Study title: High Tech and High Toch (HT2): Transforming Patient Engagement Through Portal Technology at the Bedside

NCT 02943109

Informed Consent Form

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The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: HT2 – Transforming patient engagement through portal technology at the bedside

Principal Investigator: Ann McAlearney, ScD

Sponsor: Agency for Healthcare Research and Quality (AHRQ)

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

This study is being done to gain a greater understanding of how patients use technology to manage their health.

2. How many people will take part in this study?

There may be approximately 63,000 participants in the study.

3. What will happen if I take part in this study?

If you agree to participate in this study the following will happen:

1. You will be asked to complete a 15-20 minute survey that you will take on a tablet or on paper – you can complete it any time in the next 24 hours. As a result of your participation, you will be entered into a weekly drawing to win a $100 Walmart gift card.

2. You will be providing the study team access to your personal health information including medical record number, information about your health, and how you use healthcare services. For example, if you are discharged and readmitted for the same issue, the research team will want to know. Specifically, we will be collecting information about how you use MyChart Bedside, including actions such as how often you access the home screen, access your profile, access lab results, etc. We will also collect information from your medical record including diagnoses, medications, and length of stay.

3. After you are discharged, a survey will be sent to your email of record or you will receive a phone call to ask you about your experience with technology while a patient. As a result of your participation, you will again be entered into that week's drawing to win a $100 Walmart gift card.

4. In six months, you will receive a final survey to follow up on your experience. As a result of your participation, you will again be entered into that week's drawing to win a $100 Walmart gift card.

5. We may also attempt to contact you for a 15-minute phone interview to discuss your health care experience.

4. How long will I be in the study?

The study will continue until February 29, 2020 (02/29/2020).

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

The Ohio State University's Institutional Review Board (IRB) has approved this study and determined that it presents only a minimal risk. The research team associated with this study has completed training to safeguard you from risk. While your participation in this study will be confidential and we use industry standards to secure data, because we gather data using tools that are connected to the Internet, there is a chance that someone could access your online responses without permission.

Precautions are taken throughout the project to minimize any risk associated with a breach of confidentiality, including separating your identity from your data and securing the data itself under hardware and password protection.

7. What benefits can I expect from being in the study?

Your responses will be used to improve the quality of care that all patients receive.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There will be no additional costs to participate in the study.

10. Will I be paid for taking part in this study?

By law, payments to subjects are considered taxable income. Your participation in any of the three (3) surveys will result in an entry into the weekly drawing where you may potentially win a $100 Walmart gift card. Your chance of winning will depend on the number of entries in each week. You may win more than once.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices; and
- The sponsor supporting the study, their agents or study monitors.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records, including diagnoses, medications, dates and lengths of hospital stays;
- Research records;
- Information that includes personal identifiers, including your name, address, phone number, email address, and medical record number;
- Information gathered for this research about:
  Diaries and questionnaires
- Records about how you use MyChart Bedside and OSU MyChart;

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;
- Others: No other agencies or groups have been identified to which this information would be disseminated.

IV. Your information may be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Dr. Ann McAlearney at (614) 293-8973 or via email at ann.mcalearney@osumc.edu**.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the **HIPAA Privacy Officer, Suite E2140, 600 Ackerman Road, Columbus, OH 43201, telephone 614-293-4477.**
For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. Ann McAlearney at (614) 293-8973 or via email at ann.mcalearney@osumc.edu**.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Not Applicable	**Not Applicable**
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Not Applicable	**Not Applicable** **AM/PM**
Relationship to the subject	**Date and time**