PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR
Jeffrey L. Schnipper, MD, MPH

PROTOCOL TITLE
Promoting Safer Transitions: A collaboration between the Hospital and the Patient-Centered Medical Home

FUNDING
National Patient Safety Foundation (pending)

VERSION DATE
August 10, 2012

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

The objective of this study is to: develop and implement a multi-faceted, multi-disciplinary discharge intervention with contributions from hospital and Patient-Centered Medical Home (PCMH) personnel; evaluate patients readmitted within 30 days despite receipt of this intervention; develop a risk stratification algorithm; and determine how these readmissions might have been prevented through modification of the discharge intervention.

Hypothesis: An intensive, multi-faceted discharge intervention can be developed, implemented, and refined to reduce hospital readmissions.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

An estimated 20% of patients suffer an adverse event within 30 days of discharge. Approximately two-thirds of these events may be preventable or ameliorable. Systems changes to improve patient safety during these transitions include better communication of unresolved problems at discharge, patient education regarding medications and other therapies, and monitoring of drug therapies and overall condition after discharge. Numerous interventions have been implemented and evaluated to improve the discharge process. Such interventions have received increased attention lately as the focus of health care reform efforts has shifted to increasing value (e.g., by decreasing hospital readmissions and their associated costs). We see this development as an opportunity to promote patient safety during transitions in care regardless of the economic arguments, although reducing readmissions is clearly a "win" for all stakeholders as they are not only costly but often represent serious adverse events.

One promising development in health care reform efforts is the advent of the PCMH, consisting of patient-oriented, comprehensive team-based care enhanced by health information technology and population-based disease management tools. Like hospitals, PCMH clinics are focused on improving care transitions and have a vested interest in improving the discharge process and preventing readmissions. Very few care transitions

initiatives have taken advantage of this alignment of incentives to date; moreover, it is likely that collaboration between hospital and PCMH personnel can improve their efficacy:

1. When both inpatient providers and PCPs within PCMHs are similarly motivated, optimal communication and joint collaboration of a discharge plan is more likely to be realized.
2. PCMH personnel may be more able than other PCPs to see the patient in the hospital and shortly after discharge, thus improving continuity of care.

As this model becomes more common over time, it is important to better understand how interventions that include both hospital and PCMH personnel may promote safe transitions for patients. The methods proposed here will allow an efficient but in-depth analysis of where this type of intervention falls short and how to improve it going forward. This study is well aligned with the NPSF goal of improving patient safety across the continuum of care.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

Overview:

Brigham and Women's Hospital (BWH) will collaborate with a newly designed PCMH, the Brigham and Women's South Huntington Practice (SHP). This is an observational study in the sense that all enrolled subjects will receive the intervention. The data collected will be used to refine the intervention and high-risk patient selection criteria. The data will also be used to inform others about how to design similar interventions. We estimate that 85% of eligible patients will choose to participate, or approximately 300 patients enrolled study-wide and at BWH during the 6-month study period. Part 2: While we pursue funding for the full study described throughout this protocol, we plan to do approximately 2 months of pilot data collection for the purpose of testing our risk stratification and readmission review tools in the absence of the intervention. Full rationale for this pilot data collection is explained in the amendment form submitted. In short, we will be testing novel self-reported patient and clinical team risk stratification tools. The full intervention will not be deployed until we collect baseline data from patients during these two months.

Inclusion Criteria:

Adult inpatients at Brigham and Women's Hospital on the medicine services with an SHP PCP.

Exclusion Criteria:

1. Discharge to a location other than home (or to a caregiver's home)
2. Patient does not administer own medications and absence of a caregiver who lives with patient and administers all medications
3. Police custody
4. No telephone or homeless
5. Previous enrolment in the study
6. Patient unable to communicate in either English or Spanish

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

Risk stratification refinement
For approximately 2 months, pilot data will be collected ("Part 2") without implementing the intervention in order to refine risk stratification and readmission review tools.

Intervention development and refinement of data collection tools:
For approximately 2 months, BWH will collaborate with SHP to develop the intervention and refine the data collection tools.

Implementing the Intervention:
The proposed intervention will combine elements of other successful care transitions initiatives, including several medication safety interventions evaluated by these investigators. The focus will be on efficient use of resources, risk stratification, optimizing communication between inpatient and outpatient teams, and implementing those interventions most likely to reduce serious adverse events:

1. Risk stratification: based on the medical literature and internal data, we will derive a risk-stratification tool focused on factors that predict benefit from specific discharge interventions (such as enhanced medication reconciliation). Whenever possible, factors will be abstracted automatically from hospital information systems, with additional data abstracted from the medical record by a nurse from SHP. Those patients determined to be at high risk will receive the intervention (see 2-5). Those determined to be at low risk will be screened for potential post-discharge problems and will receive selected intervention components as needed.
2. Inpatient medication safety interventions: an inpatient BWH pharmacist will conduct enhanced medication reconciliation, patient counseling, and development of an illustrated pill card similar to that used in the PILL-CVD study.10
3. Inpatient "discharge advocate": based on the role from Project RED, a nurse from SHP will facilitate: a) communication between the inpatient and primary care teams to jointly create a discharge plan; b) scheduling of follow-up appointments and tests within an appropriate time frame; c) creation of an After Hospital Care Plan, including a calendar with all follow-up appointments, danger signs to watch for, and behaviors to be done at home; and d) patient education using the AHCP as a guide.
4. Visiting nurse (VNA) appointments. Partners Healthcare at Home will provide VNA services to qualifying patients in the week after discharge. Unlike routine VNA visits, these will include a structured template to ensure that patients are fully evaluated for their ability to manage their conditions at home. Visiting nurses will have the contact information of the inpatient and primary care teams and will be encouraged to contact either with questions. They will write structured notes within the ambulatory EMR used by SHP.
5. A multi-disciplinary post-discharge SHP clinic visit within 72 hours of discharge. Working as a team, the nurse discharge advocate, clinic pharmacist, SHP social worker, and PCP will evaluate the patient's progress along the plan of care, ensure medication safety, and provide "coaching" so that the patient can manage their conditions at home and effectively interact with the health care system.

Primary outcome: Total and preventable readmissions to BWH within 30 days of discharge.

Secondary outcomes:

1. Serious preventable or ameliorable adverse events within 30 days of discharge as determined through medical records of readmitted patients
2. Interventions deemed most likely to have prevented the readmissions
3. Risk factors for readmission among those readmitted patients originally deemed to be low-risk

4. Readmission risk prediction sources (patient, inpatient MDs, PCP, outpatient nurse care coordinator, or risk prediction algorithm) deemed to most accurately predict risk.

Data Sources

Outcomes will be derived from several data sources:

1. Based on previous studies and on a tool already developed by HOMERUN (Hospital Medicine Reengineering Network), we will identify study patients currently hospitalized with a readmission. A trained research assistant (RA) will interview the patient and family to identify possible reasons for the readmission. The RA will also email a survey to the teams that cared for the patient during the original admission and the readmission and the patient's PCP. A physician co-investigator will then review this information and the medical record and complete an instrument to determine the preventability of the readmission (including contributing factors), the presence of any adverse events, and possible interventions that might have prevented them.
2. Intake interview at the time of enrolment: this brief interview will allow us to gather information on covariates such as preadmission medication adherence and previous healthcare utilization outside of Partners Healthcare. Intake interview will also allow us to gather various sources' (patient's, inpatient MDs', PCP's, outpatient nurse care coordinator's) assessments of patients' risk of readmission. This will test these sources' risk prediction capacity and help determine their utility in risk stratification.
3. BWH hospital administrative data and Partners Clinical Data Repository: this will include data on patient demographics, billing data, preadmission medication data, healthcare utilization (BWH emergency department visits and hospital readmissions in the 30 days since discharge), and laboratory values

Outcomes:

Outcome	Data Source	When Collected	How Collected
Any Hospital Readmission within 30 days of discharge	BWH Hospital Admin. Data	30 days after discharge	Data analyst abstracts data from hospital systems
Any Serious preventable or ameliorable adverse events; preventable hospital readmissions	Patient/caregiver interview during readmission, survey to PCP and providers from both hospitalizations, chart review, adjudication instrument	During readmission	RA interviews patient and family and administers survey to teams that cared for the patient. Physician adjudicator reviews all the data collected and the medical record, completes ratings.
Interventions deemed most likely to have prevented the readmissions	Patient/caregiver interview during readmission, survey to PCP and providers from both hospitalizations, chart review, adjudication instrument	During readmission	RA interviews patient and family and administers survey to teams that cared for the patient. Physician adjudicator reviews all the data collected and the medical record, completes ratings.
Risk factors for readmission among those readmitted patients originally deemed to be low-risk	Patient/caregiver interview during readmission, hospital administrative data	During readmission	RA interviews patient and family; administrative data abstracted from hospital databases

Readmission risk prediction sources (patient, inpatient MDs, PCP, outpatient nurse care coordinator, or risk prediction algorithm) deemed to most accurately predict risk	Patient/caregiver interview and survey to inpatient MDs, PCP, and outpatient nurse care coordinator. Hospital administrative data.	During index admission.	RA interviews patient and family and administers survey to teams that cared for the patient; administrative data abstracted from hospital databases.'

Analysis:

All study patients will receive the intervention (except those involved exclusively during Part 2, pilot data collection).

Hospital readmissions within 30 days of discharge will be analyzed over time as the intervention is refined using Statistical Process Control methods (i.e., to distinguish "special cause variation" from "common cause variation" and demonstrate that refinements to the intervention are improving readmission rates beyond what we would be expected due to chance). Preventable readmissions and preventable or ameliorable post-dicharge adverse events will be analyzed in the same way.

Interventions deemed most likely to have prevented readmissions and risk factors for readmission among those originally deemed to be low-risk will be analyzed descriptively.

If readmitted patients had been deemed low risk, we will explore whether certain factors identified by our methods could have been used to identify these patients as high risk. This information can then be used to refine our risk stratification tool. If patients were high risk, we will compare the interventions received with the possible contributing factors to the readmission and interventions that might have prevented adverse events. This information can then be used to modify the intervention.

Timeline:

- ❒ Part 2, Pilot Data Collection: Sept-Oct 2012
- ❒ Intervention development: Dec 2012-Jan 2013
- ❒ Pilot testing: Feb 2013
- ❒ Patient enrolment: Mar 2013 – Aug 2013
- ❒ Follow-up and adjudication: Apr – Sept 2013
- ❒ Data Analysis and manuscript preparation: Oct-Nov 2013

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

All patients from the South Huntington practice admitted to BWH will receive the intervention as part of its commitment to improve care and reduce unnecessary health care utilization.

The Table below summarizes the differences between usual care (received by patients from other primary care practices) and the study intervention:

Intervention	**Usual Care**
Risk stratification	No standardized tailoring of interventions based on low or high risk assessment

Dedicated nurse discharge advocate from the PCMH to coordinate post-discharge plan and educate patients	Post-discharge plan at discretion of physicians, education mostly by nurses
Dedicated hospital pharmacists very involved in medication reconciliation and patient medication counseling	Pharmacists less involved, most of the process done by physicians and nurses
Standardized visiting nurse (VNA) intervention with open lines of communication	Visiting nurses at discretion of team, intervention not standardized
Post-discharge clinic 3 days post discharge: PCP, nurse practitioner, pharmacist, and social worker	No post-discharge clinic; timing of follow-up variable, at discretion of medical team

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

Participation in this project will not interfere with usual care during or after the patients' hospitalization in any way. There is a theoretical risk that PHI could become known to unauthorized persons, but we will take all steps necessary to protect PHI (see below). Throughout the study we will use procedures consistent with sound research design and which do not expose subjects to unnecessary risk. Patients can withdraw from the study at any time. Data monitoring will be conducted quarterly (see below).

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

This is a minimal risk study. Patients will receive access to a number of services designed to improve their care after discharge. We will monitor study results quarterly to ensure that adverse events (e.g., hospital readmission) are not occurring more commonly in the intervention group than comparable patients from other practices (an unlikely event given that our increased monitoring should make both these outcomes less common in the study subjects – see Data Safety and Monitoring below). Given the minimal risk to patients, our data safety and monitoring procedures, the relatively small sample size, and the need to enroll 300 patients to ensure our ability to evaluate outcomes, we do not plan on having drop criteria.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

There is a theoretical risk that PHI could become known to unauthorized persons, but we will take steps to minimize this risk (see below).

Patients may find it inconvenient to receive all the planned services after discharge, but they can refuse to participate in any component of the intervention or withdraw from the study at any time.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

Patients might benefit in terms of better self-management of their illnesses or diseases, better monitoring of their medical conditions, and fewer hospital readmissions. For example, we estimate that patients will have a decrease in their readmission rate from 25% to 12.5. If this intervention is successful, then we would likely expand the various services to a wider population of patients (at other primary care practices), most likely customizing the services to those who need them the most. The results of this study and future studies would be published and may influence other hospitals, quality improvement organizations, and possibly regulatory agencies. The long-term results would be improved care (and possibly reduced costs) of patients in the immediate post-discharge period.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

Women and minorities are fully represented in the eligibility criteria. Our goal is to enroll patients whose characteristics are representative of the entire population of eligible patients. In that way, the study population will be representative of the population that stands to potentially benefit from this research.

Children will not be eligible for this study for several reasons:

1. These interventions are focused on patients who generally care for themselves.
2. BWH does not care for children. The costs of expanding this study to include a pediatric hospital would be prohibitive.

In the future, we advocate that similar studies be conducted with pediatric patients.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

Spanish-speaking individuals will be included in the study, and we will provide bilingual services as part of the intervention in order to accommodate them. For this current study, we cannot enroll patients who speak neither English nor Spanish because of the lack of a complete set of services at BWH that would accommodate them. In future studies and interventions, we will strive for a complete set of services that accommodate all patients regardless of language. We recently completed the Pharmacist Intervention for Low Literacy in Cardiovascular Disease (PILL-CVD) study and feel confident that we can provide a full range of discharge services to Spanish-speaking patients, as was done in that study.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English

http://healthcare.partners.org/phsirb/nonengco.htm

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

Patient recruitment will be performed by a trained research assistant or medical student prior to the patient's discharge. Eligible subjects will be identified each morning using the BICS computer system. Only the "minimum necessary" amount of information will be gathered prior to patient consent in order to confirm patient eligibility. Before being approached by the research assistant or medical student, patients will be asked by a member of the medical team (i.e. primary nurse or resident) if it is acceptable for him to talk to the patient about the study. We feel that the nurse is an appropriate person to include in the process because he/she will be familiar with the patient's medical history and knows best if the patient is cognitively and physically able to give informed consent for participation in the study at that time. Patients and/or their proxies will then be approached by the research assistant or medical student and asked to participate in the study (see consent procedures, below). If a patient for whom a proxy provided initial consent regains capacity at the post discharge clinic, the study Discharge Advocate will review the consent form with the patient and will ask for the patient's written consent. If patients refused to provide consent at that time, then they will be withdrawn from the study. After informed consent is obtained, we will randomize the order in which eligible patients will be approached in order to avoid any bias in enrollment. We do not plan to use special methods to ensure sufficient enrollment of women and minorities, but if an interim analysis reveals that they are under-represented compared with expected for this patient population, we will over-sample women and minorities as needed.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

Remuneration will not be provided to subjects. We expect their out-of-pocket costs related to the intervention to be small.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
http://healthcare.partners.org/phsirb/recruit.htm

Guidelines for Advertisements for Recruiting Subjects
http://healthcare.partners.org/phsirb/advert.htm

Remuneration for Research Subjects
http://healthcare.partners.org/phsirb/remun.htm

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

Inpatients at BWH will be asked by a research assistant (RA) or medical student, on the day of admission (in their hospital rooms), to provide written informed consent and authorization to access limited protected health information. The RA or medical student will first identify potential subjects on their day of admission by scanning computer-based and paper records for patients admitted to BWH and with a SHP PCP. These records include the computerized sign-outs used by all medical residents, which contains principal diagnosis, medications, and the assessment and plan. The RA or medical student will perform a focused review of the hospital chart to verify other inclusion criteria and the absence of exclusion criteria. Details that cannot be verified from the chart, such as the presence of a caregiver who administers the patient's medications if the patient does not administer them him/herself, will be assessed directly with the patient through a short screening interview.

Patients will generally enroll at the time they are approached, but if patients need more time to consider participation, the RA or medical student will return later that day or the following day. The RA or medical student may also need to postpone the consent process if proxy consent is needed (in which case arrangements will be made for a mutually agreeable time).

It is possible that some patients will be under the care of Dr. Schnipper, the PI, who attends on the general medicine service at BWH 10 weeks a year. In that case, the RA or medical student will take special care to tell the patient that their decision to enroll will have no affect whatsoever on Dr. Schnipper's care (and whenever possible, Dr. Schnipper will not be aware of which patients have been approached or enrolled in the study).

This is a minimal risk study, so it is not required that the RA or medical student be a licensed physician.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
http://healthcare.partners.org/phsirb/newapp.htm#Newapp

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects
http://healthcare.partners.org/phsirb/infcons.htm

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping

rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

As noted, the PI and project manager will review emergency department visits, and hospital readmissions in the two arms of the study on a quarterly basis. Events among study subjects will be reviewed for possible attribution to the intervention. In the unlikely event that these events are more common than comparable patients in other practices (taking risk-adjustment into account) or directly attributable to the intervention, we will contact the PHS IRB and the National Patient Safety Foundation immediately and take further action as recommended. We did not plan strict stopping rules. Because potential risk to patients is minimal (i.e., this is an intervention focused on patient behavior and monitoring, without use of novel medications, devices, or procedures), we do not plan to employ a Data Safety Monitoring Board.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

The PI will report any adverse events associated with this project (e.g., based on patient complaints) annually to the Partners IRB as stated in the Adverse Event Reporting guidelines and also as described above under Data Safety/Monitoring.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

The PI and Project Manager will work together to ensure the validity and integrity of data collection and adherence to the IRB-approved protocol. The project manager will review all data collected from the study (from medical records or obtained by patient questionnaire) on a monthly basis, ensuring accuracy and completeness. She will also verify the presence of proper informed consent forms. The PI will personally train the RA in methods of

informed consent and data collection and personally observe the consent process and medical record abstraction process initially and quarterly.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
http://healthcare.partners.org/phsirb/datasafe.htm

Adverse Event Reporting Guidelines
http://healthcare.partners.org/phsirb/adverse_events.htm

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

All information from individuals or entities in the course of these studies that identifies an individual or entity will be treated as confidential in accordance with section 903c of the Public Health Service Act (42 U.S.C.299a-1). This will be done by keeping all personal identifiers in a separate location from the data, and only the research project manager, RA, and study investigators will have access to the linked data. All machine-readable files will be stored on-line with appropriate security measures (e.g., in a password-protected database), and patients' identifiers and other data collected on paper will be kept in locked filing cabinets. Data collection instruments used during the project and stored on laptop or desktop computers will also be password protected. Printed computer data with PHI will be shredded and disposed of upon completion of the study and any record-keeping requirements. All research staff will be properly trained in the importance of confidentiality of data. The PI will be responsible for the confidentiality and security of all study databases.

These measures should be effective in preventing breaches of confidentiality.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

Not Applicable.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw

their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

Not applicable.

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

Not applicable.

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:** Amendment (AME2)
Date Received: August 31, 2012

Signatures

PI Name: Schnipper, Jeffrey L, MD, MPH
Authenticated: August 16, 2012

Amendment

Performance Sites

Are you adding or removing a performance site?

○ Yes ◉ No

Study Staff Amendment

Are you adding or removing study staff? **REMINDER: Do not add collaborators at other sites unless they are engaged in the conduct of the research at a Partners institution.**

○ Yes ◉ No

Sponsor Amendment

Is there a sponsor amendment number?

○ Yes ◉ No

Continuing Review

Indicate if this amendment is part of a continuing review submission.

○ Yes ◉ No

Sponsor / Funding

Is a Sponsor / Funding source being added?

○ Yes ◉ No

Protocol Title

Is the title of the protocol being changed?

○ Yes ◉ No

Does your study involve an **intervention / interaction** with human subjects?

NOTE: Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject (45 CFR 46.102(f)).

◉ Yes ○ No

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1. Data Forms Updates

For protocols submitted originally in Insight, indicate below what forms need to be updated as part of this amendment. After clicking the save button you will be able to open any applicable forms that need to be updated/completed on the Forms page. If the protocol was submitted prior to the eIRB implementation, you may not be presented with any additional forms unless an ancillary review is required.

☐ Ancillary Drug

☐ Ancillary Non-hospital Device(s)

☐ Diaries (e.g., Drug Diary)

☐ Drugs / Biologics / Dietary Supplements

☑ Instruments / Questionaires

☑ Informed Consent Form / Process

☐ Medical Device

☐ Nursing Implementation

☐ Privacy / Confidentiality

☐ Radiation (Ionizing)

☐ Radiation (Non-Ionizing)

☐ Recruitment

☐ Remuneration

☐ Study Type / Classification (for example, physiologic, therapeutic, genetic)

☐ Study Population (for example, enrollment targets)

☐ Study Population - Special Populations

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2. New/Revised Study Documents (Attachments)

Are you submitting new or revised study-related documents? **Note: If you answer 'no' to this question you will not be able to attach documents to this submission.**

◉ Yes ○ No

Indicate:

☑ Consent Form(s)

☐ Device Manual
☐ Diaries
☑ Instruments / Questionnaires
☐ Investigator Drug Brochure (IDB)
☐ Recruitment Materials
☐ Response to Review
☐ Schema
☐ Other Study-Related Documents
☑ Protocol Summary
☐ Protocol

Are you removing any study-related documents because they are not being used, e.g., you are no longer using advertisements?

○ Yes ◉ No

Briefly describe the proposed changes:

While we pursue funding for the full study as approved, we would like to do approximately 2 months of pilot data collection (called "Part 2"). During this pilot period, no intervention will be implemented, and we will test our risk stratification and readmission review tools in the presence of usual care alone. Part 2 will include use of "Consent Form Part 2" as a substitute for the previously approved consent form, and "Intake Questionnaire Part 2" as a substitute for the previously approved Intake Questionnaire. In both documents, reference to the intervention has been removed. Intake Questionnaire Part 2 also includes additional questions directed to members of the clinical team (inpatient MDs, primary care provider, and the outpatient nurse care coordinator), as well as to patients themselves, asking these individuals to predict patients' risk of 30-day readmissions. We will compare these individuals' risk prediction accuracy to one another and to a validated algorithm for readmission prediction. Additionally, the Readmission Review Packet has been amended to add the outpatient (South Huntington) nurse care coordinator to the list of clinical team members who will be asked to assess the reasons that patients were readmitted.

Provide rationale for the proposed changes:

The information gathered in Part 2 will be used to determine which patient characteristics and responses correspond with 30-day readmission with usual care, in the absence of the intervention and of risk stratification. There are few simple, user-friendly tools available for accurately identifying patients with a high risk of readmission; Part 2 will be novel in its testing not only of the accuracy of an objective algorithm and that of the subjective views of inpatient staff, but also of that of outpatient staff and patients themselves. The data collected during Part 2 will inform risk stratification approaches during the full study by identifying which factors are most predictive of patients' readmission risk and how interventions might be best matched to patient needs. The addition of the outpatient nurse care coordinator to the readmission review brings a key member of the clinical transitions of care team into the readmission review process.

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

Informed Consent

For guidance, refer to the PHRC web page Informed Consent of Research Subjects.

Will informed consent and authorization for participation in research be obtained **verbally (oral consent)**, or by use of a **written consent form** approved by the PHRC and signed by the subject or the subject's legally authorized representative?

◉ Yes ○ No

Indicate how informed consent and authorization will be obtained:

◉ Written
○ Verbal (oral consent)

Enter the description of the study population (as listed on page 1 of the informed consent) for each consent form.

Adult inpatients at BWH on medicine service with a South Huntington Practice PCP

Indicate who will obtain the informed consent of the subject or the subject's legally authorized representative.

☐ Licensed Physician Investigator
☑ Non-Physician Investigator
☑ Other

Explain the person's role in the study that will be obtaining informed consent and what are the individual's qualifications to obtain informed consent, e.g., a genetic counselor, nurse practitioner, etc.

A Research Assistant or medical student trained by the Principal Investigator will be obtaining informed consent. The Research Assistant or medical student will have prior experience obtaining informed consent. It does not need to be a physician because this is a minimal risk intervention that does not involve any investigational drugs, devices, or medical procedures.

Indicate from whom informed consent will be obtained. Check all that apply:

☑ Adult Subject
☐ Parent(s) / Guardian for Child
☑ Court-Appointed Guardian for Adult
☑ Surrogate for Adult, other than Guardian (e.g. health care proxy, person with durable power of attorney, spouse, adult child, or close family member).

NOTE: When surrogate consent for adults is obtained, the individuals with impaired decision-making capacity form must be completed. For guidance, refer to the following PHRC web pages, Surrogate Consent to Research for Individuals with Impaired Decision-making Capacity

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Will the research target a non-English speaking group?

◉ Yes ○ No

Enter the language spoken by each non-English speaking group being recruited.

Spanish

Do the investigators obtaining informed consent speak a language understood by the non-English speaking group?

◉ Yes ○ No

NOTE: When investigators can reasonably expect that more than an incidental number of subjects speaking the same non-English language will be enrolled (for example, if the research is targeting a non-English speaking group), the use of a written translation of the entire English version of the consent form is required. The PHRC must approve all written translated versions of the consent from and recommends that the written translation be done by an in-house medical translator from Interpreter Services or other qualified person or service recommended by Interpreter Services. Refer to the PHRC guidance on Obtaining And Documenting Informed Consent Of Subjects Who Do Not Speak English.

Will a study subject advocate participate in the consent process?

○ Yes ◉ No

NOTE: A study subject advocate may be used, for example, because subjects have limited time to consider participation in a study involving significant risk, or may feel obligated to participate.

Will subjects have less than 12 hours to decide whether or not to participate?

◉ Yes ○ No

Explain why:

We are asking that patients make a decision on participating within 12 hours of being approached since a large part of the study intervention must occur before the patient is discharged. If patients require more time to decide whether to participate, we will grant them additional time (e.g., the research assistant wil return the next day).

NOTE: The IRB may waive the requirement to obtain a signed written consent / authorization form if it finds either: (1) the only record linking the subject and the research is the consent form and the principal risk would be potential harm resulting from a breach in confidentiality; or (2) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

Instruments / Questionnaires

Will the research involve the use or development of instruments, questionnaires, surveys, interviews, and/or focus group topics?

◉ Yes ○ No

List of Instruments / Questionnaires / Surveys / Interviews / Focus Group Topics

Enter the name of the instruments, questionnaires, surveys, interview and/or focus group topics and move to the box on the right. **Do not list any that are under development.**

Intake questionnaire

Enter the name of the instruments, questionnaires, surveys, interview and/or focus group topics and move to the box on the right. **Do not list any that are under development.**

30-day follow-up questionnaire

Enter the name of the instruments, questionnaires, surveys, interview and/or focus group topics and move to the box on the right. **Do not list any that are under development.**

Chart review of readmitted patients

Enter the name of the instruments, questionnaires, surveys, interview and/or focus group topics and move to the box on the right. **Do not list any that are under development.**

Chart review of index hospitalization

Enter the name of the instruments, questionnaires, surveys, interview and/or focus group topics and move to the box on the right. **Do not list any that are under development.**

Intake questionnaire Part 2

Internet Surveys

Do you plan to use internet or web-based tools to administer a survey, questionnaire, experiment, or to collect data from subjects?

◉ Yes ○ No

Are you collecting **protected health information** **(PHI)** or **sensitive information**?

◉ Yes ○ No

NOTE: PHI and sensitive data must be encrypted during transit (use of SSL https). For information on online survey tools, please see the Partners Research Computing website.

Please indicate your secure collection methods:

☑ Survey tool hosted inside Partners firewall

Indicate:

☑ REDCap
☐ LIMESURVEY
☐ Other survey tool

☐ Survey tool hosted outside Partners firewall with a signed Data Use Agreement or Business Associate Agreement (PHS Internal only links)

NOTE: For guidance, please see refer to: Guidance on Research Using the Internet - Survey Research Using Web-Based Survey Tools and Guidance on Research Using the Internet - Informed Consent in Online Research.

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)

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 Brigham and Women's Hospital o Massachusetts General Hospital

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¿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 hablar con usted hoy para aprender más acerca de usted, incluyendo cualquier problema que pueda ter tenido para tomar sus medicamentos en el pasado y anteriores hospitalizaciones. Podemos hacer la entrevista en su habitación del hospital. La entrevistas se llevará unos 15 minutos.

También nos gusta ver a su tabla de Brigham and Women's Hospital y los registros informáticos durante el próximo mes. Estos registros se incluyen las notas de los médicos y los resultados de laspruebas de laboratorio. Los registros también nos dirá si ha ido de nuevo al hospital o sala de emergencia. Si readmitido en Brigham and 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

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de emergencia o al hospital. Esta entrevista durará aproximadamente 30 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 revisará sus medicamentos con usted y con sus médicos y también le dará algunos consejos relacionados con sus medicamentos antes de que te vas a su casa. Antes de ir a su casa, un médico responsable por los pacientes externos de su práctica de atención primaria tendrá una conferencia telefónica con usted y su médico que lo atiendio en el Hospital. Los tres de ustedes discutirán todas sus dudas y preguntas, así como su alta y el plan de seguimiento. No se grabará Esta llamada telefónica. En casa, una enfermera visitante se asegurará de que usted no está teniendo ningún problema para cuidar de sí mismo o de llevar a cabo el plan de alta. Pocos días después de regresar a su casa, usted terá una cita especial en su práctica habitual de atención primaria. En esta visita, usted verá una enfermera, un farmacéutico y su médico de atención primaria para asegurarse de que todo va 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.

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 Brigham and Women's Hospital o Massachusetts General Hospital

☐ 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

de emergencia o al hospital. Esta entrevista durará aproximadamente 30 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 revisará sus medicamentos con usted y con sus médicos y también le dará algunos consejos relacionados con sus medicamentos antes de que te vas a su casa. Antes de ir a su casa, un médico responsable por los pacientes externos de su práctica de atención primaria tendrá una conferencia telefónica con usted y su médico que lo atiendio en el Hospital. Los tres de ustedes discutirán todas sus dudas y preguntas, así como su alta y el plan de seguimiento. No se grabará Esta llamada telefónica. En casa, una enfermera visitante se asegurará de que usted no está teniendo ningún problema para cuidar de sí mismo o de llevar a cabo el plan de alta. Pocos días después de regresar a su casa, usted terá una cita especial en su práctica habitual de atención primaria. En esta visita, usted verá una enfermera, un farmacéutico y su médico de atención primaria para asegurarse de que todo va 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 oa 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:* 6.21.2013

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

Partners PCORI Transitions Study Protocol Amendments

(Please note that all other amendments not listed here only involved changes to study personnel)

The first protocol amendment (AME2) after the initial IRB application included updates to the Protocol Summary, Consent form, chart review of readmitted patients, and Part 2 of the Intake Questionnaire. The following protocol amendment (AME4) enumerated several additions and revisions beginning with changing the study title from "Promoting Safer Transitions: A Collaboration Between the Hospital and the Patient-Centered Medical Home" to "Relative Patient Benefits of a Hospital-PCMH Collaboration within an ACO to Improve Care Transitions" to match the PCORI project title. Amendment 4 also changed the funding from NPSF to PCORI and increased target enrollment from 300 to 1800 participants. Protocol Summary revisions included increasing research sites to BWH, MGH, and Partners PCP practices; using Stepped Wedged Study Design; utilizing more comprehensive data collection tools; and adding and revising instruments/questionnaires. In total, 13 instruments/questionnaires, a consent form, and a sample email to attendings were added in this amendment.

AME6 added funding from Patient Centered Outcomes Research Institute (InfoEd #2012D003554). AME 7 was comprised of Spanish language translation of patient instruments and consent forms, phrase change in the patient survey Patient Participation in Discharge Plan and Protocol Summary from "patient satisfaction" to "patient engagement," removal of question 11 asking, "After I left the hospital, I was able to meet basic needs such as food and shelter." in the Readmission Review Packet in the Readmission Patient Interview-Patient Perspectives on Reasons for Readmission, and addition of an Interviewer Guide for the 30-Day Follow-Up Patient Interview, Primary Care Physician Survey, English and Spanish version of Patient Personal Health Record, and Readmission Care Audit.

AME14 encompassed a variety of additions and revisions such as updating English and Spanish consent forms to clarify that patients will receive interventions based upon need, adding MGH to consent forms as a study site, increasing the estimate of the Patient Intake Interview to 30 minutes from 15 minutes to allow time for the new Demographics Questionnaire, and increasing the 30-Day Follow-Up Phone Call to 45 minutes from 30 minutes. It also revised English and Spanish versions of Patient Engagement survey Readmission Review Packet to change words such as "don't know," "refused," "they," and "me" to "unsure," "declined," "your care team," and "us" in response to feedback from our Patient-Family Advisory Council. The amendment incorporated other suggestions from the PFAC to revise English and Spanish versions of the 30-Day Follow-Up Phone Call guide and increased accuracy of data collection by modifying the adverse effects chart. The Readmission Care Audit revision expanded the loop diuretics listing to include torsemide for risk assessment. The amendment added a Demographics Form to the instrument/questionnaire battery to be completed during the intake interview, a Discharge Preparation Checklist adapted from a checklist by Dr. Eric Coleman (Care Transitions Intervention) for patients receiving the Discharge Advocate intervention, an Info and Contact document for each patient's chart, and a reminder letter for the 30-Day Follow-Up phone call. CES-D10 and ENRICHD were removed from instrument/questionnaires and revisions to the S-TOFHLA were made. Also, in this amendment, Katherine Reifler was approved to translate minor edits in the document to Spanish.

AME15 removed two questions, rephrased from negative to positive, and added the option "rarely" to the Patient Engagement survey. Participants were mailed the SF-12 survey with the 30-Day Follow-Up Appointment Letter, so they could follow along during the phone call. During this amendment, questions 1-8 changed to refer to PCP in 30-Day Follow-Up Phone Call guide and changed the wording in the Adverse Events assessment chart to improve clarity. The amendment also added a Readmission Survey Info Sheet for physicians to provide information on the study and added an email document to Attendings and PCPs to distribute to BWH and MGH practitioners informing them of their right to opt-out of the study. To provide for more possible locations, "other" was added as an option for a patient's residence prior to discharge. The amendment also added the question "Would you be surprised if the patient died within the next 6-12 months?" to the Provider Survey in Readmission Review Packet to help determine whether lack of advance care directives and palliative care services might have contributed to readmission. It created a shortened version of the 30-Day Follow-Up Phone call guide for patients who do not have enough time to complete the full guide and revised the protocol summary (10/17/2013) as well as the Spanish and English consent forms to include potential use of videoconferencing.

AME 17 removed one question and changed questions from negative to positive in the Spanish version of the Readmission Review Packet. AME18 added two questions to Post-discharge SF-12 Survey, an Outpatient Inventory document, and new Spanish and English versions of the Partners Health Release form while deleting a few questions in Readmission Care Audit to reduce redundancy.

AME20 added the choice "Not at all" to question 3 in section B of 30-Day Adverse Effects survey. The amendment switched the order of the out-of-pocket cost question and the caregiver missing work question, while AME22 removed 3 redundant questions from the clinician survey regarding the quality of the transition process, changed the phrases from "to use" and "hospital" to "to do" and "hospital or clinic" or "the patient care area in which you work" for clarity.

There were several additions in AME25. The amendment added a letter for PCP and Inpatient Attending of patients eligible for a home visit by a pharmacist from Dovetail Health Inc. and updated the Protocol Summary (4/10/2014) to include a question about Patient Priorities for the recovery period in semi-structured interviews. It also added an addendum consent form for study patients with Type II Diabetes Mellitus, a qualitative interview guide for patients with Type II Diabetes Mellitus, a letter for the Inpatient Attending and care team of patients who completed the Patient Priorities interview, and an Interview Guide for the Patient Priorities interview. It also updated Spanish and English versions of intake demographics form.

AME29 deleted some questions from the Readmission Adjudicator Form but added the question "Was this a clearly unavoidable adverse event?" to the AE Adjudicator Form (to save adjudicators time in clear-cut cases) and a note in the 30-Day Follow- Up Phone Call about whether a patient would be willing to give additional feedback about his/her participation in the study.

The revised Outpatient Inventory included several changes:

1. Changed abbreviations to full titles

2. Added a paragraph to clarify the survey for intensive Care Management Program (iCMP) patients and doctors who attend on their own patients in the hospital
3. Added specificty to the phrasing of questions
4. Formatted previously separate questions into tables
5. Added questions to gain more insight into practice workflow

AME33 updated the Protocol Summary (10/14/14) to include the addition of two patient focus groups to be conducted for the PCORI Transitions Project (to get feedback on the intervention from patients who experienced it) and a new verbal consent form for the patient focus group. AME35 updated the Protocol Summary (11/7/14) which added a new component to the intervention: a secure "microblog" messaging application to evaluate on general medicine units at BWH hosted by CareThread Inc. (to improve communication among clinical care team members and with patients after discharge) and added two survey instruments to assess inpatient provider and ambulatory provider satisfaction with care team communication. AME41 revised the Protocol Summary (1/14/15) to change the number of participating primary care sites from 50 to 18 and approved the Informal Provider Questions and Provider Focus Group Questions.

AME45 added a survey designed and administered using Redcap to assess provider user satisfaction with the microblog, and AME47 reformatted the layout and wording of the Microblog usability survey. Question one and six were shortened, question five moved to question three, and question four was changed to a Likert scale. A comments box was also added. AME48 added a group of questions regarding intervention components and removed a group of questions regarding perceived opinions of management in the Post-Intervention Clinician Survey.

AME50 was withdrawn, and AME52 was the last amendment. This amendment created a data collection form to review medical records of study participants that were unable to be reached and interviewed for the 30-Day Follow-Up Phone Call.