FOR IRB USE ONLY
IRB ID #: 201707154
APPROVAL DATE: 08/29/17
RELEASED DATE: 10/02/17
EXPIRATION DATE: 08/01/18

INFORMED CONSENT DOCUMENT – Aim 2 Participants

Project Title: Development and validation of a shared-decision making tool for initiation of treatment in patients with Hepatitis C infection and chronic kidney disease

Project HELP (**H**elping **E**mpower **L**iver and kidney **P**atients)

Principal Investigator: Mary C. Politi, PhD

Research Team Contact: Nerissa George, MPH (314) 747-5657

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research participant.

- You should read and understand the information in this document including the procedures, risks, and potential benefits
- If you have any questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have Hepatitis C and Kidney Disease. The purpose of this research study is to test a web-based tool we developed for people with Hepatitis C and Kidney Disease. We want to learn whether this tool could help people learn about Hepatitis C and Kidney disease and choose a treatment plan that works best for them. This tool does **not** replace a conversation with a clinician and is to be used to prepare for visits with a clinician.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate, we will ask you to fill out a brief survey. Next, we will ask you to look at some information about kidney disease and Hepatitis C. Then we will ask you fill out another survey. Everything you do for the study can be completed on a computer provided by us, on your own computer, or you can view a paper version. You may skip any question that you do not wish to answer.

HOW MANY PEOPLE WILL PARTICIPATE?

About 70 people will take part in this part of the study.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for about 30-45 minutes.

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WHAT ARE THE RISKS OF THIS STUDY?

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure, and we think the risk of accidental disclosure is very small. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because your answers may help us learn the best ways to support individuals' decisions about treating hepatitis c and kidney disease.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will receive a $20 gift card to thank you for your time. We will ask for your social security number (SSN) in order for us to pay you. You may choose to participate even if you do not wish to provide your social security number (SSN) for this purpose. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

WHO IS FUNDING THIS STUDY?

Merck Sharp & Dohme Corporation, a subsidiary of Merck & Co., Inc, is funding this research study. This means that Washington University is receiving payments from Merck Sharp & Dohme Corporation to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from Merck Sharp & Dohme Corporation for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- Merck Sharp & Dohme Corporation, a subsidiary of Merck & Co., Inc.
- University representatives, to complete University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

To help protect your confidentiality, we will give your study data a unique number that will be used on all parts of the survey. Your name, phone number, or other identifiers will not be listed on the survey. Any information you enter on the computer survey will be protected with a

password so that only the study team can access it. We will keep any paper copies in a locked filing cabinet in a locked office suite. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The research team will send study results to Merck Sharp & Dohme Corporation, a subsidiary of Merck & Co., Inc (Merck). Information sent to Merck will not be identifiable. Only information that does not have your name or identifying information will be sent so that they can also learn how to talk about treatment options for hepatitis C and chronic kidney disease. In the future, Merck may continue to use your health information that is collected as part of this study. You will not be identified by name in any reports or presentations about this study.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "*How will you keep my information confidential"*

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).

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- To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu/participants//withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
- **If you revoke your authorization:**
  - The research team may only use and share information already collected for the study.
  - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
  - You will not be allowed to continue to participate in the study.

Can we contact you by email?
We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you..

- **Links to the surveys**
- **Information about an appointment time, if we make one**
- **Reminder emails about completing your surveys, if you are completing them at home**

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____ **Yes** _____ **No**
Initials **Initials**

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IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed. You will be told in a timely manner about significant new information that might affect your decision to stay in the study.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I DECIDE TO WITHDRAW FROM THE STUDY?

You may withdraw by telling the study team you are no longer interested in participating in the study.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself or if you feel you have been harmed in any way, please contact: Mary C. Politi, PhD at (314) 747-1967.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

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This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 08/01/18.

_____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)