IRB #2134300 KC

IRB Application #472158

Submission date: **03/27/2026**
Submitted by: **Qiu, Mei Rosemary**

1. Investigators/Project Title

1. **Key Personnel - List all investigators engaged in the research by clicking on the "Add an Investigator" button.**This includes individuals interacting or intervening with subjects, collecting or accessing identifiable data, or consenting subjects. Please note, if individuals are performing services that are typically performed for non-research purposes, and they are only providing a service for this project, they do not need to be listed.

   Principal Investigator Assurance: After you hit submit on this application, the PI will be sent an email from the system requesting the completion of the PI Assurance Form. This application will not officially be submitted to the IRB until this step is complete. Note: Courtesy appointments cannot serve this role.

   Primary Contact(s): Whoever you would like to be copied on IRB correspondence, including reminders and approvals, please be sure to add them as primary contacts when prompted under the "Add an Investigator" button. There must be at least one primary contact on this application.

   Fellows and Residents: Must have a faculty member listed as the principal investigator.

   Student-Initiated Projects: Students must list their faculty advisor as Principal Investigator. Students may list themselves as sub-investigator.

   Significant Risk, Medical Treatment Study: For activities that require consent to be obtained by a licensed physician outside the scope of research, only a physician, advanced practitioner, or appropriately licensed provider may have the consent role as "authorized to obtain consent".

   Expedited and Full Board Studies: Please be sure the Principal Investigator has uploaded their Curriculum Vitae (CV) or resume to their personal document storage in eCompliance. When the PI logs into eCompliance, this will be uploaded under the "Prerequisites" column. This only needs to be uploaded once for all studies.

Role	Investigator	Department	CITI IRB Training	CITI GCP Training	Consent personnel role	Primary contact
Principal Investigator	Qiu, Mei Rosemary	Nursing - General	10/10/2023	10/10/2023	Authorized to Obtain Consent	☑
Co-Investigator	Kapp, Kelly Alexandra	Internal Medicine	01/14/2026	03/30/2025	Authorized to Obtain Consent	☐
Co-Investigator	Kremer, Howard L.	Surgery	11/26/2023	03/26/2026	Authorized to Obtain Consent	☐
Co-Investigator	Liu, Bowen	Mathematics & Statistics	11/01/2024	11/01/2024	Non-Consenting Personnel	☐
Research Staff	Korth, Stephanie Anne	Nursing - General	03/24/2026	06/18/2025	Authorized to Obtain Consent	☐

2. Contact Information (Read-Only)

Principal investigator

Qiu, Mei Rosemary

Job title

ASSOCIATE DEAN OF RESEARCH, DOROTHY & DALE THOMPSON MISSOURI ENDOWED PROFESSOR IN NURSING

Department

Nursing - General

Division

School of Nursing & Health St

Business unit

University of MO-Kansas City

Primary contact

Qiu, Mei Rosemary

Job title

ASSOCIATE DEAN OF RESEARCH, DOROTHY & DALE THOMPSON MISSOURI ENDOWED PROFESSOR IN NURSING

Department

Nursing - General

Division

School of Nursing & Health St

Business unit

University of MO-Kansas City

3. Are there any investigators listed on your study that are listed as courtesy or volunteer appointments?

○ Yes ● No

4. Project Title

If the study is externally funded or internally grant funded, this title should match the title on the grant/ contract.

Advancing Patient Care for Lymphatic Pain and Lymphedema

FORM INSTRUCTION: As you work through the form, you will be checking boxes that prompt additional questions. If you realize those additional questions do not pertain to your study, go back and uncheck the box that prompted those questions.

2. Exempt Determination

☑ **NOT EXEMPT: If you already know that your project is NOT exempt, please check this box and click Save & Continue. If you are unsure, do not check this box and continue below.**

3. Basic Project Information

1. Select from the type of research this project would likely fall under:

☑ **Biomedical** - Research that is conducted to increase fundamental knowledge and understanding of the physical, chemical and functional mechanisms of human life processes and diseases.

☑ **Social/Behavioral/Educational** - Research that encompasses a range of methodologies and seeks to answer questions to improve our understanding of human behavior, attitudes, beliefs, and interactions as well as social and economic systems, organizations, and institutions.

2. Indicate any conflicts of interests associated with this research study.

Example: Financial, personal, institutional, or other, for any study team member. If none, please indicate no conflict. We will verify your responses with existing data on file. Ensure you are aware of any specific restrictions for your department or college.

Please see this resource document for a list of what to disclose: DISCLOSURE GUIDE

☐ Financial

☐ Professional

☐ Institutional

☐ Personal

☑ Other

A. Describe the specific conflict(s) of interest related to this study and the proposed research management plan.

No conflicts

3. Is this study **limited to** a medical chart review or analysis of identifiable data (data that have been or will be collected solely for non-research purposes)?

○ Yes ● No

4. Protocol Information

For studies that do not have a sponsor drafted protocol the IRB application can serve as the "protocol" document for the study.
If you have a protocol drafted by a sponsor, please upload that protocol.

A. What is the protocol version number?

All protocols must have a version number (i.e. v1). The information pulls to the approval letter so it must match what is in the protocol uploaded.

V1.0

B. What is the protocol version date?

All protocols must have a version date. The information pulls to the approval letter so it must match what is in the protocol uploaded.

March 16, 2026

5. Is this a clinical trial?

A clinical trial is defined as a research study 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.
Click here for guidance on making this determination, if unknown.

● Yes ○ No

6. Has the study been registered on clinicaltrials.gov?

● Yes ○ No

7. If yes, provide the NCT number here:

Pending

8. Select the clinical trial phase:

N/A

9. Is there a clinical investigational drug brochure (CIDB)?

○ Yes ● No

10. Are you required to follow the guidelines for International Conference on Harmonisation Good Clinical Practice (ICH-GCP)?

If unsure and your study is sponsored, please consult with your sponsor or the information is often found in the protocol. ICH-GCP is an international standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. Please click here for more information.

○ Yes ● No

11. Is this a multi-site study?

Multi-site research refers to multiple sites (external to UMKC) conducting a portion or all of the same protocol. This means the UMKC investigator is (1) a PI on a grant with another site(s) as a sub-contracted site(s), and/or (2) taking on the role as the lead investigator/site overseeing/coordinating the conduct of the study.

○ Yes ● No

12. Select from the committees or entities that will also be responsible for reviewing and approving this study:

You may make prior contact with these areas to start the process, or you may ask the IRB staff for assistance with these additional approvals.

- ☐ **Radiation Safety** (Studies involving radiation therapy that is not considered standard of care and is protocol-driven, radioactive materials)
  UMKC Radioactive Materials Website
  E-Mail: rsc@umkc.edu
  Phone: 816-235-5241
- ☐ **Institutional Biosafety** (Studies involving recombinant or synthetic nucleic acid molecules, including the creation and the use of organisms and viruses containing recombinant or synthetic nucleic acid molecules, biohazardous materials)
  Institutional Biosafety Committee Website
  E-Mail: umkcibc@umkc.edu
  Phone: 816.235.1844 and ask to speak with the Biosafety Officer

Other:

Not Applicable

13. Select from the following to determine if HIPAA (Health Insurance Portability and Accountability Act) regulations apply to this study:
HIPAA Resource

- ☑ The study involves accessing/screening the medical record prior to contacting subjects and obtaining consent. A HIPAA waiver will be required.

  Check HIPAA waiver below.
- ☑ Data are derived from a medical record or encounter
- ☑ Data are added to the hospital or clinical medical record
- ☑ Data are created or collected as part of health care
- ☐ Data are used to make health care decisions
- ☐ The research is being conducted in a covered entity or at a location where there is patient billing
- ☐ None Apply

A. If HIPAA regulations apply, select the form that will be used (this will need to be uploaded to the attached files section in a Word document).

- ☐ Waiver or Alteration of Authorization
- ☑ Partial Waiver of Authorization
- ☑ University Health Authorization
- ☐ UMKC School of Dentistry Authorization
- ☐ UMKC General Authorization

B. Does the study involve University Health PHI?

● Yes ○ No

If yes, UH approval will be required.
Please visit the following link to access the UH Office of Research Administration website to submit the application:
https://www.universityhealthkc.org/education/research-administration/application-and-requirements/
Please reach out to hsdresearch@umkc.edu with any questions on University Health application or approval processes.

C. If data are derived from the medical record, please identify the source here.

University Health

14. Is the research funded/supported?

Select "yes" for internal or external funding. If this is an external grant, you must upload the grant narrative to this application for review under the attached files section.

● Yes ○ No

15. Select the sponsor from the drop-down menu.

If you do not see your sponsor in the drop-down menu, email umkcirb@umkc.edu to add it to the list.

BioNexus KC

16. Select the appropriate funding type:

- ☐ Internal Funding (departmental funding, research council grant, etc.)
- ☐ HHS funded (Department of Health and Human Services)
- ☐ Federally Funded
- ☐ Industry Sponsor (ex. Pharmaceutical company, device company, etc) * IRB fees apply
- ☑ Non-Federal, External Funding
- ☐ US Department of Education
- ☐ Department of Energy
- ☐ Department of Defense
- ☐ Environmental Protection Agency
- ☐ Department of Justice

17. Provide the UMKC Sponsored Program Grant Proposal Number, if applicable.

If you receive funding after IRB approval, you must update this information using the Identification Form.

Not Applicable

18. Provide a description of your study, including the research objectives.

Breast cancer is one of the top concerns in Kansas City and the United States. Lymphatic pain refers to various pain sensations (e.g., pain, aching, soreness, tenderness, burning, stabbing) following breast cancer treatment. Lymphatic pain affects more than half of 4 million patients treated for breast cancer in the United States. Lymphatic pain significantly impairs patients' daily living function, increases psychological distress, and decreases quality of life. As a significant risk of lymphedema, lymphatic pain indicates an early stage of lymphedema. Lymphedema is a chronic and incurable swelling caused by an abnormal fluid build-up following breast cancer treatment. Without timely intervention in this early stage, lymphedema can progress

into a chronic condition that no surgical or medical interventions can cure.

Patients with financial hardship are 4.64 times more likely to report lymphatic pain. Further, obesity/high body mass index is an important risk factors for lymphatic pain and lymphedema. Effective management of lymphatic pain can decrease the risk of lymphedema and reverse mild lymphedema as well as improve daily living functions, psychological distress, and quality of life. The-Optimal-Lymph-Flow (TOLF) is a non-pharmacological and digital behavioral intervention that builds patients' self-care skills to promote lymph flow and result in complete pain reduction, reduced lymph fluid level, reversed mild lymphedema, improved psychological distress and quality of life. Of concern, this effective intervention has not been adapted to reduce patient barriers (e.g., available care, cost, time, travel, competing demands) and health system barriers (e.g., intervention availability, staffing, therapist) to timely interventions faced by patients, especially those with financial hardship in Kansas City. Our recent research in Kansas City found that more than 60% of patients suffered from lymphatic pain following breast cancer treatment and many patients never heard of "lymphedema" although many of them had lymphedema.

The purpose of the project is to adapt The-Optimal-Lymph-Flow (TOLF) in clinical practice. We will implement digital lymphatic pain and lymphedema assessment in clinical practice, conduct clinician training and deliver TOLF Self-Care interventions to patients with lymphatic pain at Richard & Annette Block Cancer Center at University Health Kansas City. The objectives of the study are: 1) Conduct a pragmatic clinical implementation study with 100 patients to evaluate implementation effectiveness of lymphatic pain assessment; 2) Conduct a pragmatic, one-group, 12-week clinical trial with 35 patients with lymphatic pain to evaluate real-world clinical effectiveness of TOLF Self-Care intervention.

Each participant clinician will offer breast cancer patients who underwent breast surgery the opportunity to be evaluated for lymphatic pain during each in-person routine clinical visit. With the patient's oral consent, the participant clinician conducts the assessment and document whether the patient has lymphatic pain or not. If the patient has lymphatic pain, the clinician will offer the patient the opportunity to receive TOLF Self-care intervention. The clinician will give the patient the study flyer for the intervention study (Objective 2) or ask the patient's permission to share their contact information to the researchers to contact the patient with lymphatic pain. A total of 35 patients will receive the same intervention, this is one-group study. The patients can refuse the assessment.

The project has potential to have major impact on advancing patient care for lymphatic pain and lymphedema, especially in patients with financial hardship. The project will showcase the way of how to build clinical capacity to provide quality care for patients with lymphatic pain and lymphedema in health systems across the nation.

19. Specify what questionnaires, tests, and/or procedures included in your study are research-only (occurring only because they are a participant in the research).

Include a brief description of each questionnaire, test, and/or procedure.

Procedures and Measures for Objective 1:
Objective 1 is a quality improvement implementation study, that is UH breast clinic will implement the lymphatic pain assessment as a routine patient care for all the patients. This assessment will continue even the study is completed. as this is implementation study of the lymphatic pain assessment which is quality improvement project that does not need to have patients consent because it is part of routine care but the patients can decline the care.

Each participant clinician will offer breast cancer patients who underwent breast surgery the opportunity to be evaluated for lymphatic pain during each in-person routine clinical visit. As with other routine clinical

assessment, patient can decline the lymphatic pain assessment and can give oral consent to be assessed for lymphatic pain. The participant clinician conducts the assessment use SmartDetect software which entails to ask patients whether they have pain or other lymphedema symptoms. The software provides the assessment results as: No, lymphatic pain, Yes, lymphatic pain: A little, Somewhat, Moderate, Severe. Then, clinicians will document the patient's lymphatic pain status, i.e., No lymphatic pain, Yes lymphatic pain and severity of lymphatic pain. If the patient has lymphatic pain, the clinician will offer the patient the study flyer for the TOLF Self-care intervention study. The patients can call the researchers using the information in the flyer.

As part of clinical practice, the clinicians will record the assessment results in an electronic form, a power chart in UH's EMR system that that allow the clinicians to enter whether the patient has lymphatic pain or not. Data from this electronic form will be de-identified and shared with the research team by UH. The data will be used to evaluate the effectiveness of the implementation of SmartDetect in terms of how many patients assessed and how many have lymphatic pain. Assessing lymphatic pain is the only screening for Objective 1.

It takes about 5 minutes to complete the assessment with each patient at each clinical visit. Each participant clinician is encouraged to conduct SmartDetect with patients over 7-12 months during the study period. As part of clinical practice, the assessment will go on even when the study ends. As patients may have multiple clinical visits during the study period, a patient may receive multiple assessments over 12 months period. Ongoing assessment is essential as lymphatic pain can occur or reoccur at any time during the lifetime.

Implementation Effectiveness will be evaluated in terms of feasibility and acceptability.
Feasibility will be assessed by
(a) numbers of clinicians received training for SmartDetect© and study accrual of at least 10 clinicians (N=10) who provide direct care for breast cancer patients,
(b) protocol adherence (>70% adherence to the protocol defined in this study as the degree to which clinicians are willing and able to complete lymphatic pain assessment on at least 15 patients by each clinician over the study time), and
(c) clinician retention (>70% clinicians are willing to continue lymphatic pain assessment for patients beyond the study).

Acceptability will be assessed post-implementation using the validated scale of clinician satisfaction and rate whether TOLF-Assess program is acceptable. Clinician satisfaction will be evaluated using an anonymous survey for the individual clinician satisfaction of the use of SmartDetect©. Clinician Basic Information will be collected to include specialty, years of clinical practice, patients seen per week in the attached clinician survey. All clinicians who provide direct care for patients are invited to participate in electronic and anonymous surveys that will be sent to their email and available for completion 1-month, 3-month, 6-month, and 12-month post-implementation of the lymphatic pain assessment (i.e., SmartDetect). Clinical effectiveness of SmartDetect© will be assessed in terms of numbers of patients who complete lymphatic pain assessment (targeted patient number N=100) and number of patients with lymphatic pain are referred to TOLF Self-Care intervention (targeted patient number N=35).

Evidence of Promising Outcomes. Assuming a minimum protocol adherence of 70%, there will be at least 100 patients who will be assessed for lymphatic pain. Assuming acceptability is 50% which has the most conservative precision interval, the acceptability will be estimated within 8%. We expected at least 50% of patients who are assessed will report lymphatic pain and at least 70% of patients will be referral for TOLF Self-Care intervention (N=35).

Procedure and Measures for Objective 2:
Patients with lymphatic pain who is eligible and willing to participate in the TOLF Self-Care intervention will be enrolled in the study. Detailed recruitment and intervention delivery is described in later sections.

Patients who consent to the study will complete the study measures before the intervention and 12-week after the intervention, Detailed description of intervention delivery is described in the later sections. Patients

can choose to have the assessment in-person or virtual.

Patients in the intervention study will take part in the study for 12 weeks. The patients will learn about the self-care strategies to manage pain, swelling, and other symptoms and be instructed to perform the lymphatic exercises at least twice a day (morning and evening) during the 12 week study period. Patients can perform as many as 3-4 times of the lymphatic exercises a day for better pain and symptom management. It takes less than 8 minutes to complete the lymphatic exercises. Patients are also required to have two research visits which are specific for the research and will not be billed for their insurance for the two research visits.

Primary and Secondary Outcomes and Measures of Objective 2. The pre- and post-measures include the below measures/questionnaires.
Lymphatic Pain: The Breast Cancer and Lymphedema Symptom Experience Index (BCLE-SEI) Part I, a reliable and valid self-report instrument is used to assess self-reported lymphatic pain.2-3;38-41 The items are rated on a Likert scale from 0 (no lymphatic pain/swelling) to 4 (greatest severity of lymphatic pain/swelling).
Pain Severity and Interference: are measured using the Brief Pain Inventory-Short Form (BPI-SF) with demonstrated reliability and validity.42
Daily Living Function: Daily living function is operationalized as Activities of Daily Living (ADLs) that reflect the real-world daily living of breast cancer patients. The 13-item subscale of ADLs in BCLE-SEI Part II is used to assess self-reported difficulty in performing thirteen ADLs.2;43 Cronbach's alpha for the ADLs subscale is 0.94.2;43
Psychological Distress: The 12-item subscale of psychological/emotional distress subscale from the BCLE-SEI Part II is used to assess the distress of being frustrated, sad, guilt/self-blame, worried, irritable, fearful, angry, lonely, helpless, hopeless, anxious, and depressed. Cronbach's alpha for the psychological/emotional distress subscale was 0.91.39;41
Quality of Life: The 10-item V1.2 Patient Reported Outcome Measure Information System Global Health Scale (PROMIS GHS), (➔= 0.80-0.86)44 that captures self-perception of QOL on a scale from 1 (poor), 2 (fair), 3 (good), 4 (very good) to 5 (excellent).
Self-efficacy for Pain Management: The 5-item Chronic Pain Self-Efficacy Scale with good reliability45-46 is used to assess patients' certainty about their degree of pain control, pain during daily activities, controlling pain during sleep, and making pain reductions without extra medication.

Potential Covariate Variables.
Medical and Demographic Information: Medical and demographic information will be extracted from EMR to include age, race/ethnicity, marital status, education, income, education, insurance information, initial and/or recurrent diagnosis date, disease stage, cancer treatments (i.e., chemotherapy, radiation, surgery history/ type), medical comorbidities, height and weight, and use of antidepressant, anxiolytics, and pain medications.
Socioeconomic Needs for Health: The Accountable Health Communities (AHC) model47-52 is used to assess socioeconomic needs for health: (1) 2-item for living situation, (2) 2-item for food, (3) 1-item for transportation, (4) 1-item for utilities, (5) and 1-item for financial strain.

20. Specify what questionnaires, tests, and/or procedures included in your study are routine activities/care (occurring regardless of the research, but you will use the information in your research).

For the implementation study, patients' demographic and clinical data will be part of routine care. The UH will provide de-identified data regarding patients being assessed for lymphatic pain. Data regarding patients being assessed for lymphatic pain will be de-identified data. De-identified patient data will include: demographic data (i.e., age, ethnicity, education, marital status, employment, house-hold income, medical insurance, smoking history, alcohol intake, chronic illness, body mass index) and cancer treatment information (i.e., type of surgery, lymph nodes removed, cancer stage, radiation, chemotherapy, hormonal therapy. Lymphedema diagnosis).

21. Are there currently existing routine care/interventions or treatment alternatives for this condition/ problem besides participating in this study?

○ Yes ● No ○ N/A

22. Where will the research take place?

Indicate the location(s) of the study visits/sessions.

University Health Cancer Center and this location will also be the location that in-person visit will be held.

23. Permission to Conduct the Study

Be sure to keep documentation of permission, if required, in your research records.

● I attest that I already have permission to conduct the study at these locations.

○ I am still needing some or all permission to conduct the study, but permission will be secured prior to subject recruitment.

24. How long will the subject actively participate in the research?

Actively participate includes the protocol-specific visits/sessions that require their attendance and/or participation. Specify minutes, hours, months, or years.

Objective 1. Clinicians will assess patients as part of routine care during the study time as part of routine clinical practice during the study period of 12 months. It takes about 10 minutes to finish the clinician survey. The electronic and anonymous surveys will be sent to the clinician via email for completion 1-month, 3-month, 6-month, and 12-month post-implementation. No long term follow up for patients receive the lymphatic pain assessment as part of the routine clinical practice.
Objective 2. Patients will be in the study for 12 weeks.

25. How long will the subject be in long-term follow-up?

This means subjects that have completed all study-related treatment/interventions, but are being followed per study protocol to monitor study-related outcomes. This includes interactions that involve no more than minimal risk (i.e. quality of life surveys/follow-up surveys), and collection of follow-up data from procedures or interventions that would have been done regardless of the research (i.e routine clinical or non-clinical activities to further monitor a subject). Specify minutes, hours, months, or years.

If follow-up is not applicable, please state "no follow-up".

Only patients in the intervention study will be followed up for week 12.

26. Does the study involve a sub-study?

This means subjects enrolled in the main study may be eligible to participate in sub-study. This is not for new enrollees (you cannot have multiple studies with different populations under one IRB project)

○ Yes ● No

27. Does the study involve subject compensation?

This includes monetary payments, educational credits, etc.

● Yes ○ No

28. Describe the amount of subject compensation.

The 35 patients in the one-group intervention will receive up to a total of $ 65 gift card for taking part in this study according to the following schedule:
• $30.00 at your first visit (0-week visit)
• $35.00 at your second visit (12-week visit)

29. What is the proposed payment type?

- ☐ Check
- ☑ Gift Card
- ☐ Cash

Other:

30. Describe the timing of disbursement.

The payment cannot be contingent upon completing the entire study. If there are multiple visits/sessions, this should be pro-rated. Describe that plan here.

The 35 patients in the one-group intervention will receive up to a total of $ 65 physical visa gift card for taking part in this study according to the following schedule:
• $30.00 at your first visit (0-week visit)
• $35.00 at your second visit (12-week visit)
We will provide physical gift cards to patients as many patients from UH are not familiar with electronic gift cards. If a patient completes the study virtually, we will mail the gift care via FedEx to the patient.

31. In your opinion, will the subject be influenced by the compensation offered?

○ Yes ● No

32. If you are offering extra credit or course credit for student participation, describe the alternative assignment for students who may decline.

The alternative assignment must be comparable in effort and time commitment.

33. If you are offering subject payments, please list your departmental fiscal contact here:

For information about research participant payments, click here.

Garrie, Scott R

Job title
FINANCE AND BUDGET CONSULTANT II
Department
Finance
Division
VC Administration & Finance
Business unit
University of MO-Kansas City

34. Does the study involve audio recording, video recording, or photographing?

○ Yes ● No

4. Subject Recruitment

1. List your inclusion criteria.

This would be a description of your subject population, who you will be targeting for recruitment.

Inclusion Criteria for Clinician and Patients Participants (Objective 1)
We will engage clinicians to conduct lymphatic pain assessment for 100 patients surgically treated for breast cancer as part of clinical practice. The goal of the pragmatic implementation study project is to evaluate the implementation effectiveness of feasibility, acceptability, clinical effectiveness. The inclusion criteria for clinician participants are: 1) clinicians who are officially hired by UH; and 2) clinicians (e.g., oncology surgeons, medical oncologists, nurses, nurse practitioners, or physical or occupational therapists) who provide direct clinical care for patients surgically treated for breast cancer. The inclusion criteria for patients are: a) Patients over age 18 who received surgical treatment for breast cancer (Stage 0-3); b) Patients who are able to understand English language. Exclusion criteria include a) known metastatic disease (Stage IV).
Clinicians will assess the eligibility of the patients for the assessment and conduct the assessment for their patients only.

Inclusion and Exclusion Criteria for Patient Participants (Objective 2)
We will recruit 35 patients in a pragmatic, one-group, and 12-week trial to evaluate the real-world clinical effectiveness of TOLF Self-Care intervention for lymphatic pain. The inclusion criteria for patient participants are a) Patients over age 18 who received surgical treatment for breast cancer at least 3 months prior to the study enrollment; b) Patients reported lymphatic pain; c) Patients who are able to understand the study protocols presented in English language.

The target sample size for this single-arm trial is 35 patients, with primary outcomes assessed at pre-intervention and at week 12 post intervention. A power analysis indicated that this sample size is sufficient to support further statistical analysis using a paired t-test, with $\alpha = 0.05$ and 80% power to detect a within-group difference of 0.7 standard deviations at week 12 post-intervention. The target sample size will also provide adequate statistical power for the proposed GEE models.

2. List your exclusion criteria.

This would be a description of who cannot participate in your research, who you are not targeting for recruitment.

Exclusion Criteria for Clinician and Patient Participants (Objective 1)
The exclusion criteria for clinician participants are: 1) clinical administrators; and 2) medical assistants.
Exclusion criteria include a) known metastatic disease (Stage IV).

Exclusion Criteria for Patient Participants (Objective 2)
Exclusion criteria include a) presence of a serious psychiatric condition (e.g., schizophrenia, suicidal intent) indicated by medical chart, treating oncologist or other staff, or study staff interactions that would contraindicate safe study participation; b) known metastatic disease (Stage IV), recurrence of cancer, or lymphedema due to cancer recurrence, or cancer in the thoracic or cervical regions.

3. Explain how you will have access to this population and what method will be used to identify and recruit subjects.

Recruitment Materials - What should and should not be included in recruitment materials:

The recruitment text should be limited to:

- The name and address of the investigator or research facility
- The condition under study or the purpose of the research
- In summary form, the criteria that will be used to determine eligibility for the study
- A brief list of participation benefits, if any
- The time or other commitment required of the subjects
- The location of the research and the person or office to contact for further information

The recruitment text cannot:

- State or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol
- Include exculpatory language
- Emphasize the payment or the amount to be paid (by such means as larger or bold type)

University Health Kansas City (UH) has been serving the Kansas City Metropolitan area for over 100 years, including Truman Medical Center and Lakewood Medical Center and most patients at UH are uninsured or underinsured and rely on Medicare or Medicaid. UH is a community-based and safety-net health system that provides care to everyone regardless insurance and financial status. Missouri ranks 18th in the United States for the highest breast cancer incidence. As a not-for-profit academic health system, UH provides care to urban residents across Jackson County, which is recognized as the fifth most economically disadvantaged district in the U.S. Majority of breast cancer patients at UH rely on Medicaid and Medicare for health insurance. There are no lymphatic pain and lymphedema screening at UH and many patients cannot afford lymphedema therapy that is not part of their insurance. UH has one of the busiest adult emergency departments in the Kansas City metropolitan area with more than 60,000 visits a year.103 Many breast cancer patients visit ER because of pain or sudden swelling after breast cancer treatment. Since Dr. Fu joined UMKC in 2023, she has recruited from UH over 100 patients for her funded research. The strong support for UH and patients will ensure the success of the study.

Our team consists of experienced clinical investigators with extensive histories of successful recruitment. We have strong support from UH Breast Team, Medical Oncology and Nursing to ensure the training of the clinicians. Many clinicians are desired to have lymphatic pain assessment and are willing to use such assessment. We are confident that we will be able to recruit at least 10 clinicians who are committed to conduct at least 15 patients by each clinician during the study time (Objective 1).
We will recruit clinicians during the monthly and weekly clinical meetings. We will give a presentation to the clinician and provide training how to use SmartDetect and enter the results in the electronic form. Clinicians who give oral consent to conduct the assessment for 10 patients will be provided an information for patient eligibility and manual to use Smart Detect.

Each participant clinician will offer breast cancer patients who underwent breast surgery the opportunity to be evaluated for lymphatic pain during each in-person routine clinical visit. With the patient's oral consent, the participant clinician conducts the assessment and document whether the patient has lymphatic pain or not. If the patient has lymphatic pain, the clinician will offer the patient the study flyer for the TOLF Self-care intervention study. The patients can call the researchers. A total of 35 patients will receive the same intervention, this is one-group study. The patients can refuse the assessment.

In addition, clinicians who assess the patients will alert the study team for patients with lymphatic pain. Patients with lymphatic pain will receive the study flyer from the clinician who conducted lymphatic pain assessment. The patient can call or text the researchers via the information provided by the study flyer. In addition, the patients with lymphatic pain will receive an email or call or text message from through UH system that present the study flyer to provides the clinical trial information (Objective 2) from the research team. The email or call or text message will let the patient know that a member of the research team will call them to follow-up; an opt-out phone number will also be provided. Following information email, the research coordinator will contact potential patient participants to assess interest in the study and to further assess if the potential patients meet the inclusion and exclusion criteria for participating in the 12-week clinical trial. If patients meet eligibility criteria they will be invited to schedule informed consent in-person at UH or via telephone. All participants will continue to receive standard medical care from their medical team. The research team will closely track participant recruitment; additional clinics will be quickly implemented if recruitment has not been met at 90% in any 3-month period.

4. If you are utilizing medical records to identify and contact subjects for your study, select from the following options to confirm the appropriate steps are in place:

- [x] There is a treating relationship with a research team member listed on the IRB application.
- [x] The research team members will work directly with providers that have a treating (patient-provider) relationship to consult before contacting potential subjects.

5. What methods will be used to avoid inadvertent coercion in the recruitment process?

All recruitment procedures will comply with HIPAA guidelines. Our team consists of experienced clinical investigators with extensive histories of successful recruitment. We have strong support from UH Breast Team, Medical Oncology and Nursing to ensure the training of the clinicians.

To prevent potential coercion, we will emphasize to the clinicians that participating in the implementation study is NOT part of their job. The participation is voluntary and they can discontinue assessing patients at anytime without noticing the research team. In addition, the clinical survey is anonymous. Many clinicians are desired to have lymphatic pain assessment and are willing to use such assessment. We are confident that we will be able to recruit at least 10 clinicians who are committed to conduct at least 15 patients by each clinician during the study time (Objective 1). Clinicians who assess the patients will alert the study team for patients with lymphatic pain.

For lymphatic pain assessment, clinicians will emphasize to the patients that the assessment is optional assessment and whether they agree or not to have lymphatic pain assessment, they will continue to receive standard medical care from their medical team. Participating in the lymphatic pain assessment is voluntary and they can end the assessment at any time during the assessment. The patients will provide opportunity to consent or decline the offer for lymphatic pain assessment.

For the intervention, potential coercion will be prevented for patients with lymphatic pain who are offer the opportunity to participate in the intervention study as the clinicians are not part of intervention team. First, if the patient has lymphatic pain, the clinician will offer the patient the study flyer for TOLF Self-care intervention. Second, patients have the free will to call the research team regarding participating in the intervention study. If they patients express their willingness to participate in the intervention study in their call to the researchers, the researchers will confirm the patients' interest in the study and to further assess if the potential patients meet the inclusion and exclusion criteria for participating in the 12-week clinical trial. If patients meet eligibility criteria they will be invited to schedule informed consent in-person at UH or virtual. Patients will be given a copy of the consent form but will not sign the consent. Patients will be given enough time for questions and research staff will provide answers to all the questions. Research staff will complete the Consent Process Documentation, verbal consent will be obtained.

All participants will continue to receive standard medical care from their medical team.

6. Do you plan to recruit non-English speaking subjects?

E-mail umkcirb@umkc.edu for guidance on the inclusion of non-English Speaking Subjects.

○ Yes ● No

7. Do you plan to retain any information on recruitees not ultimately enrolled in the study?

○ Yes ● No

Enrollment

8. How many people do you expect to complete the study?

Objective 1: 10 clinicians and 100 patients; Objective 2: 35 patients

9. How many people will be enrolled (sign a written consent or consent with a waiver of documentation) to reach the number listed in the previous question?

For some studies, this number may be the same, for other studies there may be a high rate of screen failures, so you will want to account for those screen failures.

35 patients in the one-group intervention study

5. Subject Consent

Consent Form Templates (2018 Common Rule Compliant) -- Can be found here: https://ors.umkc.edu/facilities-compliance-and-commercialization/compliance/irb/informed-consent.html

1. Select what type(s) of consent will be obtained (there may be more than one):

Templates can be found on the UMKC Research & Economic Development website:
https://ors.umkc.edu/facilities-compliance-and-commercialization/compliance/irb/informed-consent.html
You can also visit this "survey" to download consent templates.
https://php2.umkc.edu/intapps/redcap/surveys/?s=CRW4X4DH99RXKYDR

☐ **Written (or the electronic equivalent)**
Note: Written consent is no longer required for screening, recruiting, or determining eligibility, if you are obtaining information through oral or written communication with the subject or legally authorized representative UNLESS you are asking subjects to do something required by the protocol (i.e. fast, withhold medications, etc.).
HIPAA regulations still apply to protected health information, and an authorization or waiver/ alteration may still be required.
Review FDA guidance describing when consent needs to be obtained when clinical procedures are performed solely for the purpose of determining eligibility for research: Screening Tests Prior to Study Enrollment

☑ **Waiver of Documentation (no signature requirement)**
Example:
Telephone interview or online survey
Note: A waiver of documentation of consent is no longer required for screening, recruiting, or determining eligibility, if you are obtaining information through oral or written communication with the subject or legally authorized representative UNLESS you are asking subjects to do something required by the protocol (i.e. fast, withhold medications, etc.).
HIPAA regulations still apply to protected health information, and an authorization or waiver/ alteration may still be required.
Review FDA guidance describing when consent needs to be obtained when clinical procedures are performed solely for the purpose of determining eligibility for research: Screening Tests Prior to Study Enrollment

☑ **Waiver or Alteration of Consent**
Examples:
1. No consent will be obtained for the entire study (i.e. record review or observational only study)

2. The study involves deception (this would be an alteration of consent since certain elements of consent are being altered)
Note: A waiver of consent is no longer required for screening, recruiting, or determining eligibility, if you are (i) obtaining information through oral or written communication with the subject or legally authorized representative; or (ii) obtaining identifiable private information or identifiable biospecimens by accessing record or stored identifiable biospecimens.
A HIPAA waiver is still required for access and use of protected health information.

2. Describe the consent process.

Describe in detail how the consent process will be presented to the subject, how subject comprehension of the study is determined, where and when consent is performed, and how questions from the subject are answered. A copy of the consent must be attached to this application.

Objective 1: In this implementation project, we will invite all the clinicians who provide direct care for patients treated for breast cancer for the training as part of clinical for the UH Breast Team. We will recruit clinicians during the monthly and weekly clinical meetings. We will give a presentation to the clinician and provide training how to use SmartDetect and enter the results in the electronic form. Clinicians who give oral consent to conduct the assessment for 10 patients will be provided an information for patient eligibility and manual to use SmartDetect. In the electronic survey, a consent form will be presented to describe the purpose of the survey and risks, clinicians can read and consent to the survey by click Agree. Completion of the anonymous surveys from the clinician denote the consent of the clinicians to the implementation project.

Each participant clinician will offer breast cancer patients who underwent breast surgery the opportunity to be evaluated for lymphatic pain during each in-person routine clinical visit.

With the patient's oral consent, the participant clinician conducts the assessment and document whether the patient has lymphatic pain or not. If the patient has lymphatic pain, the clinician will offer the patient the opportunity to receive TOLF Self-care intervention. During the visit, the clinician will give the patient the study flyer for the intervention study (Objective 2) or ask the patient's permission to share their contact information to the researchers to contact the patient with lymphatic pain.

Completion of the anonymous surveys from the clinician denote the consent of the clinicians to the implementation project. As part of routine clinical practice, patients who received surgical treatment for breast cancer will be offered to be assessed for lymphatic pain. Patients can decline the assessment as part of care. Completion of the lymphatic pain assessment indicates the patient’s consent to be assessed.

Objective 2: Once potential subjects confirmed their interest in the study, a member of the study team will meet the potential participants either in person or virtual as they prefer, the researcher will describe the study in detail, provide the patient with consent forms either in paper or electric form, and offer to answer any questions about the study. Potential participants will then be given sufficient time to read over the consent form, at which time the PI or a member of the study team will ask if they have any further questions. The final component of the consent process will involve reviewing a brief checklist that outlines the major aspects of the study to confirm that the subject fully understands the protocol.

Research subjects will also be asked to carefully review the section in the consent form, entitled, PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY, at the time they sign the general study consent form. This document, written to ensure compliance with HIPAA Privacy Rule guidelines, provides detailed information about what information is being collected, the participant’s privacy rights, and to whom the information may be disclosed.

The HIPAA authorization is being obtained verbally, incorporated into the consent form and signatures will not be collected on the consent, nor will a separate HIPAA authorization form be used. A copy of the consent

form will be given to the patients for their records. For pilot RCT, each participant will be assigned a unique study ID (e.g., Blue_001 to Blue_035). Researchers who obtained the consent will complete the Consent Document.

3. Confirm the following requirements will be met by checking the boxes:

- [x] Participants will be given enough time to consider participation between the time they are approached to participate and sign the consent. The regulations require investigators to seek consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether to participate minimizing the possibility of coercion or undue influence.
- [x] The language level of the consent will match the comprehension level of the prospective participants. The regulations require the information be understandable to the subject or the representative so you must consider the subject population and type of study.
- [x] Measures will be taken to ensure the prospective participant/representative understands the consent.

4. Who will be approached for consent?

- [x] Subject
- [ ] Subject's Legal Guardian

5. Will the consent document be placed in the medical record?

The consent will need to be placed in the medical record if the study interventions/procedures may affect their current or future health care. Mark NA if written consent is being waived in this study.

○ Yes ○ No ● N/A

6. Will the study involve accessing identifiable student educational records?

Written consent must be obtained from the subject or their legal guardian to allow the release of identifiable student educational records. Additional information can be found here: US Department of Education FAQ

○ Yes ● No

7. Your project must fall under one of the following two criteria for waiving documentation of consent. Check the criteria that applies to your study.

- [x] The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- [x] The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. [The study cannot be FDA regulated]

A. Justify how your project meets the criteria for a waiver of documentation.

A copy of the consent must be attached to this application.

The research presents no more than minimal risk of harm and involves no procedures for which written consent is normally required outside the research context. See the attached consent form.

8. Please select the option that you are requesting:

- [ ] A full waiver of consent

☑ An alteration of consent (example: deception studies)

A. Describe how the research involves no more than minimal risk to participants.

The primary risks of this study are those associated with confidentiality. Two password protected databases will be used for this study to ensure confidentiality.
Objective 1: There is some risk attendant to confidentiality of self-report data for clinicians. However, the anonymous surveys will protect the clinicians' privacy and confidentiality. Data regarding patients be assessed for lymphatic pain will be de-identified data. De-identified patient data will include: demographic data (i.e., age, ethnicity, education, marital status, employment, house-hold income, medical insurance, smoking history, alcohol intake, chronic illness, body mass index) and cancer treatment information (i.e., type of surgery, lymph nodes removed, cancer stage, radiation, chemotherapy, hormonal therapy. Lymphedema diagnosis). The anonymous clinician data and de-identified patient data will be stored on a secure server housed behind the UMKC firewall.

Objective 2: First, a tracking database will be used for recruitment and follow-up for the 35 patients in the clinical trial. This data will house information related to tracking the participants in the study, such as phone numbers and addresses. No medically sensitive or outcome data will be stored in this database. This database will also track nonparticipants (i.e., those who have declined participation) only to the barest minimum to ensure that they are not contacted again about participation. At the end of the study, all identifiable data of non-participants such as their names will be deleted. Tracking data on participants will be retained for the usual required period. Second, all study data will be stored in a separate password protected database without any personal identifiers. Data in this database will be derived from patients' direct input into the electronic patient reported outcomes system which is an online survey system; data entered into this system is stored on a secure server housed behind the UMKC firewall. Only a unique study identification number will link the electronic data to the study data file. The tracking data and study data will be stored in a file on a secure study computer which can only be accessed by necessary members of the research team. Access to the computer requires a password protected.

B. Describe how the waiver or alteration will not adversely affect the rights and welfare of the participants.

The waiver to pre-screening by reviewing medical record and telephone screening will not affect patients' right and welfare since the documentation is waived.

C. Describe how the research could not practicably be carried out without the waiver or alteration.

The research will not be possible without pre-screening to identified patients who are potentially eligible for the study.

D. Whenever appropriate, describe how the subjects will be provided with additional pertinent information after participation (debriefing).

For the patients in the intervention, patients will be given opportunity to discuss their experience of participating in the study.

E. Describe what it is you are altering.

Please click here to view the general requirements of informed consent to help explain what it is you are altering.

We request the alteration of consent only to the clinician survey consent script as this procedure would normally qualify as an exempt research procedure. The clinician survey is the evaluation of the Objective 1 the implementation of lymphatic pain assessment as part of the routine clinical practice, the clinical survey is conducted separately from Objective 2 the intervention study with patients with lymphatic pain. We request an alteration of consent only to allow for an abbreviated consent script to be used to obtain consent from clinicians for the survey.

This request only for the clinician survey. Please see the attached consent script.

F. Are you requesting an alteration of consent because the study involves deception?

Deception is defined as deliberately giving false information about some aspect of the research to the subject.

○ Yes ● No

6. Risks and Benefits

1. Describe the potential risks associated with the research and identify the procedures that will be used to prevent and/or minimize any potential risks and discomforts.

For drug studies, please do not list all drug side effects (these will go on the drug sub-form). Some examples of potential risks may include, breach of confidentiality, invasion of privacy, psychological, physical, social, economic, legal, or other.

The primary risks of this study are those associated with confidentiality. Two password protected databases will be used for this study to ensure confidentiality.
Objective 1: There is some risk attendant to confidentiality of self-report data for clinicians. However, the anonymous surveys will protect the clinicians' privacy and confidentiality. Data regarding patients be assessed for lymphatic pain will be de-identified data. De-identified patient data will include: demographic data (i.e., age, ethnicity, education, marital status, employment, house-hold income, medical insurance, smoking history, alcohol intake, chronic illness, body mass index) and cancer treatment information (i.e., type of surgery, lymph nodes removed, cancer stage, radiation, chemotherapy, hormonal therapy. Lymphedema diagnosis). The anonymous clinician data and de-identified patient data will be stored on a secure server housed behind the UMKC firewall.

Objective 2: First, a tracking database will be used for recruitment and follow-up for the 35 patients in the clinical trial. This data will house information related to tracking the participants in the study, such as phone numbers and addresses. No medically sensitive or outcome data will be stored in this database. This database will also track nonparticipants (i.e., those who have declined participation) only to the barest minimum to ensure that they are not contacted again about participation. At the end of the study, all identifiable data of non-participants such as their names will be deleted. Tracking data on participants will be retained for the usual required period. Second, all study data will be stored in a separate password protected database without any personal identifiers. Data in this database will be derived from patients' direct input into the electronic patient reported outcomes system which is an online survey system; data entered into this system is stored on a secure server housed behind the UMKC firewall. Only a unique study identification number will link the electronic data to the study data file. The tracking data and study data will be stored in a file on a secure study computer which can only be accessed by necessary members of the research team. Access to the computer requires a password protected.

2. Does the study involve drugs or any procedure that may affect (known/unknown) an unborn child?

○ Yes ● No

3. What are the potential direct benefits to the subjects?

It is possible the study has no potential for direct benefit. If this is the case, please state this.

For patients in the implementation study, the direct benefit include the detection of lymphatic pain and potential intervention for lymphatic pain by participating in the intervention study.

For patients in the intervention study, there are some direct benefits.

(a) Patients may feel empowered by learning about self-care strategies to manage pain and prevent lymph fluid build-up or lymphedema.
(b) Patients may relieve lymphatic pain and prevent lymphedema by carrying out the self-care strategies.

4. What are the potential benefits to the community and society?

Breast cancer is one of the top concerns in Kansas City and United States.1 Lymphatic pain refers to various pain sensations (e.g., pain, aching, soreness, tenderness, burning, stabbing) in the ipsilateral body or upper limb due to a compromised lymphatic system from breast cancer treatment.2-4 Lymphatic pain affects more than half of 4 million patients treated for breast cancer in the United States.1-4 Lymphatic pain significantly impair patients' daily living function,2 increases psychological distress,5 and decreases quality of life (QOL).6-7 Our recently published study detailed that patients with lymphatic pain reported impairments in 45% of activities of daily livings (ADLs) and had a significantly increased risk of having difficulty in performing all the 13 ADLs (i.e., cooking, using a knife, writing/typing, cleaning, vacuuming, laundry, carrying objects, yard work, dressing self, bathing self, driving, making bed, and taking care of children).2 Patients' psychological distress was further compounded when they felt that clinicians did nothing but "pity me."5 As a significant risk for lymphedema,2-5 lymphatic pain is a cardinal sign for an early stage of lymphedema.4,7-8 Lymphedema is a chronic and incurable condition caused by an abnormal accumulation of lymph fluid in the ipsilateral body or upper limb.9 Patients who report lymphatic pain are nearly twice as likely to develop lymphedema.4 Without timely intervention in this early stage, lymphedema can progress into a chronic condition that no surgical or medical interventions can cure.9

Patients with financial hardship are 4.64 times more likely to report lymphatic pain.2 Further, obesity/high body mass index [BMI] is an important risk factor for lymphatic pain and lymphedema.2-3;10-22 Lack of patient care for lymphatic pain and lymphedema is maintained by a lack of cost-effective, accessible, and appropriately adapted supportive care opportunities found at more resourced medical centers.18-19 This results in a large burden for patients, clinicians, and health systems with limited resources.
Effective management of lymphatic pain can decrease the risk of lymphedema, reduced lymph fluid level, reverse mild lymphedema, and improve quality of life.23-28 However, there are persistent barriers to timely interventions due to clinicians' unawareness of and lack of clinical infrastructures to deliver effective interventions to patients. The-Optimal-Lymph-Flow (TOLF Self-Care) is a non-pharmacological and digital behavioral intervention that builds patients' self-care skills to promote lymph flow that leads to complete pain reduction, reduced lymph fluid level, reversed mild lymphedema, and improved quality of life.23-28 Of concern, this effective intervention has not been adapted to reduce patient barriers (e.g., availability of care, cost, time, travel, competing demands) and system barriers (e.g., intervention availability, staffing, therapist) to timely interventions faced by patients, especially those with financial hardship. Our recent research in Kansas City found that more than 60% of patients suffered from lymphatic pain following breast cancer treatment and many patients never heard of "lymphedema" although many of them had lymphedema.29-31 Thus, building clinical capacity and enhance clinicians' awareness and training is essential in adapting effective interventions in clinical practice and advancing patient care to provide timely detection of lymphatic pain and delivery of effective interventions for lymphatic pain and lymphedema.

5. Does the study require a data and safety monitoring plan?

A plan is required if this is a clinical trial, treatment and/or intervention study, sensitive data are being collected, there is a potential for subjects to experience adverse events, etc.

○ Yes ● No

6. Will subjects be asked questions about suicidality?

For example, the administration of the PHQ-9 instrument.

○ Yes ● No

7. Do you have or plan to obtain a Certificate of Confidentiality? For more information on Certificates of Confidentiality, please go here.

Certificates of Confidentiality are issued to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. NIH funded researchers are automatically issued a CoC through their award. Other Department of Health and Human Services (HHS) agencies issue CoCs to researchers they fund. Researchers not funded by HHS can continue to apply to NIH or the FDA as appropriate to request a CoC for HHS-mission relevant research.

○ Yes ● No

8. Describe your plan to protect subjects' privacy during and after the course of the data collection?

Privacy refers to a person, not the confidentiality of their data. Confidentiality is addressed in the next section.

We will take every effort to protect patients's privacy.
For the implementation study, as the study is to assess lymphatic pain for patients as routine clinical practice, each clinician will use private patient room to protect patients' privacy as occurred during routine clinical practice.
For intervention study, we will use private room and personal zoom session to train the patients and collect data to protect the participant's privacy.

9. What are the consequences to subjects if a loss of privacy were to occur (e.g. risks to reputation, insurability, embarrassment, other social risks)?

We will take every effort to protect patients's privacy.
For patients, as this study focuses on assessing lymphatic pain and training patients to learn self-care behaviors, the loss of privacy should not have any impact on patients' reputation, insurance, embarrassment or social risks.

7. Confidentiality and Security

1. Select all identifiers that may be accessed and/or included in the research records for the study, check all that apply:

- ☑ Names
- ☑ Dates
- ☐ Postal Address
- ☑ Phone Numbers
- ☐ Fax Numbers
- ☑ E-Mail Addresses
- ☐ Social Security Number
- ☐ Medical Record Number
- ☐ Health Plan Number
- ☐ Account Numbers
- ☐ License or Certificate Numbers
- ☐ Vehicle ID Numbers

- ☐ Web URLs
- ☐ IP Address Numbers
- ☐ Biometric Identifiers
- ☐ Facial Photos or Images
- ☐ Any Other Unique Identifier

2. If you plan to disclose any subject identifiers listed above as part of the study process with anyone outside of the research team, identify the individuals or entities that will have access.

This must be disclosed in the consent document and HIPAA Authorization, if applicable.

Not Applicable

3. Will any web or electronic applications be utilized for such purposes as recruiting subjects, completing questionnaires, or processing data?

● Yes ○ No

4. List all web/electronic applications that will be used in the study.

Click here for a list of UMKC provided resources:
https://www.umkc.edu/is/resources/software.html
or here: https://www.umkc.edu/is/resources/

- ☑ Qualtrics UMKC endorsed)
- ☑ RedCap (UMKC Endorsed)
- ☑ Other

Other:

Zoom for participants in the intervention study who prefer virtual meeting. The self-care website: http://optimallymph.org/ Login

A. If other, describe the security features for the web/electronic application(s).

Participants in the intervention study will be assigned a unique ID to log in the website (http://optimallymph.org/ Login) and learn about the intervention. Please see the user manuals. The website will not allow to enter any subject profile information. No patient data will be recorded in the website. Patients will use the study ID to access the website for the intervention materials and videos.

B. If you are administering an anonymous online survey, have you checked the appropriate boxes on the survey tool to ensure that the data collected will be anonymous?

● Yes ○ No ○ N/A

5. How and where will data be stored during data collection and analysis?

All data (and backups) must be stored under two levels of security. Please list your security methods in place. i.e. Password protection on a UMKC provided computer is one, but there should be a second for electronic data (e.g., password protecting the files, storing the computer/hard drives in locked offices or cabinets at UMKC, etc.).

Paper Records (e.g., consent forms, data files, medical records, etc.):
Paper files related to human subject's participation in research must be securely stored on UMKC campus.

Access to files should be restricted to key personnel and supervised by the principal investigator(s) of the study. Locked file cabinets must be used and preferably located in secured locations (i.e., locked office or laboratory).

The primary risks of this study are those associated with confidentiality. Two password protected databases will be used for this study to ensure confidentiality.
Objective 1: There is some risk attendant to confidentiality of self-report data for clinicians. However, the anonymous surveys will protect the clinicians' privacy and confidentiality. Data regarding patients be assessed for lymphatic pain will be de-identified data. De-identified patient data will include: demographic data (i.e., age, ethnicity, education, marital status, employment, house-hold income, medical insurance, smoking history, alcohol intake, chronic illness, body mass index) and cancer treatment information (i.e., type of surgery, lymph nodes removed, cancer stage, radiation, chemotherapy, hormonal therapy. Lymphedema diagnosis). The anonymous clinician data and de-identified patient data will be stored on a secure server housed behind the UMKC firewall.

Objective 2: First, a tracking database will be used for recruitment and follow-up for the 35 patients in the clinical trial. This data will house information related to tracking the participants in the study, such as phone numbers and addresses. No medically sensitive or outcome data will be stored in this database. We will have separate dataset to track nonparticipants (i.e., those who have declined participation) only to the barest minimum to ensure that they are not contacted again about participation. At the completion of recruiting 35 patients, all identifiable data of non-participants such as their names will be deleted. Second, all study data will be stored in a separate password protected database without any personal identifiers. Data in this database will be derived from patients' direct input into the electronic patient reported outcomes system which is an online survey system; data entered into this system is stored on a secure server housed behind the UMKC firewall. Only a unique study identification number will link the electronic data to the study data file. The tracking data and study data will be stored in a file on a secure study computer which can only be accessed by necessary members of the research team. Access to the computer requires a password protected. For the intervention study (Objective 2), each participant will be assigned a unique study ID (e.g., Blue_001 to Blue_035).

6. How and where will the data be stored after the study is complete?

Note: Retain records for seven (7) years after the final report on the research project has been submitted. If the research is being done under a contract that requires a specific retention time, the contract retention time will apply.

Paper documents will be kept in a locked file cabinet, in the PI's locked office with limited access toresearch personnel listed on this application only. Digital data will be accessible to the study team only by use of an SSO protected digital source (i.e. UMKC provided computer, BOX). All digital data collection sheet(Excel, Word, REDCap, etc.) will be password protected and only accessible by the research team. Data will be kept on study computers or devices that are secured under lock and key with limited access at a UMKC facility. (File cabinets, offices, etc.).

7. If data are coded and the data key will be destroyed, please provide the anticipated date of destruction:

Leave blank if not applicable.

8. If you will retain identifiers with the data, explain the security measures you will take while the data is directly identifiable.

Leave blank if not applicable.

9. If data will be de-identified, describe the method that will be used to de-identify the data and when this process will occur.

Leave blank if not applicable.

For the implementation study, we will receive de-identified data from University Health Kansas City.
For the intervention study, each participant will be assigned a unique study ID. A tracking database will be used for recruitment and follow-up. This data will house information related to tracking the participants in the study, such as phone numbers and addresses. No medically sensitive or outcome data will be stored in this database. We will have separate dataset to track nonparticipants (i.e., those who have declined participation) only to the barest minimum to ensure that they are not contacted again about participation. At the completion of recruiting 35 patients, all identifiable data of non-participants such as their names will be deleted. Second, all study data will be stored in a separate password protected database without any personal identifiers.

8. Completion of Required Sub-Forms

1. **Select the items that are included as part of your study. For items marked, an additional form will be generated for your completion at the end of this application and is labeled "Additional Forms".**

   FORM INSTRUCTION: As you work through the list and you check a box that generates a sub-form, then you realize those additional questions in the sub-form do not pertain to your study, go back to this page and uncheck the box that generated the sub-form to make it go away.

   BIOMEDICAL SPECIFIC SUB-FORMS

- ☐ Collection of **solid tissue, biological samples, laboratory tests, and pathology data**
- ☐ Administration of a **drug or biologic** (investigational, unapproved use, or FDA approved being administered for research-only)
- ☐ Administration of a **supplement** (vitamin, mineral, etc.)
- ☐ **Cold Isotopes** (non-radioactive isotopes)
- ☐ **Medical Device**, including **Humanitarian Use Devices** in a clinical investigation (investigational, unapproved use, or FDA approved (if the device is approved and is being used for research-only))
- ☐ **Radiological Procedures** (may or may not involve radiation - MRI, xray, ultrasound, DXA Scan, etc.)
- ☐ Involves an **Exception from Informed Consent for Planned Emergency Research**

SUBJECT POPULATION SUB-FORMS

- ☐ Participants with **impaired decision-making capacities** (unable to legally consent on their own behalf)
- ☐ **Pregnant women or fetuses** (This item is for studies that will target pregnant women, or is a treatment-intervention study (i.e. drug/device) that will not exclude pregnant women/fetus)
- ☐ **Children** (under 18 in Missouri, also dependent on State law)
- ☐ **Non-viable neonates or neonates of uncertain viability** (neonates=newborns)
- ☐ **Non-English speaking subjects** (Select if it is known at this time that you will enroll non-English speaking subjects, and the study documents will need to be translated. You can always amend your study to add non-English speaking at any time)
- ☐ **Prisoners**

☐ **International Study** (data collection is taking place outside of the United States)

9. Attachments

Please attach all study related documents in the attachments section.

- Informed Script (as a stand-alone Word document)
- Survey documents (if using an online survey, please attach a PDF copy of the survey from the instrument that will be used, in the finalized form. The PDF may contain a "placeholder" indicating where an image of the finalized consent scripts will be displayed)
- Also, if applicable, stand alone documents of the following: Data Collection forms, Permission Letters, Advertisements, Recruitment letters/emails, etc.

HIPAA Waiver

1. HIPAA Waiver for the Use and/or Disclosure of Protected Health Information (PHI) in Research

1. **Why do you need this waiver? Select all that apply:**

☑ **Pre-Screening** to review inclusion and exclusion criteria to determine if individual is eligible to participate in the study. Those meeting eligibility requirements will be contacted for authorization.

☐ **Records Research -** Researchers are unable to use de-identified information, and the research could not practicably be conducted if authorization were required.

2. **Sources of PHI**

Select the source(s) of PHI

☑ Electronic Medical Record

☐ Electronic Databases in Ancillary Units (lab, pathology, radiology, pharmacy, etc.)

☐ Data being extracted from a Research Database

☐ Paper Record in Clinical Areas

☐ Other:

3. **PHI and Access (use, recording, review)**

A. Identify the covered entity where data will be requested/pulled:

☑ University Health

☐ UMKC School of Dentistry Clinic

☐ Other Entity

B. Who will access/pull the PHI for this study?

☑ Research Team on the IRB Application with authorized access to PHI

☐ Third Party (non-research team member)

i. Is it a necessity for the research team to access/pull the data?

○ Yes ● No

C. State the objective(s) of the research.

The purpose of the project is to adapt The-Optimal-Lymph-Flow (TOLF) in clinical practice. We will implement digital lymphatic pain and lymphedema assessment in clinical practice, conduct clinician training and deliver TOLF Self-Care interventions to patients with lymphatic pain at Richard & Annette Block Cancer Center at University Health Kansas City. The objectives of the study are: 1) Conduct a pragmatic clinical implementation study with 100 patients to evaluate implementation effectiveness of lymphatic pain assessment; 3) Conduct a pragmatic, one-group, 12-week clinical trial with 35 patients with lymphatic pain to evaluate real-world clinical effectiveness of TOLF Self-Care intervention.

D. Approximately how many records do you anticipate will be needed to meet the objectives of the research?

100 patients being assessed for lymphatic pain in the implementation study.

E. Provide a description of the health information that will be accessed and minimum necessary to fulfill or satisfy the intended purpose described above.

This field must be completed in detail. Blank or limited descriptions will be returned. Details may include information about specific reports, exams, images, notes, summaries, demographics, diagnostic or billing codes, recordings, etc.

The minimum necessary standard, a key protection of the HIPAA Privacy Rule, is derived from confidentiality codes and practices in common use today. It is based on sound current practice that protected health information should not be used or disclosed when it is not necessary to satisfy a particular purpose or carry out a function. Although a covered entity may rely on the determination provided by the UMKC IRB, the covered entity always retains discretion to make its own minimum necessary determination for disclosures to which the standard applies.

Objective 1: The minimal information is necessary for the implementation study include the verification of the patient's age, and breast cancer history (i.e., cancer stage and surgery, lymph node procedure radiation and chemotherapy) and health history (i.e., chronic illness) and data from lymphatic pain assessment. All the patient data from the implementation study will be de-identified.

Objective 2: The minimal information is necessary fro the intervention study include the verification of the patient's name, age, and breast cancer history (i.e., cancer stage and surgery, lymph node procedure radiation and chemotherapy) and health history (i.e., chronic illness) as well as the contact information for contact the patients for the study participation and follow up. We will safeguard the PHI information. UH will only share the PHI information with the PI (Dr. Fu) and the research team.

F. Select the identifiers that will be used in this study:

- ☐ Names
- ☐ Address - All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent codes
- ☐ Dates - All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
- ☐ Telephone numbers
- ☐ Fax numbers

- ☐ Email Addresses
- ☐ Social Security Numbers
- ☐ Medical Record Numbers
- ☐ Health Plan Beneficiary Numbers
- ☐ Account Numbers
- ☐ Certificate/License Numbers
- ☐ Vehicle Identifiers and Serial Numbers, including License Plate Numbers
- ☐ Device Identifiers and Serial Numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) Address Numbers
- ☐ Biometric Identifiers, Including Fingerprints and Voiceprints
- ☐ Full-Face Photographic Images and any Comparable Images
- ☐ Any other Unique Identifying Number, Characteristic, or Code, unless otherwise permitted by the Privacy Rule for Re-Identification

4. Justification for Waiver

The use or disclosure of protected health information must involve no more than minimal risk to the privacy of individuals. The following justification is required to determine whether this requirement is met.

A. Select from the following regarding the **storage** of PHI for this study to ensure proper use and disclosure:

Check all that apply:

- ☑ Hard Copy Information - Institutionally authorized secure physical location only accessible to research members listed on the IRB application.
- ☑ Electronic Information - Institutionally authorized secure online location only accessible to research members listed on the IRB application.

i. Describe other storage features if applicable:

Any identified PHI data will be stored in UH data storage such as the UH G/: folder. Once the the recruitment is completed for Objective 2, all the identified PHI data will be destroyed. De-identified data will be stored in password protected university research storage space such as N Drive or REDCap.

B. Select who will have **access** to the PHI to ensure proper use and disclosure:

Select all that apply:

- ☑ Members of the research team listed on the IRB application.
- ☐ Third party with institutionally authorized access assisting the research team.

i. Identify other parties if applicable:

C. Select from the following describing the plan to destroy **identifiers** at the earliest opportunity to ensure proper use and disclosure:

This should only address the destruction of identifiers - not the research data required to be kept according to institutional policy.

- ☐ Promptly - As soon as data are coded in a de-identified manner.
- ☑ After all subjects have completed the study.
- ☐ At the conclusion of the study.
- ☐ There is a health or research justification for retaining identifiers or retention is required by law.

i. Provide any additional information regarding the timing of destruction if applicable.

D. Choose from the following options describing how the research could not practicably be conducted **without the waiver.**

Check all that apply:

- ☑ The research involves pre-screening for recruitment purposes. The research requires potential participants to meet certain eligibility (inclusion/exclusion) requirements so PHI is necessary.
- ☐ Other:

E. Choose from the following options describing how the research could not practicably be conducted **without access to and use of PHI.**

Check all that apply:

- ☑ PHI will be used to contact individuals meeting eligibility requirements.
- ☑ PHI will be used to track what records have already been accessed for the research to avoid repeat access to the same record.
- ☐ PHI will be used to conduct a longitudinal study which involves continuous or repeated observations of risk factors and/or health outcomes.
- ☑ PHI will be used because it is required to answer the research question(s) and potentially improve future treatment and health care.
- ☐ Other:

5. Attestation on the Use and Disclosure of Protected Health Information

Both must be checked below:

- ☑ I attest the research team and I will only use protected health information minimally necessary in this study.
- ☑ I attest the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or other research for which the use and disclosure of PHI would be permitted.

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