

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: A Multisite Field Study Applying Novel Methods to Better Understand the Relationship between Health Information Technology and Ambulatory Care Workflow Redesign

1.2 Company or agency sponsoring the study: Agency for Healthcare Research and Quality (AHRQ)

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Kai Zheng, PhD, University of Michigan
Elizabeth Ciemins, PhD, MPH, MA, Billings Clinic
Holly J. Lanham, PhD, MBA, University of Texas at Austin
Curt Lindberg, DMan, MHA

2. PURPOSE OF THIS STUDY

2.1 Study purpose: The study will generate insights into understanding (1) the relationship between health IT implementation and ambulatory care workflow; (2) socio-technical factors and the role they play in mitigating or augmenting the impact of health IT on workflow processes; and (3) how the workflow impacts of health IT are magnified through frequently occurring disruptive events such as interruptions and exceptions. Using multiple complementary quantitative and qualitative methods, this project will generate insights into understanding how health IT implementation alters clinical workflow, in addition to the root causes and consequences of such impacts.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study? Clinicians, i.e. any health care professional that interacts with and provides medical or health service/advice to patients. Clinicians include, but are not limited to: physicians, nurse practitioners, physician assistants, nurses, medical assistants, pharmacists, and case managers.

3.2 How many people (subjects) are expected to take part in this study? The number of individuals that will participate in each data collection activity is as follows: approximately 60 in non-participant observation and contextual inquiries, 54 in time and motion studies, 90 in log analyses, 60 in semi-structured interviews, and 60 in member checking focus groups.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study? By participating in this study, you give your consent to have a research assistant observe your day-to-day proceedings. During this observation period, the research assistant will take detailed notes on the tasks you perform and how you perform them. You will also be interviewed about your workflow processes.

4.2 How much of my time will be needed to take part in this study? Depending on which phase of the study you are participating in, you might be observed up to 20 hours during one work week (four hours a day). Semi-structured interviews will last no more than 1 hour and focus groups will last up to 45 minutes.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Risks of being in the study are no greater than everyday life. This study may involve risks that are currently unforeseeable. If you wish to discuss the information above or any other risks you may experience, you may ask questions now or call the Principal Investigator listed on the front page of this form.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

5.3 How could I benefit if I take part in this study? How could others benefit?

Benefits of being in the study include the involvement in creating new knowledge for improving medical care processes and the early access to the knowledge gained by the research.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information” (below).

6.2 Could there be any harm to me if I decide to leave the study before it is finished?

No, there is no harm if you choose to leave the study before it is finished

6.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will receive a \$25 gift card to participate in this study.

8. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

8.1 How will the researchers protect my privacy?

For purposes of insuring confidentiality and the protection of private information collected from the research participants, the following steps will be taken with all data:

1. All interviews will be conducted in a private setting to ensure the privacy of the participant. Digital recorders will be on the person of the field researcher at all times. Persons being interviewed will be identified on the recording by interview identification numbers only. Persons being interviewed will be asked to avoid using names of other clinic members during the interviews.
2. Notes taken by the researcher will be on the person of the researcher at all times. These notes will not include personally identifiable information.
3. All conversation between the investigators and others not associated with the study will refrain from including personally identifiable information of all research participants.
4. All hard copies of clinic member surveys, transcripts of interviews and observation field notes will be kept in a locked file cabinet in the office of the principal investigator.
5. One electronic file of these data will be stored on a computer that is not connected to a local area network and that is password protected.
6. All removable storage devices with data will be kept in a locked file cabinet in the office of the principal investigator(s).

7. All printouts of results from data analysis will be kept in a folder in a locked file cabinet in the office of the principal investigator(s).
8. No data will be stored on a server or on a computer that is connected to a local area network.
9. For all audiotaped data, the following measures will be taken to protect participant data confidentiality:
 - (a) Interviews will be audiotaped with your permission
 - (b) Recording devices in interviews can be turned off at your request
 - (c) Audiotapes will be coded by the researcher so that no personally identifying information will be visible
 - (d) Audiotapes will be kept in a secure place. They will be kept in a locked file cabinet in the researcher's office
 - (e) Audiotapes will be heard or viewed only for research purposes by the investigator and his or her co-investigators
 - (f) Audiotapes will be erased after they are transcribed and coded

The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate you with it, or with your participation in any study.

The records of this study will be stored securely and kept confidential. All publications will exclude any information that will make it possible to identify you as a subject. Throughout the study, the researchers will notify you of new information that may become available and that might affect your decision to remain in the study

8.2 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

8.3 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

9. CONTACT INFORMATION

9.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Leave the study before it is finished
- Express a concern about the study

Project Director: Kai Zheng
 Telephone: 412-708-2202
 E-mail: kzheng@umich.edu

Co-Project Director: Elizabeth Ciemins
 Telephone: 406-238-5724 (o)
 406-281-3275 (c)
 E-mail: eciemins@billingsclinic.org

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
 2800 Plymouth Road
 Building 200, Room 2086
 Ann Arbor, MI 48109-2800
 Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
 Fax: 734-763-1234
 e-mail: irbmed@umich.edu

10. RECORD OF INFORMATION PROVIDED

10.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.*)
- Other (specify): _____

11. SIGNATURES

Research Subject:

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with {Study Team Member Name/s}. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

By signing below, I am agreeing to participate in the following study components (check as applicable):

- 1.1. Observation Time and Motion Study Log Analysis Interview Focus Group

Name (print legal name): _____

Signature of Subject: _____

Date of signature: _____

Patient ID: _____ Date of Birth (mm/dd/yyyy): _____

Legal Representative (if applicable):

Signature of Person Legally Authorized to Give Consent _____

Date of signature: _____

Name of Person Legally Authorized to Give Consent (print legal name): _____

Address of Legal Representative: _____

- Relationship to Subject (check):
- Parent
 - Spouse
 - Child
 - Sibling
 - Legal Guardian
 - Other: _____

If this consent is for a child who is a ward of the state (for example a foster child), please tell the study team immediately. The researchers may need to contact the IRBMED.

Reason subject is unable to sign for self: _____

Principal Investigator (or Designee):

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: _____

Title: _____

Signature: _____

Date of Signature: _____

Witness (optional):

I observed the above subject (or his/her legally authorized representative, if applicable) sign this consent document.

Name: _____

Title: _____

Signature: _____

Date of Signature: _____