



CONSENT AND AUTHORIZATION FORM FOR INSTITUTIONAL REVIEW BOARD APPROVED RESEARCH

Research Study Title: Medication Reconciliation: Bridging Communications Across the Continuum of Care	
Name of Investigator: Melinda Muller, MD	
Phone Number:	503-413-7074
Study Sponsor:	Center for Quality Improvement and Patient Safety Agency for Healthcare Research and Quality

1. Introduction

You have been invited to participate in a research study (the “Research Study”) being conducted by Legacy Health System. You have been invited because you or your child have recently been in the hospital and have now returned to the care of your primary care physician and/or to Home Health Services.

The purpose of this Consent Form is to provide information for you about the nature of the Research Study so you may make a decision as to whether you would like to participate in this project.

2. Purpose

Through this Research Study, Legacy Health System plans to improve medication safety across the continuum of inpatient and outpatient care by developing a single, shared, updated and reconciled medication and allergy list for each patient in the health system. This project directly supports the organizations patient safety goals and will assist in our mission of improving the health status of the community. Information and tools created through the Study will be made available to other organizations to help deal with and improve this systemic national problem.

The purpose of this Research Study is to develop and test a process that (1) assesses and accurately documents all drug allergies that you or your child may have, (2) assesses and documents all medications that you or your child are taking at the time you are admitted to the hospital, (3) reassesses and documents all medications that you or your child have been prescribed at the time you leave the hospital, (4) tracks information provided to your primary care physician and/or the next level of healthcare regarding your drug allergies and the medications you are currently taking.

The expected duration of your participation in the study is no longer than two years.

There will be at least 60 patients or parents of pediatric patients from Legacy Health System participating in this study.

3. Procedures

The Research Study will involve your participation in focus groups (interview groups) that will include both providers of healthcare (doctors, pharmacists and nurses) and patients/family members. These interviews will be conducted to help us identify your needs and other issues related to the development and ongoing maintenance of the medication and allergy summary list. You will be asked for your input on the format and content of the medication summary list; how easy is it to read, the value of the content of the information, how current is your list, etc. In addition, in the second year of this study, we will be asking additional questions of patients/families about the education you received as a Legacy patient; if it was helpful, if you have changed your behavior as a result of this education, what was useful and what was not.

Interviews will take place at a Legacy hospital and will last approximately one hour.

4. Risks

The only possible risk associated with this project is the inconveniences of participating in the interviews.

5. Benefits

You will not personally benefit from participating in this study. However, by serving as a research subject, you may contribute new information, which could benefit patients in the future.

6. Alternatives

This Study does not involve any medical care or other medical procedures, and your only alternative is to refuse participation. You are free to decline participation and should you choose to participate, you are free to withdraw from the Study at any time without penalty or loss of benefits that you would otherwise enjoy outside of the Research Study.

7. Compensation

You will not receive any sort of compensation for participating in the Research Study.

8. Voluntary Participation

You are free to refuse to participate or to withdraw from participation at any time and it will in no way affect your relationship with, or treatment at Legacy Health System.

You will receive a copy of this consent form.

9. Costs

There will be no costs to you associated with this research project.

10. Authorization to Use and Disclose Protected Health Information

You hereby authorize Legacy Health System to use and disclose your Protected Health Information (PHI) solely for the purposes of the Research Study. PHI includes any portion of your medical records that could be used to identify you such as name, address, birth date, etc.

You are free at any time to restrict Legacy Health System's use and disclosure of your PHI, for purposes unrelated to the Research Study, without penalty or other consequence. However, you may be denied participation in, or continued participation in, this Research Study if at any time you choose to restrict Legacy Health System's use and disclosure of Health Information that is necessary for the completion of the Research Study described in this Consent Form.

11. Authorized Persons and Recipients

You hereby authorize the following person(s) or class (es) of persons to request, receive and use your PHI: (1) Legacy Health System Pharmacists, Nurses, or Physicians associated with this research project (2) Personnel associated with the Center for Quality Improvement and Patient Safety, Agency for Healthcare Research and Quality, (3) possibly the FDA.

You further authorize Legacy Health System to disclose your PHI to the above-listed person(s) or class (es) of persons (the "Recipients").

12. Expiration Date

You hereby authorize Legacy Health System to use and disclose your PHI in accordance with the terms and conditions of this Consent Form until you revoke it at anytime in writing or until the end of the research study.

13. Re-Disclosures To Third Parties

Once Legacy Health System discloses PHI to the Recipient(s) identified above, Legacy Health System cannot guarantee that Recipient(s) will not re-disclose PHI to other persons who may not be bound by this Consent Form, or otherwise be permitted to use or disclose PHI in ways that you did not intend.

14. Withdrawal of Authorization to use and Disclose Protected Health Information

You may decline at any time to participate in any or all of these follow-up activities. If you choose not to participate, it will not affect your medical treatment, nor is there a penalty or loss of benefits to which you would otherwise be entitled. You may change your mind and revoke this authorization at any time. To revoke this authorization, you must write to:

Principal Investigator; Melinda Muller, MD
Address: 1200 NW 23rd, Portland, Oregon 97210
Phone; 503-413-7074

However, if you revoke this authorization, you may no longer be able to participate in the study. In addition, even if you revoke the authorization, the information already obtained by Legacy Health System and AHRQ may be used and disclosed as permitted by this authorization and this informed consent.

15. Contacts

If at any time during this Research Study, you feel that you have not been adequately informed as to the risks, benefits, alternative procedures, or your rights as a research subject, or feel under duress to participate against your wishes, you can contact Legacy Health System's Research Regulatory Specialist who will be available to speak with you during normal working hours (8:30 a.m. to 5:00 p.m.) at (503) 413-2474.

In the event of injury or illness, you should seek medical attention and contact: Dr. Melinda Muller at 503-413-7074.

The subject has been informed of the (i) nature and purpose of the procedures described above including any risks involved in the Research Study’s performance; and (ii) of how his or her Protected Health Information may be used or disclosed. The subject has been asked if any questions have arisen regarding these procedures and the subject’s privacy rights, and these questions have been answered to the best of the Legacy Health System’s ability. A copy of this Compound Consent and Authorization has been provided to the subject.

Date

[Investigator’s Signature or Designee]

I have been informed about the procedures, risks, and benefits of this Research Study and agree to participate. I know that I am free to withdraw my consent and to quit the Research Study at any time. I have read and understand the terms of this Consent Form and I have had an opportunity to ask questions about the Study and to discuss the Study with my doctor and other health care providers and my family and friends. I also have had the opportunity to ask questions about the use and disclosure of my Protected Health Information and my privacy rights. I hereby knowingly and voluntarily authorize Legacy Health System to use and disclose my Protected Health Information in the manner described in this Consent Form. I understand that I may decline to participate in this Research Study. I further understand that if I choose to participate, I may withdraw from the Research Study at any time. My decision not to participate in this Research Study or my decision at any time to withdraw from this Research Study will not cause me any penalty or loss of benefits that I am otherwise entitled to enjoy.

Subject’s Signature

Date

Subject’s Legal Representative
(if applicable)]

Date