UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Care Partner Consent Form

Protocol Title:	Technology Enabled Strategies to Promote Treatment Adherence in Liver Transplant: The TEST Trial
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Sponsor	National Institute of Diabetes and Digestive and Kidney Diseases

Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate 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 related to participating 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 participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to understand different ways to improve medication adherence and health outcomes in individuals who have recently received a liver transplant.

If you agree to join the study, you will be asked to complete the following research procedures:

- Interviews about your role in the patient's care
- Surveys about your caregiving ability

Additionally, you may be randomly placed into a group of patients and care partners who are part of enhanced post liver transplantation care. This includes but is not limited text message medication reminders for the patient, surveys asking about how the

patient has been taking their medication, and appointment reminders. Your participation will last for 18 months (540 Days).

It is possible that care partners who participate in this study may benefit in that they have a better understanding of transplant medication and how to recognize and report medication-related problems. This is a minimal risk study, but the most common risks of participation are feeling shame and/or some emotional discomfort when completing certain surveys or tests. Participation may also result in a loss of privacy.

Please note that there are other factors to consider before agreeing to participate such as 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. Your decision to participate in this research is voluntary, and you may choose to continue with your usual care routine from the transplant team. 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 18 years or older, are English or Spanish speaking, and provide care for a recent transplant recipient.

The patient's doctor may be an investigator in this research study. You do not have to participate in any research study offered by this doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, the patient's doctor is interested both in their clinical welfare and in the conduct of this study.

If you decide to participate, you will be asked to sign this form. You may be consented to this study through verbal consent, written consent, or eConsent. You will receive a copy of this consent form.

What is the purpose of this research study?

Liver transplantation is the only lifesaving treatment for end-stage liver disease. It has increasingly been performed on older adults who traditionally have more health issues. Medication adherence is key to making sure that patients who have undergone liver transplant do not develop more health issues. Taking medicine properly is important in making sure that a newly transplanted liver can function properly. However, adhering to post-transplant regimens is a very complex process with multiple medications and clinic appointments. This study will see how readily available technology-enabled tools such as texting combined with transplant center resources and care partner support can optimize medication adherence, quality of life, and health outcomes among new liver transplant recipients.

How long will I be in the study?

If you choose to participate, you will be in this study for 18 months. The entire study including all participants will last a little over three years. There are two additional sites along with the University of Pennsylvania that will be enrolling participants. We anticipate to enroll 360 participants at all sites with 120 being enrolled at the University of Pennsylvania.

What am I being asked to do?

The patient you care for will be randomly assigned to one of two groups. The first group will receive their normal standard of care from their transplant team with interviews at the beginning of the study, Month 6, Month 12, and Month 18. Interviews will last about 45-60 minutes and may include assessments that involve the following:

- Demographics
- Caregiver Inventory (CGI)
- Modified Caregiver Healthcare Task Difficulty and Preparedness Scale
- Relationship to the patient
- Hours of care provided
- Duration of responsibility
- Nature of assistance provided
- Liver Transplant Knowledge Questionnaire (LTKQ)
- Short Form Zarit Burden Interview (ZBI-12)

The second group is the intervention group. In addition to the interviews at the time points mentioned previously, participants in this group will also have interviews along with different text messages and alert reminders using our Way2Health (W2H) system:

- Monthly W2H adherence Assessment and Clinician Alerts
  - Patients and care partners will separately receive monthly, SMS text or online assessments of adherence barriers.
- Medication Reminders
  - Patient and care partners will receive twice-daily medication reminders
  - Patients and care partners will have the opportunity to change their text message preferences every 6 weeks and can opt out of reminders at any time.
- Laboratory and Appointment Notifications
  - Patients and care partners will receive transplant-specific reminders such as lab draws and clinic appointments
- Supplemental Self-Management Support
  - Patients and care partners will receive periodic supplemental information about their care through text messages and emails.

You will not be assigned to one of these groups. However, if the patient you care for is assigned to the intervention group, you may also receive text messages and alerts from the W2H system.

Below is a table showing what will be asked of you or what you will be asked to do at each interview

Care Partner Study Measures and Outcomes		Interview Timepoint			
Variable	Instrument(s) or Measure(s)	BL (Day 0-90 +30)	6M (Day 180 +/- 30)	12M (Day 360 +/- 30)	18M (Day 540 +/- 30)
Informed Consent	Informed Consent	X			
Sociodemographics	Date of Birth	X			
	Age	X			
	Address	X			
	Sex Assigned at Birth	X			
	Gender Identity	X			
	Race	X			
	Ethnicity	X			
	Marital Status	X			
	Employment	X			
	Lifetime Occupational Complexity	X			
Self-Efficacy	Caregiver Inventory (CGI)	X	X	X	X
Preparedness	Modified Caregiver Healthcare Task Difficulty and Preparedness Scale	X	X	X	X
Nature and Intensity of Care	Relationship to Patient	X	X	X	X
	Hours of Care Provided	X	X	X	X
	Duration of Responsibility	X	X	X	X
	Nature of Assistance Provided	X	X	X	X
Healthcare Navigation Skills	Liver Transplant Knowledge Questionnaire (LTKQ)	X	X	X	X
Care Partner Burden	Short Form Zarit Burden Interview (ZBI-12)	X	X	X	X

A description of each measure is listed below:

- Sociodemographic Information- this is basic information that tells us a little bit more information about you. None of the information that we will be collecting in this portion of the study will be able to identify you.

- Self-Efficacy- The Caregiver Inventory looks at a care partner's own self-care and possible positive aspects of caregiving.

- Preparedness- The Modified Caregiver Healthcare Task Difficulty and Preparedness Scale is a survey seeing if the care partner assists the transplant recipient with different tasks, and if so, how much difficulty they have performing the task. We will evaluate if tasks are scored as no difficulty, low, medium, or high difficulty.

- Nature and Intensity of Care Provided- This includes asking you about your relationship to the liver transplant recipient, hours of care you provide throughout the week, how long you have been a care partner, and how long it takes to travel to get to the transplant recipient's place of residence.

- Healthcare Navigation Skills- The Liver Transplant Knowledge Questionnaire (LTKQ) is a measure of your knowledge and navigations skills in post-transplant scenarios.

- Care Partner Burden- The Short Form Zarit Burden Interview (ZBI-12) measures the degree of burden related to the demands of daily care provided to a dependent. It is used to evaluate the influence exerted on a care partner's physical and psychological health.

What are the possible risks or discomforts?

This is a minimal risk study. However, it is possible that subjects may feel shame and/or some emotional discomfort when taking some of the assessments. Feedback from these assessments will be provided to clinical staff.

There is also a small risk of loss of privacy since people outside of the study may look at records if necessary for oversight. However, you will only be identified by a study ID number, not by name or any other identifying information (e.g. personal and/or contact information). This will be kept separate from other data. All information will be kept in secure, password protected files.

Unless required by law, only the study team will have the authority to review any study records. In such cases, they too will be required to maintain confidentiality.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

If you are enrolled in the intervention study portion, the patient may directly benefit by having a better understanding of their medication, how to take their medication, and how to recognize and report any medication-related problems and other concerns to transplant center staff.

The results of the study may also provide important information regarding how strategies can be implemented to enhance safe medical adherence in transplant recipients. This may help other transplant centers start similar programs with their patients and care partners.

What other choices do I have if I do not participate?

You do not have to participate in this study if you do not want to. Individuals that choose not to join the study will still receive their usual care.

Will I be paid for being in this study?

Participants (patients and care partners) will receive $30 for each interview they complete. With four interviews as part of the study at each timepoint, participants that complete it will receive $120 in total. You will be paid through ClinCard. It will require you to provide your social security number and fill out an I-9 form.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?

You do not have to pay for anything that is directly related to the study.

You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

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 interviews, and all information has been collected. We plan to end enrollment a little under 3 years after the beginning of the study and end the study a little under 4 years after starting. You will be expected to be a part of the study for a total of 18 months (1.5 years). This study may also be stopped at any time by the study investigator without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care. It will not impact your care or benefits. And data collected up to the point of your withdrawal will still be used as it will not include any identifying information. It will be documented whether or not each participant completes the study.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why

- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period. PHI in this study includes:

- Name
- Phone Number
- Email
- Date of Birth
- Age
- Address
- Zip Code
- Social Security Number

Each subject will be tracked using a Microsoft Excel database. The database, containing identifiers and other related information for coordinating research activities will be password protected and kept on the secure network drive at each site. Only the study team will have access this database.

Interview and Electronic Medical Record (EMR) data will be collected via REDCap. REDCap is a secure online data collection tool, which can only be accessed by authorized personnel listed on the project's IRB. Survey and text message (SMS) response data will be collected via W2H. W2H has a secure administrative platform that is password protected.

To reduce the risk of breach of confidentiality, a study identification number will be assigned to each subject in the study. This study ID will be the only means of communicating about the patient outside of the secure REDCap or Microsoft Access and will be the primary identifier in REDCap and Microsoft Access as well. All identifiable information will be deleted upon completion of the study (or as soon as a patient declines participation, if that is the case).

An external Data and Safety Monitoring Board (DSMB) will act in and advisory capacity to monitor participant's safety. They will evaluate study progress, review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses. Should data be presented to the DSMB, it will be done so in a blinded manner. Participant identities will not be shared with the DSMB

Will information about this study be available to the public?

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you.

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 have been removed. The information could be stored and shared for future research in this de-identified fashion. The information may be shared with other researchers within Penn or other research institutions. It would not be possible for future researchers 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.

Electronic Medical Record and Release of Study Related Information

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record.

If the patient has never received care within Penn Medicine and is participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for them for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of their participation in this study. In order to create their EMR, the study team will need to obtain basic information about them that would be similar to the information they would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). If they have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

As a care partner, we will not be created an EMR for you at Penn.

What may be placed in the EMR?

Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in the EMR, the patient's information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within the EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in

your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call 215-662-4484.

Will I, as a subject, have access to research related information within the EMR/?
The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of the patient's participation in this research, they will have access to research related information within their EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM).

Some information specific to this clinical research study may be shared with them in a delayed manner, shared with them at the end of the study, or not shared with them. Not sharing or delaying certain research information within their EMR may be necessary to protect the integrity of the trial results or for other reasons.

No information from this study will be kept in their EMR. Any results from interviews or assessments will not be stored in their EMR. However, communication about the study will be sent through EMR system to clinicians as needed. This will not be viewable in MPM.

Will I receive the results of research testing that may be relevant to my health?

Many of tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

However, you may check the study at ClinicalTrials.gov to see any study information that may be published.

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

The following identifying information will be collected from you for purposes of communicating with you about the study and tracking your study progress:

- Name
- Phone number
- Email

This information will be kept in a secure, password-protected excel database. It will not be used for purposes of research nor shared with other individuals or entities outside of the study team at Penn.

We will gather the below identifying information for purposes of conducting the research. It will not be shared with individuals outside of the study team at the study sites:

- Date of Birth
- Age

- Address
- Zip Code

This information will be input into the password-protected and encrypted database REDCap.

Non-identifying information that will be collected from you will include:
- Demographic information (e.g. sex, race/ethnicity, etc.)
- Information about your liver transplant
- Information about your health history
- Results of any assessments performed (e.g. MoCA, Newest Vital Sign, etc.)
- Clinical outcomes (e.g. days hospitalized, transplant complicates, etc.)
- Medical information in regards to your health status throughout the study (e.g. blood pressure, weight, eGFR)

This information will also be input into the password-protected and encrypted database REDCap. This information will be shared with other study sites.

Lastly, we will need to collect your Social Security Number in order to provide you payment for your participation in this study. This information will not be stored electronically. We will ask this information from you in-person or over the phone and write it down on the appropriate forms. These forms will then be stored in a locked cabinet for security.

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.

Where may my information be stored?

Each subject will be tracked using a Microsoft Excel database. The database, containing identifiers and other related information for coordinating research activities will be password protected and kept on the secure network drive at each site. Only the study team will have access this database.

Interview and Electronic Medical Record (EMR) data will be collected via REDCap. REDCap is a secure online data collection tool, which can only be accessed by authorized personnel listed on the project's IRB. Survey and text message (SMS) response data will be collected via W2H. W2H has a secure administrative platform that is password protected.

To reduce the risk of breach of confidentiality, a study identification number will be assigned to each subject in the study. This study ID will be the only means of

communicating about the patient outside of the secure REDCap or Microsoft Access and will be the primary identifier in REDCap and Microsoft Access as well. All identifiable information will be deleted upon completion of the study (or as soon as a patient declines participation, if that is the case).

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 Medicine and the University of Pennsylvania, including offices that support research operations
- Authorized study personnel at Northwest University and the University of Miami
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my information?

Outside organizations

- Individuals on the DSMB will be able to received blinded, de-identified information about you.
- Authorized study members at Northwestern University and the University of Miami will have access to de-identified information
- The study sponsor, National Institute on Aging (NIA)

Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)
- National Institute of Health (NIH)

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

The Principal Investigator 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 Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

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

However, Penn 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 Institutional Review Board 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.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn 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 your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. 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 at the number on page one of this form.

When you sign this form, you are agreeing to take part in this research 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 (Please Print)	Signature of Subject	Date
_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date