

***Education & Recruitment in Metastatic Breast Cancer Clinical Trials***

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Our goal is to improve outcomes for patients with metastatic breast cancer (MBC) by educating them about clinical trials. We will provide multi-media tools to facilitate physician-patient communication and help patients make informed treatment decisions.

Clinical trial participation is particularly important for metastatic patients who may have fewer treatment options as they exhaust previous lines of therapy. However, only 3-5% of adult cancer patients participate in clinical trials, and more than 90% of these participants are Caucasian. Clearly, we need more clinical trial participation across the board, and especially among racial and ethnic minorities.

We will develop culturally, linguistically, and socially sensitive pamphlets and videos which dispel the most common myths and fears regarding clinical trials. We will recruit a diverse group of our patients to participate in the creation of these tools in order to provide the most effective approach to reach future patients. The target population is women with MBC, particularly racial and ethnic minorities within this group.

We will use surveys to measure the success of the program. We will determine whether the provided decision aids taught patients important facts about clinical trials, and whether the aids were deemed helpful by patients and physicians. We will assess clinical trial enrollment before and after the intervention, and gather information from patients who accepted and declined clinical trials to better understand their reasoning.

By offering this important information through a patient's perspective, we aim to increase clinical trial accrual and ultimately improve care of metastatic breast cancer patients.

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## Overall Goal and Objectives

Our goal is to improve outcomes for patients with metastatic breast cancer (MBC) by educating them about clinical trials. Clinical trial participation is particularly important for metastatic patients who may have fewer treatment options as they exhaust previous lines of therapy. We will provide multi-media tools to facilitate physician-patient communication and help patients make informed decisions about clinical trial enrollment.

This goal aligns with the focus of the RFP because it closes important clinical practice gaps, enhances the quality of care for MBC patients, and improves their quality of life. Specifically, the project bridges the gap of clinician- patient communication. We will provide tools that enhance the doctor-patient interaction, while dispelling common myths about clinical trials and explaining the many benefits of study enrollment for our patients. As more patients understand the utility of clinical trials and begin to enroll in them, we improve the quality of care for MBC patients by exploiting the latest cutting-edge research to offer our patients breakthrough therapies. We also advance the field of breast oncology by expanding clinical trial enrollment and gathering more information about a diverse set of patients. Finally, many of the metastatic clinical trials use targeted therapies which are far less toxic than the standard-of-care chemotherapy options in many cases. Thus, we can improve quality of life for our MBC patients through smarter drugs. By expanding options for our patients and involving women from various cultural, linguistic, and socioeconomic backgrounds, we have the potential to significantly change the landscape of metastatic breast cancer.

Also, the project focuses on physician support and shared decision making. By offering an educational intervention which effectively communicates the basics of clinical trials, we expect that physicians will be able to spend more time in meaningful interactions with patients. Because the intervention will be created with patients, families, and physicians in mind, shared decision-making is another strength of this proposal. The patient is heavily influenced by her family members and friends who accompany her to the doctor's office. Thus, it is important to include the patient, family members, and health care providers in the education and discussion regarding treatment options.

Also, we will provide an educational session for health care providers (including doctors, nurses, research coordinators, and medical assistants) to teach them about the common barriers to clinical trial enrollment, especially among minority populations. The session will also provide some insight on how to overcome these barriers.

The goal aligns with Theresa's Research Foundation mission of providing improved treatment options for metastatic breast cancer because it is helping recruit patients to clinical trials which

has been shown to improve patient outcomes.

The goals align with Baylor College of Medicine because it will help clinicians provide better patient care leading to better outcomes for patients. Additionally, it will help physicians more efficiently use time in clinic, giving them more time to focus on treating patients.

### ***Key Objectives***

Our primary objective is to increase clinical trial participation for all patients, with a particular focus on those with metastatic disease and those from ethnic minority backgrounds. We propose doing this through the following objectives:

1. **We will create culturally sensitive brochures and a video, explaining the importance and benefits of clinical trials.**
  - a. Creation of culturally sensitive pamphlets which feature pictures of patients of various races, stories of patients who chose to participate in clinical trials, and why they made their choices. The pamphlet would also address common myths such as “experimentation,” “sugar pills,” and financial responsibility associated with clinical trials. The patients’ stories and all information provided would be written in an easy-to-understand, conversational tone, making for an appealing and approachable format.
  - b. Creation of a culturally sensitive video which features actual patients who tell their stories, in plain language, of why they chose to accept or decline a clinical trial, and their satisfaction with their decision. We will post the video online as well as provide tablets and other tools for patients to access the video in clinic.
2. **We will target a broad range of patients, including those who speak English, Spanish, and Vietnamese.**
  - a. Because language barriers are a major reason why minority patients do not participate in clinical trials, we will make our educational materials available in multiple languages. We also have physicians and nurses who are fluent in English and Spanish. We have Vietnamese translators available as well. Greater than 97% of our patients speak one of these three languages.
3. **We will actively involve family members and friends in experiencing the educational material and drawing them into the conversation about treatment options.**
  - a. Family members will be encouraged to watch the video and participate in the clinical discussion, at the patient’s discretion. We will also train physicians and other providers on the importance of engaging the patient as well as her accompanying family members/friends.

4. **We will train the health care professionals on common barriers to clinical trial enrollment, and how to overcome these.**
  - a. Mistrust or skepticism of the medical team is another common barrier to clinical trial enrollment, especially among minority patients. We will train health care professionals on the materials we have developed and how to better explain clinical trials to patients. We also will utilize a racially diverse team of physicians, nurses, and research coordinators to demonstrate to patients an inclusive, trustworthy clinical environment.

### **Current Assessment of Need in Target Area**

Breast cancer is the most common malignant disease in women in the Western world. In the U.S., SEER data states that over 207,000 women are diagnosed with invasive breast cancer every year, and almost 40,000 women will die of this disease[1]. Approximately 6-10% of newly diagnosed breast cancer patients initially present with metastatic disease[2]. After treatment, approximately 30% of women will develop cancer recurrence with metastatic disease[3]. Clinical trials are essential for these women, as they often offer novel, innovative targeted therapies which not only potentially benefit the individual, but also advance the science of breast cancer.

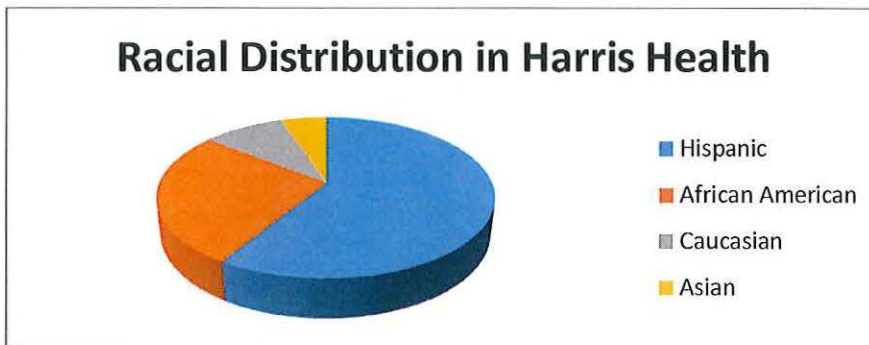
However, nationwide, only 3-5% of adult cancer patients participate in clinical trials, and more than 90% of these participants are Caucasian [4]. With such sparse participation from cancer patients in general, and especially from minority patients, we stand to lose critical information about how cancer may behave in ethnically and genetically diverse populations. For example, we are beginning to understand that BRCA mutation carriers (composed of a high proportion of Ashkenazi Jewish people) may have differential response to chemotherapy with improved response to platinum agents as compared to their non-BRCA counterparts[5]. Additionally, there are ongoing trials exclusively within the BRCA mutant population examining the efficacy of PARP inhibitors in this special group. By exploiting known deficiencies in DNA repair in this population, specific drugs and targets can be employed to effectively and specifically eradicate cancer cells with very little toxicity to the host.

In contrast, we know that African American women tend to develop breast cancer at a younger age, they have more aggressive cancer, and they die more often of breast cancer as compared to their matched Caucasian counterparts [6]. However, we do not understand what drives this poor-prognosis breast cancer in African American women; consequently, we do not have targeted agents available for this unique subset of breast cancer patients. Only with more research in these unique ethnic, racial, and geographic groups can we learn more about the biology and treatment of breast cancer in these populations.

Because most breast cancer clinical trials have such a homogenous population of patients, we are not able to learn as much about drug effect or toxicity in other populations. For example, the chemotherapy drug irinotecan cannot be given to patients with Gilbert's Disease because they lack an important liver enzyme which typically metabolizes the drug. Similarly, it has been reported that African American women may have more peripheral neuropathy from taxane chemotherapy than women of other races, possibly due to particular SNP's that are more common in African American women[7]. It is imperative that we study the effects of individual drugs in a diverse and varied population; one size does not fit all.

Previous literature documents many barriers to minority clinical trial enrollment, including medical distrust, feeling overwhelmed with diagnosis and treatment information, fear of financial responsibility, and fear of side effects. Research has also shown that a patient's partner, family, and friends can play an important role in the patient's decision to accept or decline clinical trial enrollment [8]. Finally, practical and logistical barriers also exist, such as difficulties with transportation, inability to make adequate time commitment, and language barriers. Less education and lower income have been associated with a higher rate of declining clinical trial enrollment [9]. Patients sometimes feel that they don't totally understand the treatment which is offered on the clinical trial, which makes them more wary and less likely to enroll. However, clinical trial awareness has been increasing among African Americans and Latinos as internet use increases and patients have more available avenues to educate themselves about clinical trials and treatment options [10]. Educational videos have been shown to increase clinical trial enrollment [11], especially when culturally specific videos are used [12].

At our institution, we are uniquely poised to pilot an intervention to increase minority clinical trial enrollment. Half of our breast oncology practice is housed at Smith Clinic, where we treat a very ethnically and socio-economically diverse population; the majority of them are uninsured and under-served. Half of our patients at Smith Clinic earn less than \$25,000 annually, and 60% of uninsured women in Harris County do not have a high school education. Sixty-five percent of our breast cancer patients are unable to speak proficient English. They also come from a wide variety of cultural backgrounds, with 57% Hispanic, 26% African American, 9% Caucasian, and 5% Asian patients (see Figure 2 below).



**Figure 1: Patient Race in Harris Health**

While this is the very population which tends to be the most under-represented in clinical trials, we are proud to note that 79% of our patients who are enrolled in clinical trials are racial and ethnic minorities. We track all of our clinical trial enrollment using a specialized software, so this data is easy to accurately obtain and track. From January 2015 to October 2015, we have enrolled 100 patients on clinical trials. Seventy-three patients have been from Smith Clinic, and 37 have been from Baylor Clinic. Overall, 33% have been African American, 43% have been Hispanic, 21% have been Caucasian, and 3% have been Asian. However, we strive to increase clinical trial enrollment across the board even more, particularly among under-represented populations.

### Target Audience

The Breast Center at Baylor College of Medicine (BCM) is part of the Dan L Duncan Cancer Center (DLDCC), an NCI-designated comprehensive cancer center. It has two clinical sites: an integrated multidisciplinary breast center at the Baylor Clinic, and a busy breast medical oncology service with our county affiliate, Harris Health System (aka Smith Clinic). We see 600 new breast cancer patients a year, and we service 7,000 patient visits each year. Our diverse patient population is one of our greatest strengths, as it affords us the opportunity to learn about how breast cancer may behave differently in various populations. Approximately 15% of our patients have metastatic disease. Of course, these patients stand to benefit tremendously from clinical trials which offer new and effective medicines. We have phase I, II, and III trials available for metastatic patients which offer new targeted therapies for the appropriate populations. Only by including women from various racial, socio-economic, and genetic backgrounds will we truly understand the heterogeneous biology of breast cancer. This understanding allows us to rationally target points of weakness in individual cancers. Our patients are eager to receive effective treatment for their cancer, but many of them simply do not understand that a clinical trial may be able to offer them exactly what they are looking for. We plan to recruit patients through a culturally sensitive educational campaign with pamphlets and videos in plain language, largely composed of previous patients' own words and images.

As a center which has already had fair success in recruiting a diverse population onto clinical trials, we believe that we are the ideal site to build on our previous success and engineer new approaches which could further increase clinical trial accrual in populations which have been historical non-participants. We already have in place a diverse staff, composed of physicians, nurses, navigators, and research coordinators of various races, genders, religions, and languages. The experience from our center could benefit cancer patients who receive treatment elsewhere as well because the most effective methods that we have employed for clinical trial accrual could be easily disseminated to other cancer centers.

### **Project Design and Methods:**

This project is designed for healthcare professionals to help metastatic breast cancer patients better understand clinical trials. The methodology used will be based around the development of educational materials that include videos and pamphlets. Both will be available in English, Spanish, and Vietnamese. We believe that the development of this program will help achieve our goal to improve outcomes for patients with metastatic breast cancer (MBC).

Currently, Baylor College of Medicine does not have any educational materials focused on clinical trials. We will recruit patients from diverse ethnic and linguistic backgrounds who have previously participated in clinical trials. We will ask these patients to tell their own stories through brochures and videos. We will hire a professional videographer to make the video. All materials will be available in English, Spanish, and Vietnamese. The materials will also address common myths regarding clinical trials, such as “sugar pills,” “guinea pig” subjects, and financial responsibility on a clinical trial. We will convey the importance of going on a clinical trial, and the valuable opportunity a trial may present for the right patient.

By conducting before and after surveys with patients, we will determine how fully engaged they are in the project. We will examine how their understanding of some basic clinical trial concepts may have changed as a result of reading the brochure or watching the video. For example, the surveys will ask for understanding of concepts such as randomization, and how drugs come to market. The surveys will also ask whether the patients understood and enjoyed the materials, and whether they changed the patients’ understanding of clinical trials in any way.

Additionally, we will compare clinical trial enrollment prior to the start of the program and after the educational intervention. We expect to see an increase in clinical trial enrollment, particularly within the metastatic population.



We will also have a training session for healthcare providers in order to educate physicians, nurses, and research coordinators about common barriers to clinical trial enrollment. We will also suggest techniques to overcome these barriers. We will assess this training program via a survey as well.

We have done a rather extensive online search for educational materials regarding clinical trial enrollment. However, we did not find any freely available material which was culturally sensitive and easy to understand. While some online tools do exist, none of them are geared towards metastatic patients, and they did not effectively target minority populations and common concerns within these groups. Additionally, in order to improve the clinician-patient relationship, it is key that these materials are developed at the institutional level, as we know our particular patient population rather well.

Once we have results from the initial implementation of the project we will then be happy to share these materials with other institutions at no cost. Additionally, we can develop the materials in additional languages, if it is requested from other institutions.

### Evaluation Design

For this project, we will use several metrics. Firstly, we will use before and after patient surveys to assess whether patients learned important facts about clinical trials from the video and/or brochure (see Appendices A and B). For example, concepts such as randomization, placebo, and financial responsibility on a clinical trial will be tested before and after the intervention. We will also assess whether the materials were felt to be helpful by patients. Finally, we will ask for patients' thoughts on why they did or did not choose to enroll on a clinical trial.

Secondly, we will provide a survey to physicians, nurses, and research coordinators who attend the training session on clinical trial enrollment (see Appendix C). We will assess whether health care providers felt the training session was helpful, and whether they felt that it would be helpful in recruiting patients to a clinical trial.

We will also track the number of enrolled patients in the period before the intervention and after the intervention, with special attention paid to racial background, and how many patients were metastatic. We expect to see a 15% increase in patients enrolled in clinical trials after institution of the intervention. We have a clinical trial tracking software called OnCore which easily records the number of patients screened and enrolled on clinical trials, including demographic data for each patient.

If the project is found to be successful, we plan to disseminate the findings and the materials. We will present our findings and our data at national meetings. We will submit the findings to the ASCO Breast Cancer Annual Meeting for poster presentation. Furthermore, the actual materials will be made

available online. The video would be posted to YouTube so that any clinic could allow patients to watch the video at home or in clinic. Additionally, the brochure would be available for download from the Lester & Sue Smith Breast Center website.

### **Detailed Workplan and Deliverables Schedule:**

In the first year, we will recruit metastatic patients from various cultural and linguistic backgrounds who have participated in clinical trials at our institution. Physicians will select these patients based on their current clinical condition (we will only ask patients who are feeling well to participate in this program), their experience with clinical trials (we will select patients who had varied experiences with clinical trials). We will select two English-speaking, two Spanish-speaking, and one Vietnamese-speaking patient. We will present them with a consent form which states that they agree to share their experience with clinical trial enrollment with other patients in the form of brochures and pamphlets. The patients may choose to share any part of their experience and keep others private, as they wish. The patients will also be able to review the brochures and pamphlets before they are published so that they can edit and approve the final product. We expect to have recruited all five patients within the first 3 months.

Then, we will formally hire the audio/visual consultants with whom we have already spoken about the project. The trifold pamphlets can be created, in full color, in English and Spanish for \$625.00 within 6 months. Then, we will hire Northwest translation for translation of the pamphlets into Vietnamese. We will produce these Vietnamese pamphlets by 7 months.

We will also hire the video producer who we have been working with. He will be hired by the 4<sup>th</sup> month, and he will help us in planning and designing the video shoot. He will shoot the video over 2 days, using 4 crew members. He will provide all necessary equipment, musical licenses, legal consent documents, and editing software. He will then edit the video, and include Vietnamese subtitles, for a final product. The video will be completed within 7 months.

Within the first 6 months, we will also purchase two tablets which can be used in the clinic to show the videos to patients while they wait in the exam room. During this initial 6 month period, we will also develop surveys to be given to patients and providers to assess the effectiveness of the brochures and videos. We will ask the patients to complete a brief before and after survey for the video. The pre-video survey will ask about the patient's attitude towards clinical trial enrollment, their understanding of clinical trial concepts such as informed consent, ability to withdraw from a clinical trial, randomization, blinding, placebo, and financial coverage for experimental treatments. The post-video survey will ask patients whether they understood the videos, whether they related to the women featured in the video, and many of

the same questions which were asked in the pre-video survey. Each survey will take no longer than 5 minutes. All surveys will be available in English, Spanish, and Vietnamese.

The provider survey will be created within the first 6 months of the project. The provider survey will focus on whether the brochure and video made it easier and/or faster to discuss clinical trials with patients. How was communication between physician and patient affected by the introduction of the brochure and video? Additionally, the survey will ask questions about the effectiveness of the provider training session which was offered early on in the project.

In the seventh month, we will begin training for clinic staff on how to utilize the brochures and pamphlets. This brief training will take place over 45 minutes. We will educate physicians, nurses, and research coordinators about the barriers to clinical trial enrollment, especially in minority populations. We will also talk to them about the importance of engaging not only the patient, but also the family members and friends who accompany the patient to her appointment. We will show the providers the brochure and the video, and explain that these resources are now available for patients who are candidates for clinical trials. We will also ask providers to start officially recording all patients who are offered a clinical trial, whether they enter the screening process or not. This will allow us to gather more accurate information on how many patients are being offered clinical trials, and how many of these are accepting.

In the eighth month, we will begin to disseminate the brochures to breast cancer patients who are candidates for clinical trials.

At 2 years, once the program has been in effect for over a year, we will examine clinical trial enrollment during the periods before and after the intervention was introduced. We will also examine the sociodemographic factors of patients who were offered and accepted clinical trials, as well as those who declined before and after the intervention. We expect to see an increase in clinical trial enrollment after utilization of the intervention, especially in the population of metastatic, minority breast cancer patients.

Finally, at the conclusion of the two year project, we will prepare an end-of-project report which contains information about how many patients participated in clinical trials before and after the institution of the intervention, as well as important socio-demographic data of these patients. We will also report the survey data from patients and physicians which assesses the perceived utility of the interventions in a number of different ways.

<b>Deliverable</b>	<b>Completion time (from start of project)</b>
Signed consent from 5 patients (English, Spanish, and Vietnamese-Speaking) to participate in creating the brochure and video	3 months
Brief before-and-after patient surveys	5 months
Provider surveys	5 months
Purchase two tablets for clinic patients to view the clinical trial educational videos which will be created	5 months
Translation of patient surveys into Spanish and Vietnamese	6 months
500 tri-fold, color brochures (created in English and Spanish)	6 months
Translation of the brochures into Vietnamese	7 months
Completion of educational video in English and Spanish, with Vietnamese subtitles	7 months
Provider training	8 months
End-of-Project report detailing the metrics of the program	24 months

## Appendix A: Patient Pre-Survey

Please place an "X" in the box which describes how well you agree or disagree with each statement.

<i>Statement</i>	<i>Strongly Agree</i>	<i>Agree</i>	<i>Neutral</i>	<i>Disagree</i>	<i>Strongly Disagree</i>
I am aware that clinical trials are an option for cancer treatment.					
I would consider enrolling in a clinical trial.					
If I go on a clinical trial, I could end up getting a "sugar pill" or placebo as my cancer treatment.					
Clinical trials are somewhat dangerous because doctors don't know what type of side effects the experimental drugs may cause.					
If I enroll in a clinical trial, I may have to pay more money for my treatments because insurance will not cover the cost of investigational drugs.					
I trust my doctors to recommend the best treatment for me.					
<b>Additional Comments:</b>					

## Appendix B: Patient Post-Survey

Please place an "X" in the box which describes how well you agree or disagree with each statement.

<i>Statement</i>	<i>Strongly Agree</i>	<i>Agree</i>	<i>Neutral</i>	<i>Disagree</i>	<i>Strongly Disagree</i>
I am aware that clinical trials are an option for cancer treatment.					
I would consider enrolling in a clinical trial.					
If I go on a clinical trial, I could end up getting a "sugar pill" or placebo as my cancer treatment.					
Clinical trials are somewhat dangerous because doctors don't know what type of side effects the experimental drugs may cause.					
If I enroll in a clinical trial, I may have to pay more money for my treatments because insurance will not cover the cost of investigational drugs.					
I trust my doctors to recommend the best treatment for me.					
The video/brochure taught me helpful facts about clinical trials.					
I am glad that I had access to the video or brochure to help me make my decision about clinical trials.					
<p><b>Please write 1-2 sentences about why you chose or declined to participate in a clinical trial:</b></p>					

## Appendix C: Physician Survey

Please place an "X" in the box which describes how well you agree or disagree with each statement.

<i>Statement</i>	<i>Strongly Agree</i>	<i>Agree</i>	<i>Neutral</i>	<i>Disagree</i>	<i>Strongly Disagree</i>
I felt that the training session was helpful.					
The training session taught me useful facts which will help me better explain clinical trials to patients.					
I think that other providers who work with potential clinical trial candidates should also take this course.					
I believe the video and brochure will be useful tools to aid physician-patient communication.					
<b>Additional Comments:</b>					