Title: Relative patient benefits of a hospital-PCMH collaboration within an ACO to improve care transitions
Sponsor Name:
PI Name: Schnipper, Jeffrey L **Protocol #:** 2012P000096 **Type:** Continuing Review (CR7)
Date Received: January 08, 2019

Study Staff

Name	Role	Degree	Organization	Citi Certified
Bahadori, Ali	Research Coordinator/Manager		BWH	11/26/16
Bakshi, Salina	Co-Investigator		BWH > Medicine > General Medicine	10/18/18
Bates, David	Co-Investigator	MD, MSC	BWH > Medicine > General Medicine	06/21/17
Bitton, Asaf	Co-Investigator		BWH > Medicine	03/02/18
Carter, Jocelyn	Research Coordinator/Manager	MD, MPH,	MGH > Medical Services	03/11/18
Celi, Ann	Research Coordinator/Manager	MD	BWH > Medicine	09/10/16
Clark, Cheryl	Research Coordinator/Manager	MD, SCD	BWH > Medicine > General Medicine	08/10/18
Cotran, Nina	Research Coordinator/Manager	MD	BWH > Medicine > Women's Health	09/19/16
Dalal, Anuj	Co-Investigator	MD	BWH > Medicine > General Medicine	06/28/19
Decastro, Racquel	Research Assistant		BWH > Psychiatry	02/17/17
Downing, Nicholas	Research Coordinator/Manager		BWH > Medicine	06/02/17
Fiskio, Julie	Data Coordinator/Manager		BWH > Medicine > General Medicine	01/23/17
Ganguli, Ishani	Research Coordinator/Manager	MD	MGH > Medical Services	04/25/19
Gershanik, Esteban	Research Coordinator/Manager	MD	BWH > Medicine > General Medicine	08/15/18
Gunaratne, Shauna	Research Coordinator/Manager		MGH > Other	06/19/18
Hwang, Andrew	Research Coordinator/Manager		MGH > Medical Services > General Internal Medicine	10/17/16
Kore, Idil	Research Coordinator/Manager		BWH > Medicine	12/31/16
Labonville, Stephanie	Co-Investigator		BWH > Administration	02/16/19
Ludford, Kaysia	Research Coordinator/Manager		BWH > Medicine > General Medicine	05/23/17
Maviglia, Saverio	Research Coordinator/Manager	MD, MSC	BWH > Medicine > General Medicine	01/25/17
Minahan, Jacquelyn	Research Assistant	BA, MA	BWH	04/04/17
Mueller, Stephanie	Research Coordinator/Manager	MD, MPH	BWH > Medicine	12/22/16
Nolido, Nyryan	Research Coordinator/Manager	MA	BWH > Psychiatry	06/12/18
O'Fallon, Erin	Research Coordinator/Manager		BWH > Medicine	11/17/16

Name	Role	Degree	Organization	Citi Certified
Orav, Endel	Statistician	Ph.D	BWH > Medicine > Other	10/23/18
O'Reilly, Molly	Research Assistant		MGH > Medical Services > General Internal Medicine	05/15/17
Park, Elyse	Co-Investigator	Ph.D	BWH	02/15/18
Samal, Lipika	Co-Investigator	MD	BWH > Medicine	06/21/19
Schnipper, Jeffrey	Principal Investigator	MD, MPH	BWH > Medicine > General Medicine	01/24/19
Schoenfeld, Sara	Research Coordinator/Manager	MD	MGH > Medical Services	08/18/17
Sherritt, Karen	Co-Investigator		BWH > Medicine > Other	04/03/19
Snyder, Gregory	Research Coordinator/Manager		BWH > Medicine > Other	08/09/17
Stefanescu, Ada	Research Coordinator/Manager	MD	MGH > Medical Services > Cardiac Unit	12/10/16
Thomas, Cristina	Research Coordinator/Manager		MGH > Dermatology	09/15/17
Thompson, Ryan	Co-Investigator	MD	MGH > Medical Services > General Internal Medicine	
Urman, Richard	Research Coordinator/Manager	MD	BWH > Anesthesia	02/10/19
Wei, Nancy	Regulatory Coordinator/Manager	MD	MGH > Medical Services	05/22/18
Yoon, Catherine	Data Coordinator/Manager	MS	BWH > Medicine > General Medicine	04/10/18
Zwart, Dorien	Co-Investigator		BWH > Medicine > General Medicine	01/04/17

Non Study Staff

Name	Degree	Organization
Bander, Kay		Partners
Baughman, Amy	MD	BWH > Medicine > General Medicine
Digregorio, Debra	BSc	BWH > Medicine > General Medicine
Goldberg, Joel	MD	BWH > Surgery > General Surgery (General and GI)
Henderson, Aureldon		Partners
Hodges, Winthrop		Partners
Salzberg, Dena		BWH > Central-Admin-COO > Social Service
Spikes, Karen	Ph.D	BWH
Weil, Eric	MD	MGH > Central Admin-COO > Central Administration

Signatures

PI Name: Schnipper, Jeffrey L, MD, MPH
Authenticated: January 08, 2019

Continuing Review - Intervention / Interaction

For help with the preparation of a continuing review submission, print and read the **Continuing Review Submission Instructions**

1. Sponsor / Funding Information

Is the research funded at this time?

○ Yes ◉ No

Explain:

The contract with the Sponsor PCORI has ended, however, we continue to work on submitting manuscripts for publication.

Has the funding source changed since the last review?

○ Yes ◉ No

2. Drug and Device Studies

Does the research involve an Investigational New Drug or Investigational Device Exemption (IND/IDE)?

○ Yes ◉ No

3. Project Status

Indicate the project status.

○ Active - Open to Enrollment
◉ Active - Closed to Enrollment
○ Inactive - Study Completed (including analysis of data)
○ Inactive - Study Closed Prior to Completion

Select:

○ Research Interventions/Assessments Continue
○ All Research Activities Complete, Long Term Follow-up Only (e.g., following for survival where the only remaining procedures done for research are review of subject's medical record or a phone call)
◉ All Research Activities Complete, Data Analysis Only (data analysis being performed by or on behalf of Partners investigators)

Enter Date Closed to Enrollment (mm/dd/yyyy):

09/30/2015

4. Enrollment Target

Enrollment target (study-wide): Enter the number of evaluable subjects needed across all sites to achieve results.

1800

NOTE: Target enrollment study-wide can usually be found in the biostatistical analysis section of the

protocol and is often based on a sample size calculation that supports the number of evaluable subjects needed to demonstrate statistical significance.

Enrollment target / number of subjects expected to sign the consent form across Partners sites and sites relying on the Partners IRB as the IRB of record:

1800

NOTE: Target enrollment at Partners sites is the number of subjects expected to provide written or verbal consent, or consent by voluntary completion of a survey or participation in a focus group. The study-wide target enrollment may be lower than the target enrollment at Partners sites because Partners definition of enrolled subjects may differ from the sponsors definition of enrolled subjects.

Has enrollment been slower than anticipated?

◉ Yes ○ No

Explain the reasons for slow enrollment, and if relevant, what steps have been / will be taken to increase enrollment.

The rate of patient enrollment was on target, however, the start of the pilot and live phases of the study were delayed 3 weeks at BWH and 4 months at MGH due to intervention and staffing challenges that were later resolved. Enrollment has now been completed, and we enrolled close to our target number of subjects.

NOTE: The PHRC takes subject accrual into consideration when conducting continuing review. When it appears that the accrual goal may never be achieved and the research question may never be answered, the PHRC may determine that the risks to subjects now outweigh the benefits, if any, to subjects as well as the knowledge that may reasonably be expected to result from the research.

Institutions/Entities Relying on the Partners IRB

Does this approved protocol cover multiple performance sites relying on the Partners IRB? Answer YES if this protocol includes multiple Partners performance sites (e.g., BWH and MGH) or one Partners site and one or more non-Partners sites (e.g., MGH and Broad or BWH and BIDMC).

◉ Yes ○ No

Enter institution name and move to the box on the right. Repeat for each institution relying on the Partners IRB.

Brigham and Women's Hospital

Enter institution name and move to the box on the right. Repeat for each institution relying on the Partners IRB.

Massachusetts General Hospital

NOTE: The subjects enrolled at other institutions relying on the Partners IRBs MUST be accounted for in section 5 Cumulative Summary of Subjects Enrolled to-Date below.

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5. Cumulative Summary of Subjects Enrolled To-Date

NOTE: Enrolled is the number of subjects who gave consent to participate, either in writing, orally, or by voluntary completion of a survey or participation in a focus group. Only include the number of subjects enrolled by the investigators/study staff listed in this application. Do not include study-wide enrollment at sites that are covered by another institution's IRB.

Have subjects been enrolled to-date?

◉ Yes ○ No

5.1. Enter the number of subjects who gave consent to participate, either in writing, verbally, or by voluntary completion of a survey or participation in a focus group:

1680

NOTE: Enrollment numbers entered for questions 5.2 - 5.10 must equal the total number of subjects that have given consent to participate as entered in question 5.1. All subjects who gave consent to participate in the study MUST be accounted for below.

5.2. Of those that have given consent to participate, are there any subjects currently undergoing screening procedures to determine study eligibility?

○ Yes ◉ No

5.3. Of those that have given consent to participate, have any subjects been found **ineligible**? For example, subject was determined to be ineligible after screening exams and tests.

◉ Yes ○ No

Enter number found ineligible:

5

Explain why these subjects were found ineligible:

Five patient met exclusion criteria after being enrolled. Reasons included not belonging to a participating primary care practice and being homeless.

5.4. Are there any subjects still **currently active / on study**? For example, subjects receiving study interventions / interactions or long-term follow-up.

○ Yes ◉ No

5.5. Have any subjects **completed** the study (without events leading to early termination / withdrawal from the study)?

◉ Yes ○ No

Enter the number completed:

1662

5.6. Have any subjects **voluntarily withdrawn consent** after enrolling? For example, after signing the consent form, the subject changed his/her mind and decided not to participate, or to stop participating after completing some of the study procedures.

◉ Yes ○ No

Enter the number that have voluntarily withdrawn consent:

9

Explain why these subjects voluntarily withdrew consent:

Nine subjects withdrew consent from the study citing various reasons: concerned about confidentiality due to profession; too sick to participate; and too many people to talk to in order to participate in the study.

5.7. Have any subjects been **terminated / withdrawn** from the study by the investigator due to toxicity / adverse event(s)? For example, subject met toxicity drop point or experienced a serious adverse event.

○ Yes ◉ No

5.8. Have any subjects been **terminated / withdrawn** from the study by the investigator due to other reasons? For example, non-compliance with the protocol, pregnancy, etc.

○ Yes ◉ No

5.9. Have any subjects been **lost to follow-up**?

◉ Yes ○ No

Enter the number lost to follow up:

4

Explain why these subjects were lost to follow up:

759 patients did not complete the 30-day follow-up phone survey. There are several reasons why these subjects were lost to follow-up: patient did not return or pick up multiple phone calls and message from research participants; patient moved out of state; patient was readmitted at the time of the 30-day phone call; and patient declined the interview but agreed to let us continue to look at their medical record. We have completed medical record review to see if any of these patients had new or worsening symptoms in the 30 days after discharge as noted in the medical record. Of these, 4 have been identified so far with no post-discharge documentation. Thus, these patients have no data on which to determine post-discharge adverse events and therefore are lost to follow up.

5.10. Are there subjects **no longer participating** for reasons other than those above, for example, death unrelated to participation in the study?

○ Yes ◉ No

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6. Enrollment of Non-English Speaking Subjects

Have you obtained the informed consent of any non-English speaking subjects to enroll them in the study?

◉ Yes ○ No

Indicate the consent form/process used to enroll non-English speaking subjects:

☐ Short Form Consent Document in the language understood by the subject and hospital medical interpreter from Interpreter's Services
☑ PHRC-approved written translation of the English version of the Consent Document

Enter the number of non-English speaking subjects enrolled using the PHRC translated consent document:

43

☐ Other

For more information, see the PHRC policy 'Obtaining and Documenting Informed Consent of Non-English Speakers.'

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7. Progress Report

The primary purpose of continuing review is to re-assess the risk-benefit ratio at intervals appropriate to the degree of risk associated with the study procedures, but not less than once per year. At the time of continuing review, the PHRC must ensure that the regulatory criteria for IRB approval at 45 CFR 46.111, and when applicable at 21 CFR 56.111, continue to be satisfied. Please answer the following questions so that both you and the PHRC can determine whether any new information has emerged, either from the research itself or from other sources that could alter the PHRC's previous determinations, particularly with respect to risk to subjects.

Provide a summary of the progress of the study:

The study analysis is now complete, and the final report has been submitted and accepted by PCORI. We are now in the process of writing and submitting manuscripts. A manuscript describing the evolution of the intervention over time was rejected by BMJ Quality and Safety. We have decided to combine this manuscript (as an appendix) with the main results of the study and submit to JAMA Internal Medicine. A manuscript describing the results of the baseline staff surveys and inventories of transitional care activities is also being submitted. After that, we will submit a mixed methods analysis, describing why we found the results we did.

Provide a summary of any significant protocol changes approved by the IRB since the last continuing (or initial) review. DO NOT include changes to staff or recruitment materials.

None.

Complaints About the Research

Since the last continuing (or initial) review, have any subjects or others complained about the research?

○ Yes ◉ No

Minor Deviations

Have any **minor** protocol deviations occurred since initial approval?

◉ Yes ○ No

NOTE: Investigators should maintain a cumulative minor deviation tracking log in chronological order by date of discovery and submit the updated log each year with the continuing review. You can download a minor deviation log here.

Have any minor deviations occurred since the minor deviation log was submitted with the last continuing review?

◉ Yes ○ No

NOTE: You must submit the updated minor deviation log for review.

Major Deviations

Since the last continuing (or initial) review, have any **major protocol deviations** occurred **without** prospective IRB approval?

○ Yes ◉ No

Serious Adverse Events

Since the last continuing (or initial) review, has the **nature, frequency or severity of serious adverse events** (adverse event/risk profile) differed from that expected?

○ Yes ◉ No

Other Unanticipated Problems

Since the last continuing (or initial) review have there been any **other unanticipated problems (UAP)**, for example, medication or laboratory errors, loss or unintended disclosure of confidential information, investigator suspension or termination?

○ Yes ◉ No

Findings To Date

Has there been an interim analysis or are there any preliminary findings to report?
Include publications or references to articles that have resulted from the research.

◉ Yes ○ No

Provide results of interim analysis or a brief summary of findings. Include publications or references to articles that have resulted from the research:

We submitted the revised Final Research Report to PCORI on 10/6/2017. An excerpt from the Conclusions section of the Public Abstract are below: Results showed no difference in adjusted 30-day readmission rates among patients in the two study arms, likely due to lower than expected intervention fidelity and the low proportion of readmissions that are truly preventable in this patient population. However, the intervention was associated with a reduced rate of new or worsening symptoms in the post-discharge period and on post-discharge adverse events, outcomes more sensitive to change than readmissions. As with readmissions, efficacy was likely limited by intervention fidelity. Limitations include confounding by indication for some of the intervention components. Further study is needed to further explore the causes and effects of low intervention fidelity, determine the most important components of the intervention, and explore variation in care by hospital, inpatient unit, and primary care practice.

Data and Safety Monitoring

Is/was the trial subject to oversight by a Data Safety and Monitoring Board (DSMB), Data Safety Monitoring Committee (DMC), other similar body (e.g., coordinating or statistical center), or group with responsibility for review of adverse events and interim findings?

○ Yes ◉ No

Have there been **any** adverse events including expected, non-serious or unrelated events since the study was initiated?

○ Yes ◉ No

For investigator-monitored studies, you must attach a cumulative report of all adverse events, including any expected, non-serious and unrelated events, in the Attachments section of this

application using the Attachment Type 'Other.' The PHS QI Program has developed an adverse event tracking log for this purpose.

NOTE: When completing this section refer to the Data and Safety Monitoring plan outlined in the Detailed Protocol and/or Protocol Summary.

Other Information Relevant to the Research

Since the last continuing (or initial) review, have there been major advances, changes in standards of care, drug approvals, device recalls, new black box warnings, or key publications in major peer-reviewed journals, which would alter the risk/benefit assessment of this study?

○ Yes ◉ No

Investigator's Assessment of Risks and Benefits

Since the last continuing (or initial) review, have the risks to subjects changed?

○ Yes ◉ No

Since the last continuing (or initial) review, has the magnitude of benefit or likelihood of benefits to subjects changed?

○ Yes ◉ No

Do the risks to subjects continue to be reasonable in relation to anticipated benefits to subjects, if any, and the importance of the knowledge that may reasonably be expected to result?

◉ Yes ○ No

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8. Study Staff

After completing this continuing review form, review the approved study staff list and make changes as needed to reflect current study staff.

NOTE: Check to see if study staff CITI training certification is expiring within the next 60 days. Remind them to take the refresher as soon as possible to avoid holding up re-approval. Instructions for taking the CITI refresher are available in Research Navigator.

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9. Amendments / Proposed Changes to the Research

Are any changes to the research proposed at this time?

◉ Yes ○ No

Briefly describe the proposed changes:

An amendment is being filed to remove study staff who are no longer involved in the study and whose CITI training has expired.

Provide rationale for the proposed changes:

All currently involved study staff must have up to date CITI approval.

Will the proposed change(s) significantly alter the risk to benefit assessment the IRB relied upon to approve the protocol?

○ Yes ◉ No

Will the proposed change(s) significantly affect the integrity of the protocol?

○ Yes ◉ No

Race and Ethnicity Enrollment Report
Subjects Enrolled To-Date by Ethnicity and Race
This form is consistent with the NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research.The NIH policy is available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.htmlÂ

Self-Reported Ethnicity and Gender of All Enrolled Subjects

Category	Males	Females	Unknown	Total
Hispanic or Latino	70	131	0	201
Not Hispanic or Latino	688	784	0	1472
Unknown or not reported	4	3	0	7
Totals of all enrolled subjects	762	918	0	1680

Self-Reported Race and Gender of All Enrolled Subjects

Category	Males	Females	Unknown	Total
Black or African American	56	88	0	144
American Indian/Alaska Native	3	9	0	12
Asian	7	9	0	16
Native Hawaiian or Other Pacific Islander	2	3	0	5
More than one race	0	0	0	0
Unknown or not reported	73	126	0	199
White	621	683	0	1304
Totals of all enrolled subjects	762	918	0	1680

Self-Reported Race and Gender of All Enrolled Hispanic or Latino Subjects

Category	Males	Females	Unknown	Total
Black or African American	2	11	0	13
American Indian/Alaska Native	1	5	0	6
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	2	0	2
More than one race	0	0	0	0
Unknown or not reported	53	71	0	124
White	14	42	0	56
Totals of all enrolled subjects	70	131	0	201

Ethnic and Racial Definitions for the Minimum Standard Categories Above

Hispanic or Latino:	A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
American Indian or Alaska Native:	A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.
Asian:	A person having origins in any of the original peoples of Far East, Southeast Asia, or the Indian subcontinent.

Native Hawaiian or Other Pacific Islander:	A person having origins in any of the Hawaii, Guam, Samoa, or other Pacific Islands.
Black or African American:	A person having origins in any of the black racial groups of Africa.
White:	A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Clinical Trials Registration

Clinical Trials Registration and Results Reporting

Investigator–initiated clinical trials must be registered on ClinicalTrials.gov to comply with federal FDA requirements in FDA 42 CFR 11 (Final Rule) and/or NIH Policy. Studies that fallsunder both FDA and NIH requirements only need to be registered once. The information posted on ClinicalTrials.gov (CT.gov) must be updated and verified at least every 12 months.

The following information is used to identify studies that require clinical trials registration and results reporting, and to inform Principal Investigators (PI) of their responsibilities for registration and results reporting.

IMPORTANT NOTE: Even if your investigator-initiated clinical trial does not meet the NIH or FDA clinical trials registration requirements, you are strongly advised to read and consider registering your trial to comply with the following additional requirements:

- **International Committee of Medical Journal Editors (ICMJE) for publication purposes**
- **Center for Medicare & Medicaid for research billing claims for qualifying clinical trials (Partners Clinical Trials Office will notify you as applicable if required)**
- **Research funders now requiring registration and results reporting: May 18, 2017 Joint Statement**

For additional information, please see the QI Program website for Clinical Trials Registration.

Is this a Partners investigator – initiated research study?

◉ Yes ○ No

Is this research funded in whole or in part by NIH **AND** does this research meet the NIH's definition of **clinical trial**?

NIH defines a clinical trial as any research study that meets all of the following criteria:

- The study involves human participants;
- The participants are prospectively assigned to an intervention;
- The study is designed to evaluate the effect of the intervention on participants; **AND**
- The effect being evaluated is a health-related, biomedical or behavioral outcome.

◉ Yes ○ No

This study meets the NIH Policy requirements for clinical trials registration and results reporting. Partners Institutions have delegated responsibility for clinical trials registration,

periodic updates, and results and adverse event reporting to the Principal Investigator ("Responsible Party"). This study must be registered on ClinicalTrials.gov prior to the first subject being enrolled into the study. You may submit the protocol to the IRB, however, IRB approval will be contingent upon registering the study and providing the assigned National Clinical Trial (NCT) number to the IRB.

Responsible Party

Enter Name of Responsible Party, for example Jane Doe, MD:

Jeffrey Schnipper, MD

Enter the full name of the Institution, for example, Massachusetts General Hospital:

Brigham and Women's Hospital

The Institution requires a **Registration and Reporting Designation Letter to be completed.** The designation letter outlines the Responsible Party's responsibilities for registration, periodic updates, and results reporting. The letter must be printed, signed, scanned and uploaded to the Attachments page of this submission.

Documentation of ClinicalTrials.gov Registration

Have you submitted registration information to ClinicalTrials.gov?

◉ Yes ○ No

Indicate if a National Clinical Trial (NCT) registration number has been assigned:

○ Pending
◉ Assigned

Enter the NCT number; for example NCT12345678:

NCT02130570

Results Reporting

ClinicalTrials.gov results reporting is required within 12 months of the primary endpoint completion date defined as the date that the final subject was examined or received the intervention for the purposes of collection of primary outcome. Early consultation is strongly advised. Please contact the QI Program for assistance:

Partners Human Research Quality Improvement (QI) Program:
humanresearchqi@partners.org

Additional information can be found at:
QI Program website for **Clinical Trials Registration**
www.ClinicalTrials.gov

Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: February 2010

Protocol Title: Promoting Safer Transitions: A collaboration between the Hospital and the Patient-Centered Medical Home

Principal Investigator: Jeffrey L. Schnipper, MD, MPH

Site Principal Investigator: Jeffrey L. Schnipper, MD, MPH

Description of Subject Population: Adult inpatients at Brigham and Women's Hospital on the medicine services

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead we will ask the person's authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the study.

Why is this research study being done?

The purpose of the study is to see if there are things we can do to help you recover fully after you leave the hospital and prevent you from having to come back to the hospital or emergency room. We have asked you to participate because you are an adult inpatient on a medicine service at Brigham and Women's Hospital and have a South Huntington Practice Primary Care Physician. Overall, we're hoping to include 75 patients in this study, all from BWH.

How long will I take part in this research study?

Your participation in this research study will last 30 days after being discharged from the hospital. If you agree to participate, you will be asked to complete:

A brief health interview before leaving the hospital

- If you are readmitted to the hospital within 30 days of being discharged, we will interview you again for 10-15 minutes, review your medical records, and send a questionnaire to your physicians to see whether anything could have been done to prevent the readmission.

What will happen in this research study?

If you agree to participate, we (the Researchers) will talk to you today in order to learn more about you, including any issues you have had taking your medicines in the past and previous hospitalizations. We can do the interview in your hospital room. Today's interview will take about 15 minutes.

We would also like to look at your Brigham and Women's hospital chart and computer records over the next month. These records will include your doctors' notes and lab test results. The records will also tell us whether you have been back to the hospital or emergency room. If you are readmitted to Brigham and Women's Hospital, we may talk to you again to find out why you had to come back to the hospital.

We would be the only ones looking at this information. We would keep it private.

What are the risks and possible discomforts from being in this research study?

Whether you decide to participate in this project or you decide not to participate in this project, this project will not interfere with your usual care during or after this hospitalization in any way. There is a theoretical risk that information about you could become known to unauthorized persons, but we have safeguards in place to prevent this from happening. If you agree to participate, all information will be kept strictly confidential and in locked files belonging to the researchers. We will not share the information with anyone not working directly on this study or caring for you. All identifying patient information will be removed before analyzing the data.

What are the possible benefits from being in this research study?

We may learn things in the study that will help you and other patients in the future in terms of fewer medication side-effects or an easier time taking your medications properly, better ability to

take care of yourself at home, and maybe fewer readmissions to the hospital or emergency room. There is also the possibility of no direct benefit.

What other treatments or procedures are available for my condition?

Participation in this project is strictly voluntary, and you may choose not to participate at all. In that case, you will get the usual care provided to adult inpatients from the South Huntington practice during and after the hospitalization.

You may also refuse to answer any questions that are asked of you, or stop participating in the study whenever you wish.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

It is possible that we will have to ask you to drop out before you finish the study. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

You will not be paid to take part in this research study.

What will I have to pay for if I take part in this research study?

There will be no cost for you to participate in this study. Your routine medical care will not be disrupted by participation in this study. The cost of your routine medical care and the post-discharge clinic visit will be billed to you or to your health insurance company in the usual way. If you park for the post-discharge clinic visit at the South Huntington practice, you will need to pay for the cost of parking.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Jeffrey Schnipper, MD, MPH is the person in charge of this research study. You can call him at (617) 732-7063, Monday – Friday 9am-5pm. You can also call the Research Project Manager Nyryan Nolido at (617) 525-6653, Monday – Friday 9am-5pm with questions about this research study.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers

- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent _____ Date/Time _____

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject _____ Date/Time _____

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Print Name (check applicable box below) _____

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin

_____ _____
Signature Date/Time

Relationship to Subject:_____

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

_____ _____
Hospital Medical Interpreter Date/Time

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Name Date/Time

Consent Form Version: 8/8/2012

Partners HealthCare System
Research Consent Form / Spanish
Formulario de consentimiento para participar en estudios para investigación en entidades de *Partners HealthCare System*

Subject Identification

General Template /
Version Date/ versión de: February 2010

Título del estudio/ Protocol Title: Relative patient benefits of a hospital-PCM collaboration within an ACO to improve care transitions

Investigador principal / Principal Investigator: Jeffrey Schnipper, MD, MPH

Investigador encargado en el recinto / Site Principal Investigator: Jeffrey Schnipper, MD, MPH

Descripción de la población sujeto del estudio / Description of Subject Population: -Los pacientes adultos ingresados en un servicio médico o quirúrgico en BWH o MGH, que puedan ser dados de alta, con un PCP que pertenece a una práctica de cuidado primario participante

Información sobre este formulario de consentimiento / *About this consent form*

Por favor lea detenidamente este formulario; éste contiene datos importantes sobre un estudio de investigación. Además, un integrante de nuestro grupo de investigadores le hablará acerca de participar en este estudio. A los que acceden a participar en estudios de investigación se les conoce como "sujetos". Esta palabra se usa repetidamente en este formulario.

El sistema de salud *Partners HealthCare System* está compuesto por hospitales afiliados a *Partners*, personal de atención médica e investigadores. En el resto de este formulario de consentimiento nos referiremos a él simplemente por el nombre *Partners*.

Si tiene alguna pregunta acerca del estudio o sobre este formulario, por favor pregúntenos. La participación en este estudio es a opción suya. Si elige participar en este estudio, deberá firmar este formulario para indicar que desea participar. Le entregaremos una copia firmada y fechada del formulario para su archivo personal.

¿Por qué está haciéndose el estudio? / *Why is this research study being done?*

El propósito del estudio es ver si hay cosas que podemos hacer para ayudar a que se recupere completamente después de salir del hospital y evitar que usted tenga que volver al hospital o sala de emergencia. Les hemos pedido que participe porque usted es un paciente adulto hospitalizado en el servicio de medicina o cirugía del hospital de Brigham y Women's o de Massachusetts General y los registros informáticos durante el próximo mes.

El propósito del estudio es ver si hay cosas que podemos hacer para ayudar a que se recupere completamente después de salir del hospital y evitar que usted tenga que volver al hospital o sala de emergencia. Les hemos pedido que participe porque usted es un paciente adulto hospitalizado en el servicio de medicina o cirugía del Hospital Brigham y Women's o Massachusetts General.

¿Durante cuánto tiempo participaré en este estudio? / *How long will I take part in this research study?*

Su participación en este estudio tendrá una duración de 30 días después de haber salido de alta del hospital. Si decide participar, se le pedirá que complete:

- Una breve entrevista médica antes de salir del hospital
- Si usted es re-admitido al hospital dentro de los 30 días de haber sido dado de alta, lo entrevistaremos nuevamente durante 10-15 minutos, revisaremos sus registros médicos, y enviaremos un cuestionario a sus médicos para ver si hay algo que se podría haber sido hecho para evitar la readmisión.
- Una encuesta por teléfono 30 días después de ser dado de alta del hospital

¿Qué sucederá en este estudio? / *What will happen in this research study?*

Si usted decide participar, nosotros (los investigadores) vamos a hablar con usted hoy para aprender más acerca de usted, incluyendo como estaba su salud hace un mes. Podemos hacer la entrevista en su habitación del hospital. La entrevista se llevará unos 30 minutos.

También nos gusta ver a su tabla de Brigham y Women's Hospital o Massachusetts General y los registros informáticos durante el próximo mes. Estos registros se incluyen las notas de los médicos y los resultados de las pruebas de laboratorio. Los registros también nos dirá si ha ido de nuevo al hospital o sala de emergencia. Si está readmitido en Brigham y Women's Hospital, podemos hablar con usted otra vez para averiguar por qué tuvo que regresar al hospital.
Treinta días después de haber sido dado de alta del hospital, le llamaremos por teléfono para averiguar cómo se ha sido tu salud, el grado de satisfacción que ha estado con la atención médica que ha recibido, si usted ha tenido problemas inesperados con su salud, o si tuvo que ir a una sala de emergencia o al hospital. Esta entrevista durará aproximadamente 45 minutos.

Nosotros vamos a ser los únicos que miran a esta información. Vamos a mantener en privado.

Dependiendo de cuando esté inscrito en este estudio, usted estará en uno de dos grupos. Si estás en un grupo, usted obtiene la atención que reciben los pacientes normalmente. Esto significa que los médicos y enfermeras te cuidarán durante y después de salir del hospital como siempre han hecho.
Si usted está en el otro grupo, una enfermera especial en el hospital le ayudará a coordinar el plan de alta con su proveedor de atención primaria, programar sus citas de seguimiento, y proporcionar educación adicional sobre el plan después de que regrese a su casa. Un farmacéutico puede revisar sus medicamentos con usted y con sus médicos y también le puede dar algunos consejos relacionados con sus medicamentos antes de que usted se va a su casa. Antes de ir a su casa, un médico responsable por los pacientes externos de su práctica de atención primaria puede tener una conferencia de video con usted y su enfermera. Los tres de ustedes pueden discutir todas sus dudas y preguntas, así como su alta y el plan de seguimiento. No se grabará esta conferencia de video. En casa, una enfermera le puede visitar para asegurar que usted no está teniendo ningún problema para cuidar de su mismo o de llevar a cabo el plan de alta. Pocos días después de regresar a su casa, usted puede tener una cita especial en su práctica habitual de atención primaria. En esta visita, usted puede ver una enfermera, un farmacéutico y su médico de atención primaria para asegurarse de que todo vaya bien y para que le ayuden a cuidar de usted mismo. Una enfermera de la práctica también puede llamar durante el mes después del alta para ayudar a cuidar de sus condiciones médicas. Usted puede recibir servicios adicionales si necesario.

¿Cuáles son los posibles riesgos y molestias de participar en este estudio? / *What are the risks and possible discomforts from being in this research study?*

La participación en este proyecto no va a interferir con su tratamiento habitual durante o después de la hospitalización de ninguna manera. Hay un riesgo teórico de que la información sobre usted podría llegar a ser conocidos por personas no autorizadas, pero tenemos medidas de seguridad para evitar que esto suceda. Si usted acepta participar, toda la información será estrictamente confidencial y en los archivos bloqueados pertenecientes a los investigadores. No vamos a compartir la información con cualquier persona que no trabaja directamente en este estudio o el cuidado de usted. Toda la información de identificación del paciente se retira antes de analizar los datos. Si usted decide participar en este estudio, puede negarse a recibir cualquiera de estos servicios adicionales en cualquier momento.

¿Cuáles son los posibles beneficios de participar en este estudio? / *What are the possible benefits from being in this research study?*

Podemos aprender cosas en el estudio que le ayudarán a usted ya otros pacientes en el futuro en materia de un menor número de efectos colaterales de los medicamentos o más facilidad de tomar correctamente sus medicamentos, mejor habilidad para cuidar de sí mismo en su casa, y tal vez un menor número de readmisiones al hospital o sala de emergencia. También existe la posibilidad de ningún beneficio directo.

¿Qué otros tratamientos o intervenciones están disponibles para mi enfermedad? / *What other treatments or procedures are available for my condition?*

La participación en este proyecto es estrictamente voluntaria y usted puede elegir no participar en absoluto. En ese caso, obtendrá la atención habitual proporcionada a los pacientes adultos durante y después de la hospitalización. También puede negarse a contestar cualquier pregunta que se hacen de usted, o dejar de participar en el estudio cuando lo desee.

Si no participo, o si dejo de participar en este estudio, ¿podré seguir recibiendo atención médica en los hospitales y centros médicos de *Partners*? / *Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?*

Sí. La decisión de no participar o de dejar de participar no cambiará la atención médica que recibe en los hospitales y centros médicos de *Partners*, ni ahora ni en el futuro. No se le sancionará ni dejará de recibir ninguno de los beneficios que esté recibiendo actualmente o a los pueda tener derecho.

La decisión de participar en este estudio es suya. Usted puede optar por no participar. Aunque ahora opte por participar, si más adelante cambia de parecer podrá retirarse del estudio. Le

avisaremos si nos enteramos de datos nuevos que pudieran hacerlo cambiar de parecer sobre la participación en este estudio.

¿Qué debo hacer si quiero dejar de participar en el estudio? */ What should I do if I want to stop taking part in the study?*

Si participa en el estudio y luego desea retirarse del estudio, debe avisarnos. Nos cercioraremos de que su participación termine de un modo que sea seguro para usted. También le hablaremos acerca de la atención de seguimiento, si es necesario.

Puede que tengamos que pedirle que se retire del estudio antes de que pueda completarlo. Si esto sucede le avisaremos por qué. También le ayudaremos a hacer arreglos para la atención de seguimiento, si es necesario.

¿Se me pagará por participar en el estudio? / *Will I be paid to take part in this research study?*

No se le paga para tomar parte en este estudio.

¿Qué tendré que pagar si participo en este estudio? / *What will I have to pay for if I take part in this research study?*

No habrá ningún costo para que usted participe en este estudio. Su atención médica de rutina no se verá afectado por la participación en este estudio. El costo de su atención médica de rutina y la visita a la clínica después del alta se le cobrará a usted o a su compañía de seguros de salud en la forma habitual. Si estaciona en la visita a la clínica de atención primaria después de su alta, usted tendrá que pagar por el costo de estacionamiento.

¿Qué sucederá si me lesiono a consecuencia de participar en este estudio? /

What happens if I am injured as a result of taking part in this research study?

Le ofreceremos la atención médica que necesite para tratar cualquier lesión que sea consecuencia directa de participar en este estudio. Nos reservamos el derecho de cobrarle a su aseguradora o a terceros por atención que reciba para la lesión. Haremos el esfuerzo de obtener pagos por los gastos pero puede que usted tenga que responder por algunos de ellos. Por ejemplo, si a su aseguradora se le cobra por la atención que usted recibe, usted tendrá la responsabilidad de pagar todos los deducibles y copagos que su aseguradora le exija.

A veces durante una investigación se producen lesiones de las que nadie tiene la culpa. No tenemos previsto pagarle ni indemnizarlo de ninguna otra manera si se presentara una lesión. Sin embargo, al firmar este formulario usted no renuncia a ninguno de sus derechos legales.

Si opina que ha sufrido una lesión o si presenta algún problema médico como resultado de participar en este estudio, avísele lo antes posible al encargado del estudio. Los nombres y números de teléfono del investigador están en el siguiente apartado de este formulario de consentimiento.

¿A quién puedo llamar si tengo preguntas o inquietudes sobre este estudio? / *If I have questions or concerns about this research study, whom can I call?*

Puede llamarnos para hacernos preguntas o hablar de sus inquietudes. Puede hacer preguntas tan a menudo cómo quiera. Estos son nuestros números de teléfono:

Jeffrey Schnipper, MD, MPH es el encargado de este estudio. Puede llamarlo al (617) 732-7063, de lunes - viernes de 9am a 5pm. Además puede llamar a Nyryan Nolido al (617) 525-6653, de lunes - viernes de 9am a 5pm con preguntas acerca de este estudio.

Si desea hablar con alguien independiente del estudio (alguien que no tenga nada que ver con el estudio), llame a la oficina del comité para investigación de *Partners, Partners Human Research Committee*. El número de teléfono es 617-424-4100.

Puede llamar para hablar acerca de:

- Sus derechos como sujeto de investigación
- Sus inquietudes acerca del estudio
- Quejas que tenga acerca del estudio

Además, si siente que lo están presionando para que participe en el estudio, o para que siga participando, el personal de esta oficina está interesado en saberlo y puede ayudarle al respecto.

Si participo en el estudio, ¿qué medidas se tomarán para proteger mi privacidad? / *If I take part in this research study, how will you protect my privacy?*

Durante esta investigación se recolectará información acerca de su salud con la que se podría deducir su identidad. En el resto de esta sección nos referimos a esta información simplemente como "información de salud". En términos generales, las leyes federales disponen que la información de salud debe ser de carácter confidencial. Sin embargo, esta regla tiene sus excepciones. Usted debe saber quiénes pueden ver, usar y compartir su información de salud en una investigación y por qué pueden tener que hacerlo.

Es posible que en este estudio recolectemos su información de salud a partir de lo siguiente / *In this study, we may collect health information about you from*:

Sus historias clínicas pasadas, presentes y futuras

- Las actividades de investigación, entre ellas consultas del estudio, pruebas, entrevistas y cuestionarios.

Quiénes pueden ver, usar y compartir la información de salud a partir de la cual se puede deducir su identidad y por qué pueden tener que hacerlo / *Who may see, use, and share your identifiable health information and why they may need to do so:*

- El personal de investigación de *Partners* que participe en este estudio
- El patrocinador o los patrocinadores del estudio y las personas o grupos contratados por ellos para colaborar en la investigación
- Otros investigadores e instituciones médicas que participen en este estudio, así como los comités de ética de dichas instituciones
- Un grupo que supervise los datos (la información) y los aspectos de seguridad del estudio
- El personal de *Partners* que no realice labores de investigación pero necesite esta información para desempeñar su trabajo (por ejemplo, para gestiones de tratamiento, de pago y facturación, o de atención médica)
- El comité de ética de *Partners* que supervise la investigación y los programas de mejoramiento de la calidad de la investigación de *Partners*
- Los representantes de organizaciones que se encarguen de la acreditación independiente y la supervisión de los hospitales y las investigaciones clínicas

- Las personas u organizaciones que contratemos para desempeñar ciertas labores, tales como empresas de almacenamiento de datos, aseguradoras y abogados
- Las agencias federales y estatales (por ejemplo, la Administración de Alimentos y Medicamentos de Estados Unidos, el Departamento de Salud y Servicios Humanos, los Institutos Nacionales de Salud y otros organismos gubernamentales nacionales o extranjeros que supervisen o evalúen la investigación)
- Las autoridades de salud pública y seguridad sanitaria (por ejemplo, si obtenemos información que pueda representar peligro para usted o para otras personas, es posible que tengamos que notificarles, según lo exija la ley)
- Otros:

Es posible que algunas personas o grupos que reciban su información de salud no tengan que cumplir las mismas reglas de privacidad que nosotros cumplimos. Compartimos su información de salud sólo cuando es necesario y solicitamos que los que la reciban protejan su privacidad. Sin embargo, no podemos prometer que su información conserve su carácter confidencial una vez que haya salido de *Partners*.

Debido a que la investigación es un proceso continuo, no podemos darle una fecha en la cual su información de salud será destruida o dejará de usarse o compartirse.

Los resultados de este estudio pueden publicarse en un libro médico o en una revista médica, o pueden usarse como material de enseñanza. Sin embargo, en ese caso **no** se usará su nombre ni ningún otro dato que permita deducir su identidad si no contamos con su permiso explícito para hacerlo.

Su derecho a la privacidad / *Your Privacy Rights*

Usted tiene derecho a **no** firmar este formulario que nos permitiría usar y compartir su información de salud para investigación. Sin embargo, si no lo firma no podrá participar en este estudio.

Usted tiene derecho a retirar la autorización que nos permite usar o compartir su información de salud para este estudio. Si desea retirar su autorización, tiene que avisarle por escrito al encargado de este estudio. En cuanto haya retirado su autorización no podrá seguir participando en el estudio.

Si retira su autorización, no podremos recuperar la información que ya se haya usado o compartido con otros.

Usted tiene derecho de ver la información de salud suya que se use o comparta en gestiones de tratamiento o de pago, y de obtener una copia de ésta. Para solicitar esta información tendrá que comunicarse con el encargado de este estudio. Sólo podrá obtener esta información cuando el estudio haya concluido.

Consentimiento informado y autorización
Informed Consent and Authorization

Declaración del médico o de la persona que obtiene el consentimiento / *Statement of Study Doctor or Person Obtaining Consent*

- Le he explicado la investigación al sujeto de estudio. */ I have explained the research to the study subject.*
- He respondido todas las preguntas sobre este estudio. */ I have answered all questions about this research study to the best of my ability.*

Médico del estudio o persona que obtiene el consentimiento *Study Doctor or Person Obtaining Consent*	Fecha y hora *Date/Time*

Declaración del sujeto o de la persona que da su consentimiento o asentimiento / *Statement of Subject or Person Giving Consent/Assent*

- He leído este formulario de consentimiento.
- Se me explicó este estudio, con explicación de los riesgos y posibles beneficios (si hay alguno) y se me explicaron las opciones de tratamiento o intervenciones y otros aspectos importantes acerca del estudio.
- He tenido oportunidad de hacer preguntas.
- Entiendo la información que he recibido.

Firma del sujeto participante / *Signature of Subject*:

Doy mi consentimiento para participar en este estudio y accedo a que mi información de salud se use y comparta como se describe en este documento.
I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Sujeto /
Subject

Fecha y hora /
Date/Time

Firma del tutor o representante autorizado de un adulto / *Signature of Guardian or Authorized Representative for Adult*:

Doy mi consentimiento para que la persona a quien estoy autorizado para representar participe en este estudio y accedo a que su información de salud se use y comparta como se describe en este documento.
I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Nombre en letra de imprenta (marque la casilla correspondiente a continuación) /
Print Name (check applicable box below)

- ☐ Tutor nombrado por tribunal *(Court-appointed Guardian)*
- ☐ Apoderado para cuestiones de salud *(Health Care Proxy)*
- ☐ Poder notarial duradero *(Durable Power of Attorney)*
- ☐ Pariente o allegado *(Family Member/Next-of-Kin)*

Firma /
Signature

Fecha y hora /
Date/Time

Parentesco con el sujeto:
Relationship to Subject

Obtención del consentimiento de un sujeto que no habla inglés mediante el uso del "formulario corto" en el idioma que el sujeto habla */ Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language*

Declaración del intérprete médico del hospital */ Statement of Hospital Medical Interpreter*

En mi calidad de persona que entiende tanto el idioma inglés como el idioma que el sujeto habla, declaro que interpreté en el idioma del sujeto la exposición que el investigador hizo del formulario de consentimiento en inglés. El sujeto tuvo la oportunidad de hacer preguntas.
As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Intérprete médico del hospital *Hospital Medical Interpreter*	Fecha y hora *Date/Time*

O

Declaración de otra persona que no sea el intérprete / *Statement of Other Individual (Non-Interpreter)*

En mi calidad de persona que entiende tanto el inglés como el idioma que el sujeto habla, declaro que la versión en inglés de este formulario de consentimiento se le presentó verbalmente al sujeto en su propio idioma y que el sujeto tuvo la oportunidad de hacer preguntas.
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Nombre *Name*	Fecha y hora *Date/Time*

Versión de este formulario de consentimiento / *Consent Form Version:* 10/30/13

***Translated from English to Spanish by: Jorge Chiquie Borges, MD, PhD, MPH (jcborges@partners.org)

PARTNERS HEALTHCARE

AUTHORIZATION FOR RELEASE OF PROTECTED OR PRIVILEGED HEALTH INFORMATION

__ Release Copies of Health/Medical Record
__ Review Health/Medical Record
__ Obtain Copies of Health/Medical Record from Another Facility

atient Name: _____ Patient Date of Birth: _____

atient Medical Record #: _____

atient Address: Street: _____ Apt. #: _____

City: _____ State: _____ Zip Code: _____

elephone Contact #: Day: ( ) _____ Evening: ( ) _____

, _____ do hereby authorize _____ to release my
(Patient Name/Legal Representative) (Facility)

protected health information including copies of my medical record of care received at _____ to
he following persons at the locations/facilities listed below, for the purposes described:

Person(s)/Facility/Address (include name and address)	Purpose (check the appropriate box)
The BWH PCORI (Patient-Centered Outcomes Research Institute) Transitions Project Principal Investigator: Jeffrey Schnipper, MD, MPH, FHM 1620 Tremont Street Boston, MA 02120	☐ Medical Care ☐ Insurance* ☐ Legal Matter* ☐ Personal* ☐ School ☒ Other (please specify)* Research Study

Please refer to the Partners HealthCare Privacy Notice for information on copying fees that may be associated with this request.
**** There may be additional charges for copies of photographs.***

NFORMATION TO BE RELEASED (Please check all that apply and specific dates):

☒ Clinic visit notes: Date admission to 30 days post-discharge
☒ Discharge summary: Date admission to 30 days post-discharge
☒ Lab Reports: Date admission to 90 days post-discharge
☒ Operative Reports: Date admission to 30 days post-discharge
☒ Pathology Reports: Date admission to 30 days post-discharge
☐ Photographs**
☒ Radiation Reports: Date admission to 30 days post-discharge
☒ X-rays/Scan reports: Date admission to 30 days post-discharge
☒ Other (please specify): Pharmacy and pharmacy benefit manager information: Date admission to 90 days post-discharge
☒ Medical Record Abstract (e.g. History & Physical, Operative Report, Consults, Test Reports, Discharge Summary): Date admission to 30 days post-discharge

See Page 2 on Reverse

PARTNERS HEALTHCARE

AUTHORIZATION FOR RELEASE OF PROTECTED OR PRIVILEGED HEALTH INFORMATION

lease answer YES or NO to each of the following questions, to indicate if we may release the information below (if it is in your medical ecord):

☐ Yes ☐ No **Alcohol and Drug Abuse Records** Protected by Federal Confidentiality Rules 42 CFR Part 2 (FEDERAL RULES PROHBIT ANY FURTHER DISCLOSURE OF THIS INFORMATION UNLESS FURTHER DISCLOSURE IS EXPRESSLY PERMITTED OR WRITTEN CONSENT OF THE PERSON TO WHOM IT PERTAINS OR AS OTHERWISE PERMITTED BY 42 CFR PART 2). This consent may be revoked by oral upon written request.

☐ Yes ☐ No **Other(s):** Please list:

☐ Yes ☐ No Details of Mental Health Diagnosis and/or Treatment provided by a Psychiatrist, Psychologist, Health Clinical Nurse Specialist, or Licensed Mental Health Clinician (LMHC) (*I understand that my permission may not be required to release my mental health records for payment purposes)*

☐ Yes ☐ No Confidential Communications with a Licensed Social Worker

understand that:

- I may withdraw my authorization at any time by submitting a written request to the Department or Office where I originally submitted this authorization. Authorization may be withdrawn except for the following:
  - to the extent that action has been taken in reliance on this authorization
  - if the authorization is obtained as a condition of obtaining insurance coverage, other laws provide the insurer with the right to contest a claim under the policy
- I may refuse to sign this authorization. If I refuse to sign this authorization, my treatment, payment, health plan enrolment, or eligibility for benefits will not be affected
- Information released on this authorization, if rediisclosed by the recipient, is no longer protected by Partners HealthCare.
- I undestand that this authorization will automatically expire in 6 months unless otherwise specified.

have carefully read and understand the above, have had any questions explained to my satisfaction, and do herein expressly and oluntarily authorize disclosure of the above information about, or medical records, of, my condition to those persons or agencies listed bove.

Patient's Signature: _____ **Date:** _____

Print Name: _____

When patient is a minor, or is not competent to give consent, the signature of a parent, guardian, or other legal representative is required.

ignature of Legal Representative: _____ **Date:** _____

Print Name: _____ **Relationship of representative to patient:** _____

For Internal Use Only

nformation Released/Reviewed By: _____ Date: _____

Clinic/Office: _____

ick-up Identification:

_____ license _____State ID _____Passport _____Other Photo ID _____

UTORIZACIÓN PARA EXPEDIR / RECIBIR FORMACIÓN MÉDICA PROTEGIDA (AMPARADA OR LEY)

UTHORIZATION FOR RELEASE/RECEIPT OF PROTECTED OR RIVILEGED HEALTH INFORMATION

__**EXPEDIR COPIAS DE HISTORIA CLÍNICA** /
RELEASE COPIES OF HEALTH / MEDICAL RECORD _ ___**REVISAR HISTORIA CLÍNICA** / *REVIEW HEALTH/MEDICAL RECORD*

ACIENTE: _____

ATIENT NAME: NOMBRE / *NAME* APELLIDO / *LAST NAME*

NÚMERO DE REGISTRO MÉDICO:_____FECHA DE NACIMIENTO: _____

atient Medical Record # (if addressograph stamp is not used) *Patient Date of Birth*

DIRECCIÓN DEL PACIENTE: Calle/*Street*:_____Apartamento/*Apt*. # _____

atient Address

Ciudad/*City*:_____Estado/*State*:_____Código/*Zip*: _____

ELÉFONO: DÍA: ( )_____NOCHE: ( ) _____

elephone #: Day *Evening*

_____por medio del presente formulario autorizo a: Nombre del paciente / *Patient name*
_____a expedir mi información médica protegida (amparada por ley),
tidad o recinto / *Facility* incluyendo copias de la historia clínica de la atención médica que se me ha prestado en
_____, Entidad o recinto / *Facility* a las siguientes personas en las siguientes direcciones o entidades:

Persona / o personas o entidad / *Person(s) / Facility* Por motivo de: (Escriba nombre y dirección) (marque la casilla debida)

2. ❒ Atención médica / *Medical care* _____
Seguro* / *Insurance*
unto jurídico* / *Legal matter*_____❒ Asunto
rsonal* / *Personal*
tidad educativa / *School* _____ _____ [x] Otro / *Other*
or favor detalle)

ersona(s)/Edificio/Direccion

he BWH PCORI (Patient-Centered Outcomes Research Institute) Transitions Project
incipal Investigator: Jeffrey Schnipper, MD, MPH, FHM
20 Tremont Street Boston, MA 02120

Por favor consulte la NOTIFICACIÓN de Partners para información sobre cobros por gastos de fotocopia que pudiera asionarle esta solicitud. **Las copias de fotografías pueden tener costo adicional.

**** Por favor consulte la NOTIFICACIÓN de Partners para información sobre cobros por gastos de fotocopia que pudiera ocasionarle esta solicitud.***

*****Las copias de fotografías pueden tener costo adicional.***

INFORMACIÓN A EXPEDIR / *Information to be released*
(Marque el tipo de información y anote las fechas)

❒ Apuntes de consulta / *outpatient notes:*
Fecha de admision → 30 dias despues de la fecha de alta /
Date admission → 30 days after date discharge

❒ Informe de alta / *discharge summary:*
Fecha de admision → 30 dias despues de la fecha de alta /
Date admission → 30 days after date discharge

❒ Informes de laboratorio / *lab reports:*
Fecha de admision → 90 dias despues de la fecha de alta /
Date admission → 90 days after date discharge

❒ Informes de cirugía / operative reports *Fecha de admission:*
Fecha de admision → 30 dias despues de la fecha de alta /
Date admission → 30 days after date discharge

❒ Informe de patología / pathology report:
Fecha de admision → 30 dias despues de la fecha de alta /
Date admission → 30 days after date discharge

❒ Resumen de historia clínica (exámenes, informes de cirugía, consultas, pruebas, resumen clínico de alta) / *Medical Record Abstract (e.g. History & Physical, Operative Report, Consults, Test Reports, Discharge Summary) Fecha de admission:*
Fecha de admision → 30 dias despues de la fecha de alta /
Date admission → 30 days after date discharge

❒ Fotografías** / *photographs* _____

❒ Informes de radioterapia / *radiation reports:*
Fecha de admision → 30 dias despues de la fecha de alta /
Date admission → 30 days after date discharge

❒ Radiografías o informes de radiología / *X-rays/ scan reports:*
Fecha de admision → 30 dias despues de la fecha de alta /
Date admission → 30 days after date discharge

❒ Otro / *other* (por favor detalle):
Farmacia y informacion del gerente de beneficio de la farmacia /
Pharmacy and pharmacy benefit manager information:
Fecha de admision → 90 dias despues de la fecha de alta /
Date admission → 90 days after date discharge

AUTORIZACIÓN PARA EXPEDIR INFORMACIÓN MÉDICA EXPLÍCITAMENTE PROTEGIDA (AMPARADA POR LEY)

AUTHORIZATION FOR RELEASE OF SPECIFICALLY PROTECTED OR PRIVILEGED INFORMATION

Por favor marque una casilla (**Sí** o **No**) en cada uno de los siguientes puntos para indicar si autoriza que se expida ese tipo de información (si está en su historia clínica).

❒ Sí ❒ No Informes sobre consumo de alcohol o drogas, amparados por reglamento federal de confidencialidad

Alcohol and drug abuse records protected by Federal Confidentiality Rules 42 CFR Part 2
(EL REGLAMENTO FEDERAL PROHÍBE QUE ESTA INFORMACIÓN SE DIVULGUE DE NUEVO A MENOS QUE SE PERMITA EXPLÍCITAMENTE O QUE HAYA CONSENTIMIENTO POR ESCRITO DE LA PERSONA DE QUIEN SE TRATE O SEGÚN LO PERMITA LA REGLA 42 CFR PARTE 2.) Esta autorización puede anularse solicitándolo por escrito o verbalmente.

❒ Sí ❒ No Otros / *other(s)*: Por favor dé el detalle:

_____

❒ Sí ❒ No Detalles de diagnóstico o tratamiento de salud mental dado por un psiquiatra, psicólogo, enfermera especialista en salud mental, o personal clínico licenciado para salud mental *(Licensed Mental Health Clinician). Entiendo que puede que no sea necesario obtener mi permiso para expedir mi historia clínica de salud mental si es con motivo de tramitar pagos.*

❒ Sí ❒ No Comunicaciones confidenciales con asistente social licenciado para salud mental / *Confidential communications with Licensed Social Worker*

Entiendo que:

• Puedo retirar esta autorización en cualquier momento entregando aviso por escrito al mismo Departamento o consultorio en el cual entregué esta autorización originalmente. La autorización puede retirarse excepto: -según se haya obrado de acuerdo con lo dispuesto en esta autorización, -si la autorización se obtiene como una condición de lograr cobertura de seguro, hay otras leyes que proveen al asegurador el derecho de impugnar reclamos bajo la póliza.

• Puedo rehusarme a firmar esta autorización. Si me rehúso a firmarla, eso no afectará mi tratamiento, pago, afiliación a plan de salud, ni posibilidad de ser considerado para recibir beneficios.

• La información expedida bajo esta autorización dejará de estar amparada por Partners HealthCare si es divulgada por la parte que la reciba.

• Esta autorización se vencerá automáticamente en 6 meses a menos que se detalle lo contrario: *(Specify if date of expiry*

is different than automatic 6 months:)

_____ He leído y entendido este documento y se han respondido todas mis preguntas satisfactoriamente; y por medio del presente autorizo explicita y voluntariamente que se expida la información aquí nombrada, o la historia clínica, sobre mi enfermedad, a aquellas personas o entidades aquí nombradas.

FIRMA DEL PACIENTE / *Patient's signature*:_____ **FECHA** / *Date*: _____

Escriba su nombre en letra de molde / *Print name*:

_____ Si el paciente es menor de edad o si

está incapacitado para autorizar, se exige la firma de uno de los padres, tutor legal u otra persona autorizada. *(If patient is a minor or unable to consent, parent, guardian or authorized signature is required)*

FIRMA AUTORIZADA / *Authorized signature*_____**FECHA** / *Date*: _____

Escriba nombre en letra de molde / *Print name*:_____**Parentesco** / *Relationship*: _____

Casilla de uso interno / For Internal Use Only Information released by:

_____ Date:_____ C linic / Office: _____

Form 2: Introduction and RA Instructions

Hello, my name is _________. I'm a research assistant in the Division of General Medicine here at Brigham and Women's Hospital. I'm here to ask if you would be interested in participating in a research study to help us learn if there are additional ways we can make sure you have a smooth transition home and as complete a recovery as possible. Your name came to us because you are an inpatient at the Brigham and your primary care doctor belongs to a practice that is participating in this study. Your doctor or nurse in the hospital also knows about this study and says that it's OK for us to talk with you about it.

If this is something you might like to do, I'd like to check a few things to make sure you're eligible and if you are, then explain the study in more detail. I'll ask you questions about the study to make sure my explanation was clear, and answer any questions you may have. As part of this, we'll go over this informed consent document, which is like a "permission slip" that says exactly what will happen during the study. If you choose to participate, you sign the form and we each keep a copy.

Do you think you might be interested in hearing more?

Is this a good time to talk? [If no] when would be a good time for me to come back?

[If at any time during the introduction and consent you detect that the patient may not be fluent in English/Spanish, see section 1.A) FLUENCY ASSESSMENT]

First.

1. Do you have a phone that we can consistently reach you on? Can we leave voicemail messages on this phone?
2. Who is your primary care physician?

   Name: __ __ __ __ __ __ __ __ __ __ __ __ __ __   __ __ __ __ __ __ __ __ __ __ __ __ __ __ __
   LAST   FIRST

3. Can you name the practice your physician belongs to?

   Practice: __

[If ineligible, see below]

[If cognitively impaired]: So, how have things been going in the hospital?

Do you have someone who helps take care of you? Who is that? Do they live with you?

Thanks very much for your help with this study – it was nice meeting you.

Eligible	Ineligible
"O.K. You are eligible for the full interview. Let's start by going over the study in more detail, using this consent form. *-See Procedure for Consenting Participants, below*	"O.K. From the answers you've given me, it looks like we don't need to do a full interview. I do thank you for your time and I hope everything goes well with your hospital stay" *-Record reason for exclusion on the **Screening Log***

1. A) FLUENCY ASSESSMENT

When introducing yourself and the study, you can often easily observe if a patient does not fully comprehend you, and can then begin to assess the 4 components of fluency:

- Listening comprehension
- Pronunciation
- Vocabulary
- Grammar

To determine the level of fluency as "adequate" or "inadequate," use interview techniques such as socially conversing. For example, asking:

-What are you in the hospital for? How long have you been in the hospital?

-Where are you from? Where do you live?

-Ask opinions about the weather, the traffic, the hospital (service, food, etc.)

Also, any questions used in patient screening would be used to assess fluency.

Examples of inadequate fluency

- Comprehension:
  - Patient asks to repeat the question and/or indicates that he/she doesn't understand
  - Patient responds but the answer does not address the question or otherwise shows poor comprehension
- Pronunciation:
  - Interviewer cannot understand the words (this is different from having an intelligible accent)
- Vocabulary:
  - Using native language words in English language speech
  - Having to point to objects or asking others in the room to translate or guess words
- Grammar: (This is probably the hardest to master for a non-native speaker)

- Consistently mixing up word order so that the interviewer cannot follow what the patient is saying
- Using incorrect pronouns or incorrect verb tenses would not be counted as inadequate fluency unless they are used repeatedly and in a way that makes the speech difficult to understand

[If patient is not fluent in English but is fluent in Spanish, then patient is eligible to participate in Spanish with a Spanish interpreter or fluent research personnel and with forms in Spanish]

1. B) PROCEDURE FOR CONSENTING PARTICIPANTS

1) Orient patients to the consent process by telling them that you will explain the study to them to see if they're interested in participating, and that you'll ask them some questions afterwards to make sure your explanation was clear. If they're interested in participating, you will ask for their signature on a piece of paper that is called the informed consent document, which is like a permission slip to be enrolled in the study. **[See *Introduce the study* script above]**
2) Give the patient the informed consent document to look over. Avoid using the word "read." Make sure you have a copy in the appropriate language (English or Spanish)
3) Provide a verbal synopsis of the consent document, referring to the appropriate places in the document. We should take our time with this. Slowing down the speed of conversation really just takes about 1-2 extra minutes, which is time well spent.
4) **Informed Consent Key Points to Cover**

Purpose: Okay, so let me tell you some more about the study so you can decide if you want to participate. The project's goal is to improve patients' experience transitioning from the hospital back to their home and community.

Just some main points that are important for you to know-

Participation: If you do choose to participate, we would go through a brief health interview before you leave the hospital that should last no more than 30 minutes and another one over the phone 30 days after your discharge that may last up to an hour. You would also be interviewed if you are readmitted to the hospital within 30 days to see if anything could have been done to prevent your readmission. Study staff may also review your medical records to see how your health was in the 30 days after discharge.

As a participant in the study, you will be assigned to one of two groups. Which group you are assigned to depends on your primary care provider and the time of year. One group will receive usual care: nurses, care coordinators, physicians, and others in the hospital and in your primary care practice would look after you as they normally would. The other group will receive some additional services to make for a smoother transition from the hospital back home and to make sure you have as full a recovery as possible. Have you ever had any problems back home after leaving the hospital? [if yes, have them describe it, then say something like "Okay, so in our study you might receive X to prevent that kind of problem for occurring." If don't have an example, could say "well for example, some patients have problems with their medications after they leave the hospital, and in our study, a pharmacist may meet with you while you are in the hospital to review any changes made to your medication regimen."] In all

cases, these extra services will be tailored to your needs, and you would only get them with your permission and that of your doctors and other health care providers.

Your participation is completely voluntary and choosing not to participate will not otherwise interfere with rest of the care you receive at Partners.

Benefits: By participating in this study, you may benefit from improved communication among your health care providers, a smoother transition as you leave the hospital, and a smaller chance of having to be readmitted to the hospital. You would be helping contribute to the effort of hospitals and health care providers across the United States to provide better quality care.

Risks: The potential risks involved in this study include your confidentiality, but we have safeguards in place to protect your information. It may be an inconvenience for you to receive the additional services or complete the interviews with me.

If you choose to participate, you may refuse any service or decide not to participate at any time. You can also refuse to answer any survey questions you don't want to answer.

HIPAA: If you participate, the people doing the research will not look at ***all*** of your medical records. We will only look at a few things in your hospital chart and computer records like visits to clinics and the hospital, lab test results, and prescriptions filled. We will keep all this information private and under lock and key. However, sometimes the people that pay for or watch over the research may need to look at our records to make sure we're doing everything ok. These people include the Patient-Centered Outcomes Research Institute, who is paying for this study, and the Partners Research Committee, who watched over all studies at the Brigham.

Other: There is contact information for study staff included in this form if you have any questions and there is also a contact for the Partners Human Research Committee if you wish to speak to someone besides the study staff.

Ask the patient "**What questions do you have for me**?" (Not "Do you have any questions?") Answer them.

[Teach back:]

Do a teach-back of each of the most important areas of the consent. Introduce it by saying something like, "I would like to make sure I explained this well by asking you to repeat back some of the information." Then ask about these 7 areas and any others that you choose.

a. "Could you please tell me, what is the main purpose of this research study?" (Correct: to see if there are extra things that the hospital and my PCP's practice can do to help me do better after I leave the hospital)

b. "If you choose to participate, what would you need to do?" (Correct: complete an interview now and in about a month by phone and also if I am readmitted)
c. "You could end up in 1 of 2 groups. How would we figure out which group you're in?" (Correct: who my PCP is, the month I am in the hospital) "What would happen if you're in the group that gets regular care? What would happen if you're in the group that gets extra services?" (Correct: reasonable description of usual care and intervention, including inpatient pharmacist)
d. "What would be the benefits of participating in this study?" (Correct: patient could have a better recovery, we could learn how to help other patients in the future)
e. "What are the potential risks of participating?" (Correct: not many, takes some time, potential breach of confidentiality)
f. "What happens if you choose not to participate?" (Correct: nothing, it's voluntary, patient gets usual care)
g. "We will keep your information private, but who might need to look at it to monitor the study?" (Correct: PCORI, IRB)

If the patient gets anything wrong, re-teach the information before going on to the next question. Then re-assess understanding via teach-back of the areas the patient got wrong initially. This can be done either immediately after re-teaching, or after you get to the end of the teach-backs. Intro with something like, "Let me see if I did a better job explaining it this time" and then prompt the teach-back using the above prompts.

Patients generally don't like being asked to teach-back the same thing more than twice. If they don't correctly teach-back a certain item after 2 attempts, you can, at your discretion, ask the patient something like, "Do you feel comfortable enough with your understanding of this to move on or would you like us to talk about it some more?"

At the end, ask patients if they would like to participate in the study, and if so, get their signature on the consent form. If hesitant, ask again what questions they might have, and let them know they can look over the document some more, and that you can check back with them a little later. If need more time to decide: "If you need more time to decide that is fine. Is it okay if I come back later today or tomorrow morning? What works best for you?"

Patient agrees to participate	**Patient declines to participate, at any point during the introduction and consent**
Have them sign 2 copies of the form and leave one copy with the patient	"Thank you for taking the time to talk with me, and good luck with the rest of your stay here at the Brigham."
"Ok then, if this is a good time, we will go ahead and start the interview. If your doctors or nurses need to talk with you during the interview, we'll stop the interview and pick up where we left off after they have done what they need to.	

2. Beginning the Interview

In this interview, I will ask you questions about your health and a few about your living situation. The reason we ask these questions is to determine which patients might benefit the most from the extra services we plan to offer. I will also ask you to look at some medical instructions and answer some questions about them.

Remember, this interview is completely confidential. It will be seen only by the researchers and not by any of the doctors or nurses who are looking after you.

Please try to answer these questions as honestly as possible. There are no right or wrong answers to the questions. I'm looking for your own answer for each question, not what you think your doctor or I might want you to say. You can stop me at any time if you want me to repeat something, or if you need to take a break. Please don't feel that you have to spend a long time over each question. Often the first answer that comes to you is the best one.

3. Baseline Data Collection—Enrollment Interview

A) Demographics Form

-Ask:

- What is the best phone number where we can reach you after you leave the hospital?
- What is another number where we may contact you if we cannot reach you at the first number?
- When are the best times and days we could reach you by phone?
- What are the names and phone numbers of 1 or 2 other people who would be able to reach you if, for some reason, we had a problem contacting you?

-Continue with questions on ***Form 3 Demographics*** *as they are written on the form.*

-For "people 18 or older living in your household": count only those who live in the home for a majority of the year.

B. SF-12

I am now going to ask you some questions about what your health was like 1 month before you were admitted to the hospital.

-Administer SF12-Pre. Hand them the survey so they can see the answer choices for each set of questions

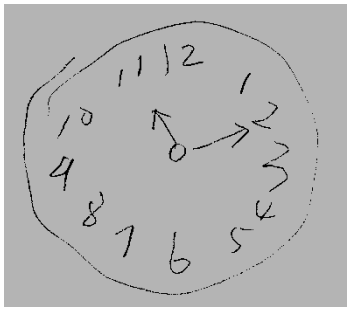
C. MINI-COG

-These next few questions well help us compare the memory level of all the patients we talk to.

-Instructions for administration are on the form.

CLOCK SCORING

NORMAL CLOCK

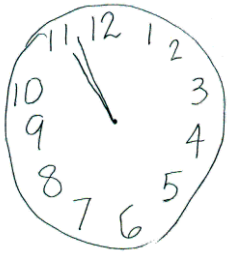


A NORMAL CLOCK HAS ALL OF THE FOLLOWING ELEMENTS:

All numbers 1-12, each only once, are present in the correct order and direction (clockwise). Two hands are present, one pointing to 11 and one pointing to 2.

ANY CLOCK MISSING EITHER OF THESE ELEMENTS IS SCORED ABNORMAL. REFUSAL TO DRAW A CLOCK IS SCORED ABNORMAL.

SOME EXAMPLES OF ABNORMAL CLOCKS (THERE ARE MANY OTHER KINDS)



Abnormal Hands

Missing Numbers

-Record the clock score.

D. s-TOFHLA

-BEGIN THE READING COMPREHENSION EXERCISE WITH:

Here are some other medical instructions that you might see around a hospital. There are words missing in these instructions. I want you to fill in the missing words. Just below the blank line, we've listed 4 possible words to complete the sentence. Choose the word that makes the most sense. Remember that the instructions may not apply to you – we just want you to fill in the blank so that the sentence makes sense. Bubble in the circle in front of the word you choose, then go on to the next blank space and pick the best word for it. Continue until you complete all of the pages or until I stop you after 7 minutes.

-Hand them the reading passages and a pencil with eraser, start timing them for 7 minutes.

-Check that the form is filled out correctly, and clarify any mistakes in bubbling in the answers.

E. Ending the Enrollment Interview

That's all the questions we have for you now. If you are in the extra services group, you will likely meet Cherlie Magny-Normilus, our discharge advocate, and maybe a hospital pharmacist. You will also get a program describing the different people providing these services. I'd like to remind you that you will receive a follow-up call about a month after you leave the hospital. When we call, we may call it the PCORI Transitions Study so you'll know it's us, but try not to let the caller know if you ended up getting extra services, since this could affect the information that we collect. Thank you again for participating. It was great meeting you.

Patient Name: _____ Subject ID: _____

FORM 3: DEMOGRAPHICS

Interview completed by (initials): __ __ __ Date of Enrollment/Interview: __ __/__ __/__ __
MM DD YY

Preferred phone (__ __ __) __ __ __ - __ __ __ __ Second phone (__ __ __) __ __ __ - __ __ __ __

Best times to reach you: __ __: __ __ ☐ am ☐ pm to __ __: __ __ ☐ am ☐ pm

Or __ __: __ __ ☐ am ☐ pm to __ __: __ __ ☐ am ☐ pm

Best days: ☐ Mon. ☐ Tues. ☐ Wed. ☐ Thurs. ☐ Fri. ☐ Sat. ☐ Sun.

Name (1st alternate contact; last, first): _____, _____

Name (2nd alternate contact; last, first): _____, _____

Telephone (1st contact): (__ __ __) __ __ __ - __ __ __ __

Telephone (2nd contact): (__ __ __) __ __ __ - __ __ __ __

Are you Hispanic or Latino?

☐ Yes ☐ No ☐ Don't know/Not sure ☐ Declined

Which one of the following would you say best represents your race? (select one)

☐ White ☐ Black or African American ☐ Asian ☐ Native Hawaiian or Other Pacific Islander

☐ American Indian or Alaska Native ☐ Other (specify): _____

☐ Don't know/Not sure ☐ Declined

Marital Status: Are you… (select one)

☐ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Single/never married

☐ A member of an unmarried couple ☐ Declined

How many people age 18 or older live in your household (not including yourself)?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10+

Employment: Are you currently… (select one)

☐ Employed for wages (full-time) ☐ Employed for wages (part-time) ☐ Self-employed ☐ Out of work

☐ A homemaker ☐ Retired ☐ Unable to work (disabled) ☐ Declined ☐ Other

Patient Name: _____ Subject ID: _____

What was the highest grade or year of school you completed? (select one)

□ None or only kindergarten □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8
□ 9 □ 10 □ 11 □ 12/GED
□ 13 □ 14 □ 15 □ 16
□ 17 □ 18 □ 19 □ 20
□ 21 □ 22 □ 23 □ 24 □ 25+ □ Declined

Do you have health insurance?

□ Yes □ No □ Don't know/Not sure □ Declined

What is your primary type of health insurance?

□ Medicaid/MassHealth □ Medicare □ Private/ Commercial □ Self Pay □ Other (specify):

_____

Do you have a caregiver, a relative or friend who helps you with your activities of daily living, such as feeding, bathing, dressing, grooming, shopping, banking, and housework, or your health care needs?

□ Yes □ No □ Don't know/Not sure □ Declined

Who is that? _____

Is that person available to help you full-time or part-time?

□ Full-time □ Part-time □ Don't know/Not sure □ Declined

Which of the following activities does that person help you with: (check all that apply)

□ Basic activities of daily living such as feeding, bathing, going to the bathroom, dressing, or getting around the house

□ Other activities of daily living such as housework, cooking, shopping, banking, or other errands

□ Help with health care needs such as taking your medications, getting to medical appointments, understanding medical instructions, helping you make medical decisions, taking notes about your medical conditions, helping you with diet and exercise, or doing other health-related tasks like blood pressure checks or wound care

Are you the caregiver for someone else?

□ Yes □ No □ Don't know/Not sure □ Declined

[If yes]: Are you needed full-time or part-time?

□ Full-time □ Part-time □ Don't know/Not sure □ Declined

If you are not available to care for that person, is there someone else who can?

□ Yes, fully □ Yes, partly □ No □ Don't know/Not sure □ Declined

Subject Number:
Initials:
Date:

SF-12v2™ Health Survey (PRE)

This survey asks for your views about your health one month ago. This information will help keep track of how you felt and how well you were able to do your usual activities.

Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health was one month ago:

Excellent	Very good	Good	Fair	Poor
1	2	3	4	5
○	○	○	○	○

2. The following questions are about activities you might do during a typical day. Approximately one month ago, did your health limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	○	○	○
b Climbing several flights of stairs	○	○	○

Subject Number:
Initials:
Date:

3. About one month ago, how much of the time did you have any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
	1	2	3	4	5
a Accomplished less than you would like	○	○	○	○	○
b Were limited in the kind of work or other activities	○	○	○	○	○

4. One month ago, how much of the time did you have any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
	1	2	3	4	5
a Accomplished less than you would like	○	○	○	○	○
b Did work or activities less carefully than usual	○	○	○	○	○

Subject Number:
Initials:
Date:

5. One month ago, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
1	2	3	4	5
○	○	○	○	○

6. These questions are about how you felt and how things were with you about one month ago. For each question, please give the one answer that comes closest to the way you were feeling at that time.
How much of the time about a month ago...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
	1	2	3	4	5
a Did you feel calm and peaceful?	○	○	○	○	○
b Did you have a lot of energy?	○	○	○	○	○
c Did you feel downhearted and depressed?	○	○	○	○	○

7. One month ago, how much of the time did your physical health or emotional problems interfere with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5
○	○	○	○	○

Subject Number:
Initials:
Date:

8. What are your most important goals for your recovery after you leave the hospital? For example, what kinds of things do you want to be able to do one month after returning home?

PCVD4-1

MINI — COG

Instructions: Please read each item and fill in the bubble (like this,●). Use black ink or a soft-leaded pencil.

Dementia Test - MINI-COG ™

1) I am going to say three words that I want you to remember. The words are
Banana Sunrise Chair.

Please say them for me now.

[Give the patient 3 tries to repeat the words. If unable after 3 tries, go to next item.]

[Hand the patient a pencil/pen and sheet of paper for the clock drawing test.]

[SAY ALL THE FOLLOWING PHRASES IN THE ORDER INDICATED]:

Please draw a clock on the paper I gave you. Start by drawing a large circle.

[When this is done, say]

Put all the numbers in the circle.

[When done, say]

Now set the hands to show 11:10 (10 past 11).

3) What were the three words I asked you to remember?

_____ _____ _____ (Score 1 point for each)

3-Item recall score: ◯ 0 ◯ 1 ◯ 2 ◯ 3

Clock score: ◯ Abnormal clock, 0 points ◯ Normal clock, 2 points

Tracking Number (Official Use Only) ☐☐☐

Passage A

Your doctor has sent you to have a _____X-ray.

- ○ stomach
- ○ diabetes
- ○ stitches
- ○ germs

You must have an _____ stomach when you come for _____.

- ○ asthma
- ○ empty
- ○ incest
- ○ anemia

- ○ is
- ○ am
- ○ if
- ○ it

The X-ray will _____ from 1 to 3 _____ to do.

- ○ take
- ○ view
- ○ talk
- ○ look

- ○ beds
- ○ brains
- ○ hours
- ○ diets

THE DAY BEFORE THE X-RAY

For supper have only a _____snack of fruit, _____ and jelly, with coffee or tea.

- ○ little
- ○ broth
- ○ attack
- ○ nausea

- ○ toes
- ○ throat
- ○ toast
- ○ thigh

After _____, you must not _____ or drink

- ○ minute,
- ○ midnight,
- ○ during,
- ○ before,

- ○ easy
- ○ ate
- ○ drank
- ○ eat

anything at _____ until after you have _____ the X-ray.

- ○ ill
- ○ all
- ○ each
- ○ any
- ○ are
- ○ has
- ○ had
- ○ was

THE DAY OF THE X-RAY

Do not eat _____.

- ○ appointment
- ○ walk-in
- ○ breakfast
- ○ clinic

Do not _____, even _____.

- ○ drive
- ○ drink
- ○ dress
- ○ dose
- ○ heart
- ○ breath
- ○ water
- ○ cancer

If you have any _____, call the X-ray _____ at 616-4500.

- ○ answers
- ○ exercises
- ○ tracts
- ○ questions
- ○ Department
- ○ Sprain
- ○ Pharmacy
- ○ Toothache

PASSAGE B

I agree to give correct information to _____ if I can receive Medicaid.

- ○ hair
- ○ salt
- ○ see
- ○ ache

I _____ to provide the county information to _____ any

- ○ agree
- ○ probe
- ○ send
- ○ gain
- ○ hide
- ○ risk
- ○ discharge
- ○ prove

statements given in this _____ and hereby give permission to

- ○ emphysema
- ○ application
- ○ gallbladder
- ○ relationship

the _____ to get such proof. I _____ that for

- ○ inflammation
- ○ religion
- ○ iron
- ○ county
- ○ investigate
- ○ entertain
- ○ understand
- ○ establish

Medicaid I must report any _____ in my circumstances

- ○ changes
- ○ hormones
- ○ antacids
- ○ charges

within _____ (10) days of becoming _____ of the change.

- ○ three
- ○ one
- ○ five
- ○ ten
- ○ award
- ○ aware
- ○ away
- ○ await

I understand _____ if I DO NOT like the _____ made on my

- ○ thus
- ○ this
- ○ that
- ○ than
- ○ marital
- ○ occupation
- ○ adult
- ○ decision

case, I have the _____ to a fair hearing. I can _____ a

- ○ bright
- ○ left
- ○ wrong
- ○ right
- ○ request
- ○ refuse
- ○ fail
- ○ mend

hearing by writing or _____ the county where I applied.

- ○ counting
- ○ reading
- ○ calling
- ○ smelling

If you _____ AFDC for any family _____, you will have to

- ○ wash
- ○ want
- ○ cover
- ○ tape
- ○ member
- ○ history
- ○ weight
- ○ seatbelt

_____ a different application form. _____, we will use

- ○ relax
- ○ break
- ○ inhale
- ○ sign
- ○ Since
- ○ Whether
- ○ However
- ○ Because

the _____ on this form to determine your _____.

- ○ lung
- ○ date
- ○ meal
- ○ pelvic
- ○ hypoglycemia
- ○ eligibility
- ○ osteoporosis
- ○ schizophrenia

PCORI 30 Days Post Discharge Surveys

Record ID _____

[Inline Image: "PCORI Logo_horiz.ipg.png"]

Study ID: _____

FSU 30 Day Follow-Up Call

Hello, I am calling for Mr./Ms. _____. My name is _____ and I am a research assistant from [Brigham and Women's Hospital / Massachusetts General Hospital]. I'm calling as part of the PCORI Transitions Project you are participating in and I'd like to talk with you for about 30-45 minutes about how you're doing since you left the hospital. Is this a good time for you? (If it is, proceed. If not, ask when to call back and record result in Contact Log) .

Do you remember talking to me {or whoever talked with them} in the hospital? We talked about things that we could do to help you have a good recovery after leaving the hospital? (Give overview of project as needed).

Since we will be asking you about any doctors visits or hospital utilization over the past 30 days, would you be able to take a few minutes to collect any records, such as discharge paperwork, paperwork from the visiting nurses or any office visits, emergency room visits, or readmissions, your medication list, and the letter we sent you with the survey questions.

I'd like to ask you some questions similar to what we talked about in the hospital last month. There are questions about how helpful the discharge process was, the follow-up health care you have received, and whether you have had any health problems since leaving the hospital. Please remember, this interview is confidential. There are no right or wrong answers. Your answers will be seen only by the researchers, unless it seems that you are experiencing problems that need to be handled by your doctors, in which case we will contact your doctors and let them know about these issues. Let's begin.

	Completed	Declined (records ok to use)	Withdrew
Interview Result	☐	☐	☐

Interviewer _____

Call Number _____

Date and time: _____

Length _____

Interview completed by ☐ Participant ☐ Surrogate

A. Follow-Up and Health Care Utilization

"Now I have some questions about any health care visits you've had since leaving the hospital on (_____), including home nursing visits, doctors visits, clinic visits, emergency room visits and hospital admissions. - [Use MM/DD/Y format for all data entry and recording- estimate date if necessary, and then use an * to indicate approximate dates.]

12. Have you visited the emergency department since your discharge from the hospital? Yes No

ED Visit One ☐ Yes ☐ No

If so, when?

_____

Where?

_____

Why did you go?

How was the decision made for you to go to the emergency department?

What was done for you there?

ED Visit Two ☐ Yes ☐ No

Etc.

Since your discharge on (_____date), were you readmitted to a hospital or rehab/SNF? ☐ Yes ☐ No

Readmission 1 ☐ Yes ☐ No

14. If so, when?

_____

Where?

_____

What were you admitted for?

What was done for you at the hospital?

Readmission 2 ☐ Yes ☐ No

Etc.

B. AE SCREEN

-SURROGATES (designated caregiver): Adapt script accordingly (how much problem bothered patient not surrogate)

-"Patients sometimes develop medical problems after hospitalization. Have you had any symptoms that are new or worse since you left the hospital?"

-If match with any of the symptoms below, then ask the follow-up questions below. Group symptoms as the patients does. Then go through the rest of the symptoms in order.

-"In order to figure out if you've had any other problems related to the medical care you received (rather than your medical conditions), I'm going to read off a list of symptoms, and I want you to tell me if that symptom is new or has gotten worse since you left the hospital; if it has, then I will ask you a few questions about it to get more details."

-Question A. Start with the first symptom (problems with sleep) and ask if the patients has had that problem (new or worse) since getting out of the hospital last month.

(If no, go to next symptom. If yes, ask to describe the symptom in as much detail as possible in the Table)

Fill out chart in accordance with each symptom

	Yes	No
Problems with sleep	☐	☐
Changes in mood	☐	☐
GI problems like nausea, vomiting, diarrhea, constipation, stomach pain, loss of appetite	☐	☐
Dizziness, lightheadedness or fainting	☐	☐
Headache	☐	☐
Fatigue or weakness	☐	☐
Muscle or joint aches	☐	☐
Falls, injuries, or trouble with balance	☐	☐
Problems urinating or with sexual function	☐	☐
Skin rash, redness, pain, or itching	☐	☐
Cough	☐	☐
Shortness of breath	☐	☐
Chest pain	☐	☐
Swollen legs	☐	☐

Bleeding	☐	☐
Infection, fever	☐	☐
Complication from surgery or procedure you had in hospital	☐	☐
Problem diagnosing or treating a medical problem you had in the hospital	☐	☐
Anything else	☐	☐

Adverse Event One ☐ Yes ☐ No

Type of Problem

_____

Describe the problem

When did the problem start or get worse?

☐ While in hospital
☐ Day of discharge
☐ 1-3 days after
☐ 4-7 days after
☐ >1 week after

How long did the problem last?

☐ < 1 day
☐ 1-3 days
☐ 4-7 days
☐ >1 week

How did the problem affect you? (Did this problem...)

☐ Not affected
☐ Cause you worry/discomfort
☐ Affect your sleep
☐ Affect your leisure activities
☐ Affect your physical activities
☐ Affect your ability to get out of bed, go to the bathroom, get dressed, or feed yourself (ADLs)
☐ Affect your affect your ability to do chores like food shopping, cooking, cleaning the house, or paying bills (IADLs)
☐ Other

Specify which ADLs

_____

Other

_____

How much did this problem bother you (or participant) (on a scale from 1 to 10, 1 "did not bother me," 10 "bothered me a great deal")

_____

How much did this problem limit your activities?

- ☐ Not at all
- ☐ Very little
- ☐ Somewhat
- ☐ Quite a lot
- ☐ Could not do usual activities

How many more days did you miss work because of this problem?

_____

Did you have any out of pocket costs (i.e., medication, private help, equipment) because of this problem?

_____

How many more days did your caregiver miss work because of this problem?

_____

Additional days caregiver needed to care for you because of this problem

_____

Did you seek medical attention?

- ☐ No
- ☐ Additional Clinic visit
- ☐ Lab test
- ☐ Emergency room visit
- ☐ Hospitalization
- ☐ Other

Was the clinic visit scheduled or unscheduled?

- ☐ Scheduled
- ☐ Unscheduled

Other

_____

How long after problem started did you seek medical attention?

_____

What do you and your doctors think the cause of this problem was?

- ☐ Medication
- ☐ Complication of a procedure
- ☐ Problem with diagnosis
- ☐ Treatment didn't work
- ☐ Hospital-related infection
- ☐ Unable to follow discharge instructions
- ☐ Medical condition getting worse
- ☐ Other

Other

_____

Which medications?

Why do you or your doctors think the problem was medication related?

- ☐ Doctor told me
- ☐ Pharmacist told me
- ☐ Other health professional told me
- ☐ Media (TV, radio, newspaper)
- ☐ Package insert
- ☐ Associated with every dose
- ☐ Associated with starting or increasing dose of med
- ☐ Similar problem in the past to same/similar med
- ☐ Discharge instructions
- ☐ Other

Other

_____

Why did you or your doctor think that was the cause?

_____

Did you or your doctors do anything about this problem?

_____

If medication related

- ☐ Continued medication
- ☐ Treated symptom with a different medication
- ☐ Medication replaced or discontinued
- ☐ Dose changed
- ☐ Resumed medication
- ☐ Other
- ☐ Nothing

Other

_____

Why not?

_____

Did your problem improve with these actions?

- ☐ Yes
- ☐ No
- ☐ Don't know

Describe

Adverse Event Two ☐ Yes ☐ No

Etc.

During our intake interview you completed an additional consent form so that we can obtain relevant medical information if need be. May we contact this health care facility in order to obtain these medical records?

☐ Yes
☐ No

Contact Information of health care facility?

Patient Participation in the Discharge Plan

"I would like to ask you some questions about your communication with the doctors and nurses who took care of you when you were getting ready to leave the hospital a month ago"

	Always	Often	Sometimes	Rarely	Never	Declined or unsure
When you were getting ready to leave the hospital one month ago, how often did your care team use medical terminology that you did not understand?	☐	☐	☐	☐	☐	☐
How often did you feel confused about what was going on with your medical care because they did not explain things well?	☐	☐	☐	☐	☐	☐
How often did they give you enough time to say what you thought was important regarding your medical care?	☐	☐	☐	☐	☐	☐
How often did they listen carefully to what you had to say?	☐	☐	☐	☐	☐	☐
How often did you feel pressured by them to have a treatment you were not sure you wanted?	☐	☐	☐	☐	☐	☐
How often did they ask if you might have problems actually doing the recommended treatment (for example, taking the medication corretly or attending follow-up visits)?	☐	☐	☐	☐	☐	☐

Care Transitions Measure

Please tell me how much you agree with the following statements regarding your hospitalization at [Brigham and Women's Hospital/Massachusetts General Hospital] that ended on _____.

	Strongly agree	Agree	Disagree	Strongly disagree	Don't know/Don't remember/Not applicable
When I left the hospital, I understood what I was supposed to do to take care of myself.	☐	☐	☐	☐	☐

	Strongly agree	Agree	Disagree	Strongly disagree	Don't know or declined
After I left the hospital, I was able to take each of my medications correctly every day.	☐	☐	☐	☐	☐
After I left the hospital, I knew what danger signs to watch out for AND what to do if I had them.	☐	☐	☐	☐	☐
After I left the hospital, I knew how to contact my doctor if I needed to.	☐	☐	☐	☐	☐
After I left the hospital, I was able to get to my doctor's appointments or other tests.	☐	☐	☐	☐	☐
After I left the hospital, I was able to follow the diet they ordered for me.	☐	☐	☐	☐	☐
After I left the hospital, I had enough support from friends, family, or others to recover from my illness.	☐	☐	☐	☐	☐

SF-12 Health Survey (POST)

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

In the past week, how would you say your overall health is?

☐ Excellent
☐ Very good
☐ Good
☐ Fair
☐ Poor

The following questions are about activities you might do during a typical day. During the last week, did your health limit you in these activities? If so, how much?

	Limited a lot	Limited a little	Not limited
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐

Climbing several flights of stairs	☐	☐	☐

During the past week, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Accomplished less than you would like	☐	☐	☐	☐	☐
Were limited in the kind of work or other activities	☐	☐	☐	☐	☐

During the past week, how much of the time have you had any of the following problems with your work or other regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Accomplished less than you would like	☐	☐	☐	☐	☐
Did work or activities less carefully than usual	☐	☐	☐	☐	☐

During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ Not at all A
☐ little bit
☐ Moderately
☐ Quite a bit
☐ Extremely

These questions are about how you felt and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past week...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Have you felt calm and peaceful?	☐	☐	☐	☐	☐
Did you have a lot of energy?	☐	☐	☐	☐	☐
Have you felt downhearted and depressed?	☐	☐	☐	☐	☐

During the past week, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

☐ All of the time
☐ Most of the time
☐ Some of the time
☐ A little of the time
☐ None of the time

Ability to Carry Out Recovery Goals

When you were in the hospital, you said your most important goal for your recovery after leaving the hospital was (RA fill in):

During the past week, how much have you been able to accomplish that goal (those goals)?

- ☐ Not at all A
- ☐ little bit
- ☐ Moderately
- ☐ Quite a bit
- ☐ Completely

Goal 2 (RA fill in):

During the past week, how much were you able to accomplish that goal?

- ☐ Not at all A
- ☐ little bit
- ☐ Moderately
- ☐ Quite a bit
- ☐ Completely

Goal 3 (RA fill in):

During the past week, how much have you been able to accomplish that goal (those goals)?

- ☐ Not at all A
- ☐ little bit
- ☐ Moderately
- ☐ Quite a bit
- ☐ Completely

While you were in the hospital, did anyone besides me ask you what your most important goal was for your recovery?

- ☐ Yes
- ☐ No
- ☐ Don't Know/Unsure

Did your discharge instructions address this goal adequately?

- ☐ Not at all A
- ☐ little bit
- ☐ Moderately
- ☐ Quite a bit
- ☐ Completely

To what degree do you think you and your care team shared the same health concerns for your recovery period?

- ☐ very high
- ☐ high
- ☐ moderate
- ☐ low
- ☐ don't know
- ☐ refused

To what degree do you think your care team proposed treatment plans for your recovery period that were acceptable to you?

- ☐ very high
- ☐ high
- ☐ moderate
- ☐ low
- ☐ don't know
- ☐ refused

To what degree do you think you and your care team shared the same desired health outcomes for your recovery period?

- ☐ very high
- ☐ high
- ☐ moderate
- ☐ low
- ☐ don't know
- ☐ refused

Patient appropriate for continued conversations?

- ☐ Yes

PCORI Chart Review Form

PCORI Study ID:_____ Reviewer Initials: _____

Admit Date:_____ Discharge Date: _____

Were any outpatient records available? Yes:____No:____(if no, then done)

Review of Hospital DC Summary:

- Pending labs/diagnostics:_____
- Anticipated follow-up labs/plans:_____

<u>Follow-Up and Health Care Utilization</u>

Did the patient see PCP within 30 days after discharge? Yes:____No: ____

- If yes:
  - Name of Provider/Clinic: _____ Date Seen: _____
  - Reason for Visit? Follow-up:_____Other:_____(specify)
  - Notes/Comments: _____

  - Name/Clinic #2: _____ Date Seen: _____
  - Reason for Visit? Follow-up:_____Other:_____(specify)
    Notes/Comments: _____

Did the patient see other providers since discharge? Yes:____No: ____

- If yes:
  - Name/Clinic #1: _____ Date Seen: _____
  - Reason for Visit? Follow-up:_____Other:_____(specify)
  - Notes/Comments: _____

  - Name/Clinic #2: _____ Date Seen: _____
  - Reason for Visit? Follow-up:_____Other:_____(specify)
  - Notes/Comments: _____

Was the patient ordered for home care services after returning home (VNA, PT, OT, elder care, etc.)?

Yes:____No:____Don't Know: ___

- If yes:
  - Which Services? _____
  - What company? _____
  - How often were they scheduled to visit? _____

Did the patient visit the emergency department within 30 days after discharge? Yes:____No: ____

- If yes:
  - When? _____
  - Where? _____
  - Why did the patient go? _____
  - How was the decision made for the patient to go? _____
  - What was done for the patient there? _____
  - Was the patient admitted? Yes:____No:____(if yes, check to see if this was recorded in database/interview conducted/will be sent for adjudication)

AE Screen

New or Worsening Symptoms? Based on provider notes or ED visits

- Problems with sleep Yes:____No:____*(on each)*
- Change in mood
- GI problems like nausea, vomiting, diarrhea, constipation, stomach pain, loss of appetite
- Dizziness, lightheadedness, or fainting
- Headaches
- Fatigue or weakness
- Muscle or joint aches
- Falls, injuries, or trouble with balance
- Problems urinating or with sexual function
- Skin rash, redness, pain, or itching
- Cough
- Shortness of breath
- Chest pain
- Swollen legs
- Bleeding
- Infection, fever
- Complication from surgery or procedure patient had in hospital
- Problem diagnosing or treating medical problem patient had while in the hospital
- Anything else

New or worsening symptom #1 *(up to 5 drop downs)*: _____

Describe the problem(s): _____

_____

When did the problem start or get worse:

- While in the hospital

- Day of discharge
- 1-3 days after
- 4-7 days after
- >1 week after

Additional comments about duration, severity, how patient was affected, etc.:

_____ _____

_____

Did the patient seek medical attention? Yes:____No: ___

- If yes, what kind?_____
- How long after the problem started did the patient seek medical attention? _____
- Did healthcare provider(s) indicate the cause of the symptom/problem? Yes:____No:___
- If yes, describe _____

Did healthcare provider or patient do anything about the symptom/problem? Yes:____No: ___

- If yes, describe: _____
- Did symptom/problem improve with these actions? Yes:____No:___
- Describe: _____

Notes/Comments: _____

<u>New significant labs? Review chem 7, general chemistries, LFTs, CBC, coags in the 30 days after discharge</u>

Significant lab abnormalities:

- **Any INR greater than 6:** Yes:____No: ___
  - Value(s): _____ Date(s)**:**_____*(4 drop downs each lab)*
- **Any Potassium less than 3 mEq/L:** Yes:____No: ___
  - Value(s): _____ Date(s)**:**_____
- **Any Potassium greater than 6 mEq/L:** Yes:____No: ___
  - Value(s): _____ Date(s)**:**_____
- **Any Glucose less than or equal to 40 mg/mL:** Yes:____No: ___
  - Value(s): _____ Date(s)**:**_____
- **Creatinine 50% increase from discharge value:** Yes:____No: ___
  - Value(s): _____ Date(s)**:**_____
- **PLT (platelets) less than 12,000:** Yes:____No: ___
  - Value(s): _____ Date(s)**:**_____
- **Elevation in SGOT(ALT) to >=3 times upper limit of normal:** Yes:____No: ___
  - Value(s): _____ Date(s)**:**_____
- **Elevation in CK to >=3 times upper limit of normal:** Yes:____No: ___
  - Value(s): _____ Date(s)**:**_____

Did the patient have a subsequent health care encounter? Yes:____No: ____

- If yes, what kind?_____
- Did healthcare provider(s) indicate the cause of the lab abnormality? Yes:____No:____
- If yes, describe _____

Did healthcare provider or patient do anything about the lab abnormality? Yes:____No: ____

- If yes, describe: _____
- Did the lab abnormality improve with these actions? Yes:____No:____
- Describe: _____

Notes/Comments: _____

NAE_____ PAE _____

Additional comments:

_____
_____
_____
_____
_____

PCORI Adverse Event Adjudication

Record ID _____

PCORI ID: _____

Adverse event description: _____

Adjudicators:

☐ Andrew Synn
☐ Ranga Papanna
☐ Kiran Gupta
☐ Amy Baughman
☐ Neil Shah
☐ Stephanie Mueller
☐ Marine Lipartia
☐ Nancy Wei
☐ Touqir Zahra
☐ Steven Knuesel

AE number:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13
☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ No AEs for this patient

Was this a clearly unavoidable adverse event?

☐ Yes
☐ No

What were the additional healthcare utilization consequences (indicate all that apply)?

☐ None
☐ Telephone contact with MD
☐ Visit to a physician's office
☐ Visit to a health facility for laboratory or radiology testing
☐ Visit to an ER
☐ Readmission to hospital

What were the functional consequences?

☐ Signs/symptoms only
☐ Mild effects on ADLs
☐ Major effects on ADLs
☐ Death

Please rate the duration of the injury:

☐ Up to 1 day of symptoms
☐ 1-3 days of symptoms
☐ 4-7 days of symptoms
☐ > 1 week of symptoms

Please rate the severity of the injury (see below):

☐ Significant (e.g., rash, diarrhea due to antibiotics, nausea due to PO KCl)
☐ Serious (e.g., GI bleed, delirium due to medications, ARF due to gentamycin)
☐ Life-threatening (e.g., respiratory failure requiring intubation, anaphylaxis)
☐ Fatal

Does this event meet the FDA definition of a "serious" event?

☐ Yes ☐ No

Clinical findings associated with the event:
[please note if patient-reported symptoms or MD-confirmed signs and lab abnormalities]

	Patient Report	MD Report / Objective Evidence
Anorexia	☐	☐
Anticholinergic	☐	☐
Cardiovascular	☐	☐
Dermatologic/allergic	☐	☐
Electrolytes/fluid balance	☐	☐
Fall	☐	☐
Functional decline	☐	☐
Gait problems	☐	☐
Gastrointestinal	☐	☐
Hemorrhagic	☐	☐
Hepatic	☐	☐
Infection	☐	☐
Metabolism/endocrine	☐	☐
Neuropsychiatric	☐	☐
Renal	☐	☐
Respiratory	☐	☐
Syncope/dizziness	☐	☐
Other	☐	☐

please describe:

_____

What level of confidence do you have that the injury relates to health care management (as opposed to the patient's underlying health condition)? In other words, confidence that this is an adverse event:

☐ No evidence for causation
☐ Slight evidence for causation
☐ Causation less than 50-50 but close call
☐ Causation more than 50-50 but close call
☐ Strong evidence for causation
☐ Virtually certain evidence for causation

Could there be a drug implicated with this adverse reaction? If no, please jump to "Was the adverse event due to another cause (an adverse event but not an ADE)" ☐ Yes ☐ No

Name and Category of Drug Implicated in Adverse Event

If more than one drug but only one event, use the drug most likely to have caused the event; if more than one event, please fill out one record per event.

Attribution: Modified Naranjo Algorithm to help determine whether AE due to medication

Are there previous conclusive reports of this reaction?

☐ Common ☐ Rare ☐ Don't know ☐ No

Did the adverse event appear after the suspected drug was administered?

☐ Good timing ☐ Fair timing ☐ Don't know ☐ No

Did the adverse reaction improve when the drug was discontinued or a specific antagonist administered?

☐ Yes ☐ Maybe ☐ Don't know ☐ No

Are there alternative causes (other than drug) that could, on their own, have caused the reaction?

☐ No ☐ Unlikely ☐ Don't know ☐ Likely

Was the reaction more severe when the dose was increased or less severe when the dose was decreased?

☐ Yes ☐ Maybe ☐ Don't know ☐ No

Did a physician think that the suspected drug was responsible?

☐ Yes ☐ Maybe ☐ Don't know ☐ No

Did the patient have a previous reaction to this drug or another drug in this class?

☐ Yes ☐ Maybe ☐ Don't know ☐ No

Total score: _____

What level of confidence do you have that the injury relates to medication use (ie., this is an ADE)?

☐ No evidence for causation
☐ Slight evidence for causation
☐ Causation less than 50-50 but close call
☐ Causation more than 50-50 but close call
☐ Strong evidence for causation
☐ Virtually certain evidence for causation

Name of drug: _____

Categories of drug involved:

☐ Analgesics (non-narcotic)
☐ Anti-Alzheimer
☐ Anti-coagulants
☐ Anti-depressants
☐ Anti-epileptic
☐ Anti-histamine
☐ Anti-hyperlipidemic
☐ Anti-infectives
☐ Anti-neoplastics
☐ Anti-Parkinsonian
☐ Anti-psychotics
☐ Cardiovascular (excluding diuretics)
☐ Gastrointestinal
☐ Gout
☐ Hypoglycemics
☐ Muscle relaxants
☐ Nutrients (herbs, vitamins, and supplements)
☐ Ophthalmic
☐ Opioids
☐ Osteoporosis
☐ Respiratory
☐ Sedative/hypnotics
☐ Steroids
☐ Topical
☐ Other:

please describe: _____

Was the adverse event due to another cause (an adverse event but not an ADE):

☐ Hospital-acquired infection
☐ Procedure complication
☐ Surgical complication
☐ Diagnostic error
☐ Management error

Was the adverse event preventable?

☐ Definitely preventable
☐ Probably preventable
☐ Probably not preventable
☐ Definitely not preventable

How would this event have been prevented?

If the event was not preventable, was the adverse event ameliorable?

☐ Definitely ameliorable
☐ Probably ameliorable
☐ Probably not ameliorable
☐ Definitely not ameliorable

Ameliorable in... ☐ Severity ☐ Duration ☐ Both

How could this event have been ameliorated?

Were the medical records related to this event available for adjudication?

☐ Yes ☐ No

Any other comments?

READMISSION REVIEW PACKET

Apply patient ID card stamp or sticker here

Patient's Name: _____ _____

Last pt_name_last First pt_name_first

Patient MRN: _____

pt_mrn_num

Patient Encounter Number: _____

Patient perspectives on reasons for readmission

My name is <<>> and I am working with a team which is trying to understand why patients come back to the hospital after they go home. I'd like to ask you some questions about how things went after your last hospitalization, and what ideas you have about how things might have gone better.

Who was interviewed? Patient: ☐ Caregiver: ☐ Both: ☐

1. Did you have a follow-up appointment scheduled for a date ***before*** you came back to the hospital? YES ☐ 1 NO ☐ 2

2. Were you able to attend your scheduled visit before you came back to the hospital? YES ☐ 1 NO ☐ 2 NO VISIT SCHEDULED ☐ 2

"Now, I would like to ask you some questions about your communication with the doctors and nurses who took care of you when you were getting ready to leave the hospital last time."

3. When you were getting ready to leave the hospital last time, how often did your care team use medical words that you did not understand?
☐ Always ☐ Often ☐ Sometimes ☐ Rarely ☐ Never ☐ Don't know or declined

4. How often did you feel confused about what was going on with your medical care because your care team did not explain things well?
☐ Always ☐ Often ☐ Sometimes ☐ Rarely ☐ Never ☐ Don't know or declined

5. How often did your care team give you enough time to say what you thought was important?
☐ Always ☐ Often ☐ Sometimes ☐ Rarely ☐ Never ☐ Don't know or declined

6. How often did your care team listen carefully to what you had to say?
☐ Always ☐ Often ☐ Sometimes ☐ Rarely ☐ Never ☐ Don't know or declined

7. How often did you feel pressured by your care team to have a treatment you were not sure you wanted?
☐ Always ☐ Often ☐ Sometimes ☐ Rarely ☐ Never ☐ Don't know or declined

8. How often did your care team ask if you might have problems actually doing the recommended treatment (for example, taking your medications correctly)?
☐ Always ☐ Often ☐ Sometimes ☐ Rarely ☐ Never ☐ Don't know or declined

"Now, I'm going to read some statements about when you left the hospital last time and ask if you agree or disagree."

9. When I left the hospital, I understood what I was supposed to do to take care of myself.

❒ Strongly agree ❒ Agree ❒Disagree ❒ Strongly disagree ❒ Don't know or declined

"Next I would like to ask you about some problems that you might have faced after you left the hospital last time. I will read more statements, and ask if you agree or disagree."

10. "After I left the hospital, I was able to take each of my medications correctly every day."

❒ Strongly agree ❒ Agree ❒Disagree ❒ Strongly disagree ❒ Don't know or declined

11."After I left the hospital I knew what danger signs to watch out for AND what to do if I had them."

❒ Strongly agree ❒ Agree ❒Disagree ❒ Strongly disagree ❒ Don't know of declined

12. "After I left the hospital, I knew how to contact my doctor if I needed to."

❒ Strongly agree ❒ Agree ❒ Disagree ❒ Strongly disagree ❒ Don't know or declined

13."After I left the hospital I had transportation to get to my doctor's appointments or other tests."

❒ Strongly agree ❒ Agree ❒ Disagree ❒ Strongly disagree ❒ Don't know or declined

14. "After I left the hospital, I was able to follow the diet ordered for me."

❒ Strongly agree ❒ Agree ❒Disagree ❒ Strongly disagree ❒ Don't know or declined

15. "After I left the hospital, I had enough support from friends, family, or others to recover from my illness."

❒ Strongly agree ❒ Agree ❒ Disagree ❒ Strongly disagree ❒ Don't know or declined

16. "In your own words, can you tell us more about any problems or difficulties you've had getting better or staying healthy since you left the hospital last time?"

_____
_____
_____
_____
_____
_____
_____

17. “Is there anything you think might have helped you stay out of the hospital this time?”

_____
_____
_____
_____
_____
_____
_____

18. “Is there anything else you’d like to tell us about returning home after leaving the hospital last time?

_____
_____
_____
_____
_____
_____
_____
_____
_____

Admitting Physician Survey

(**Please note: This survey will also be administered to: 1) the patient's Primary Care Physician from the index hospitalization, 2) the discharging physician from the index hospitalization, and 3) the responsible outpatient clinician from the index hospitalization.)

Dear Reviewer,
Thank you for taking this survey and being a part of the PCORI study. Please refer to the email containing the link to this survey to remind you of the patient to whom it refers. Feel free to talk about the case with your own residents or the discharging case coordinator or social worker. If you have any questions about the survey, please do not hesitate to email us.

In your opinion, which of the following factors might have contributed to the readmission? (CHECK ALL THAT APPLY)

1. PATIENT UNDERSTANDING AND ABILITY TO SELF-MANAGE

☐ 1 Patient or caregiver lack of understanding of the post-discharge plan
☐ 2 Patient or caregiver inability to manage his/her medications
☐ 3 Patient or caregiver inability to manage his/her symptoms
☐ 4 Patient inability to otherwise care for him/herself or caregiver's inability to otherwise provide care
☐ 5 Insufficient or ineffective patient or caregiver education

2. CONTINUITY OF CARE AND PROVIDER COMMUNICATION

☐ 6 Insufficient communication with post-acute care providers re: post-discharge plan
☐ 7 Discharge summary unavailable in a timely manner
☐ 8 Discharge summary poorly written or with missing or erroneous information
☐ 10 Failure to obtain an appropriately timely follow-up appointment or follow-up studies
☐ 11 Inability of the patient to keep the follow-up appointment or follow-up studies
☐ 12 Insufficient monitoring of the patient's condition(s) after discharge

3. SOCIAL SUPPORTS

☐ 13 Inappropriate choice of discharge destination
☐ 14 Inadequate support for non-clinical issues (such as food, heat, transportation, or ability to afford medications)
☐ 15 Inadequate home services or equipment after discharge

4. PROBLEMS WITH INDEX (INITIAL) ADMISSION

☐ 16 Misdiagnosis made during the index admission
☐ 17 inappropriate/inadequate treatment of the patient during the index admission
☐ 18 Discharged from the hospital too soon after index admission
☐ 19 Absent, erroneous, or incomplete medication reconciliation
☐ 21 No or inadequate end of life or goals of care planning

5. PROBLEMS WITH TRIAGE AFTER INDEX (INITIAL) DISCHARGE

☐ 20 Patient inappropriately went/sent to ED or inappropriately readmitted from ED

How probable do you think each of these potential types of interventions might have been in

preventing this readmission?

6. More complete communication of information (e.g. tests or appointments to be completed after discharge)
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

7. Improved clarity, timeliness or availability of information provided at discharge
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

8. Improved self-management plan at discharge (e.g. patient-centered discharge instructions, transition coaches)
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

9. Provision of resources to manage/monitor care and symptoms after discharge (e.g. telephone monitoring of body weight)
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

10. Greater engagement of home and community supports (e.g. enlisting help of community agencies)
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50

❑ Strongly probable
❑ Nearly certain

11. Improved discharge planning (e.g. appointments scheduled in advance)
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

12. Improved coordination of care between inpatient and outpatient providers (e.g. shared medical records)
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

13. Improved attention to medication safety (e.g. medication reconciliation)
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

14. In addition to the previous categories, is there anything else you think contributed to this readmission?

15. Would you be surprised if the patient died within the next 6-12 months?
❑ Yes
❑ No

16. Please list all the people who helped fill out this form (e.g. Attending, Resident, Intern, Case Manager, etc):
_____
_____

Adjudicator review

Date of review: ____/____/ 20 ____		
Adjudicator name (last, first):		

	Readmitted from: □ home; □ shelter/street; □ clinic □ rehabilitation/SNF; □ hospice; □ chronic care hospital/nursing home;□ acute hospital; □ unable to determine; □ other: _____
Was the patient readmitted to (please check all that apply): ☐ Same service? ☐ Same team? ☐ Same nursing unit?	
Does this patient have a primary care or subspecialist relevant to the principal diagnosis from the index admission affiliated with this hospital?(e.g. Index admission for CHF? Does patient have an affiliated PCP or cardiologist?) □ YES; □ NO; □ unable to determine Did the patient have at least one appointment scheduled with this provider prior to being readmitted? □ YES; □ NO; □ unable to determine Did the patient attend this visit? □ YES; □ NO, readmission occurred prior to scheduled appointment; □ NO, other reasons.; □ unsure;□ N/A	

READMISSION

Based on all the information from medical record review and patient/caregiver/provider interviews, which of the following may have contributed to this readmission? Check all that apply (i.e. evidence for causation more than 50-50 but close call, strong evidence for causation, or virtually certain evidence for causation)

<u>Monitoring and Managing Symptoms after Discharge</u>

- ❒ Inappropriate choice of discharge location (e.g. SNF vs. Home)
- ❒ Inappropriately long time between discharge and first follow-up with outpatient provider(s)
- ❒ Patient was not able to keep post-discharge appointments

❒ Discharge without needed procedure
❒ Lack of disease monitoring (e.g., following daily weights, etc.)

Social and Community Supports
❒ Patient required additional or different home services than those included in discharge plans
❒ Patient was not able to access services at home (or turned them down after plans were made)
❒ Patient required additional help from patient's family, caregivers, friends that was not available or sufficient
❒ Patient required community programs (e.g., elder day programs, meals on wheels) not included in discharge plans
❒ Inpatient assessment of physical needs (e.g. commode, transportation) were incomplete or missed important patient requirements

Self-management instruction
❒ Patient lacked awareness of who to contact, when to go (or not go) to the ED
❒ Patient lacked awareness of follow-up appointments or other post-discharge plans
❒ Patient or family had difficulty managing symptoms at home
❒ Patient or family had difficulty managing other self-care activities at home

Continuity of Care
❒ Team did not ensure the patient had a PCP
❒ Follow-up appointments were not scheduled prior to discharge
❒ Follow-up appointments were not sufficiently soon after discharge
❒ Team did not relay important information to PCP or other outpatient providers re: tests that required follow-up, or important changes in care plan (e.g., transition to DNR status)
❒ Patient unable to be reached for post discharge care coordination (e.g. phone follow-up, calls to arrange appointments).
❒ Test result ordered by initial team was not followed up appropriately

End of life/advanced care planning
❒ Patient nearing end of life but still wants hospitalization and full treatment measures
❒ Patient receiving palliative or hospice care, but unable to manage symptoms
❒ Patient with end-stage illness but palliative care not consulted
❒ Patient with end-stage illness and goals of care discussion not documented

Diagnostic or therapeutic problems
❒ Missed diagnosis during the index admission
❒ Inadequate treatment of medical conditions during the index admission (other than Pain)
❒ Inadequate treatment of pain during index admission
❒ Patient discharged too soon from index hospitalization

Decision-Making Concerning readmission
❒ Patient inappropriately sent from sub-acute facility to ED
❒ Patient inappropriately told to come to ED from home
❒ ED inappropriately decided to admit patient

Medication problem or adverse drug event
❒ Errors in taking the preadmission medication history during the index admission

❒ Errors in discharge orders
❒ Drug-drug or drug-disease interaction
❒ Patient/caregiver misunderstanding of the discharge medication regimens (including changes from preadmission regimen, indications, directions, and potential side-effects
❒ Patient/caregiver inability to manage medications at home/Inadequate drug level monitoring
❒ Inadequate monitoring for side effects or non-adherence
❒ Inadequate steps to ensure patient could afford medications (e.g., non-formulary drug, no prior authorization)

Use this space to fill in up to 5 other potential contributing causes for the READMISSION (include social, psychological, and medical reasons):

1.
2.
3.
4.
5.

PREVENTION
In your assessment, was this readmission preventable?
DEFINITION: A readmission that could have been avoided had reasonable assessment, treatment, monitoring, access, and services been put in place and appropriate systems been available to support the patient's care transition.

a. No evidence for preventability
b. Slight evidence for preventability
c. Preventability less than 50-50 but close call
d. Preventability more than 50-50 but close call
e. Strong evidence for preventability
f. Virtually certain evidence for preventability

In your assessment, where would the intervention(s) to prevent the readmission been most effective?

a. In the hospital prior to index discharge
b. Home
c. Usual provider's clinic
d. Emergency Department
e. Other: _____

How probable do you think each of these potential types of interventions might have been in preventing this readmission?

More complete communication of information (e.g., improved discharge documentation)?
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable

❑ Nearly certain

Improved clarity, timeliness or availability of information provided at discharge (e.g., timely communication with
post-discharge providers)?
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

Improved self-management plan at discharge (e.g., discharge coach, discharge information in the patient's own
language, increased engagement of patient/caregiver to ensure understanding of the discharge plan)?
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

Provision of resources to manage care and symptoms after discharge (e.g., follow-up phone call, nurse home visit,
intensive disease management system, post-discharge ongoing case management, access to index hospital team for
questions/concerns after discharge)?
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

Greater engagement of home and community supports (e.g., non-clinical social support assistance such as adult
daycare, meals on wheels)?
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

Improved discharge planning (e.g., faster follow-up with ambulatory providers, appointments made at times patient
could attend)?
❑ No probability

❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

Improved coordination between inpatient and outpatient providers (e.g., with primary care office, shared medical
records, communication that includes all team members, provider continuity)?
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

Improved attention to medication safety (e.g., medication list with pictures, filling prescriptions prior to discharge or
having them delivered to home, improved medication reconciliation)?
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

Financial, insurance, or transportation assistance?
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

Improved MD or care team recognition of or attention to patient symptoms (such as pain, dyspnea, depression,
anxiety)?
❑ No probability
❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

Improved advanced care planning (e.g. establishment of health care proxy, discussion of goals of care, palliative
care consultation, hospice services)?
❑ No probability

❑ Slightly probable
❑ Slightly less than 50-50
❑ Slightly more than 50-50
❑ Strongly probable
❑ Nearly certain

Please list all the people who helped fill out this form (e.g. Attending, Resident, Intern, Case Manager, etc):

_____
_____
_____
_____
_____
_____
_____

Additional comments:

_____
_____
_____
_____
_____
_____

VERBAL CONSENT

Hello, my name is Nyryan Nolido and I am a Project Manager at the Brigham and Women's Hospital for the PCORI Transitions Project you were participating in.

Dr. Jeffrey Schnipper is the researcher in charge of this study.

I'd like to ask you to participate in a patient focus group for the PCORI Transitions Project. The focus group will be conducted by the Executive Director of the Center for Patients and Families at the Brigham and Women's Hospital and members of our Patient Family Advisory Council.

We are asking you to join this focus group because you recently received the intervention piece of the PCORI Transitions Project and are at least 30-days out from discharge.

If you agree to be in this focus group, we will ask you to come to the Brigham and Women's Hospital for a 90 minute focus group. The purpose of this focus group is to get your impressions of the extra services you received so that we can improve the program for future patients. You will be joined by about 5 other patients who were in the study and 3 members of our patient-family advisory council. We will keep all of your information confidential. You will be compensated $100 for your time and your parking fee will be covered.

Being in this focus group is optional, and you can tell me if you want to stop being in the study at any time.

Do you have any questions about the focus group or the study?

Would you like to participate?

If you have questions about this study in the future, you can contact Nyryan Nolido at 617-525-6653. If you have questions or concerns about your rights as a research participant, you can call the Partners Human Research Committee office at 617-424-4100.

INFORMATION SHEET:

We are asking you to take part in a patient focus group for the PCORI Intervention being done by Dr. Jeffrey Schnipper at the Brigham and Women's Hospital.

We are holding a focus group to learn about your experience with the PCORI Transitions Project and how we can further improve both the project and transitions of care here at the Brigham and Women's Hospital. The focus group will last about 90 minutes.

You can skip questions that you do not want to answer or leave the group at any time.

We will keep the data we collect confidential, and we will not share your personal information with anyone outside the research team.

We will ask you and the other people in the group to use only first names during the focus group. Please do not to tell anyone outside the group what any particular person said. However, we cannot guarantee that each participant will keep the discussions private.

Being in this focus group is optional.

Questions? Please contact Nyryan Nolido at 617-525-6653. If you have questions or concerns about your rights as a research participant, you can call the Partners Human Research Committee office at 617-424-4100.

Draft Semi-structured interview guide for patients meeting with PFAC re: PCORI Transitions Study

I'm Maureen Fagan, and I'm the Executive Director for the Center for Patients and Families at Brigham and Women's Hospital. It's been my job to help connect patient and family advisors with this PCORI Transitions of care study. There are 3 advisors here today (all 3 should introduce themselves). They are patients and caregivers at Brigham and Women's Hospital or Mass General Hospital - just like you. They have been asked to help give feedback on this study and will be helping us ask questions. You're here because we want your impressions of the extra services you might have received because you were part of this study. This is a "focus group," where people with similar experiences can get tell others their thoughts, feelings, and opinions and can bounce ideas off each other so that others can learn from them. In this case, we want to know what you thought of these extra services. We want your honest answers so that we can make this project as successful as possible – we want to improve the quality of the transition from hospital to home, so patients do as well as possible after discharge. Please don't just tell us what you think we want to hear – just tell us how you felt – there are no right or wrong answers.

For the caregivers in the room, when we say "you," that sometimes means the patient, but often it includes you as well. We want to know if the services involved both the patient and you as a member of the care team.

Let's go around the room and introduce ourselves (first names only are fine). Please let us know whether you were a patient or a caregiver and which hospital you were admitted to.

On the handout in front of you is a list of the different extra services you might have received as part of the PCORI Transitions Project. We'd like to evaluate how helpful these services were to you. Some or all of these extra services may have been offered to you, and you had the choice of accepting or declining these services.

Some of the extra services you might have been offered included the following:

1. A nurse in the hospital talking to you more about what it would be like during your recovery period
2. A pharmacist talking with you about your medications while you were still in the hospital
3. A home visit by a visiting nurse from Partners Healthcare at Home
4. A phone call from a nurse from your primary care practice a couple of days after returning home
5. A home visit by a pharmacist as part of the "Partners Healthy Transitions Program"

Please note that is likely that you did not receive all of these services. Sometimes, providers were not available to give them. Sometimes, you may not have been eligible to receive some of these services. Please don't worry about that – we want to know your opinions of the services you were offered.

1) **First I'd like to ask you about the transitions care team. There were likely several providers who gave you extra services. Please tell us** who gave you these extra services.
   What did you think of the way they provided these services?

Probes:

Did you feel that (team member identified) understood your care plan?

Did (TM) understand what would be the best care plan for you?

Did (TM) understand what type of care plan you wanted?

Did they respect your privacy? Did anyone make you feel uncomfortable?

Did you feel that everyone was working with you on your care plan?

If you were admitted to a specialty service (like surgery, cardiology, or oncology) and were contacted after discharge, would you have preferred to have been contacted by your PCP's office or the specialists' office? Why?

[For caregivers]: did you feel like you were treated as a valued member of the care team? Did they include you in the after-hospital care plan?

[Note: if possible, help participants distinguish between those providers who gave the extra services and the providers on their usual care team]

2) **How was your experience in the hospital and returning home?**

How was it different than in the past?

Probes:

How was your experience being discharged?

How was your experience after returning home?

Please tell me which extra services were offered to you.

Were the goals of these extra services explained to you?

Please tell me what some of these goals were.

3) **Let's start with the services that you accepted.**

Which did you accept? Why? What did you think of them?

Probes:

Which were helpful? How so?

Which were not helpful? How so?

Please explain if the services felt coordinated.

How did they change the way you took care of yourself after going home?

Did they give you confidence you could take care of yourself after going home? How so?

4) **Which services did you decline? Why?**

5) **Overall, which services would you say were the MOST helpful?**

Probes:

Would you want to have these kinds of services again?

Which ones? Why? Why not?

6) **Now I'd like to ask you about your impressions of the PCORI transitions program in general. (Asked by Advisors)**

Probes:

Please tell me if the services offered fit the issues that you needed help with.

Were there issues that were not addressed but you feel should have been?

What did you think about the time spent on these services?

Were they delivered at a useful time during your recovery period?

Were there services that you didn't receive but you wish you did receive?

Would you recommend this program to others?

7) **How could we make this program better? (Asked by the PCORI advisors):**

Probes:

Please tell me about any improvements that we could make to any of the services.

Any services we need to add?

Services that you think we don't need to offer?

8) **As you know, coordination of care among care team members, and with the patient and family, is important to the success of programs like this one.**

From your experiences, what recommendations could you make for improving the coordination of services?

Probes:

How could we involve caregivers more?

9) **When describing this program to friends and family, how would you explain it?**

Probes:

How would you describe what the program is about or the kinds of services you received?

How would you describe the possible benefits of being in such a program?

How would you describe the possible drawbacks of being in such a program?

(Provide an example if they are having trouble with this)

10) **Is there anything else we should know about this program and your impressions?**

Thank you so much for participating in the study and in this focus group. We won't be contacting you again, but we hope to publish the results and then get the messages from this study out the public, so hopefully you'll be hearing more about this study in the future. Thank you again!