ATTACHMENT 3

Forms to be used in the project "Improving Quality Through Health IT: Testing the feasibility and assessing the impact of using existing health IT infrastructure for better care delivery" that have been submitted to the Yale University School of Medicine/Yale-New Haven Hospital Human Investigation Committee

Form Approved
OMB No. 0935-XXX
Exp. Date XX/XX/20XX

INFORMATION AND INVITATION TO JOIN US IN STUDYING OUR NEW MESSAGING SYSTEM!

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

(Patient/Guardian)

Project Title: Secure Messaging in a Pediatric Respiratory Medicine Setting
Principal Investigators: *Alia Bazzy-Asaad, MD, Andrea Benin, MD, & Allen Hsiao, MD*
Funding Source: *US Agency for Healthcare Quality and Research*

As you may have heard already, we are excited to be installing and using a new electronic messaging system in our Pediatric Respiratory Medicine Clinic! Among the many new things and services we can offer with it, we can now communicate safely and effective with our patients and their families by email! All patients and their families are eligible to use this system, and to use it as much or little as you would like. There is no cost to use this service!

We would like to invite you and your child to join us in studying how well this system works. If you agree, we would ask you complete a short survey before you use the system, and then again after you have signed up and had the opportunity to use it. That's it! There is no pressure to join us; you can absolutely use our new messaging system as much or as little as you want, whether or not you decide to be part of the study.

If you decide to join the study, your opinion and thoughts through completion of a brief survey will be very valuable in determining how helpful the system is. For instance, your opinions may determine how widely this system is used in other clinics. As with any study, it is important you know what the risks and benefits are to make an informed judgment. The only potential risk would be accidental disclosure of information about the care you receive. For this reason, your name and the name of your child and other identifiers will be removed from any survey results you agree to provide, and the surveys will be analyzed anonymously.

There are no costs to you for being part of this study, nor will you receive any money. Your thoughts are very helpful to us however, and we would be very grateful! Remember, you are free to choose not to participate and if you agree to take part but change your mind, you can do so at *any* time, just let any of our staff or your healthcare provider know. Completing the survey will serve as your permission to participate.

Please feel free to ask about *anything* you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision. *If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Allen Hsiao 203-688-7970.*

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED IN THE HIC OFFICE

THIS FORM IS VALID ONLY UNTIL:
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CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

(Patient/Guardian)

Study Title: Secure Messaging in a Pediatric Respiratory Medicine Setting
Principal Investigators: *Alia Bazzy-Asaad, MD, Andrea Benin, MD, & Allen Hsiao, MD*
Funding Source: *US Agency for Healthcare Quality and Research*

Invitation to Participate and Description of Project

You are invited to participate in an interview as part of a research study designed to see if secure health messaging (a type of electronic communication similar to email) is a useful and well-received tool in the care of children with chronic disease. You are part of a small group that has been chosen to participate. Your opinions and thoughts are very important to us because you currently receive care at the Yale Pediatric Respiratory Medicine Clinic.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of participation, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participate in this study, we will invite you to meet with two of our staff to discuss your thoughts and opinions about the system. Your responses will be anonymous and pooled with the responses of other patients to allow us to evaluate satisfaction with this system as part of our research reports. Information we are interested in includes the ease with which you were able to contact a clinic staff member or health care provider, and your satisfaction with the different forms of communication. Of course, specific information that would identify you or your child will be removed prior to preparation of any research report.

Risks and Inconveniences

The major risk would be unintentional disclosure of information about the care you provide. We plan to remove your name and other identifiers from all materials used for our analysis and reporting and substitute a unique study identifier. The key that would allow someone to identify you using this identifier will be kept locked in Dr. Hsiao's office.

Benefits

It is difficult to predict, but it is possible you may benefit directly from participating in this study as a result of improved or more efficient workflow as secure messages will be automatically logged into each patient's Centricity electronic medical record. This may save some time and effort, but may not be very significant. The quality improvement effort will likely lead to improvements in the documentation of care you receive and potentially will lead to health improvements for your patients with chronic respiratory diseases.

Economic Considerations

We anticipate no economic costs to you occurring as a result of this study.

Confidentiality

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

Representatives from the Yale Human Investigation Committee may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

The data we collect will be destroyed after analysis and publication of the data + 3 years. In the event that a publication does not result from this research, the data will be destroyed 5 years after its collection.

Voluntary Participation and Withdrawal

You are free to choose not to participate and if you do become a subject you are free to withdraw from this study at any time during its course. If you choose not to participate or if you withdraw it will not harm your relationship with faculty or with Yale-New Haven hospital.

The researchers may withdraw you from participating in the research if necessary.

Questions

Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject:_____

Signature:_____

*Relationship:*_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

*If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator [*include name and full telephone number*]. If you have any questions concerning your rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688.*

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Patient Assent for Being in a Research Study
Yale-New Haven Hospital/Yale University School of Medicine
(12-17years)

Title: Computer Messaging for Children with Lung Problems

Why am I here?

We are asking you to take part in a research study because we are trying to learn more about how well computer messaging works for children and their families to talk to doctors and nurses. We are inviting you to be in the study because you are a patient in our clinic and this is something the doctors and nurses here are interested in studying.

Why are they doing this study?

We think computer messaging will be an easy way for you and your family to talk with the doctors and nurses at this clinic. However, no one has studied this well to see if it really is a helpful way of talking.

What will happen to me?

If you and your family agree to join this study, we will ask for an email address for your family and study how often computer messaging is used by all of you. We will meet with you and your family after several months to ask what you all liked or did not like about the system.

Will the study hurt?

Not at all! We just ask for a little your time to tell us what is good or bad about computer messaging.

Will the study help me?

If your family/parents/guardians find it an easy way to talk/communicate with the doctors and nurses, it may help them do so. It probably won't change things for you a lot, however.

burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (0935-XXXX)
AHRQ, 540 Gaither Road, Room # 5036, Rockville, MD 20850

What if I have any questions?

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call Dr. Allen Hsiao (203-688-7303) or ask me next time. As always, you may call the Respiratory Medicine clinic at any time to ask questions about your disease or treatment.

Do my parents know about this?

This study was explained to your parents and they said that you could be in it. You can talk this over with them before you decide.

Do I have to be in the study?

You do not have to be in the study. No one will be upset if you don't want to do this and there will be no change in the care you receive here or the ways you and your family can communicate with the doctors and nurses here. . If you don't want to be in this study, you just have to tell them. You can say yes now and change your mind later. It's up to you.

Writing your name on this page means that that you agree to be in the study, and know what will happen to you. If you decide to quit the study all you have to do is tell the person in charge.

_____ _____
Signature of Child Date

_____ _____
Signature of Researcher Date

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Child's Assent for Being in a Research Study
Yale-New Haven Hospital/Yale University School of Medicine
(7-12 years)

Title: Computer Talk for Kids with Lung Problems

Why am I here?

We are asking you to help us study how well the computer helps kids and their families talk to doctors and nurses.

Why are you doing this study?

We think it will help your parents to use the computer to talk with doctors and nurses, but we have to make sure it really does help by doing this study and asking you what you think.

What will happen to me?

If you and your family agree to join this study, we will ask for an email address for your family and study how often you use to computer to talk to the doctors and nurses here. We will meet with you and your family after a few months to ask what you all liked or did not like about the system.

Will the study hurt?

Not at all! We just ask for a little your time to tell us what is good or bad about computer messaging.

Will the study help me?

If your family/parents/guardians find it an easy way to talk/communicate with the doctors and nurses, it may help them do so. It probably won't change things for you a lot, however.

What if I have any questions?

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call Dr. Allen Hsiao (203-688-7303) or ask me next time. As always, you may call the Respiratory Medicine clinic at any time to ask questions about your disease or treatment.

Do my parents know about this?

This study was explained to your parents and they said that you could be in it. You can talk this over with them before you decide.

Do I have to be in the study?

You do not have to be in the study. No one will be mad if you don't want to do this and all your care will stay the same. Also, you and your parents can still use the computer to talk to the doctors if they want. If you don't want to be in this study, you just have to tell them. You can say yes now and change your mind later. It's up to you.

Writing your name on this page means that that you think it is ok to be in the study, and know what will happen.. If you decide to quit the study all you have to do is tell the person in charge.

_____ _____

Signature of Child Date

_____ _____

Signature of Researcher Date

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YALE UNIVERSITY
RESEARCH AUTHORIZATION

Subject Name:		**Medical Record #:**	
Principal Investigator:	Allen Hsiao, MD	**IRB #:**	
Principal Investigator's Contact Information:	840 Howard Avenue, New Haven CT 203-688-7303		

To the Subject:

The health-related information that we gather about you and your child in this study is personal. The Yale School of Medicine and the Yale New Haven Hospital researchers are required by law to protect the privacy of the information known as protected health information or PHI. All reasonable efforts will be made to protect the confidentiality of your and your child's PHI, which may be shared with others to support this research, to conduct public health reporting, and to comply with the law as required. Despite these protections, there is a possibility that information about you and your child could be used or disclosed in a way that it will no longer be protected by federal law. For example, some of the individuals listed on page 2 of this form may not be required by law to meet HIPAA standards for privacy of health information. These individuals or companies are nonetheless required through other agreements with Yale to keep your information confidential.

In this form, we describe who will be working with this information and ask for your permission to use the information in the research study.

Please read this form carefully. If you have any questions, please ask the Principal Investigator listed above before signing this form.

By signing this form, you give permission for the researchers to use and/or disclosure the information as described below, for this research study. The reason for the uses and disclosures is to examine how useful Computer Secure Messaging is for families to communicate with their healthcare providers.

You have a right to refuse to sign this form. Your (your child's) health care outside the study, the payment for your (your child's) health care, and your (your child's) health care benefits will not be affected if you do not sign this form.

Public reporting burden for this collection of information is estimated to average 10 minutes per response, the estimated time required to complete the survey. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (0935-XXXX) AHRQ, 540 Gaither Road, Room # 5036, Rockville, MD 20850

If you sign this form, you may change your mind at any time, but the researchers may still use the information collected before you changed your mind in order to complete the research.

This form will never expire unless and until you change your mind and retract it. To retract the permission to use your information, please write to **Allen Hsiao, MD.**

You have a right to receive a copy of this form after you have signed it. If after you have signed this form you have any questions about your rights, please contact the Yale Privacy Officer at 203/436-3650.

Use and Disclosure Covered by this Authorization

(1) Who will disclose, receive, and/or use the information?

The following person(s), class(es) of persons, and/or organization(s) may share, use, and receive the information listed below in connection with this Study. These persons are authorized to use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law.

[Check appropriate boxes and add requested information on names/classes of recipients of PHI. Delete all boxes and categories that do not apply. Note that when the specific individual may change over the course of the project it is preferable to list their class as opposed to specific names. For example reference the "research coordinator" as opposed to the name of the current individual performing that role.]

- ❑ The following health care facilities or research site(s) and research staff involved in this study:

  Yale University School of Medicine and Yale-New Haven Hospital.
- ❑ Health care providers at Yale Pediatric Respiratory Medicine Clinic who provide services to you in connection with this study
- ❑ The members and staff of the Human Investigation Committee that approved this study
- ❑ Principal Investigators: Alia Bazzy-Asaad MD, Andrea Benin MD, & Allen Hsiao MD
- ❑ Additional members of the Research Team
- ❑ Agency of Healthcare Quality and Research (sponsors of the study)

(2) What personal health information will be used or disclosed?

The following information about you may be used and disclosed: Your (your child's) responses to the interview questions, medical history, and relevant history of contacting healthcare providers may be used as part of the study, but strictly confidential.

[Check appropriate box and provide description of PHI, Delete all boxes and categories that do not apply]

- ❑ Research study records.
- ❑ Medical and laboratory records of only those services provided in connection with this Study.
- ❑ The following information: Your (your child's) responses to interview questions during focus groups or one on one interview sessions.

Signature

I have read this form and all of my questions about this form have been answered. By signing below, I authorize the described uses and disclosures of information.

_____
Signature of Subject or Personal Representative

_____
Print Name of Subject or Personal Representative

_____
Date

_____
Description of Personal Representative's Authority

Contact Information

The contact information of the subject or personal representative who signed this form should be filled in below.

Address:

_____
(daytime)

_____
(evening)

_____

_____

_____

Telephone:

_____

_____

Email Address (optional):

THE SUBJECT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED WITH A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED