RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Evaluate the efficacy of Smartphone App-based communication to track patient recovery at home after discharge from hospital.

SPONSOR: Midas+ Solutions, a Xerox Company, and PARC, a Xerox Company

SITE(S): IU Health Goshen Hospital, 200 High Park Ave., Goshen, IN 46526

STUDY-RELATED CONTACT NAMES, ADDRESSES, and PHONE NUMBER(S):

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INVITATION TO PARTICIPATE IN RESEARCH STUDY:

You are invited to participate in a research study to evaluate the efficacy of using Smartphone App-based communication to track patient recovery at home after discharge from hospital.

The purpose of this consent form is to help you decide if you want to be in the research study. You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. Your doctor will continue to treat you regardless of whether you decide to (or decide not to) take part in this study,

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

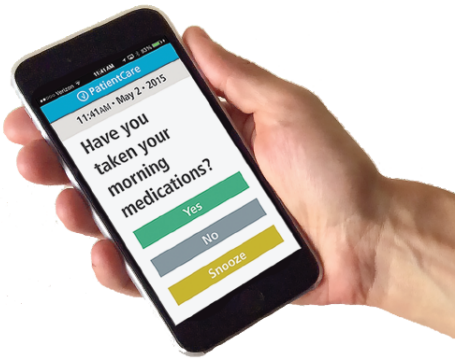
- This research is being done to evaluate the effectiveness of using Smartphone App-based communication between patients and the healthcare coordination team at the hospital, to track the recovery of patients after discharge from the hospital.
- Up to 200 patients who own and regularly use a Smartphone will be enrolled in the study out of which up to 100 patients chosen at random will be provided access to a smartphone app. The App will be used to pose questions to patients related to their general health and respective hospital discharge instructions for a period of 30 days after time of discharge from the hospital. The questions posed may be in a multiple-choice format or may require type-in responses (e.g., entering your weight, etc.).
- The patients given access to the Smartphone App will have questions posed to them every day through the App which they need to respond to and, their responses will be recorded and relayed to the respective healthcare coordination team at the hospital . These responses will be used to track the patient's recovery process, address any questions or concerns and contact the patient via phone if necessary.
- At the end of the study period (30 days after discharge), the research team and hospital staff's access to the patient's Smartphone-App will be disabled and questions will no longer be posed to the patient through the App.

DESCRIPTION OF SUBJECT INVOLVEMENT (PROCEDURES)

- **Smartphone App:** As determined by the research team, some of the subjects enrolled in the study will be chosen randomly to be given access to the 'Patient Engagement' Smartphone App. The remaining subjects will NOT be provided access to the 'Patient Engagement' Smartphone App.

  Once given access, the patient will download the 'Patient Engagement' App from the Google® Play or Apple® iOS app store in to their personal Smartphone running either an Android or iOS operating system respectively, upon accepting the necessary terms and conditions of use by the respective Smartphone App store.

- **Training on use of App:** If you are given access to and download the 'Patient Engagement' App in to your Smartphone you will be taught how to use it by the study personnel:



  - The study personnel will help you register by entering a unique enrollment ID in your Smartphone App, which will serve as your subject ID during the study. The subject ID will serve as the only patient identifiable information used by the App.
  - The study personnel will demonstrate the use of the App by posing sample questions and guiding you to answer them using your Smartphone interface.

- On the left is a view of an example of the 'Patient Engagement' Smartphone App interface with a sample multiple-choice question posed requiring you to choose either a 'Yes' or 'No' response.
    - When a question is posed to you, your Smartphone will vibrate and provide audio and/or visual notification of a pending question which will require your response in the App.
    - You will be asked to respond to up to 5 sample questions through the Smartphone App, with the help of the study personnel in order to complete the training process.
    - The study personnel will answer any questions you may have regarding the use of the Smartphone App.
    - At the end of the training, a study brochure / quick-reference guide will be provided for your reference to take home after discharge from the hospital.

- **Periodic questions posed to patients via App:** If you are provided access to the Smartphone App, for a period of 30 days after time of discharge from the hospital, you will be posed questions on it every day requiring not more than a total of 15 minutes per day to respond and your responses will be recorded. Your responses to questions will be regularly reviewed and/or analyzed, and used to help the hospital staff to track your recovery process. If necessary, the hospital staff may contact you directly to provide feedback and/or address any questions or concerns you may have, as part of your usual medical care.

- **End of Study:** At the end of the study period (30 days after discharge), the research team and hospital staff's access to your Smartphone-App will be disabled and questions will no longer be posed to you through the App. At this point, you will be free to delete the Smartphone App from your Smartphone.

RISKS AND DISCOMFORTS

The Smartphone App is NOT an alternative to regular medical care and NOT a direct means of communication with your doctor. In the event of an emergency or if you would like to speak to your doctor or another member of your care team, please follow the discharge instructions provided by the hospital.

The researchers have taken steps to minimize your risks in taking part in this study. Even so, you may still have problems or side effects related to your participation in this study, even when the researchers are careful to avoid them. These risks may include the following:

- Time burden in answering questions on Smartphone App: Researchers have mitigated this risk by ensuring that a limited number of questions are posed to the patient every day requiring a maximum of 15 minutes of your time per day.
- Confidentiality of your answers to questions posed on Smartphone App: Researchers have mitigated this risk by ensuring that your responses are de-identified and relayed

only to the concerned hospital staff tracking your post-discharge recovery via a HIPAA-compliant communication channel.

BENEFITS

It cannot be promised that you will receive any medical benefits from participating in this study. Although you may not directly benefit from being in this study, others may benefit in the future as follows:

- The study may help in developing a good communication system between the patient and hospital staff, so that patients have an improved recovery process post hospital discharge.
- The study may help ensure that patients are asked appropriate questions at the right time in order to ensure efficient tracking of patient's recovery process post hospital discharge.

ALTERNATIVE TREATMENT

This is not a treatment study. Your alternative is not to be in this study. Your decision to join or not to join this research study will not cause you to lose any medical benefits. Regardless of whether (or not) you decide take part in this study, your doctor will continue to treat you.

COSTS

The participants will incur no additional expenses as a result of participation. You or your insurance company may be billed for any standard medical care given during this research study. By signing this consent form, you agree that you do not have any rights, either present or future, to any invention, concept, idea, intellectual property, product, method, or device that is conceived, reduced to practice, created, developed, derived from, or improved by the study or that otherwise results from or is associated with this study.

CONFIDENTIALITY

Authorization to release your protected health information
Agreeing to be in this study gives researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Your information will only be used for analyzing the results of the study. The only information from your health records that will be used for the study is the following:

1. Patient's Name or Initials
2. Patient's age
3. Date & Time of hospital admission
4. Clinical diagnosis for hospital admission
5. Date & Time of hospital discharge
6. Date & Time of re-admission(s) (if any)
7. Clinical diagnosis for hospital re-admission(s) (if any)

We plan to publish the results of this study, but will not include any information that would personally identify you. There are some reasons why people other than the researchers may need to see information you provided as part of the study. This includes organizations responsible for making sure the research is done safely and properly, including IU Health Goshen Hospital, Midas+ Solutions, and Palo Alto Research Center (PARC), A Xerox Company.

To keep your information safe, the researchers will store your information on a HIPAA compliant server with adequate data security, and only the researchers on the project may have direct access to any information that could identify you. Only derived, unidentifiable information, such as number of patients, average duration of stay of the patients, etc., will be shared beyond the researchers.

The privacy law protects your health information. It requires your permission to allow the researchers to use and share your protected health information with others for research. You will be asked to sign a separate form to let the researchers to use health information for this research.

VOLUNTARY NATURE OF THE STUDY

Participating in this study is completely voluntary. If you take part in this research study, you have the right to the information you provide during your participation in the study. Even if you decide to participate now, you may change your mind and stop at any time. If you decide to terminate your participation in the study, or if you are removed from the study by the principal investigator, you may revoke this authorization to obtain your private health information. To end your authorization, you must notify the IU Goshen Hospital point of contact in writing at the address provided on Page 1 of this consent form. Upon termination of your participation in the study, the research team and hospital staff's access to the 'Patient Engagement' Smartphone-App will be disabled and questions will no longer be posed to you through the App. However, information that has already been collected cannot be removed from the study or medical records.

If significant new knowledge is obtained through the course of the research which may relate to your willingness to continue participation, you will be informed. You may be asked to sign a new consent form in that event, and you will be free to decline / terminate your participation from this study at that or any other time, if you prefer.

The study personnel may remove you from the study at any time, without asking you, if he or she feels it is in your best interest because:

(1) You fail to follow instructions given by the study personnel
or
(2) The sponsor stops the study for any reason.

WHOM TO CALL FOR ANSWERS TO QUESTIONS

You have the right to ask any questions you have about this research before you sign. Do not sign this consent form unless you have had all your questions answered.

If you have any questions about the research study or subject rights. Please feel free to contact any of the study points of contact individuals listed on page 1 of this form.

PARTICIPANT'S ACKNOWLEDGEMENT:

I have read and understand this consent form. I agree to take part in this study. By signing this form I do not waive my legal rights.

I have received a satisfactory explanation:

- Of the procedures to be followed
- Of the risks and possible benefits
- Of alternative treatments
- About the release of my medical records
- That my doctor may stop the study at any time
- That I may stop at any time without penalty or loss of benefits

I will receive a signed copy of this consent form.

_____	_____	_____
Subject's Name (Typed or Printed)	Signature	Date

ACKNOWLEDGEMENT OF PERSON OBTAINING CONSENT:

I attest to the following: (1) that the requirements of informed consent for the medical research project described in this form have been satisfied (2) that the subject has been provided with the Experimental Subject's Bill of Rights, if appropriate (3) that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

_____	_____	_____
Name of Person Obtaining Consent (Typed or Printed)	Signature	Date

RESEARCH STUDY AUTHORIZATION FOR THE USE AND DISCLOSURE OF PRIVATE HEALTH INFORMATION

Name of Study:
Evaluate the efficacy of Smartphone App-based communication to track patient recovery at home after discharge from hospital.

Patient's Name:

_____

Use and Disclosure of Your Medical Information
By signing this form, you are authorizing the use and disclosure of your private health information in connection with your participation in this research study. Your information will only be used in accordance with the provisions of this authorization and any other disclosure laws that we may be required to follow.

Do I need to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside of the study**.**

What Information Will Be Used or Disclosed?
Your information related to this study, including, but not limited to, your name and / or initials, age, date & time of hospital admission, clinical diagnosis for hospital admission, date & time of hospital discharge, date & time of re-admission(s) (if any), clinical diagnosis for hospital re-admission(s) (if any), may be used or disclosed in connection with this research study.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:
- IU Health Goshen Hospital

Who May Receive/Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

Study Sponsors:

- Midas+ Solutions, A Xerox Company
- Palo Alto Research Center (PARC), A Xerox company

If any information from this study is published (e.g., in a research paper or other public forum such as at a research conference), or otherwise made available to anyone beyond the above-listed entities, only de-identified information will be used (e.g., high-level summary such as number of patients in the study, size of patient groups with specific reasons for admission or readmission, statistical analyses of the cause of and rates of post-discharge readmission events or follow-up events based on information collected during the study, etc.) Personally identifiable information about you will not be shared in any external publications and will only be available to your care team and those individuals conducting and/or administering this study.

Expiration

Your authorization for the use and/or disclosure of your health information will expire January 1, 2025.

When Access to Your Information May Be Limited

You may not be allowed to see or copy certain information in your medical or study records collected in connection with your participation in this research study while the research is still in progress. This information includes, but is not limited to, your responses to questions posed on the Smartphone. However, if it is necessary for your medical care as determined by your physician at IU Health Goshen Hospital, your health information will be provided to you or your physician.

Revocation

If you decide to terminate your participation in the study, or if you are removed from the study by the principal investigator, you may revoke your authorization to obtain your private health information. To end your authorization, you must notify the IU Health Goshen Hospital point of contact in writing at the address provided on Page 1 of this consent form. Upon termination of your participation in the study, the research team and hospital staff's access to the 'Patient Engagement' Smartphone-App will be disabled and questions will no longer be posed to you through the App. However, information that has already been collected cannot be

removed from the study or medical records.

The study personnel may remove you from the study at any time, without asking you, if he or she feels it is in your best interest because:

(1) You fail to follow instructions given by the study personnel
or
(2) The sponsor stops the study for any reason.

Signature

Signature of Study Participant	Date
Signature of Legally Authorized Representative (if applicable)	Date

Description of Representative's Authority to Act for Subject