Permission to Take Part in a Human Research Study

Title of Research Study: "The SEQUENCE Trial": **S**hould **E**ndobronchial ultrasound **QU**eue b**E**fore or e**N**suing to roboti**C**-assisted bronchoscopy for p**Er**ipheral pulmonary nodule biopsy? A patient randomized control trial assessing the effect of the ordering of robotic-assisted bronchoscopy and linear EBUS during the same anesthesia event on diagnostic yield from peripheral pulmonary nodule biopsy.

Principal Investigator: Christopher Kapp, MD

Supported By: This research is supported by Northwestern University.

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are planning to undergo a peripheral nodule biopsy.

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.
- 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.
- You can ask all the questions you want before you decide.

Why is this research being done?
Peripheral pulmonary nodules, or abnormal growths in the lung, are being found more often due to the wider availability of lung cancer screening. Once found, patients typically undergo a bronchoscopy with biopsy of a peripheral pulmonary nodule to determine if the nodule is cancerous. During this procedure, the patient's lymph nodes are also typically investigated. We do not know the best sequence to perform these procedures. This study will determine if a diagnosis is more likely to be obtained when a robotic-assisted bronchoscopy is performed first followed by investigation of the lymph nodes or vice versa (i.e., investigation of the lymph nodes is performed first followed by a robotic-assisted bronchoscopy).

How long will the research last and what will I need to do?
We expect that you will be in this research study for the duration of your scheduled procedure.

If you agree to the study, you will be randomized to receive your bronchoscopy in one of two orders, either robotic-assisted peripheral biopsy first, followed by linear EBUS (endobronchial ultrasound) to assess the lymph nodes or vice versa (starting with linear EBUS followed by robotic-assisted peripheral biopsy). The group you get will be chosen by chance, like flipping a

coin. Neither you nor the study doctor will choose what group you get. You will be told which group you received and your study doctor will know. You will have an equal chance of getting in either group. You will also be asked to allow us to collect data from your medical record, including demographics (age, sex, race/ethnicity), size of the nodule(s) and lymph node(s) being biopsied, information about the bronchoscopy procedure (number of needle passes, total procedure time, biopsy tool, size of the nodule, any problems reported during the procedure), and diagnosis resulting from the EBUS bronchoscopy.

Is there any way being in this study could be bad for me?

There is no expected risk related to the sequence of the procedures being performed. Either is standard of care and there is no expert consensus on which is better.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include future optimization of this procedure to potentially improve diagnostics, save environmental costs or time under anesthesia in the future.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 312-503-6520, Monday to Friday, 9 AM – 5 PM.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-1376 or irbcompliance@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect about 352 people across all study sites will be in this research study.

What happens if I say "Yes, I want to be in this research"?
If you agree to the study, you will be randomized to receive your bronchoscopy in one of two orders, either robotic-assisted peripheral biopsy first, followed by linear EBUS (endobronchial ultrasound) to assess the lymph nodes or vice versa (starting with linear EBUS followed by robotic-assisted peripheral biopsy). The group you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what group you get. You will be told which group you received and your study doctor will know. You will have an equal chance of getting in either group.

You will also be asked to allow us to collect data from your medical record, including demographics (age, sex, race/ethnicity), size of the nodule(s) and lymph node(s) being biopsied, information about the bronchoscopy procedure (number of needle passes, total procedure time, biopsy tool, size of the nodule, any problems reported during the procedure), and diagnosis resulting from the EBUS bronchoscopy.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to:
- Follow the instructions given to you by the study doctor and study staff.
- Report any illness or injury to the the study doctor and study staff.

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the research team at 312-503-6520.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you stop being in the research, already collected data may not be removed from the study database.

Detailed Risks: Is there any way being in this study could be bad for me?
There is no expected risk related to the sequence of the procedures being performed. Either is standard of care and there is no expert consensus on which is better.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

We will do our best to protect your data during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that people who are not supposed to might access your data. In either case, we cannot reduce the risk to zero.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

You will not be paid for your participation in this study.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include future optimization of this procedure to potentially improve diagnostics, save environmental costs or time under anesthesia in the future.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

Data from the procedure will be stored in a de-identified and confidential manner with no protected health information accessible. It will be stored in a secure database hosted by Northwestern that is password protected and accessible only to study team members.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. See the information found under **"Will my data be used for future research?"**

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Will my data be used for future research?

This study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Your data may be shared with researchers around the world. Our goal is to make more research possible. We plan to keep your data for up to 10

years after completion of this study. To get your data, future researchers must seek approval from this institution and review by an IRB may be required.

We will protect the confidentiality of your information to the extent possible. Your data will be coded to protect your identity before they are shared with other researchers. Only the study team will have a code key that can be used to link to your identifying information. The code key will be securely stored.

Participating in this study means you agree to share your data. You can change your mind later, but researchers might still use your data if they have already been shared. If you do not want your data used for other research studies, you should not participate in this study.

What else do I need to know?

If you become ill or are injured as a result of this study's procedures, you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

You will not be paid for your participation in this study.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Name and medical record number
- Contact information (address, telephone email address)
- Demographic information (age, sex, race/ethnicity)
- Dates (including date of birth, date of procedure, etc.)
- Size of lymph node(s), peripheral nodule(s) and other characteristics
- Information related to the bronchoscopy procedure itself.
- Bronchoscopy results (diagnosis) and if non-diagnostic, one year follow up of outcomes from the nodule.

During this study, you may be coming to a Northwestern Memorial HealthCare/Northwestern Medicine entity for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing.

To revoke your authorization, write to:

PI's Name: Chris Kapp
Institution: Northwestern Hospital
Department: Pulmonary and Critical Care Medicine
Address: 676 N. St. Clair Street, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Permission to Take Part in a Human Research Study

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent