Protocol ID#	202005217
Clinicaltrials.gov number:	NCT04491591
Title:	Implementing Breast Reconstruction Clinical Decision Support in Diverse Practice Settings
Version date:	01/20/2023

Washington University in St. Louis

Human Research Protection Office

IRB ID #: 202005217

To: Mary Politi

From: The Washington University in St. Louis Institutional Review Board,

Re: Implementing Breast Reconstruction Clinical Decision Support in Diverse Practice Settings

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Approval Date: 01/20/23
Next IRB Approval Due Before: 01/19/24

2018 Common Rule/Equivalent Protections Yes

Type of Application:

- ☐ New Project
- ☒ Continuing Review
- ☐ Modification

Type of Application Review:

- ☐ Full Board:
  Meeting Date:
- ☒ Expedited
- ☐ Exempt
- ☐ Facilitated

Approved for Populations:

- ☐ Children
  - ☐ Signature from one parent
  - ☐ Signature from two parents
- ☐ Prisoners
- ☐ Pregnant Women, Fetuses, Neonates
- ☐ Wards of State
- ☐ Decisionally Impaired

Criteria for approval are met per 45 CFR 46.111 and/or 21 CFR 56.111 as applicable.
Project determined to be minimal risk per 45 CFR 46.102(i) and/or 21 CFR 56.102(i) as applicable.

Source of Support:
Agency for Healthcare Research & Quality (DHHS)
Implementing Breast Reconstruction Clinical Decision Support in Diverse Practice Settings (Mary Politi, PhD; Clara Lee, MD)

MATERIALS APPROVED

Consent/Assent Materials:

Consent & Assent Forms

R18_Aim3_Informed consent_surgeon_9.3.2020clean.rtf
R18_Aim 3_Informed consent_patient_1.21.21 clean AC and JV changes (4).rtf
R18_Aim 3_phone consent or written waiver_surgeon_9.3.2020 clean.rtf

Recruitment/Advertisement Materials:

Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers

R18_Aim3_Flyer_3.22.21 (3).rtf

Recruitment: Website

Website 7.27.21.rtf

Recruitment Script: Phone

R18_Patient_Phone_Script_screening_6.8.21.rtf

Recruitment: Email or letters

MyChart_email message to patients_Aim_3_4.28.21.rtf
R18_ surgeon screening email 9.3.2020clean.rtf

Recruitment: Other

BREASTChoice_Recruitment_Video_(HD_1080_-_WEB_(H264_4000)).mp4

Questionnaires:

Subject Data Collection Instruments

Patient survey_intervention Aim3_v8.docx
Patient survey_control Aim3_v1.docx
Clinician survey SDM_Aim 3 pre_post_May2020.docx

This approval has been electronically signed by IRB Chair or Chair Designee:
Sunny Warren, MSW
01/20/23 1351

IRB Approval: IRB approval indicates that this project meets the regulatory requirements for the protection of human subjects. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.

Recruitment/Consent: Your IRB application has been approved for recruitment of subjects not to exceed the number indicated on your application form. If you are using written informed consent, the IRB-approved and stamped Informed Consent Document(s) are available in *my*IRB. The original signed Informed Consent Document should be placed in your research files. A copy of the Informed Consent Document should be given to the subject. (A copy of the *signed* Informed Consent Document should be given to the subject if your Consent contains a HIPAA authorization section.)

Continuing Review: Federal regulations require that the IRB re-approve research projects at intervals appropriate to the degree of risk, but no less than once per year. This process is called "continuing review." Continuing review for non-exempt research is required to occur as long as the research remains active for long-term follow-up of research subjects, even when the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and to occur when the remaining research activities are limited to collection of private identifiable information. Your project "expires" at midnight on the date indicated on the preceding page ("Next IRB Approval Due on or Before"). You must obtain your next IRB approval of this project by that expiration date. You are responsible for submitting a Continuing Review application in sufficient time for approval before the expiration date, however you will receive reminder notice prior to the expiration date.

Modifications: Any change in this research project or materials must be submitted on a Modification application to the IRB for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects. The investigator is required to promptly notify the IRB of any changes made without IRB approval to eliminate apparent immediate hazards to subjects using the Modification/Update Form. Modifications requiring the prior review and approval of the IRB include but are not limited to: changing the protocol or study procedures, changing investigators or funding sources, changing the Informed Consent Document, increasing the anticipated total number of subjects from what was originally approved, or adding any new materials (e.g., letters to subjects, ads, questionnaires).

Unanticipated Problems Involving Risks: You must promptly report to the IRB any unexpected adverse experience, as defined in the IRB/HRPO policies and procedures, and any other unanticipated problems involving risks to subjects or others. The Reportable Events Form (REF) should be used for reporting to the IRB.

Audits/Record-Keeping: Your research records may be audited at any time during or after the implementation of your project. There are Federal, State and Institutional requirements for record retention. Check with your organization and your funding agreement to learn more about what record retention requirements apply to your project.

Additional Information: Complete information regarding research involving human subjects is available in the "Washington University Institutional Review Board Policies and Procedures." Research investigators are expected to comply with these policies and procedures and to be familiar with the Belmont Report, 45CFR46, and other applicable regulations prior to conducting the research. This document and other important information is available on the HRPO website http://hrpo.wustl.edu/.

Aim 3: BREASTChoice RCT

PI: Mary Politi
IRB ID #: 202005217

Project Details

1. Demographics

1.1 Project Title:
Implementing Breast Reconstruction Clinical Decision Support in Diverse Practice Settings

1.2 Short Title (required):
Aim 3: BREASTChoice RCT

1.3 Project is primarily:
Social Science/Behavioral (includes History/Anthropology)

1.4 Type of Study:
Other Interventional

1.4.a Is your research study one in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (NIH clinical trial definition).
Yes

1.5 Select how you plan to obtain consent:
- Sign a consent document or a consent letter
- Letter or information sheet with no signature
- Script for use either in person or over the phone with no signature

2. Source(s) of Support

2.1 Source(s) of Support

Type/Source	Grant Title	Name of PI on Grant	Status
Federal Agency Agency for Healthcare Research & Quality (DHHS)	Implementing Breast Reconstruction Clinical Decision Support in Diverse Practice Settings	Mary Politi, PhD; Clara Lee, MD	AWARDED

3. Research Team

3.1 Principal Investigator

Name	E-mail	Title	Schoo
Mary Politi	mpoliti@wustl.edu	Prof of Surgery (Public Health Sciences)	School

3.2 Team Members

Research Team Members

Role	Name	Role Desc	Student	Email	Title	School	Department	C
PI	Mary Politi, PHD		No	mpoliti@wustl.edu	Prof of Surgery (Public Health Sciences)	School of Medicine	Surgery - Public Health Sciences (PHS)	
	Krista Cooksey, BA, CER		No	kcooksey@wustl.edu	Public Health Research Coordinator II	School of Medicine	Surgery - Public Health Sciences (PHS)	
	Randi Foraker, PHD		No	randi.foraker@wustl.edu	Prof of Medicine	School of Medicine	DOM - General Medical Sciences	

	Melissa Gendron, BS		No	mgendron@wustl.edu	Business Analyst I	Central Fiscal Unit (CFU)	CFU - WashU IT - Capital Projects MyDay	
	Hannah Kinzer, BA, MPH		No	h.kinzer@wustl.edu	Graduate Fellowship	Brown School	Brown School Administration	
	Terence Myckatyn, BSc(Hon), MD		No	myckatyn@wustl.edu	Prof of Surgery (Plastic & Recon Surg)	School of Medicine	Surgery - Plastics	
	Margaret Olsen, PHD		No	molsen@wustl.edu	Statistical Data Analyst III	School of Medicine	DOM - Infectious Diseases	
	Viktoria Schmitz, BS, Public Health		No	schmitzv@wustl.edu	Public Health Research Coordinator II	School of Medicine	Surgery - Public Health Sciences (PHS)	

Team Member Financial Interest

Name	Financial Interests
Mary Politi, PHD	none
Krista Cooksey, BA, CER	none
Randi Foraker, PHD	none
Melissa Gendron, BS	none
Hannah Kinzer, BA, MPH	none
Terence Myckatyn, BSc(Hon), MD	**Company/Organization** / **Types**: Allergan Medical and RTI Surgical — • Consulting Services not otherwise specified — No
Margaret Olsen, PHD	none
Viktoria Schmitz, BS, Public Health	none

4. Other Institutional Reviews/Requirements

4.1 Do any of the objectives of this study involve the diagnosis, prevention, screening, evaluation, treatment or support of cancer patients?
Yes

4.2 Are more than 30% of the patients involved in this study likely to have an active cancer diagnosis?
Yes

4.12 Will a Certificate of confidentiality be used for this research?
No

4.13 Does this project need to be registered on ClinicalTrials.gov?
Yes

4.13.a Who is the Responsible Party for registering this study in ClinicalTrials.gov?
Principal Investigator

4.21 Mark all that apply to your study:

1. Protocol

1.1 Is there a separate, written protocol that will be submitted in addition to this form? (Note: a grant application is not considered to be a protocol)
No

1.2 Select up to three key words below that best describe this research study:
- Public Health
- Surgery
- Plastic

1.3 Provide a short summary/abstract of the purpose and procedures of the study proposed in this IRB application.

- DO NOT include information on studies not proposed in this application.
- Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.

- DO NOT cut and paste technical abstracts from source of support applications that may not be understood by a general audience.

Purpose:
Breast reconstruction after mastectomy is a highly personal decision. Although it can restore quality of life for many, there are numerous risks associated with the procedure. The risk of complications exceeds that of most elective procedures. A clinical decision support tool, BREASTChoice, with personalized risk information and patient preferences, was created to be used to address these issues. The randomized control trial will evaluate whether the implementation of BREASTChoice into usual care is more effective than a control website, at improving the quality of reconstruction decisions.

Procedures:
This study aim will evaluate the effects of BREASTChoice on post-mastectomy breast reconstruction decision quality, decisional conflict, and treatment choice in a multi-site randomized trial. After receiving their breast cancer diagnosis from their breast surgeon and (when possible) before their plastic/reconstructive surgery visit discussing breast reconstruction, participants will receive a link to the BREASTChoice tool or control website through MyChart or email if they do not have a MyChart account. Depending on the clinic work-flow, the patients may be sent the tool or control website: 1) by email, prior to their visit with the plastic or reconstruction surgeon, for them to complete from home or in the waiting room (ideal and preferred approach); 2) by email or link, in person or virtually at the time of their plastic or reconstruction visit, for patients that have same-day breast surgeon and plastic reconstruction surgeon visits, with time to wait in between appointments; or 3) by email, after the plastic surgery appointment, if they have not yet made a decision about reconstruction after mastectomy (e.g., if they are undergoing neoadjuvant chemotherapy, or they want or need more time to decide on their surgery choices).

Participants in the intervention group will complete BREASTChoice, and a summary of their risks and preferences will be sent to their plastic/reconstructive surgeon to view in the electronic health record. All participants will be sent a link to complete an online survey after their plastic/reconstructive surgery visit. After enrollment, we will monitor participants' breast reconstruction receipt including whether they opted to have breast reconstruction, and if so, the type and timing of reconstruction.

Clinicians will be trained on BREASTChoice tool functions and how the tool is integrated into EHR. We will assess clinicians' shared decision making pre - and post-trial.

Prior to the beginning of the Randomized Control Trial (RCT), a pilot phase will be launched. The purpose of the pilot phase is to test the workflow and procedures. We plan to recruit up to 20 patients, continuing until procedures are smooth and ready for the randomized trial. We will follow the same procedures as the trial (above), other than randomization, to test the workflow and tool use programming.

1.4 Specify your research question(s), study aims or hypotheses:
The main hypotheses of this study is that a workflow - aware clinical decision support tool, BREASTChoice, is more effective than a control website at improving the quality of breast reconstruction decisions among women with stages 0-III breast cancer, eligible for post-mastectomy breast reconstruction.

The goal of this aim is to evaluate the effects of the updated BREASTChoice on decision quality, decisional conflict, and treatment choice in a randomized controlled trial in a diverse population. Patients considering mastectomy will be randomized to BREASTChoice or an informational website.

1.5 Background and significance and/or Preliminary studies related to this project:
Decisions about whether to have breast reconstruction following a mastectomy due to breast cancer, when to have it, and what type of reconstruction are often discordant with patients' personal preferences about risk, appearance, recovery, and number of surgeries. There are currently no reliable methods for integrating patient-specific information into the clinician-patient encounter to personalize these decisions. Incomplete or insufficient information could lead to unexpected complications, additional operations, and decision regret. Compared to most elective procedures, major complications from breast reconstructive surgery are high. As many as 50% of patients having reconstruction, experience wound complication and about 15% of patients experience complications that require additional surgeries. For some patients, complications lead to 15-20 additional procedures.

Patients often lack knowledge of complication risks for reconstructive surgery. This lack of knowledge can lead to poor satisfaction and regret. In one study, only 15% of patients understood potential risks and complications of post-mastectomy reconstruction options. Additionally, gaps exists in how breast reconstruction decision – making is addressed between clinicians and different populations. For example, Black women report unmet information needs and have greater knowledge deficits about reconstruction. Older (65+) women are less likely to be offered reconstruction compared to younger women.

Due to the higher risk of major complications from reconstructive surgery, and gaps in the decision making process, the BREASTChoice (Breast Reconstruction Education And Support Tool) tool was developed in our earlier work. The BREASTChoice tool helps women, who are undergoing a mastectomy, make decisions with their clinician about reconstructive surgery based on their personal risk factors and preferences.

BREASTChoice incorporates personalized, predictive risk analytic modelling, developed and validated using institutional and national claims data from over 17,000 patients. The tool is an interactive website and can be sent through My Chart and integrated into the electronic health record. The formative work on this tool and subsequent pilot testing demonstrated an increase in self-reported knowledge for patients in the intervention group, and usability was high.

During Aim 1 of the current study, we conducted qualitative interviews with stakeholders including clinicians, patients, informatics staff and hospital administrators to assess implementation barriers and facilitators, perceptions

of the tool, views on relative advantages of implementation, difficulty of implementation, timing of implementation, and external policies and incentives. We modified the tool based on this feedback, and identified clinic work-flow processes that could impact implementation into usual care. Additionally, the study team updated the risk prediction model using the latest peer-reviewed research.

Aim 2 of this study includes usability testing of this tool and examines optimal timing of intervention delivery and refinement of BREASTChoice, focusing on changes that facilitate implementation into existing patient routines and clinical workflows. We will embed the tool into the Epic EHR environment and facilitate its transferability to other EHR platforms.

This current Aim (Aim 3) will conduct a multi-site randomized trial to evaluate the tool. This protocol is for our site-specific procedures at Washington University in St. Louis (other sites will submit their own protocols to their own IRBs, per discussion and approval by the funders and HRPO).

1.6 Literature cited/references (if attaching a grant enter N/A):

1. Gordon LG, Merollini KMD, Lowe A, Chan RJ. A Systematic Review of Financial Toxicity Among Cancer Survivors: We Can't Pay the Co-Pay. The Patient. 2017;10(3):295-309.
2. Zafar SY, Abernethy AP. Financial toxicity, part I: a new name for a growing problem. Oncology (Williston Park, NY). 2013;27(2):80.
3. Fessele KL. Financial toxicity: Management as an adverse effect of cancer treatment. Clin J Oncol Nurs. 2017;21(6):762-764.
4. Bernard DS, Farr SL, Fang Z. National estimates of out-of-pocket health care expenditure burdens among nonelderly adults with cancer: 2001 to 2008. Journal of Clinical Oncology. 2011;29(20):2821-2826.
5. Carrera PM, Kantarjian HM, Blinder VS. The financial burden and distress of patients with cancer: Understanding and stepping-up action on the financial toxicity of cancer treatment. CA: A Cancer Journal for Clinicians. 2018;68:153-165.
6. Davidoff AJ, Erten M, Shaffer T, et al. Out-of-pocket health care expenditure burden for Medicare beneficiaries with cancer. Cancer. 2013;119(6):1257-1265.
7. Singleterry J. Costs of Cancer. American Cancer Society Cancer Action Network;2017.
8. Gilligan AM, Alberts DS, Roe DJ, Skrepnek GH. Death or Debt? National Estimates of Financial Toxicity in Persons with Newly-Diagnosed Cancer. The American journal of medicine. 2018;131(10):1187-1199.
9. Abbott DE, Voils CL, Fisher DA, Greenberg CC, Safdar N. Socioeconomic disparities, financial toxicity, and opportunities for enhanced system efficiencies for patients with cancer. J Surg Oncol. 2017;115(3):250-256.
10. Shankaran V, Jolly S, Blough D, Ramsey SD. Risk factors for financial hardship in patients receiving adjuvant chemotherapy for colon cancer: A population-based exploratory analysis. Journal of Clinical Oncology. 2012;30(14):1608-1614.
11. Kelly RJ, Forde PM, Elnahal SM, Forastiere AA, Rosner GL, Smith TJ. Patients and physicians can discuss costs of cancer treatment in the clinic. Journal of Oncology Practice. 2015;11(4):308-312.
12. Jagsi R, Ward KC, Abrahamse PH, et al. Unmet Need for Clinician Engagement Regarding Financial Toxicity After Diagnosis of Breast Cancer. Cancer. 2018.
13. Zafar SY, Peppercorn JM, Schrag D, et al. The financial toxicity of cancer treatment: a pilot study assessing out-of-pocket expenses and the insured cancer patient's experience. The oncologist. 2013;18(4):381-390.
14. Wong Y-N, Egleston BL, Sachdeva K, et al. Cancer patients' trade-offs among efficacy, toxicity and out-of-pocket cost in the curative and non- curative setting. Medical care. 2013;51(9).
15. Zafar SY, Ubel PA, Tulsky JA, Pollak KI. Cost-related health literacy: a key component of high-quality cancer care. Journal of oncology practice. 2015;11(3):171-173.
16. Schrag D, Hanger M. Medical oncologists' views on communicating with patients about chemotherapy costs: A pilot survey. Journal of Clinical Oncology. 2007;25(2):233-237.
17. Politi MC, Kaphingst KA, Liu JE, et al. A Randomized Trial Examining Three Strategies for Supporting Health Insurance Decisions among the Uninsured. Med Decis Making. 2016;36(7):911-922.
18. Housten A, Furtado K, Kaphingst K, et al. Stakeholders' perceptions of ways to support decisions about health insurance marketplace enrollment: a qualitative study. BMC Health Services Research. 2016;16(1):634.
19. Zhao J, Mir N, Ackermann N, Kaphingst KA, Politi MC. Show Me Health Plans: Dissemination of a Web-based Decision Aid for Health Insurance Plan Decisions. Journal of Medical Internet Research. 2018;In press.
20. Smith KT, Monti D, Mir N, Peters E, Tipirneni R, Politi MC. Access is necessary but not sufficient: factors influencing delay and avoidance of health care services. Medical Decision Making Policy and Practice. 2018.
21. MacQueen KM, McLellan E, Kelly K, Milstein B. A codebook development for team-based qualitative analysis. Cultural Anthropology Methods Journal. 1998;10:31-36.
22. Coffey A, Atkinson P, eds. Making sense of qualitative data: Complementary research strategies. Thousand Oaks, CA: Sage Publications; 1996.
23. Dzewaltowski D, Glasgow R, Klesges L, Estabrooks P, Brock E. RE-AIM: Evidence-based standards and a Web resource to improve translation of research into practice. Annals of Behavioral Medicine. 2004;28(2):75-80.

1.7 Describe EACH of your participant populations

- Include description of any control group(s)
- Specify the Inclusion/Exclusion criteria for EACH group

Adult women (18+) in one of the study sites over an 18-month period, with a diagnosis of incident or recurrent stage 0-III breast carcinoma will be eligible.

We will exclude patients with Stage IV disease (treatment is primarily medical, not surgical) or histology type besides ductal/lobular carcinoma (e.g.,phyllodes, sarcoma; these rare tumors differ in treatment and prognosis). We will exclude patients who have had prior mastectomy and are seeking delayed reconstruction, so that we can evaluate decisions about reconstruction timing. We will exclude those without a malignancy (i.e., considering mastectomy for prophylaxis only) because their reconstructive surgery visit or surgery may occur long after the initial consultation. We will exclude patients who cannot give informed consent or use our study materials due to self-reported or observed cognitive, visual,

or emotional barriers.

Plastic and reconstructive surgeons working at Barnes Jewish Hospital Siteman Cancer Center, Barnes Jewish West County, and Christian Hospital North East, who provide breast reconstruction after mastectomy, are eligible for this study.

We will exclude plastic and reconstructive surgeons working at other breast clinic locations, and surgeons who do provider breast reconstruction care to patients who have undergone a mastectomy due to breast cancer.

1.8 Check all materials/methods that will be used in recruiting participants:

- Telephone script
- Ads/Brochures/Posters/News Release/Fliers
- Email or letters
- Website or Social Media (printed pages)
- Other Materials - Video describing study to put on study website
- Medical Records or Other PHI
- Epic - MyChart

Attachment Name	Category	Version	Date Attached
R18 surgeon screening email 9.3.2020clean.rtf	Recruitment: Email or letters	3	09/03/20
R18_Patient_Phone_Script_screening_6.8.21.rtf	Recruitment Script: Phone	10	06/11/21
MyChart_email message to patients_Aim_3_4.28.21.rtf	Recruitment: Email or letters	11	04/29/21
R18_Aim3_Flyer_3.22.21 (3).rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	11	09/12/21
Website 7.27.21.rtf	Recruitment: Website	1	07/27/21
BREASTChoice_Recruitment_Video_(HD_1080_-_WEB_(H264_4000)).mp4	Recruitment: Other	2	09/17/21

1.8.b List the individual data elements you will access from the medical records (or other source of PHI) to identify potential participants for recruitment and, if applicable, any individual data elements that you will include on a screening log prior to consent.
We will review medical records for names, age, race, telephone numbers, mailing addresses, email addresses, language spoken at home, and breast cancer diagnosis stage and previous breast cancer surgery.

We will collect participants' reconstruction decision from the electronic health record after enrollment.

1.8.c What is the plan for individual identifiers obtained to identify participants and, if applicable, those identifiers maintained on a screening log prior to consent?
Identifiers for those who do NOT enroll will be destroyed at the earliest opportunity, consistent with the conduct of the research (for example when recruitment and enrollment are completed.)

1.8.d Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule?
Yes

1.10 Describe where the consent discussion will occur (check all that apply):

- By phone
- Online

1.11 Participants and/or their legally authorized representative will have (check all that apply to the consent process and explain process in Question 1.12 below):

- Limited time based on when they must be treated clinically or when research procedures begin. However they:
    - Will have an opportunity to thoroughly review the consent materials with knowledgeable members of the research team, with family and/or friends as appropriate
    - Will have sufficient time to have all of their questions answered
    - Will not be asked to consent when under the influence of drugs that have the potential to impact cognitive abilities such as sedation.
    - Will not be asked to consent at a time when they may be unable emotionally to fully consider the consent information (e.g. immediately following significant diagnosis.)

1.12 Provide a description of the enrollment and consent process in sequential order and address EACH of the bulleted points below:

- Describe each study population separately including control population
- Describe when recruitment and consent materials are used
- Indicate how much time individuals will have to consider participation
- If eConsent will be used to obtain an electronic signature, describe how the eConsent will be presented to participants, how their questions will be answered and how the participant will receive a copy of the final, signed consent

- Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process

The WU project coordinator will screen through EPIC to identify potentially eligible patients at the participating study sites. They will retrieve the phone numbers, email addresses if available, and mailing addresses of potentially eligible patients. Patients will be contacted after the patient has received their breast cancer diagnosis.

Then WU research staff can approach eligible patients by phone, after the breast surgery visit and before the reconstructive surgery visit to provide study information. The patient can choose to complete the consent form 1) in clinic (with signed consent document), 2) virtually (waiver of documentation of written consent by providing an information sheet electronically), or the 3) WU research staff can review the consent information sheet with them over the phone or zoom. The waiver of documentation of consent will be sent via secure email or MyChart (process approved by the MyChart, Epic1, and BJC clinical informatics teams).

Because of the public health response to COVID19, we anticipate that some patients will have virtual clinical encounters instead of in-person clinical encounters. If this occurs during the trial, participants would be offered electronic waiver of documentation of informed consent information sheets or phone consent instead of paper consent forms. Study staff will be available through phone, zoom or email to answer the participants' questions.

Depending on the circumstances (as described in the following), WU research staff may approach potential participants in one of three ways.

1) If potential participants may be reached prior to their visit with the plastic or reconstruction surgeon, they will be approached virtually, by phone, or in-person at the clinic before their appointment (preferred method).

2) For some participating sites that have same-day breast surgeon and plastic surgeon reconstruction visit clinic work-flows, the study staff will not have a chance to contact these patients by phone for consent prior to their visit with their plastic/reconstructive surgeon. These potential participants will be approached in person or virtually by the study staff to provide information about the study and complete informed consent. Potential participants contacted virtually will be sent e-consent forms.

3) Some potential participants may be approached after their breast reconstruction visit (but before they make their reconstruction decision) due to clinic workflows that have same day breast and reconstruction surgeon visits, or clinics that add a patient visit to the clinic schedule that day. These patients with same day breast surgeon and breast reconstruction appointments will complete consent and study procedures after the reconstruction visits and before their next reconstruction visit or surgery.

For recruitment, we will approach WUSM faculty who see patients that are eligible for the study. Before the study began, Dr. Politi and Dr. Myckatyn presented the information about the study to WUSM’s Department of Surgery’s Division of Plastic and Reconstructive Surgery. At the meeting, clinicians expressed interest in participating in the study. We will retrieve eligible clinician email addresses and/or phone numbers from the WUSM system.

Eligible surgeons will be emailed by WU research staff with study information. If interested the research coordinator will call the surgeon and review the phone consent information sheet. The surgeon could alternatively request a waiver of documentation of informed consent or complete the consent in-person.

1.13 Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.

Describe study populations separately if they will be participating in different procedures

DESCRIBE:

- Control populations, if applicable
- Any randomization, if applicable
- What participants will be asked to do/what happens in the study (in sequential order)
- The time period over which procedures will occur
- Long-term follow-up and how it occurs

After the patient participant consents to be in the study, we will randomize (using computer random assignment, RCT only) participants to view the clinical decision support tool, BREASTChoice or the attention control website (https://www.cancer.gov/types/breast/reconstruction-fact-sheet), using block randomization (block size 4). Depending on the clinic work-flow, the patients may be sent the link to the tool or control website: 1) by email or MyChart message, prior to their visit with the plastic or reconstruction surgeon, for them to complete from home or in the waiting room (ideal and preferred approach); 2) by email or MyChart, in person or virtually at the time of their plastic or reconstruction visit, for patients that have same-day breast surgeon and plastic reconstruction surgeon visits, with time to wait in between appointments; or 3) by email or MyChart, after the plastic surgery appointment, if they have not yet made a decision about reconstruction after mastectomy (e.g., if they are undergoing neoadjuvant chemotherapy, or they want or need more time to decide on their surgery choices). Participants will be sent the link via MyChart unless they do not have a MyChart account. In that case, they will be sent the link via email. Study staff will be available to answer questions about MyChart via phone or email.

The following privacy protections will be enacted for all email communications involving PHI; 1) a test email will be sent to the participant to verify their identify (confirm correct recipient) and that this email will be sent in a secure manner (i.e., [secure] in subject line); 2) The body of the email will instruct the participant to send all information as a response to this thread and to not remove the "[secure]" from the subject line; 3) document in your research records the participant's agreement to provide information over email.

We will randomly choose to audio-record the visits of 20% of participants with their plastic surgeon. We have included in our consent documents for patients and clinicians that their visit may be audio recorded. As part of the consent documents we ask participants if they are willing to have their visit audio recorded. If they say no, they can still be a part of the study.

Clinicians who consent to participate in the trial will receive a brief virtual training on how BREASTChoice functions and the features, including placement of the patient tool summary in the electronic health record. Clinicians will complete pre/post trial survey about shared decision making. Clinician survey participation will take less than 5 minutes. They will receive a $50 gift card as a thank you for their time.

BREASTChoice will be hosted in a secure location with a secure database, integrated with Epic by the BJC Center for Clinical Excellence decision support informatics team. This team is working closely with the Epic team for security compliance. The tool will use security authentication procedures, data encryption, the app Orchard, and exchange information using Fast Healthcare Interoperability Resource (FHIR). The tool will undergo and receive approval through the hospital security review process, which includes a vulnerability scan.

The tool will auto-populate patient health information from the electronic record. Participants can modify their personal health information in the tool in case data such as current health conditions listed in their record are out-of-date, but cannot modify their personal health information in the electronic medical record. Participants can view a summary at the end of BREASTChoice that includes the tailored risk information and their values and preferences. The summary will be sent to their clinician to view in the electronic health record, via the Epic portal. After patients view the BREASTChoice tool or attention control website, all participants will complete an online survey assessing socio-demographics, knowledge, values/preferences, health literacy, decisional conflict, measure of patient engagement, health-related quality of life, preferred decision role, consult time and usability of the tool. All measures were chosen based on their short length so as not to burden participants. After enrollment, we will monitor reconstruction receipt including type and timing, and assess clinician satisfaction after Aim 3 study recruitment is complete.

Participation is expected to take about 25 minutes. Participants will receive a $20.00 gift card as a thank you for their time.

1.14 Will participants be randomized?
Yes

1.15 Will any of the following be used to collect information from the participant or others?

- Screening questions or screening/eligibility questionnaires
- Surveys
- Questionnaires
- Stimuli
- Any other written assessments

Yes

Attachment Name	Category	Version	Date Attached
Patient survey_intervention Aim3_v8.docx	Subject Data Collection Instruments	1	05/29/20
Patient survey_control Aim3_v1.docx	Subject Data Collection Instruments	1	05/29/20
Clinician survey SDM_Aim 3 pre_post_May2020.docx	Subject Data Collection Instruments	1	05/29/20

1.16 Does this project involve creating any audio, video, or photographs?
Yes

1.17 Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?
Examples:

- Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.
- Participants will be provided with false information regarding the particular behaviors of interest in the research.
- Procedures include a confederate pretending to be another participant in the study.
- Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.
- Study is designed to introduce a new procedure (or task) that participants are not initially told about.

No

1.18 Indicate any payments or reimbursements to participants (check all that apply)

- Gift or Debit Card

1.19 Does this study have a plan to have an individual or committee review combined data from all participants on a periodic basis (such as summary or aggregate safety and/or efficacy data)?
Yes, but it's not described in an attached protocol

A Data and Safety Monitoring Committee (DSMC) will be convened for this trial to review outcomes data at least every 6 months following study activation. The DSMC will consist of no fewer than 3 members including 2 clinical

investigators and a biostatistician. All DSMC members will be familiarized with the research protocols and plans for data safety and monitoring. Like investigators, DSMC members are subject to university policies regarding standards of conduct. Individuals invited to serve on the DSMC will disclose any potential conflicts of interest to the trial principal investigator and/or appropriate university officials, in accordance with institution policies. Potential conflicts that develop during a trial or a member's tenure on a DSMC must also be disclosed. The DSMC report will be prepared by the study statistician with assistance from the study team, will be reviewed by the DSMC.

1.20 What have you done to minimize any risks?

- Other - It is possible participants may feel uncomfortable with some of the questions or photos in the tool. They can skip any questions they do not want to answer, or skip parts of the tool. Another risk if a participant joins the study is that confidential information about them may be accidentally disclosed. Their information will be secure, in password-protected network drives that only the study team can access. We will identify participants by a number and not by their name. We will report our findings in summary form and not linked to any one person.

1.21 What are the potential benefits related to this project for:

- the participant (if any)
- benefits to society (if any)

This project may not present a direct benefit to the participants. Some breast cancer patients randomized to the BREASTChoice arm of the Aim 3 trial may benefit from receiving additional information about breast reconstruction, their potential risk of complications, and evaluating their preferences. Society may benefit from the development of new clinical communication tools for discussing breast reconstruction options with patients and clinicians.

1.22 Provide a summary of the analysis methods you will use, including, if applicable, the data points or outcomes you will analyze.
Descriptive statistics will be calculated for demographic and clinical characteristics (race, age, comorbidities, etc.) and for knowledge, preference concordance, decisional conflict, and CollaboRATE.

The primary endpoints of knowledge, preference concordance, and decisional conflict will first be evaluated with univariate analyses through the use of t-tests and chi-square analyses as appropriate. We will explore the use of transformations and non-parametric alternatives for these responses if necessary. We will use generalized linear mixed models to explore differences between patients randomized to BREASTChoice and to the control arm. Models will be adjusted for important clinical and demographic variables and will include relevant interactions. Specifically, we will include an interaction between group (i.e., BREASTChoice or control)and time, to test for differences in randomized group over time that could be due to changes in surgeon practices. A random effect for surgeon will also be included in the model. Missing data will be handled through imputation, and associations between covariates and the missing indicator will be explored. The same analytic procedure will be used to examine the impact of BREASTChoice on patient engagement (CollaboRATE).

A secondary goal is to explore whether the intervention is associated with fewer high-risk patients choosing reconstruction. Patients will be considered high-risk if their risk exceeds 2 times the population average.38 We will explore whether age or race modifies the association between intervention and decision quality (knowledge and preference concordance). Descriptive statistics will be calculated for these outcomes, and associations will be assessed using appropriate chi-square or Fisher's exact tests.

We also will explore whether provider intention to engage in shared decision making increases during the trial, by examining changes in the mean of
the CPD-Reaction scale, through the use of the Wilcoxon signed-rank test. Preferred decision role will also be assessed through chi-square or Fisher's exact tests.

1.23 Provide the rationale or power analysis to support the number of participants proposed to complete this study.
The sample size needed to detect an effect size of 0.3 and power of at least 80% in decisional conflict, comparable to what was seen in a similar study,122 is 170 per group. With this sample size,the study will be adequately powered to detect at least a 15% difference in the percent of patients with knowledge scores > 50%, assuming that the control group percentage of patients scoring > 50% is 34%.

If instead we wish to compare differences in knowledge score between groups, this same sample size will provide > 90% power to detect a difference of a mean 10 points. The effect size was also chosen based on an RCT aiming to reduce decisional conflict about breast reconstruction via online decision aid (DA). That
study found that at 1 and 6 months, the DA group had significantly less decisional conflict (effect sizes of 0.35and 0.29, respectively). The DA group scored on average at levels consistent with having made a decision, while the control group still had scores reflecting indecision. These differences can lead to clinically meaningful differences in quality of life in cancer patients. In addition, the DA group had a reduction in decisional conflict to a level below a cutoff for clinically significant scores (score <25), while the control group reported clinically significant decisional conflict (score > 25).124 Thus, our effect size is both statistically and clinically meaningful.

1.25 Will any data from this project be stored for use in future research studies?
No

1.26 Does this project involve the collection or use of biological samples or genetic data?
No

1.27 Are you requesting institutional certification to contribute human data or samples to a repository or database for broad sharing (public or restricted access)?
No

2. Participants

2.1 Will there be any adult participants?
Yes

2.1.a How many adult participants do you expect to consent or enroll under a waiver for this project?
240

2.1.b What is the age of the youngest adult participant?
18.0

2.1.c What is the age of the oldest adult participant?
No age limit

2.2 Will there be any minor participants?
No

2.3 Will there be any emancipated minor participants?
No

2.7 Do you plan to recruit/enroll non-English speaking people?
No

2.8 Do you propose to enroll any of the following in this study as participants?

- Employee of the PI or employee of a research team member
- Individual supervised by PI or supervised by member of research team
- Individual subordinate to the PI or subordinate to any member of the research team
- Student or trainee under the direction of the PI or under the direction of a member of the research team

No

2.9 Is this project about pregnant women?
No

2.10 Will this project involve fetuses?
No

2.11 Does this project involve the use of fetal tissue from any source?
No

2.12 Does this project recruit adult participants who may be incompetent or have limited decision-making capacity on initial enrollment into the study?
No

2.13 Does this project involve prisoners as participants?
No

3. Performance Sites

3.1 Indicate type of site(s) where research will occur (check all that apply):

- Hospital
- Academic Institution

3.2 Where will project procedures take place (check all that apply)?

- School of Medicine
- Other WUSTL campus site - Christian Hospital NE and Barnes Jewish West County WUSM clinics

3.3 Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?
Yes

3.3.a What is your site's role(s) for this project (check all that apply)?

- Clinical/participating site
- Data analysis, statistical analysis or data management

3.3.g What are participating site roles for this project?
- Clinical/participating site - 2
- Data analysis, statistical analysis or data management - Ohio State University, Columbus Oh

5. Privacy & Confidentiality

5.1 Indicate your plans to protect the privacy interests of the participants during the conduct of the study (check all that apply):
- Only the minimum necessary private information is collected for the purposes of the study
- Any procedures or interventions conducted as part of the study will be conducted in private setting to the extent possible
- Recruitment/consent will occur in a private setting
- Participants will be able to ask questions in a private setting

5.2 Are you collecting or using the Social Security Number of any participants for any purpose?
Yes

5.2.a Provide the intended usage of SSN:
- To provide compensation to participants

5.3 Project uses paper or hard copy consents, surveys, data collection forms, research subject binders, or other hard copy materials (check all that apply):
Yes
- All materials are stored in secured environment
- Access is limited to research team members only

5.4 Project collects, stores and/or transmits electronic data on mobile devices, desktop computers, servers including cloud servers, email, or any other information in electronic form (check all that apply):
Yes
- Password protected
- Access is limited to research team only
- Data are encrypted
- Data in Redcap
- Other - The BREASTChoice tool will be approved by the Barnes Jewish Hospital security review team prior to the start of the trial and will undergo and pass a vulnerability scan to be approved for use in the clinic. The tool uses secure authentication methods, Fast Healthcare Interoperability Resource (FHIR), the app Orchard, and is house outside of the electronic health record.

5.5 Project collects or uses biologic specimens (check all that apply):
No

5.6 Identify any additional protections in place for data and or samples (check all that apply):
- Formal research staff training process