## Cover Page for ClinicalTrials.gov

**Official Study Title:**
Evaluation of a Cultural Dexterity Training Program for Surgeons: The PACTS Trial

**NCT Number:**
NCT03576495

**Document:**
Informed Consent Form

**Document Date:**
March 21, 2023

# THE PROVIVIDER AWARENESS AND CULTURAL DEXTERITY TOOLKIT FOR SURGEONS (PACTS) TRIAL

## INFORMATION FOR PATIENTS

Please keep this copy for your reference.

### Who are we?

We are researchers from the Brigham and Women's Hospital Center for Surgery and Public Health. We are working in partnership with nine academic medical centers across the United States to address disparities in surgical care.

### What is the purpose of the study?

The purpose of this study is to collect your feedback on a cultural dexterity curriculum that is a part of the Provider Awareness and Cultural dexterity Toolkit for Surgeons (PACTS) Trial. Your feedback is vital in ensuring that the PACTS Trial will provide adequate training for surgical residents to ensure they are equipped to address the needs of culturally diverse patient groups. Additionally, we will be collecting feedback regarding the patient survey that will be used by patients treated by residents who have undergone the cultural dexterity training to evaluate their satisfaction and clinical quality. The survey will be used to evaluate patient satisfaction with pain management, communication, trust-building, and comprehension of the informed consent.

### Why have I been asked to participate in the study?

You were recruited as a patient advisor through Brigham and Women's Hospital Center for Patients and Families after demonstrating an interest in the content of our study.

### What is involved?

You will be provided one e-learning module and didactic training including two role-playing scenarios for you to review prior to the focus group you are scheduled for. The focus group will be a 1 hour-long session that will be guided by a facilitator. By participating in the focus group, you are agreeing to take part in this research. The recording of the focus group and notes taken will only be seen by our research team and your responses will be stored securely and the data deidentified.

### Do I have to participate?

Your participation is voluntary and will not impact your performance or standing within your residency program. You are free to withdraw at any time without any consequences.

What are the risks and possible discomforts?

The study poses low risk and discomfort. Participants in the focus groups may feel nervous sharing their opinions. Participants should not feel the need to share anything in the focus groups that they are uncomfortable with.

Will I be paid for participation?

You will be awarded a $25 Amazon gift card for your participation in the focus group. Please note that if you choose to withdraw, you will no longer be eligible for the gift card.

**Study Information:** Please contact the Project Manager Emma Reidy at (617) 732-8177, Monday to Friday from 9-5, with questions about this study. If you would like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee at 857-282-1900.

**Study Contact Email:** pactstrial@gmail.com

Thank you for your time and participation.

# THE PROVIDER AWARENESS AND CULTURAL DEXTERITY TOOLKIT FOR SURGEONS (PACTS) TRIAL

## INFORMATION FOR PATIENTS

Please keep this copy for your reference.

### Who are we?

We are researchers from the Brigham and Women's Hospital Center for Surgery and Public Health. We are working in partnership with eight academic medical centers across the United States to address disparities in surgical care.

### What is the purpose of the study?

The purpose of this study is to collect your feedback on a cultural dexterity curriculum that is a part of the Provider Awareness and Cultural dexterity Toolkit for Surgeons (PACTS) Trial. The survey will be used to evaluate patient satisfaction with pain management, communication, trust-building, and comprehension of the informed consent. We are asking you to complete the survey now before the study starts so that we can make sure that the questions are clear and that it doesn't take too long to complete.

### Why have I been asked to participate in the study?

You were recruited as a patient advisor through Brigham and Women's Hospital Center for Patients and Families after demonstrating an interest in the content of our study.

### What is involved?

You will be asked to complete a short (~35 question) online survey. The survey can be completed online and at your convenience. No in-person participation is expected. By completing the survey, you are agreeing to take part in this research.

### Do I have to participate?

Your participation is voluntary and will not impact your involvement with the Brigham and Women's Hospital Center for Patients and Families. You are free to withdraw at any time without any consequences. You

### What are the risks and possible discomforts?

The study poses low risk and discomfort. Participants in survey may feel nervous sharing their opinions. Participants should not feel the need to share anything that they are uncomfortable sharing.

Will I be paid for participation?

No, you will not be paid for completing this survey.

**Study Information:** Please contact the Project Manager Emma Reidy at (617) 732-8177, Monday to Friday from 9-5, with questions about this study. If you would like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee at 857-282-1900.

**Study Contact Email:** ereidy@bwh.harvard.edu

Thank you for your time and participation.

# PACTS TRIAL INFORMATION SHEET FOR PATIENTS

Please keep this copy for your reference.

Study Information: This project is led by Douglas Smink, MD, and Adil Haider, MD. If you have any questions about this research study, you can call the Senior Project Manager, Emma Reidy at 617-732-8177 M – F 9 -5, or e-mail ereidy@bwh.harvard.edu.

## Who are we?

We are researchers from eight medical centers across the country including Johns Hopkins Medicine, Brigham and Women's Hospital, Rhode Island Hospital, Sentara Norfolk General Hospital, Massachusetts General Hospital, Beth Israel Deaconess Medical Center, Washington University Medical Center, and Howard University Hospital.

## What is the purpose of this study?

The purpose of this study is to see if an educational program for surgical residents is effective. The program teaches residents how to best interact with patients. We think your views as a patient are very important to help us study the educational program. Using a survey, we want to understand your satisfaction with pain management, communication and trust with your doctor, and understanding of informed consent. We will also look at your health outcomes after surgery using national databases and your electronic health record. We will look at outcomes like how long your stay was and if you had any more visits to the surgeon after your surgery.

## How did you get my name and how many people will take part in this study?

We got your name from a list of patients seen by your surgical resident. We would like to enroll about 2400 patients across the country.

## How long will it take?

First we will ask you to take a 5-minute screening test to see if you can agree to participate. If so, we will ask you to complete a survey that should take about 10 – 15 minutes. There are no right or wrong answers to the questions. You may stop taking the survey at any time.

## Are there any benefits for me?

There are no direct benefits to you for participating in this study. We hope that the results of this study will inform medical education across the country and will help future surgeons to provide better care to all patients.

## If I take part in this research study, how will you protect my privacy?

By completing this survey, you are agreeing to take part in this research. Your response to this survey, or any individual question on the survey, is completely voluntary. Deciding not to participate won't affect medical care you receive today or in the future. Your responses will not be stored with your name, but instead will be associated with your resident's study ID number. None of your responses will be shared with your surgical resident.

We are also required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does not describe all details of this requirement. During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy.

Also, the agency that funds this study provides a Certificate of Confidentiality to our team. This helps protect your privacy by making sure we can't share identifiable, sensitive information to anyone outside the research team, unless you give us permission to.

### What will happen if I do not participate in this study?

Participation in the study is completely voluntary. You may withdraw at any time without consequences. Participation or declining for participation will be kept confidential and will not be shared with the resident who provides your surgical care.

### What if I have questions about my rights as a research participant?

If you'd like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee at 857-282-1900.

# THE PROVIDER AWARENESS AND CULTURAL DEXTERITY TOOLKIT FOR SURGEONS (PACTS) TRIAL

## INFORMATION FOR RESIDENTS
## Please keep a copy for your reference

**Who are we?**

We are researchers from the Brigham and Women's Hospital Center for Surgery and Public Health. We are working in partnership with eight academic medical centers across the United States to address disparities in surgical care.

**What is the purpose of the study?**

The purpose of this study is to collect your feedback on the Provider Awareness and Cultural dexterity Toolkit for Surgeons (PACTS) Trial curriculum that you have recently been involved with. We are hoping to ascertain the relevance of the PACTS curriculum in your patient care, specifically with regards to two current events.

**Why have I been asked to participate in the study?**

You recently completed the PACTS curriculum. We are hoping that you would be willing to provide your opinion on its content, your engagement, and the usefulness of the curriculum within two current events.

**What is involved?**

You will be provided with refresher materials on the PACTS curriculum before the focus group to review if you feel it is necessary. The focus group will be a 1-hour virtual session that will be guided by a facilitator. The recording of the focus group and notes taken will only be seen by our research team and your responses will be stored securely and the data will be de-identified.

**Do I have to participate?**

Your participation is voluntary and will not impact your performance or standing within your residency program, or your participation within the PACTS Trial. You are free to withdraw at any time without any consequences.

**What are the risks and possible discomforts?**

The study poses low risks and discomfort. At times, participants in the focus group may feel nervous sharing their thoughts and/or opinions. Participants are not obligated to share anything with the group that they are uncomfortable with.

**Will I be paid for participation?**

You will be awarded a $25 Amazon gift card for your participation in the focus group. Please note that if you choose to withdraw, you will no longer be eligible for the gift card.

**Study Information:** Please contact the Project Manager Emma Reidy (ereidy@bwh.harvard.edu) or Project Director Dr. Gezzer Ortega (gortega1@bwh.harvard.edu) Monday to Friday from 9-5, with questions about this study. If you would like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee at 857-282-1900.

Thank you for your time and participation.

# THE PROVIDER AWARENESS AND CULTURAL DEXTERITY TOOLKIT FOR SURGEONS (PACTS) TRIAL

## INFORMATION FOR STUDY PARTICIPANTS

Please keep this copy for your reference.

### Who are we?

We are researchers from the Brigham and Women's Hospital Center for Surgery and Public Health. We are working in partnership with eight academic medical centers across the United States to address disparities in surgical care.

### What is the purpose of the study?

The purpose of this study is to collect your feedback on a cultural dexterity curriculum that is a part of the Provider Awareness and Cultural dexterity Toolkit for Surgeons (PACTS) Trial. This survey will be used as a pre-/post-test for residents participating in the trial to determine changes in their knowledge, attitudes, and skills (self-assessed). We are asking you to complete the survey now before the study starts so that we can make sure that the questions are clear. We also want to determine the best knowledge questions to use to ensure that the pre-assessment is not too easy.

### Why have I been asked to participate in the study?

You were contacted based on your participation in a focus group on this curriculum at the Academic Surgical Congress in February 2019.

### What is involved?

You will be asked to complete an online survey. The survey can be completed online and at your convenience. No in-person participation is expected. By completing the survey, you are agreeing to take part in this research.

### Do I have to participate?

Your participation is voluntary and will not impact your status within your residency program. You are free to withdraw at any time without any consequences. You

### What are the risks and possible discomforts?

The study poses low risk and discomfort. Participants in survey may feel nervous sharing their opinions. Participants should not feel the need to share anything that they are uncomfortable sharing.

Will I be paid for participation?

No, you will not be paid for completing this survey.

**Study Information:** Please contact the Project Manager Emma Reidy at (617) 732-8177, Monday to Friday from 9-5, with questions about this study. If you would like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee at 857-282-1900.

**Study Contact Email:** ereidy@bwh.harvard.edu

Thank you for your time and participation.

# PACTS TRIAL INFORMATION SHEET FOR RESIDENTS

Please keep this copy for your reference.

This is a research study being conducted by researchers at Brigham and Women's Hospital (PI: Dr. Douglas Smink, Dr. Adil Haider) in partnership with eight residency programs across North America with culturally diverse patient populations. **The purpose of this study is to assess (1) the cross-cultural knowledge, attitude, and skills of general surgery residents and (2) whether cultural dexterity training impacts resident performance and patient outcomes.** All general surgery residents in participating academic medical centers receive or will receive an e-learning module and didactic training involving role-playing scenarios followed by structured feedback from your peers and facilitators.

By completing this survey, you are agreeing to take part in this research. You will be asked to complete a pre- and post-test questionnaire to assess your knowledge, attitudes and skills. Your performance on the questionnaires, modules and role-play scenarios will only be seen by our research team and your responses will be stored securely and without any identifying information. Your participation is voluntary and will not impact your performance or standing within your residency program.

In addition, to evaluate the impact of cultural dexterity training on patient outcomes, we will survey a small selection (4-5) of patients you see on their care experience. In addition, we will use a national database to track their health outcomes post-surgery. You will be blinded as to which patients of yours have been recruited and enrolled in the study, and patient outcomes will have no bearing on your performance in your residency program. Your Program Director will not see the results of the patient surveys.

If you have questions about this survey, you may contact the Senior Project Manager, Emma Reidy, at 617-732-8177 or ereidy@bwh.harvard.edu. If you'd like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee at 857-282-1900.

The survey will take approximately 15-20 minutes to complete. Thank you for your time and participation.

# PACTS TRIAL INFORMATION SHEET FOR RESIDENTS

Please keep this copy for your reference.

This is a research study being conducted by researchers at Brigham and Women's Hospital (PI: Dr. Douglas Smink, Dr. Adil Haider) in partnership with eight residency programs across North America with culturally diverse patient populations. **The purpose of this study is to assess (1) the cross-cultural knowledge, attitude, and skills of general surgery residents and (2) whether cultural dexterity training impacts resident performance and patient outcomes.** All general surgery residents in participating academic medical centers receive or will receive an e-learning module and didactic training involving role-playing scenarios followed by structured feedback from your peers and facilitators.

By completing this survey, you are agreeing to take part in this research. You will be asked to complete a pre- and post-test questionnaire to assess your knowledge, attitudes and skills. Your performance on the questionnaires, modules and role-play scenarios will only be seen by our research team and your responses will be stored securely and without any identifying information. Your participation is voluntary and will not impact your performance or standing within your residency program.

In addition, to evaluate the impact of cultural dexterity training on patient outcomes, we will survey a small selection (4-5) of patients you see on their care experience. In addition, we will use a national database to track their health outcomes post-surgery. You will be blinded as to which patients of yours have been recruited and enrolled in the study, and patient outcomes will have no bearing on your performance in your residency program. Your Program Director will not see the results of the patient surveys.

If you have questions about this survey, you may contact the Senior Project Manager, Emma Reidy, at 617-732-8177 or ereidy@bwh.harvard.edu. If you'd like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee at 857-282-1900.

The survey will take approximately 15-20 minutes to complete. Thank you for your time and participation.

# THE PROVIDER AWARENESS AND CULTURAL DEXTERITY TOOLKIT FOR SURGEONS (PACTS) TRIAL

## INFORMATION FOR RESIDENTS

Please keep this copy for your reference.

### Who are we?

We are researchers from the Brigham and Women's Hospital Center for Surgery and Public Health. We are working in partnership with nine academic medical centers across the United States to address disparities in surgical care.

### What is the purpose of the study?

The purpose of this study is to collect your feedback on a cultural dexterity curriculum that is a part of the Provider Awareness and Cultural dexterity Toolkit for Surgeons (PACTS) Trial. Your feedback is vital in ensuring that the PACTS Trial will adequately assess (1) the cross-cultural knowledge, attitude, and skills of general surgery residents and (2) whether cultural dexterity training impacts resident performance and patient outcomes. We will also be asking your opinion regarding the implementation of such a curriculum at surgical training sites.

### Why have I been asked to participate in the study?

We are reaching out to all general surgery residents who are not currently training at the nine academic medical centers (Brigham and Women's Hospital, Massachusetts General Hospital, Beth Israel Deaconess Medical Center, Brown University, Johns Hopkins University, Howard University, Eastern Virginia Medical School, University of Michigan, University of British Columbia) participating in the PACTS Trial.

### What is involved?

You will be provided one e-learning module and didactic training including two role-playing scenarios for you to review prior to the focus group you are scheduled for. The focus group will be a 1 hour-long session that will be guided by a facilitator. By completing the Google form and/or participating in the focus group, you are agreeing to take part in this research. The recording of the focus group and notes taken will only be seen by our research team and your responses will be stored securely and the data deidentified.

### Do I have to participate?

Your participation is voluntary and will not impact your performance or standing within your residency program. You are free to withdraw at any time without any consequences.

What are the risks and possible discomforts?

The study poses low risk and discomfort. Participants in the focus groups may feel nervous sharing their opinions. Participants should not feel the need to share anything in the focus groups that they are uncomfortable with.

Will I be paid for participation?

You will be awarded a $25 Amazon gift card for your participation in the focus group. Please note that if you choose to withdraw, you will no longer be eligible for the gift card.

**Study Information:** Please contact the Project Manager Emma Reidy at (617) 732-8177, Monday to Friday from 9-5, with questions about this study. If you would like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee at 857-282-1900.

**Study Contact Email:** pactstrial@gmail.com

Thank you for your time and participation.