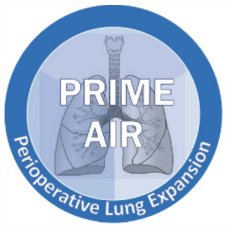
PRIME-AIR Consent Form

Massachusetts General Hospital

NCT04108130

Document date: 5.30.2023



Subject Identification

Certificate of Confidentiality Template
Version Date: November 2021

Protocol Title: PRIME-AIR STUDY- An Anesthesia-Centered Bundle to Reduce Postoperative Pulmonary Complications

Principal Investigator: Dr. Oluwaseun Johnson-Akeju, MD, MMSc

Site Principal Investigator: Brigham and Women's Hospital (BWH)- George Frendl

Description of Subject Population: Adult patients planning to undergo open abdominal surgery

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects". This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners".

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get at our hospitals now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

We want to learn if different ways of doing routine anesthesia and patient care before, during and after their surgery can reduce breathing problems after abdominal surgery.

How long will you take part in this research study?

The total time of the study is 3 months. A member of the study team will visit you daily while you are in the hospital up to 7 days after your surgery. After you leave the hospital, study staff will make 3 short follow up phone calls to you.

What will happen if you take part in this research study?

If you decide to join this study, your abdominal surgery will **not** change in any way. The anesthesia medications and techniques that you will receive in this study are generally used in clinical care. However, as part of the study, they will be in a study specific regimen. Your doctors will have the final say in deciding what they believe is best for you during your surgery.

We will assign you by chance (like a coin toss) to one of two groups: the Usual Care group or the Intervention group. Both groups will receive anesthesia care according to current clinical standards. If you are assigned to the Usual Care group, you will be cared for as usual by the team assigned to your surgery and anesthesia. If you are assigned to the Intervention group, during surgery, the medications to keep your muscles relaxed will be guided by the study protocol using a clinical device to check the level of your muscle relaxation. Also, the breathing assist machine will be adjusted using a method in which doctors try to find the pressure that makes your lungs expand the best during surgery.

Both groups may receive educational materials before the surgery, which may differ depending on what group you are in. You will be visited and called daily by study staff after the surgery while in the hospital. Either group may be asked to perform specific breathing exercises and move out of bed while in the hospital.

Why might you choose to take part in this study?

You may not benefit from taking part in this research study. It is possible that your breathing problems are reduced if you take part in this study, but we cannot guarantee this. What we learn from this study may help future patients who will receive abdominal surgery and may be at risk of developing lung problems.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Because you are having elective abdominal surgery, several important risks are present even if you do not participate in the study. These risks will be discussed with you by your doctors. Some of the risks of the study include the breathing problems, discomfort with blood draws, privacy concerns, or that you may find some of the questions in the health questionnaire sensitive or distressing.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?".

What other treatments or procedures are available for your condition?

Use of a breathing assist machine and muscle relaxants are part of the regular care during abdominal surgery. As a component of your regular medical care, it will be done whether or not you take part in the research. Different anesthesiologists have different preferences on the pressure settings they use during artificial breathing and doses of muscle relaxants. To date, there is no established guideline for the ranges of pressures that are used. Breathing exercises and encouraging you to get out of bed and walk after surgery are used for clinical care during recovery from surgery.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Oluwaseun Johnson-Akeju is the person in charge of this research study and at the MGH site. You can call him at 617-726-3030 Monday-Friday from 9 am to 5 pm. You can also contact Dr. Alexander Nagrebetsky at 617-724-6845 Monday- Friday 9 am to 5 pm with questions about this research study or about the scheduling of study visits or calls at the MGH site.

For the BWH, Dr. George Frendl is the person in charge. You can call him at 617-732-5910 Monday-Friday from 9am to 5pm. You can also page him through the hospital page system at 617-732-5500 on the off time or on the weekends with questions about this research study. You can also call Shruti Vaidyanathan at the BWH at 617-525-8831 Monday-Friday from 7am-3pm with questions about this research study or about the scheduling of study visits or calls.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

A description of this clinical trial will be available on *http://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.

Why is this research study being done?

We are doing this study to find out if we can reduce breathing problems after surgery by doing a combination of things that try to keep your lungs well expanded during and after surgery, compared to the usual care.

Everything we will do in the study (how we use the breathing machine and muscle relaxation during surgery and care after surgery) has been used in patients before. We would like to find out if doing this specific set of steps helps to decrease the risk for lung problems during and after surgery.

For the type of surgery that you will have, patients are given general anesthesia. General anesthesia is medication given to prevent pain and awareness during surgery. While under general anesthesia, medications are given to relax your muscles to allow an anesthesia machine to breathe for you. This means you will breathe with the help of a breathing assist machine that is connected to a tube placed in your windpipe.

Breathing assist machines push air into the lungs at different levels of pressure. The way to control the pressure is by changing the settings on the machines, like the volume control on a radio. Recently, doctors have found that some settings used in the breathing machines may cause less harm to the lungs than others. In this study we want to find the best settings to be applied by the breathing assist machine during your surgery. We will compare a method that uses a protocol to expand the lungs in a certain way during surgery, with the condition when no specific guidance is given to the anesthesia team. This method has been used in patients before, and we would like to find out if it causes fewer lung problems during and after surgery.

During abdominal surgery, muscle relaxants are usually given to relax the muscles of your belly and make the surgery easier. Before you wake up from anesthesia, medications are sometimes given to reverse the effect of those muscle relaxants and return your normal muscle tone. The doses of all these medications can change the risk for breathing problems after surgery. In this study, we will follow a protocol to give you these doses. This method has been used in patients before, and we would like to find out if it causes fewer lung problems during and after surgery.

You may be asked to do breathing exercises and start moving out of bed after surgery. All these are part of the routine care after surgery.

Who will take part in this research?

This will be a study in multiple medical centers in the US for a total of 750 patients. We expect to enroll a total of 114 subjects at the Massachusetts General Hospital (MGH), and the Brigham and Women's Hospital.

The National Institutes of Health, National Heart, Lung and Blood Institute is paying for the study to be done.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

It is important to know that if you agree to take part in this study, your abdominal surgery will **not** change in any way. The anesthesia medications and techniques that you will receive in this study are generally used in clinical care. However, as part of the study, they will be in a study specific regimen. Your doctors will have final say in deciding what they believe is best for you during your surgery. You will be asked to sign a separate consent form for your abdominal surgery.

Assignment to Study Group
We will assign you by chance (like a coin toss) to the Usual Care group or the Intervention group. You and the study doctor cannot choose your study group. You will have an equal chance of being assigned to either group**.** You won't know which study group you are in, but the study doctor will know.

Usual care group: You will receive medications for general anesthesia that are used for routine care, including medications to keep your muscles relaxed during surgery and return them to normal at the end of surgery. You will receive breathing assistance from the breathing assist machine using the pressure settings typical for your type of surgery deemed to be appropriate by your anesthesia team.

Intervention group: You will receive medications for general anesthesia that are used for routine care. Doses of medications to keep your muscles relaxed, and returned to normal at the end of surgery will be determined by the study protocol and guided by a device to check the level

(or depth) of muscle relaxation. You will receive breathing assistance from the breathing assist machine in which study doctors try to find the pressures that make your lungs expand the best during surgery. This is done by adjusting the pressures settings to allow your lungs to expand with the least amount of change in pressure during breathing.

Both groups: You may receive educational materials before the surgery, which may differ depending on what group you are in. You will be visited and called daily by study staff after the surgery while in the hospital. Either group may be asked to perform specific breathing exercises and move out of bed while in the hospital.

As part of this study, we will review your medical record and collect basic information about your medical history and ask you to fill out two one-page questionnaires about your level of shortness of breath and fatigue before your surgery.

We will also draw three blood samples: before your surgery, at the end of surgery and the day after your surgery. We will draw about 2 teaspoons of blood each time and a total of 6 teaspoons of blood during the entire course of this research study. We will analyze these blood samples for signs of lung injury and inflammation as part of this study.

After your surgery, we will give you follow up phone calls, or visit you, if you are still at the hospital, 7, 30 and day 90 days after your surgery. The phone calls will be about 15-20 minutes with questions about your lungs and health after the surgery.

You can give us permission to get this information from a representative (for example, your wife/husband). If we cannot get in contact with you or this representative, investigators will try to get information needed for this study follow-up through your medical records, community physicians or other hospitals, by telephone and/or in writing.

Review of Medical Records from Hospital Admissions or Emergency Department Visits.
Partners has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study.

Study Information Included in Your Electronic Medical Records.
A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example: list of allergies, results of standard blood tests done at the hospital labs.)

Optional storing of blood samples in a biorepository:
After the study ends, we would like to store some of your blood samples in the National Heart Lung and Blood Institute (NHLBI) Biologic Specimen and Data Repository (BioLINCC). After transfer to BioLINCC, other investigators outside of this study may request the blood samples. If the NIH/NHLBI grants them permission, investigators may use these blood samples to answer research questions related to lung conditions, anesthesia, surgery, and perioperative medicine.

You can choose **not** to have your blood samples stored in the BioLINCC repository. You can still take part in the research study whether or not you give permission for sharing and use of the blood samples and health information for the BioLINCC.

How are my samples and health information stored in the blood bank?
Staff at the PRIME-AIR biorepository in the University of Colorado will receive your samples and health information de-identified. A code number to your samples and health information will be assigned prior to shipment. Your name, medical record number, or other information that identifies you will not be stored with your samples or health information. The key to the code that connects your name to your samples and information will be stored securely in a separate file at the facility where your surgery took place. This information can only be accessed by approved study staff at this facility.
Once the study is finished, samples will be submitted to the NHLBI BioLINCC. If BioLINCC approves the samples, samples will be sent to their repository. The code number that identifies you will not be provided to BioLINCC. Therefore, your samples cannot be withdrawn.

Which researchers can use my samples and what information about me can they have?
In order to allow researchers to share research results, agencies such as the National Institutes of Health (NIH) have developed secure banks, including the **NHLBI Biologic Specimen and Data Repository (BioLINCC**) that collect and store research samples and health-related information and data, including genetic studies. BioLINCC or other NIH central banks may share these samples or information with other qualified and approved researchers to do more studies. Results or samples given to the central banks will not contain information that directly identifies you. There are many safeguards in place at these banks to protect your privacy.

How long will the bank keep my blood samples and information?
We may store your blood samples and information indefinitely.

Can I stop allowing your samples and information to be stored and used for research?
You can withdraw your blood samples while this study is active and your samples are in the PRIME-AIR biorepository. Once biospecimens go into the NHLBI BioLINCC repository, there is no option for you to withdraw consent for their use.

What are the risks of the BioLINCC repository?
The main risk of storing your blood samples and health information into the BioLINCC repository is a potential loss of privacy. By coding your samples and health information we reduce that risk.

You can still take part in the research study whether or not you give permission for the storage, use, and sharing of the samples and health information for other research through the BioLINCC.

Do you agree to let us store and use your blood samples linked to your health information for future research projects at the BioLINCC or other NIH-approved biorepositories?

☐ YES ☐ NO Initials _____

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. If you join this study, we will remove all information that identifies you (for example your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions, or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

Your doctors will get information that affects your clinical care, for instance, if you particularly benefit from lung expansion. You and your doctor should not expect to get information about the general results of the research study or the results of your individual participation in the research study. We and the researchers involved in this study will study samples and information from many people. It could take many years before anyone knows the results of the study.

What are the risks and possible discomforts from being in this research study?

How your surgery will be performed will be decided by your treating physicians and is completely unrelated to your taking part in this study. Your doctors will discuss with you the risks of your surgery and you'll be asked to sign a separate consent form for your surgery and anesthesia.

There are a few risks associated with taking part in this study. It is important to understand that these risks are an unavoidable part of the use of a breathing assist machine and muscle relaxants during anesthesia for abdominal surgery even if you do not participate in the study.

- **Lung problems related to artificial breathing and abdominal surgery:** Any person who goes under general anesthesia and has a breathing tube placed into their windpipe has a risk of lung problems. Doctors use forced air flow through the tube in your airways to help you breathe and this may rarely cause either inflammation or air leaks in your lungs if the pressure is too high. Problems because of low lung volumes (less air than usual inside the lungs) are common during and after general anesthesia and abdominal surgery. Low lung volumes may increase the risk of lung problems after surgery such as pneumonia. The use of the low-pressure ranges with the use of a breathing assist machine may also be associated with low lung volumes.

- **Risk of muscle weakness:** During anesthesia and abdominal surgery, your muscles are relaxed during surgery. This is routinely done with medications. At the end of surgery, this muscle relaxation is reversed before you wake up from general anesthesia. In case there is any muscle weakness after surgery, you could have problems with your breathing, including shallow breathing, low oxygen levels and higher risk of infection in your lungs (pneumonia).

- **Low blood pressure:** During anesthesia and surgery, anyone can develop low blood pressure. The use of the high-pressure ranges for artificial ventilation can increase the tendency for low blood pressure, which produces the need for a person to receive fluids and medications to help control the blood pressure. Your blood pressure is measured frequently during surgery (at least every 3 minutes) so that blood pressure can be promptly corrected if low.

- **Blood drawing risks:** You may have a bruise (a black and blue mark) or pain where we take the blood samples. There is also a small risk of feeling lightheaded, fainting, or infection. We will draw blood from the IV catheter that is placed in your arm as part of your routine care for your surgery whenever possible. Once the IV catheter is in place, you should not have any discomfort from having blood drawn.

- **Risk of pain and lightheadedness** from breathing exercises and getting out of bed (and walking) after surgery. These are part of routine care to improve your breathing and facilitate your recovery after surgery. They can make your pain worse, and they can make you feel lightheaded temporarily if you try to do it too fast

- There is the risk that you might find some of the questions in the **health questionnaires** sensitive or distressing. You are free to decline to answer any particular question you do not wish to answer for any reason.

- **Risk of loss of confidentiality:** There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be completely guaranteed.

The anesthetics and monitoring used for this study are used routinely and extensively in everyday clinical practice. You should not experience any discomfort because you will be under general anesthesia during your surgery.

What are the possible benefits from being in this research study?

You may not benefit from taking part in this study. It is possible that your breathing problems are reduced if you take part in this study, but we cannot guarantee this. What we learn from this study may help future patients who are undergoing abdominal surgery and may be at high risk of developing lung problems.

What other treatments or procedures are available for your condition?

If you choose not to take part in this study, your care will be given at the discretion of your anesthesia and surgery team. This is the same as when you are assigned to the usual care group in the study.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study

You will not be paid for taking part in this research study.

What will you have to pay for if you take part in this research study?

Study funds will pay for certain study-related items and services (special blood tests for markers of lung injury collected before and after surgery) that will be done only for the research. You/your health insurer will be billed for routine costs of surgery and anesthesia that you would receive even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We 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.

If you are injured as a direct result of taking part in this research study, we will assist you in obtaining the medical care needed to treat the injury.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. 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 in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners 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 identifiable 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 information and why:

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

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely 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 identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable 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 identifiable 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 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.

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. You may only get such information after the research is finished.

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.

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.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

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.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

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.

Hospital Medical Interpreter	Date	Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name	Date	Time (optional)

Consent Form Version Date 11/16/2021