NCT Number:	NCT03651076
Official Title:	Randomized controlled trial of panniculus retraction methods for cesarean delivery
Document Type:	Study Protocol, including Informed Consent
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PART B
STUDY DESCRIPTION

TITLE OF PROTOCOL	**Randomized controlled trial of panniculus retraction methods for cesarean delivery**
Principal Investigator	**Ai-ris Y.Collier, MD**

B1. PURPOSE OF PROTOCOL

Our following three aims will test the central hypothesis that the use of the self-retaining panniculus retraction device (traxi®) will improve operative outcomes, as well as provider and patient satisfaction, for obese patients undergoing planned cesarean delivery.

AIM 1. Determine whether the use of traxi decreases surgical times in obese patients requiring panniculus retraction. We know from the available literature that surgical times, both from incision to delivery and incision to closure, in cesarean deliveries are longer in obese patients than non-obese patients. We hypothesize that the use of traxi will decrease surgical time.

AIM 2. Determine whether the use of traxi improves cardiopulmonary function in obese patients undergoing cesarean delivery. Vital capacity has been shown to be drastically reduced in obese pregnant patients, as compared to non-obese pregnant patients. We hypothesize that the use of traxi will improve pulmonary function testing and oxygen saturation obtained intraoperatively.

AIM 3. Determine whether that the use of traxi improves patient-reported and provider-reported experience. We hypothesize that the use of traxi will improve patient satisfaction due to maintenance of dignity and overall improved delivery experience. We postulate that provider satisfaction will improve due to facilitated visualization and easier cesarean delivery.

B2. SIGNIFICANCE AND BACKGROUND FOR THE STUDY

Introduction

Obesity rates have reached an all-time high in the general U.S. population. Currently, it is estimated that 25.6% of pregnant people have a BMI >30 and are considered obese [1]. Studies have shown that obese pregnant people are at higher risk for cesarean delivery and that their risk increases proportionately with increased BMI [2]. From a provider perspective, performing a cesarean delivery on an obese individual can be more technically challenging given the need for panniculus retraction to facilitate visualization of vital anatomic structures and delivery of the infant. As a result, operative times can be longer and additional personnel may be required in the operating room to assist in the delivery [3]. In addition, vital capacity has been shown to be drastically reduced in obese pregnant patients, as compared to non-obese pregnant patients [5,6].

The traxi® panniculus retractor (Clinical Innovations, Murray, UT) is designed to reliably retract the panniculus during surgery, thereby reducing the need for extra personnel for retraction; improve visualization to decrease operating time; and improve patient satisfaction with the delivery experience by preserving patient dignity. While the producers of this device claim that traxi is associated with these improved outcomes, no clinical trials exist to support these claims. A single clinical trial was initiated but was terminated due to low enrollment with only four subjects [7]. Given the absence of primary data in support of this device, we propose this clinical trial to examine traxi's utility and potential benefits to this patient population.

References

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B3. DESCRIPTION OF RESEARCH PROTOCOL

A. Study Design – Overview, Methods, Procedures

Overview

To determine whether the traxi® device warrants incorporation into routine practice, we will conduct an open-label, randomized, controlled trial to evaluate the use of traxi for obese patients undergoing non-urgent cesarean delivery. We will examine operative time, cardiopulmonary function, and patient/provider satisfaction.

Methods

Enrollment/randomization

Screening, recruitment, and enrollment of participants will occur in the obstetrical clinics and on Labor and Delivery at Brigham and Woman's Hospital (BWH), Beth Israel Deaconess Medical Center (BIDMC) and at Massachusetts General Hospital (MGH). Possible eligible patients may be handed a brochure about the study by their OBGYN provider at BIDMC so they can decide make an informed choice about participating. We will review the medical record of potentially eligible patients to confirm eligibility. At the time we approach each patient, we will review the eligibility criteria with the patient to further ensure eligibility. A script is available for the consenter. Specifically, consistent with standard medical care, we will confirm with patients that they do not have a history of allergic reaction to adhesives, such as those used in medical tape.

Participants who meet eligibility criteria and provide written, informed consent will be randomized to the traxi arm or standard of care (control) arm. We will use computer-generated block randomization to randomize participants in a 1:1 ratio to the traxi arm or the control arm. Randomization will be stratified by whether the patient has a history of cesarean delivery / open abdominal surgery versus no history of cesarean delivery / open abdominal surgery.

Study procedures

After the participant is in the operating room and before the cesarean delivery, we will use a spirometer to measure forced vital capacity, forced expiratory volume, vital capacity and tidal volume. We will perform these measurements while the participant is in the supine position both before any retraction has occurred and after the traxi device or standard method for panniculus retraction has been applied.

After the cesarean delivery is complete, we will assess provider satisfaction by administering a brief questionnaire developed by our research team. The survey will be distributed to personnel involved in

the delivery either on paper or via REDCap.

We will assess participant satisfaction via a survey that will be available either on paper or via REDCap.

We will conduct a medical record review to collect data on the secondary outcomes below that are not available via spirometry or questionnaire.

Outcomes
The primary outcome will be total operative time, time from incision to closure.

Secondary outcomes will include:

- Spirometry: forced vital capacity, forced expiratory volume, vital capacity and tidal volume
- Provider satisfaction
- Participant satisfaction
- Intraoperative data, such as estimated blood loss and number of scrubbed personnel
- Neonatal outcomes, such as Apgar score and NICU admission
- Length of stay postoperatively,
- Maternal complications, such as need for re-admission and wound disruption or infection.

B. Statistical Considerations

Sample Size Justification: Our sample size calculation is based on data from a prior study that reported total operative time (incision to closure) by BMI [7]. In that study, for patients with a BMI ≥40 the mean total operative time was 55.0 minutes (±26 minutes). We hypothesize that the operative time in the control arm will be similar to that in the prior study and that the mean operative time in the traxi arm will be 45 minutes (±10 minutes). Using a two-sided alpha of 0.05, in order to achieve 85% power to detect the specified difference we will need 102 participants per arm. To allow for 15% loss to follow-up, we will aim to enroll 120 participants per arm.

We hypothesize that participants will have a baseline forced vital capacity of 2.0L and that after retraction the forced vital capacity will drop by 0.1L to 1.9L in the control am. Assuming a two-sided alpha of 0.05, we will have more than 85% power to detect a difference between the 0.1L decrease in the control arm and a 0.19 L decrease in the traxi arm (assuming a standard deviation of the difference of 0.2L).

Data Analysis: We will employ an intention-to-treat approach for the data analysis. Descriptive data will be presented as a proportion, mean with standard deviation or median with interquartile range. Comparisons will be made using Chi-square or Fisher's exact test for categorical variables and parametric or non-parametric tests for continuous variables based on data distribution.

We will use linear regression to estimate beta and 95% confidence intervals for difference in the primary outcome, time from incision to closure, between the traxi and control arms. While we anticipate that randomization will balance the distribution of measured and unmeasured potential confounders in the two study arms, if this is not the case, we will assess the influence of potential confounders as needed. We will use a similar analytic approach for the secondary outcomes, which also are continuous. All data will be analyzed with SAS 9.4 (SAS Institute Inc., Cary, NC, USA). All tests will be two sided and a P value <0.05 will be required to confer significance.

Release of Data
Data from study participants enrolled at BWH and MGH will be sent to BIDMC, the coordinating site. A data use agreement will be executed to facilitate data transfer. Data will be sent via secure data transfer.

The PI will create a research steering committee that includes the PI and at least one other co-investigator. All requests to use data from the study must be made in writing and will be reviewed by the steering committee. Release of data may occur after appropriate data use agreements have been enacted.

Investigators can request to use 1) data that contain elements of a limited dataset or 2) data that are completely de-identified. Investigators who wish to obtain data that contain elements of a limited dataset first must obtain approval from the steering committee and then will have to obtain appropriate approval from the BIDMC Committee on Clinical Investigations (CCI) and from their own institution. After obtaining approval, data may be given to the researchers. Investigators who wish to receive completely de-identified data may do so after approval by the steering committee and after signing a letter indicating that they will not attempt to obtain the identity of any of the participants. A data use agreement or material transfer agreement will be executed as needed.

C. Subject Selection

Inclusion criteria for patients

- Pregnant
- Age 18-50 years
- BMI greater than or equal to 40 kg/m^2
- Undergoing non-emergent cesarean delivery
- Able and willing to provide written, informed consent
- Singleton gestation

Inclusion criteria for providers

- Listed as a provider on the patient's delivery summary
- May include nurse, resident, attending, medical student, anesthesiologist, physician's assistant, surgical technician

Exclusion criteria for patients

- Fetal demise
- Disruption of abdominal skin, such as due to infection, rash, abrasion or laceration
- Known adhesive allergy

B4. POSSIBLE BENEFITS

We do not know whether participants in the study will gain any direct benefit from participation. However, we hope that this study will provide data to inform how we can improve care for future patients. It is possible that participants who are randomized to the intervention arm of this study will have a better delivery experience due to increased preservation of dignity. It also is possible that providers will benefit by improving retraction capability and thus visualization while operating and operative efficiency.

B5. POSSIBLE RISKS AND ANALYSIS OF RISK/BENEFIT RATIO

There are very few anticipated risks involved in this study. Patients with an allergy to adhesives may experience a contact dermatitis allergic reaction to the adhesive of the traxi device or the medical tape.

Additional risks are largely psychosocial. Obesity can be a difficult topic to navigate with patients. As this device is used only in obese patients, some patients may feel uncomfortable when approached for this study. Study staff will be sensitive to this issue when approaching patients for enrollment.

To protect patient privacy and prevent a breach of confidentiality, all data will be handled in a confidential manner. We will use REDCap, a HIPAA-compliant, web-based data collection tool to securely store all data.

B6. RECRUITMENT AND CONSENT PROCEDURES

Recruitment

At BIDMC and MGH, study staff will review the cesarean delivery schedule and the census on Labor and Delivery to identify patients who may be eligible for the study. To the extent possible, eligibility will be confirmed by reviewing the medical record before the patient is approached. The study staff also will confer with the one of the patient's clinicians to ensure that it is okay to approach the patient about the study. Possibly eligible patients will be handed a brochure by their providers. They may also see the brochure in the OBGYN department and choose to read about it on their own. Patients will be approached on Labor and Delivery in a private space and clinic visits.

In addition, BWH permits study staff to call and email patients for study recruitment. Thus, BWH study staff will approach potentially eligible BWH patients via phone and email, in addition to using the in-person recruitment described above.

Providers who participated in the delivery will be sent an email to ask to participate in a REDCap survey on provider experience. Providers will be identified by looking at the list of providers in the patient's delivery summary.

Consent

Members of the study team will obtain written informed consent from participants when they are in a private clinical space. The participant will be provided with a copy of the informed consent. A script is available for use during enrollment. Providers will be consented in the email communication. The email contains required consent elements so that the providers can be well informed about participation, and they will opt in by responding to the survey.

Subject Protection

We do not believe that pregnant patients are vulnerable. Nonetheless, patients approached will be assured that their participation is completely voluntary and will not affect their clinical care. Participation in the provider survey is voluntary.

B7. STUDY LOCATION

Privacy

We will obtain consent in a private clinical setting at the hospital, and surveys will be administered to participants in a private post-partum or OBGYN exam room.

Physical Setting

Study activities will take place at BIDMC, Brigham and Women's Hospital (BWH) and at Massachusetts General Hospital (MGH).

B8. DATA SECURITY

All electronic data will be kept in a restricted-access folder on the BIDMC or MGH secure server, behind the firewall. Any paper resulting from this study will be kept in a locked office belonging to a member of the study staff. We will use REDCap, a HIPAA compliant, web-based collection tool to securely store all data.

B9 Multi-Site Studies

Is the BIDMC the coordinating site? ☒ Yes ☐ No

Is the BIDMC PI the lead investigator of the multi-site study? ☒ Yes ☐ No

We are planning to have at minimum a quarterly conference call with the traxi personnel at BWH and MGH to discuss anything about the study. We may have more frequent calls to discuss changes and important updates if necessary. If unanticipated problems, adverse events and/or noncompliance arise, we plan to follow BIDMC/CCI post-approval reportable event guidelines to report these issues. We are working closely with MGH personnel to ensure that they will submit and follow a protocol similar to the one we do. Changes made to the protocol by BWH and MGH must also be approved by us. These amendments can be discussed in conference calls.

B10 Dissemination of Research Results

We will not provide research results directly to participants. Aggregate results will be presented via poster, oral presentation and manuscript.

FOR CCI USE ONLY
Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 6/17/2023

Protocol Number: 2018P000369

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

BRIGHAM AND WOMEN'S HOSPITAL

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Randomized controlled trial of panniculus retraction methods for cesarean delivery
PRINCIPAL INVESTIGATOR: Ai-ris Collier, MD
BWH Site Investigator: Hope Yao Yu, MD
PROTOCOL NUMBER: 2018P-000369
RELYING SITE PROTOCOL NUMBER: 2022P003331

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you are pregnant.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- Your participation is completely voluntary.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide.
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Brigham and Women's Hospital (BWH)

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **RANDOMIZED CONTROLLED TRIAL OF PANNICULUS RETRACTION METHODS FOR CESAREAN DELIVERY**
PRINCIPAL INVESTIGATOR'S NAME: **AI-RIS COLLIER, MD**
RELYING SITE PRINCIPAL INVESTIGATOR: **HOPE YAO YU, MD**
PROTOCOL #: **2018P-000369**
RELYING SITE PROTOCOL NUMBER: **2022P003331**

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Ai-ris Collier, MD. Clinical Innovations, LLC is providing Dr. Collier at BIDMC, Dr. Barth at MGH and Dr Yu at BWH materials to perform this research. Neither BIDMC, Dr. Collier, MGH, Dr Yu at BWH, nor Dr. Barth have additional interests in this research project or in Clinical Innovations, LLC.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Ai-ris Collier at BIDMC at [617] 667-1726. You may also Dr. Yu at BWH at [617]-732-7801.

PURPOSE

The rate of cesarean delivery, also known as C-section, is higher in obese patients compared with non-obese patients. Studies show that the total operating time is longer for obese women undergoing cesarean delivery; this can lead to increased risk of blood loss, infection, and complications. The cesarean delivery can be complicated in this population because the excess abdominal skin (panniculus) needs to be moved away from the operating site. However, there is no standard method to move the abdominal skin out of the way. Methods currently used include someone holding the skin out of the way or using medical tape to retract the excess abdominal skin. traxi® is a new device made of soft plastic and adhesive that has been approved by the FDA to move the excess abdominal skin out of the way in cesarean delivery. There is no data that proves this device is better than other methods. Thus, we are conducting a study to determine whether traxi® improves outcomes.

To conduct this study, we are collecting data from surveys and medical records. Our primary aim is to determine whether the use of traxi® will reduce surgical time in the operating room. Secondly, we aim to determine if traxi® will improve lung function, patient satisfaction, provider satisfaction, and complication rates.

STUDY PARTICIPANTS

You have been asked to be in the study because you are pregnant aged 18 to 50 years old, undergoing a cesarean delivery and have a BMI ≥40.Approximately 240 people will take part in this study at BIDMC, MGH, and BWH

DESCRIPTION OF STUDY DETAILS

If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

BRIGHAM AND WOMEN'S HOSPITAL

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1. Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, there are no screening procedures.

2. Randomization Procedures: You will be randomly assigned (like the flip of a coin) to either the traxi® group or the standard of care group. You have a 1 in 2 chance of being in the traxi® group. You will not be able to choose the study group to which you will be assigned.

3. Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures:

· After you are in the operating room, you will be asked to blow into a device, called a spirometer, to measure the air flow in your lungs before and after your abdominal skin is moved away from the operating site.

· If you are in the traxi® group, your doctor will use the traxi® device to move the abdominal skin away from the operating site. If you are in the standard of care group, your doctor will use their typical method for moving the abdominal skin away from the operating site.

· We will collect information from your medical record, such as how long your surgery took and any complications.

4. Monitoring/Follow-Up Procedures. Procedures performed to evaluate the effectiveness and safety of the research procedures are called “monitoring” or “follow-up” procedures. For this research study, the monitoring/follow-up procedures include:Before you are discharged from the hospital, we will ask you to complete a survey about your experience with your delivery. If we are unable to obtain your responses to the survey before discharge, we may contact you in person at your postpartum appointment with your obstetric provider, or via phone or email.

RISKS AND DISCOMFORTS

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

Rare (<1%): The primary risk of this study is that the traxi® device or medical tape may cause a skin reaction from the adhesive or plastic material.

In addition, the use of the traxi® medical device may rarely result in bruising around the area of

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incision. Bruising can also occur with cesarean delivery procedure, however.
There are no other known risks associated with the use of either the traxi® device or medical tape.

LOSS OF CONFIDENTIALITY

There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

CONFIDENTIALITY

Information learned from your participation in this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, and by the traxi® panniculus retractor manufacturer, Clinical Innovations, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the BIDMC with protection of confidentiality so far as permitted by applicable law. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

MEDICAL RECORD

A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Brigham and Women's Hospital. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Brigham and Women's Hospital and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Brigham and Women's Hospital and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient at Brigham and Women's Hospital in order to participate in this research.

POSSIBLE BENEFITS

It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. Instead of being in this study, you have the option to not

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RELYING SITE PROTOCOL NUMBER: **2022P003331**

participate in this study. We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at BWH.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. BWH or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

You will not be charged for materials that are part of this research study. However, you and your insurance company will be charged for other tests, procedures or medications of this study that are considered standard treatment for your medical condition.

CO-PAYMENT/DEDUCTIBLE STATEMENT

You will be responsible for any co-payments or deductibles that are standard for your insurance coverage.

PAYMENTS TO YOU

You will not receive any payments for participating in this study.

COST OF RESEARCH RELATED INJURY

We, Mass General Brigham (MGB) hospitals, will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer. To ask questions about this, talk to the study doctor or study staff. Be aware that your

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health care payer/insurer might not cover the costs of study-related injuries or illnesses. Injuries sometimes happen in research even when no one is at fault. There are no plans for MGB to pay you or give you other compensation for any injury. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed on the second page of this consent form.

OTHER IMPORTANT INFORMATION

A description of this clinical trial will be available on www.ClinicalTrials.gov as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

IF I TAKE PART IN THIS RESEARCH STUDY, HOW WILL YOU PROTECT MY PRIVACY?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as “identifiable information.”

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires.

Who may see, use, and share your identifiable health information and why they may need to do so:

- MGB research staff involved in this study in order to conduct the research.
- The sponsor(s) of this study, and the people or groups it hires to help perform this research.
- Other researchers and medical centers that are part of this study and their ethics boards.
- A group that oversees the data (study information) and safety of this research
- Non-research staff within MGB who need identifiable information to do their jobs (such as for treatment, payment (billing), or hospital operations [such as assessing the quality of

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PROTOCOL #: **2018P-000369**
RELYING SITE PROTOCOL NUMBER: **2022P003331**

care or research])

- Beth Israel Deaconess Medical Center IRB: a group of people who review research studies to protect the rights and welfare of research participants.
- People from organizations that provide independent accreditation and oversight of hospitals and research.
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers.
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records.
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside MGB, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

Your Privacy Rights

You have the right not to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **RANDOMIZED CONTROLLED TRIAL OF PANNICULUS RETRACTION METHODS FOR CESAREAN DELIVERY**
PRINCIPAL INVESTIGATOR'S NAME: **AI-RIS COLLIER, MD**
RELYING SITE PRINCIPAL INVESTIGATOR: **HOPE YAO YU, MD**
PROTOCOL #: **2018P-000369**
RELYING SITE PROTOCOL NUMBER: **2022P003331**

this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.
If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.0
You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study, listed on page 2 of this form. You may only get such information after the research is finished.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

You may contact the Human Subjects Protection Office at [617] 975-8500 at BIDMC in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study. You may also contact Partners Human Research Committee at MGH at [857] 282-1900 for any additional questions.

THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

INFORMED CONSENT AND AUTHORIZATION

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.
- By signing this form, I do not give up any of my legal rights.
- I will get a signed copy of this consent form.

BRIGHAM AND WOMEN'S HOSPITAL

SUBJECT'S NAME:
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PROTOCOL #: **2018P-000369**
RELYING SITE PROTOCOL NUMBER: **2022P003331**

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date/Time

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date/Time

THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE

BRIGHAM AND WOMEN'S HOSPITAL

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **RANDOMIZED CONTROLLED TRIAL OF PANNICULUS RETRACTION METHODS FOR CESAREAN DELIVERY**
PRINCIPAL INVESTIGATOR'S NAME: **AI-RIS COLLIER, MD**
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PROTOCOL #: **2018P-000369**
RELYING SITE PROTOCOL NUMBER: **2022P003331**

UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____

For CCI Use Only

Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 6/07/2023

Protocol Number: 2018P000369

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
06/06/2024
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

Participant's Name:
Title of Research Protocol: Randomized controlled trial of panniculus retraction methods for cesarean delivery
Principal Investigator: Ai-ris Collier, MD
Protocol Number: 2018P-000369

INTRODUCTION

- This is a research study;
- Your participation is voluntary;
- A research study includes only people who choose to take part;
- You may or may not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research;
- You may leave the study at any time;
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Ai-ris Collier, MD. Clinical Innovations, LLC is providing Dr. Collier at BIDMC and Dr. Barth at MGH materials to perform this research. Neither BIDMC, Dr. Collier, MGH, nor Dr. Barth have additional interests in this research project or in Clinical Innovations, LLC.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Ai-ris Collier at BIDMC at [617] 667-1726. You may also contact Dr. William Barth Jr. at MGH at [617] 643-5483.

PURPOSE

The rate of cesarean delivery, also known as c-section, is higher in obese patients compared with non-

Subject's Name:
Title of Research Protocol: Randomized controlled trial of panniculus retraction methods for cesarean delivery
Principal Investigator's Name: AI-RIS COLLIER, MD
Protocol #:2018P-000369

obese patients. Studies show that the total operating time is longer for obese women undergoing cesarean delivery; this can lead to increased risk of blood loss, infection, and complications. The cesarean delivery can be complicated in this population because the excess abdominal skin (panniculus) needs to be moved away from the operating site. However, there is no standard method to move the abdominal skin out of the way. Methods currently used include someone holding the skin out of the way or using medical tape to retract the excess abdominal skin. traxi® is a new device made of soft plastic and adhesive that has been approved by the FDA to move the excess abdominal skin out of the way in cesarean delivery. There is no data that proves this device is better than other methods. Thus, we are conducting a study to determine whether traxi® improves outcomes.

To conduct this study, we are collecting data from surveys and medical records. Our primary aim is to determine whether the use of traxi® will reduce surgical time in the operating room. Secondly, we aim to determine if traxi® will improve lung function, patient satisfaction, provider satisfaction, and complication rates.

STUDY PARTICIPANTS
You have been asked to participate in the study because you are pregnant, aged 18 to 50 years old, undergoing a cesarean delivery and have a BMI ≥40.

Approximately 240 people will take part in this study at BIDMC and MGH.

DESCRIPTION OF STUDY DETAILS
If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

1. Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, there are no screening procedures.

2. Randomization Procedures: You will be randomly assigned (like the flip of a coin) to either the traxi® group or the standard of care group. You have a 1 in 2 chance of being in the traxi® group. You will not be able to choose the study group to which you will be assigned.

3. Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures:
   - After you are in the operating room, you will be asked to blow into a device, called a spirometer, to measure the air flow in your lungs before and after your abdominal skin is moved away from the operating site.
   - If you are in the traxi® group, your doctor will use the traxi® device to move the abdominal skin away from the operating site. If you are in the standard of care group, your doctor will use their typical method for moving the abdominal skin away from the

Subject's Name:
Title of Research Protocol: Randomized controlled trial of panniculus retraction methods for cesarean delivery
Principal Investigator's Name: Ai-ris Collier, MD
Protocol #: 2018P000369

operating site.
- We will collect information from your medical record, such as how long your surgery took and any complications.

4. Monitoring/Follow-Up Procedures. Procedures performed to evaluate the effectiveness and safety of the research procedures are called “monitoring” or “follow-up” procedures. For this research study, the monitoring/follow-up procedures include: Before you are discharged from the hospital, we will ask you to complete a survey about your experience with your delivery. If we are unable to obtain your responses to the survey before discharge, we may contact you in person at your postpartum appointment with your obstetric provider, or via phone or email.

RISKS AND DISCOMFORTS
As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

Rare (<1%): The primary risk of this study is that the traxi® device or medical tape may cause a skin reaction from the adhesive or plastic material.

In addition, the use of the traxi® medical device may rarely result in bruising around the area of incision. Bruising can also occur with cesarean delivery procedure, however.
There are no other known risks associated with the use of either the traxi® device or medical tape.

Loss of Confidentiality
There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

CONFIDENTIALITY
Information learned from your participation in this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, and by the traxi® panniculus retractor manufacturer, Clinical Innovations, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the BIDMC with protection of confidentiality so far as permitted by applicable law. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

MEDICAL RECORD
A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess

Subject's Name:
Title of Research Protocol: Randomized controlled trial of panniculus retraction methods for cesarean delivery
Principal Investigator's Name: AI-RIS COLLIER, MD
Protocol #:2018P-000369

Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

POSSIBLE BENEFITS
It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS
Taking part in this study is voluntary. Instead of being in this study, you have the option to not participate in this study. We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY
Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at BIDMC.

INVESTIGATORS RIGHT TO STOP THE STUDY
The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. BIDMC or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU
Costs Covered by Study
You will not be charged for materials that are part of this research study. However, you and your insurance company will be charged for other tests, procedures or medications of this study that are considered standard treatment for your medical condition.

Co-Payment/Deductible Statement

Subject's Name:
Title of Research Protocol: Randomized controlled trial of panniculus retraction methods for cesarean delivery
Principal Investigator's Name: Ai-ris Collier, MD
Protocol #: 2018P000369

You will be responsible for any co-payments or deductibles that are standard for your insurance coverage.

Payments to You
You will not receive any payments for participating in this study.

Cost of Research Related Injury
If you are injured as a direct result of your participation in this study you should contact the Investigator at the number provided under the section “Whom to Call if You Have Questions” in this form. You will be offered the necessary care to treat your injury. You or your insurance company will be billed for medical care and/or hospitalization related to this injury. You will be responsible for all co-payments and deductibles required under your insurance. BIDMC will consider reimbursement of injury related expenses not covered by your insurance on a case-by-case basis. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

OTHER IMPORTANT INFORMATION
A description of this clinical trial will be available on www.ClinicalTrials.gov as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION
As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

Protected Health Information [PHI]
By signing this informed consent document, you are allowing the investigators and other authorized personnel to use [internally at BIDMC] and disclose [to people and organizations outside the BIDMC workforce identified in this consent] health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, and mental health records if applicable as well as any new information generated as part of this study. This is your Protected Health Information.

People/Groups at BIDMC Who Will Share and Use Your Protected Health Information
Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared and used by other health care providers at BIDMC who have

Subject's Name:
Title of Research Protocol: Randomized controlled trial of panniculus retraction methods for cesarean delivery
Principal Investigator's Name: Al-RIS COLLIER, MD
Protocol #:2018P-000369

treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of BIDMC, which is responsible for reviewing studies for the protection of the research subjects.

People/Groups Outside of BIDMC With Whom Your Protected Health Information Will Be Shared

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

- The funding source and/or sponsor of this study Clinical Innovations and, where applicable, the people and companies that the funding source and/or sponsor use to oversee, administer, or conduct the research (for example, clinical research organizations are companies that are sometimes hired by research sponsors to help manage and run a clinical research study)
- The other hospitals and medical centers taking part in this study and research collaborators at those institutions
- Any external health care providers who provide services to you in connection with this research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study (if applicable)

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

Why We Are Using and Sharing Your Protected Health Information

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not

Subject's Name:
Title of Research Protocol: Randomized controlled trial of panniculus retraction methods for cesarean delivery
Principal Investigator's Name: Ai-ris Collier, MD
Protocol #: 2018P000369

all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

No Expiration Date – Right to Withdraw Authorization
Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Dr. Ai-ris Collier at 330 Brookline Avenue, Boston, MA 02215. If you enrolled at MGH, you we ask that you send the letter of withdrawal to Dr. William Barth Jr. at Founders 4 Suite 418 55 Fruit Street Boston, MA 02114. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

Refusal to Sign
Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

Right to Access and Copy your PHI
If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

Subject's Name:
Title of Research Protocol: Randomized controlled trial of panniculus retraction methods for cesarean delivery
Principal Investigator's Name: AI-RIS COLLIER, MD
Protocol #:2018P-000369

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Subject's Name:
Title of Research Protocol: Randomized controlled trial of panniculus retraction methods for cesarean delivery
Principal Investigator's Name: Ai-ris Collier, MD
Protocol #: 2018P000369

THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the BIDMC has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor)

Date and Time

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.

Subject's Name:
Title of Research Protocol: Randomized controlled trial of panniculus retraction methods for cesarean delivery
Principal Investigator's Name: Al-RIS COLLIER, MD
Protocol #:2018P-000369

THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness:

Printed Name of Witness:

Date:

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness:

Printed Name of Witness:

Date:

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____