the study that may cause you to re-think your decision to continue participation.

Risks and Inconveniences

The risk to patient privacy is that of any computer system that collects personally identifiable information or protected health information. The Hugo application, like many other personal health record applications, is not a considered a covered entity; this means that the HIPAA privacy rule does not apply to this platform. The Hugo platform takes all necessary precautions, including industry-standard encryption, to minimize privacy and security risks to personally identifiable information stored on behalf of study participants. Hugo makes publicly available its Security Statement (http://hugophr.com/security), its Privacy Notice (http://hugophr.com/privacy-notice), and Terms of Service (http://hugophr.com/terms-of-service/). Access to your YNHH medical record will only be within the Epic electronic medical records system; information will not be entered or removed.

You will be asked to volunteer your time to answer questions, and this is considered inconvenience.

There is no extra procedure or medications given for this study, and being on this study does not alter your care from the care you would receive had you not participated in this study.

Benefits

A possible benefit of this study is that you will have easy access to the information contained in your Yale New Haven Health and outside health records that may exist at other participating health systems. Seeing the summary of questionnaire response may also help you and the family to gain awareness and information regarding your health.

You will still be responsible for any costs associated with routine follow-ups or doctor visits, but there will be no additional follow-ups or doctor visits necessary for this study. You are responsible for data charges that may be incurred for utilizing online features of the Hugo when not connected to Wi-Fi.

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Treatment Alternatives/Alternatives

If you decide not to participate in this study, you will still have access to your medical records as you would normally. The alternative is to not to participate.

Confidentiality and Privacy

The risk to patient privacy is no different with this study than it is with any other study that securely collects and appropriately stores personally identifiable information or protected health information. Any data transferred as part of the research protocol will be sent via secure and encrypted standard methods. Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission. When the results of the research are published, or discussed in conferences, no information will be included that would reveal your identity, unless your specific consent is obtained.

The information about your health that will be collected in this study includes:

- Electronic medical records from health systems that you import into the Hugo Health, including from Yale New Haven Health system
- Mobile questionnaires that you respond to
- Records about phone calls or emails made as part of this research
- Records about your clinical visits
- Pre-operative, intra-operative and discharge notes within Hugo or the YNHH Electronic Medical Record

Information about you and your health which might identify you may be used by or given to:

1. Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
2. The Principal Investigator, along with other research staff and collaborators who are assisting with this study
3. Me2Health, the company that owns the mobile application for troubleshooting purposes
4. Health care providers who provide services to you in connection with this study

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and, therefore, may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential. In addition, note that the Hugo is not

required to comply with HIPAA but is required to maintain the confidentiality of your information as described in the privacy notice to be provided when you sign up for Hugo.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

Voluntary Participation and Withdrawal

Participating in this study is voluntary and you are free to choose not to take part in this study. **Declining to participate or withdrawing will involve no penalty or loss of benefits to which you are otherwise entitled** (such as your health care outside the study, the payment for your health care, and your health care benefits). It will not harm your relationship with your own doctors or with Yale-New Haven Health or the care that you receive.

If you do become a study participant, you are free to stop and withdraw from this study at any time during its course.

To withdraw from the study, you can call a member of the research team to let them know that you would no longer like to take part. The telephone number to do this is 475-201-8349. You may also email the intent to makoto.mori@yale.edu.

When you withdraw from this study, no new health information identifying you will be gathered after that date. Information that has already been collected may still be used until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

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Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Print Name of Participant:_____

Signature:_____

Date:_____

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Research Associate, Makoto Mori, at 475-201-8349 or at makoto.mori@yale.edu. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research participant, you may contact the Yale Human Investigation Committee at 203-785-4688.