This Box for IRB Office Use Only –
Do Not Delete or Revise
*Template Rev Date: 6-19-14*

**RESEARCH SUBJECT INFORMATION AND CONSENT FORM**

**RESEARCH SUBJECT CONSENT FORM**

**TITLE: Health IT generated PROs to Improve Outcomes in Cirrhosis**

**VCU IRB NO.**: **HM20003950**

**SPONSOR**: Agency for Health Care Research and Quality

## AN OVERVIEW OF THE STUDY AND KEY INFORMATION

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.** Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

**Why is this study being done?**

The purpose of this research study is to find out whether using an educational Application, the Patient Buddy on your smartphones, can reduce the need for you to be hospitalized again after your recent discharge from the hospital. You are being asked to participate in this study because you have cirrhosis and were admitted to the hospital.

**What will happen if I participate?**

If you decide to be in this research study, you will be asked to have a remote consent discussion regarding this consent form, and verbally indicate agreement. We will also ask your companion to verbally indicate agreement of consent, authorizing them to communicate with us regarding your health. Your participation in this study will last for 4 weeks or can be less in case you are hospitalized within those four weeks.
Within 3 days of your discharge, you will be assigned to one of 3 groups. You will be assigned to a group based on the order you were enrolled on a repeating basis. For example, the first patient will be assigned to group 1, the second to group 2, the third to group 3, the fourth to group 1, etc. If you decide to be in this research study, you will be asked to verbally agree to this consent form. We will also ask an adult who is familiar with you and will be able to report on your daily activities for 4 weeks, to verbally agree to a separate consent form. Your participation in this study will last for 4 weeks or can be less in case you are hospitalized within those four weeks.

Within 3 days of your discharge, you will be assigned to one of 3 groups. You will be assigned to a group based on the order you were enrolled on a repeating basis. For example, the first patient will be assigned to group 1, the second to group 2, the third to group 3, the fourth to group 1, etc.:



Approved by the VCU IRB on 6/9/2020

1. *Standard of Care Group*:
   You will receive the current standard hospital discharge teaching and follow-up instructions by the health care team. You will be given the contact number of the study team to call as needed and you will return for the scheduled follow-up clinic visit 30 days after discharge. We, the study staff, will also conduct an end of study visit remotely, and will ask you if you have been admitted in the past 30 days to an outside hospital for any reason. If so, they will request a discharge summary.

2. *Health-IT only group:*
   You and your care giver will be given a smart phone and trained on the educational app (Pt Buddy and Encephalapp), receive standard hospital discharge instructions to include a 30 day follow-up clinic visit by the health care team, and will communicate through the app if we do not hear from you within 24 hours. We will also schedule a virtual end of study visit at about day 30. During your 30 day post discharge virtual follow-up visit, you will be reminded to return all study issued equipment via mail, and the study staff will ask you if you have been admitted in the past 30 days to any hospital for any reason. If so, they will be interested in if the admission could have been avoided and will request a discharge summary for review. Also, the study staff will ask you to evaluate the App. This survey will be a paper survey that the study team will do vebally with you and your caregiver individually, as well as an open discussion of questions regarding your experiences both good and bad.

3. *Health-IT+Scheduled Follow-up Group:*
   You and your care giver will be trained and given a smart phone with the educational app (Pt Buddy and Encephalapp), receive standard hospital discharge instructions by the health care team with Follow-up, and will communicate daily through the app. In addition, you will receive study team phone calls to check on you at weeks 1 and 3 and virtual visits with the study team at weeks 2 and 4. The week 2 visit is a virtual research visit and during this visit we will discuss any issues you may be having with the buddy app, update your medications and any new medical issues. We may ask you and your caregiver to practice documenting the medications taken, your weight, and you may be given the stroop and orientation test. During your 30 day post discharge virtual follow-up visit, you will be reminded to return all study issued equipment and the study staff will ask you if you have been admitted in the past 30 days to any hospital for any reason. If so, they will be interested in if the admission could have been avoided and will request a discharge summary for review. Also, the study staff will ask you to evaluate the App. This survey will be a paper survey that the study team will do verbally with you and your caregiver individually, as well as an open discussion of questions regarding your experiences both good and bad.



Approved by the VCU IRB on 6/9/2020

This Box for IRB Office Use Only –
Do Not Delete or Revise
*Template Rev Date: 6-19-14*

**What are the risks and benefits of participating?**
There are both risks and benefits of participating in research studies.

**Risks and Discomforts**

- Even though the Smartphones do not have any identifying information on them, there is a small risk of your data being compromised. All data that is on the phones is sent to a secure server operated by our collaborators that is compliant with the HIPAA regulations. This de-identified data will be analyzed by the study team to determine if any re-admissions could have been prevented.

- Even though the Buddy App. allows you to communicate with the study team, the app is not a substitute for your regular care and you should not hesitate to contact your doctor or 911 if you have concerns that cannot wait for communication through the app.

- You may feel anxious about completing the cognitive tests especially if you notice a decline. However, since hepatic encephalopathy is a major reason for admissions, this cognitive testing app is a critical tool for the study and will be required in order to help us check on your status.

- If you are randomized in groups 2 and 3 and you are in greater contact with your care team, you may be referred to your medical team for treatment or medication changes (for example), which may result in unanticipated costs or may have their own attendant risks.

- The daily interactions necessary between patient-caregiver-provider may cause strain on those relationships due to daily interactions in groups 2 and 3.

- There may be unforeseen risks related to using the Patient Buddy App which cannot be anticipated. The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

**Benefits to You and Others**
You may not get any direct benefit from this study, but, the information we learn from people in this study may help us prevent hospitalizations in patients with cirrhosis. It may also increase your and your companion's understanding about cirrhosis and its complications.

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the



Approved by the VCU IRB on 6/9/2020

rest of this document. If there is anything you don't understand, be sure to ask the study staff.

## DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

This is a multi-center study and includes VCU Medical Center, Richmond McGuire VA Medical Center, and Mayo Clinic Rochester. We expect to enroll a total of 450 cirrhotic patients and 450 caregivers (150 patients and 150 caregivers per center).

If you are in group 2 or 3, the study staff will teach you and your adult caregiver about important issues that may come up regarding your cirrhosis after your hospital discharge. This education will be focused on weight, infections, confusion, and changes in medications and in how you are feeling. You will also be trained to measure your belly girth and weight, temperature, and will be asked to note the medicines you have taken every day. In addition, we will also train you to perform mental tasks on the smartphone every week that will be reported to us. We will also give you a list of what specific alarming symptoms should trigger a phone call to us through the App, or to emergency services if you are not willing to use the App.

After this training at the time of enrollment, if you are in group 2 or 3, you will be given a smart phone with a data plan that can be used to link it with a similar device with the study team. You will be given a log-in ID and password for the Smart Phone that will be specific to you only. The Smart Phone will not store any identifying information on it. It will be loaded with a user-friendly Patient Buddy Application. The Patient buddy is an App which can be used to communicate in both directions using the data plan between the study team and you and your caregiver. You and your caregiver will also receive a brochure about Patient Buddy, how the app will be used, and the safeguards in place to protect your information.

In the App, you will be asked to enter your weight, belly girth and medicines that you have taken with their doses. Your caregiver will do these separately on their Smart Phone so they will need to observe you every day. Some measurements are required every day (weight, belly girth, temperature, and medicine details) while others are required every week (questions to find out if you are confused and mental tasks,) or if the caregiver or you feel that you have something going on that needs medical attention. The daily app tasks for you and your caregiver will take approximately 10 minutes of your time each day.

Your participation will last up to 4 weeks after hospital discharge. If you are in group 1 or 2, you will do a virtual visit at 30 days after your discharge as scheduled by the study team. During this period, if you are in group 3, we will call you at week 1 and week 3 and do virtual visits with you and your caregiver at weeks 2 and 4. For all groups the 30 day virtual visit is part of the end of study.



Approved by the VCU IRB on 6/9/2020

During the phone calls for group 3 at weeks 1 and 3, we will discuss if you are having any issues with the App, or any specific issues that need further training and whether you were hospitalized anywhere else apart from VCU in the interim. The two phone calls will typically last around 20 minutes while the virtual visits will last around one hour each. We will try our best to schedule the virtual visits at a time that works well with you and your caregiver. Similar questions will be asked during the virtual visits and your phones will be examined to make sure you are able to understand and do not have any issues with the App or the phones.

In addition, for group 2 and 3, we will be in touch with you through the App communications if we do not hear from you within 24 hours.

At the end of the study during the 30 day post discharge virtual follow-up visit, If you were in group 2 or 3, you will be asked to return all study issued equipment via mail. The study staff will ask all study participants in all groups if you have been admitted in the past 30 days to any hospital for any reason. If so, they will be interested in if the admission could have been avoided and will request a discharge summary for review. Also, the study staff will ask you to evaluate the App. This survey will be a paper survey that the study team will do verbally with you and your caregiver individually, as well as an open discussion of questions regarding your experiences both good and bad. We will ask you questions about the App that will help us make it more user-friendly in future studies. These eight questions will take approximately 10 minutes to complete.

In general, we will not give you any individual results from the study. Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

**COSTS**

There will be no study costs for participating in this study.
However, you may have unanticipated healthcare costs resulting from added medical appointments/interventions as your healthcare team may be able to care for your medical problems earlier than your scheduled appointments. Also, If your medical condition deteriorates, you may need to be hospitalized. All required medical care will not be covered by the study, but may be billed to you or your insurance company.

**PAYMENT FOR PARTICIPATION**

After you have completed all study visits and return the study equipment, you will receive a $100.00 check which will be mailed to you. Study participants will not be compensated until the study phone is returned.

It is very important that you return the study phone because the phone will be used by participants after you. When a phone is not returned, it slows down the research and keeps us from being able to collect data. If the phone is not returned, we will not be able to compensate you.



Approved by the VCU IRB on 6/9/2020

You may be asked to provide your social security number in order to receive payment for your participation. Your social security number is required by federal law. It will not be included in any information collected about you for this research. Your social security number will be kept confidential and will only be used in order to process payment.

**ALTERNATIVES**
The alternative is to not participate in the study.

**CONFIDENTIALITY**
Potentially identifiable information about you will consist of data from your medical records, your virtual visits and the records generated through your use of the App and phone calls. Data is being collected only for research purposes.

Your data will be identified by ID numbers and dates of collection, not names, and stored separately from research data in a locked research area. All personal identifying information will be kept in password protected files and these files will be deleted 6 years after the study end. Unidentified files will be kept indefinitely. Access to all data will be limited to study personnel.

We will not tell anyone the answers you give us; however, information from the study and information from your medical record and the consent form that has your name logged and is signed by the study team, may be looked at or copied for research or legal purposes by the sponsor of the research, Agency for Healthcare Research and Quality (AHRQ), or by Virginia Commonwealth University. Personal information about you might be shared with or copied by authorized officials of the Department of Health and Human Services, Food and Drug Administration or other federal regulatory bodies.

In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent. What we find from this study may be presented at meetings or published in papers, but your name will not ever be used in these presentations or papers.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

## HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?



Approved by the VCU IRB on 6/9/2020

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered "Protected Health Information" that is protected by federal law.

**What type of health information will be used or shared with others during this research?**

The following types of information may be used for the conduct of this research:

- ☒ Complete health record
- ☐ Diagnosis & treatment codes
- ☐ Discharge summary
- ☐ History and physical exam
- ☐ Consultation reports
- ☐ Progress notes
- ☐ Laboratory test results
- ☐ X-ray reports
- ☐ X-ray films / images
- ☐ Photographs, videotapes
- ☐ Complete billing record
- ☐ Itemized bill
- ☐ Information about drug or alcohol abuse
- ☐ Information about Hepatitis B or C tests
- ☐ Information about mental health
- ☐ Information about sexually transmitted diseases
- ☐ Other physical or mental health information (specify):

**Who will use or share protected health information about me?**

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law
- Study Sponsor
- Data Coordinators
- Research Collaborators
- Data Safety Monitoring Boards

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

**When will this authorization (permission) to use my protected health information expire?**

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.



Approved by the VCU IRB on 6/9/2020

This Box for IRB Office Use Only –
Do Not Delete or Revise
*Template Rev Date: 6-19-14*

**Statement of Privacy Rights**

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL**

You do not have to participate in this study. You may decide to not participate in this study. Your decision not to take part will involve no penalty or loss of benefits to which you are otherwise entitled. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study.

Your participation in this study may be stopped at any time by the study staff or the sponsor without your consent. The reasons might include:

- the study staff thinks it necessary for your health or safety;
- you have not followed study instructions;
- the sponsor has stopped the study; or
- Administrative reasons require your withdrawal.
- If terminated from the study, if you are in Group 2 or 3, we will require the return of all the study issued equipment via mail (smart phones and digital scale) We will also ask you to complete the study App evaluation/survey virtually with study team.

**QUESTIONS**

If you have any questions, complaints, or concerns about your participation in this research, contact:

**Jasmohan Bajaj, MD or Sara McGeorge, BS CNA**
**Division of Gastroenterology, Hepatology and Nutrition**
**Virginia Commonwealth University,**
**14th Floor, West Hospital, 1200 E Broad St,**
**Richmond, VA 23298**
**Telephone: (804)-828-9780**

The investigators named above are the best persons to call for questions about your participation in this study.

If you have any general questions about your rights as a participant in this or any other research, you may contact:



Approved by the VCU IRB on 6/9/2020

This Box for IRB Office Use Only –
Do Not Delete or Revise
*Template Rev Date: 6-19-14*

Office of Research, Virginia Commonwealth University
800 East Leigh Street, Suite 3000
Box 980568, Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk with someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

## CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

| Participant name printed | Participant agreed Y/N | Date |
|---|---|---|

_____

*Method by which the participant indicated agreement*

_____

Name of Person Conducting Informed Consent Discussion
(Printed)

_____ _____

Signature of Person Conducting Informed Consent Discussion — Date

_____ _____

Principal Investigator Signature (if different from above) — Date



Approved by the VCU IRB on 6/9/2020