NCT#: NCT06804837

Title: Project SCORE Aim 3: A Randomized Stepped Wedge trial to Implement and test visual consent template and process

IRB Approval Date: 01/28/2026

[Site Specific Letterhead May Be Inserted Here]

Hello,

I am writing to invite you to participate in a research study being led by Washington University in St. Louis. You are invited because you are thinking about joining one of the three participating research studies at Washington University, University of Utah, or University of North Carolina at Chapel Hill. We have obtained your information from the participating research studies to better understand the consent process.

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

Key Information

What is the purpose of the study?
The goal of this research study is to find out how people feel about using a visual summary page as part of informed consent for research. We are trying to learn whether a visual summary page helps people understand details of studies and think about whether they want to join.

What do I need to do to be part of the study?
We will ask you to fill out a 5-10 minute survey about your thoughts on the informed consent process for the research study you were thinking about joining.

Who can be part of the study?
Adult patients (18+) who are thinking about joining one of the three participating research studies at Washington University, University of Utah, or University of North Carolina at Chapel Hill.

Will I be paid for taking part in the study?
Yes, we will give you a $40 gift card if you choose to take the survey.

Will I benefit from being in the study?
You will not benefit personally. However, we hope that others may benefit in the future from what we learn as a result of this study.

What are the risks of being in the study?
The main risk if you join the study is that confidential information about you could be accidentally disclosed. We do our best to keep your information secure using standard procedures described later in this document.

Do I have to be part of the study?
No, you do not have to be in this study and participating is voluntary. Filling out this survey is your choice and does not affect your enrollment in the larger trial.

The rest of this document provides more details about the study.

The purpose of the study is to determine if a visual summary page helps people understand details of studies and think about whether they want to join.

Research Funding

The Agency for Healthcare Research and Quality (AHRQ) is funding this research study.

We expect up to **[number your site will enroll]** people will take part in this study conducted by investigators at [Site Name]. Approximately 500 people will take part in this study across all sites.

Study Participation

If you agree to participate, you will fill out a 5-10 minute survey online. If you would like to complete the survey over the phone, you can let a research team member know. Someone will reach out to you to go over this information and get your responses to the survey questions.

You can skip any questions that you prefer not to answer.

About half of people will see a visual summary page when joining a participating research study. The other half will see a summary using text. You can participate in this study no matter which version you see, and you will be asked the same questions about how you liked the informed consent process.

There are no known risks from being in this study.

Identifying information may be removed from your data, so that the data cannot be connected to you. If this occurs, we may share your data with other researchers without asking you for additional consent

Costs & Payment

You will not have any costs for being in this research study.
[Site Specific Cost Information May Be Inserted Here]

You will receive a $40 gift card for being in this research study. You will be asked to provide your name, email address, and social security number (SSN) for us to pay you.
[Site Specific Payment Information May Be Inserted Here]

Privacy & Confidentiality

We will keep the information you provide confidential by:

- storing information in password-protected network drives that only the study team can access;
- identifying you by a number and not by your name; and
- reporting our findings in a way that does not identify you.

However, the Agency for Healthcare Research and Quality (AHRQ), federal regulatory agencies, including the Office for Human Research Protections, and Washington University, including the Washington University Institutional Review Board (a committee that reviews and approves research studies) and the Human Research Protection Office, may inspect and copy records pertaining to this research. **[Any other entities with whom PHI may be shared]**

If we write a report about this study, we will do so in such a way that you cannot be identified.

The funding source for this research may require that we share the data from this study with others to make sure the results are correct and to use for future research. Your information will be shared in a way that cannot directly identify you.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Declining or Leaving the Study

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in the study, you may stop participating at any time. Any data that was collected as part of this study will remain as part of the study records and cannot be removed. If you decide not to take part in the study or if you stop participating at any time,

you won't be penalized or lose any benefits for which you otherwise qualify.

Contact Information

We encourage you to ask questions.

If you have any questions about the research study itself, please contact:
[site contact name(s), phone number(s)].
If you feel you have been harmed from being in the study, please contact**[site contact name(s), phone number(s)].**.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445 or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.
[Local IRB contact information is permitted to be inserted here if needed. Please provide the information if required.]

Thank you very much for your consideration. Completing this survey or questionnaire will indicate your willingness to participate in the study.

Sincerely,

[site contact name(s) and Title]