Permission to Take Part in a Human Research Study

Title of Research Study: Are Two Needles Really Better than One? A Time, Economic, and Environmental Evaluation of EBUS-TBNA.

Principal Investigator: Chris Kapp, MD

Supported By: This research is supported by Northwestern University.

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study: Dr. Wahidi, an investigator on this study, has been paid by the maker of the device in this study for consulting services.

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 an endobronchial ultrasound (EBUS) bronchoscopy procedure for your standard of care.

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?
Currently, the EBUS bronchoscopy procedure uses either one or two needles to perform the biopsy of the lymph node based on physician preference. We want to determine the optimal number of needles to use for future EBUS bronchoscopy procedures like the one you are scheduled to have for your care and investigate the economic and environmental impact and time involved in using one versus two needles.

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 EBUS bronchoscopy procedure with either one or two needles. 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 the group with one needle versus the group with two needles. You will also be asked to allow us to collect data from your medical record, including demographics (age, sex, race/ethnicity), size of the lymph node being biopsied, information about the EBUS bronchoscopy procedure (number of needle passes, total procedure time, 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 whether one or two needles are used for the EBUS bronchoscopy procedure.

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?".**

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 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) 503-13769338 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 140 people here will be in this research study.

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~~investigator~~.

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.

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.

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 or samples be used for future research?"**

Will my data or samples 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.

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 and other characteristics
- Information related to the EBUS bronchoscopy
- EBUS bronchoscopy results (diagnosis)

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.

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