The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: Prospective trial to analyze endobronchial ultrasound-guided transbronchial needle-aspiration (EBUS-TBNA) samples obtained with and without suction

Principal Investigator: Peter Kneuertz, MD

Sponsor: The James Cancer Hospital and Solove Research Institute (The James)

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study
The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

Lung cancer is one of the most common cancers. One of the ways the cancer can spread is through the lymph nodes. Your medical team is planning to sample lymph nodes in your chest around the main airways. This is routinely done using a bronchoscopy camera with an ultrasound to visualize the lymph nodes, and samples are obtained using needles through the scope. The biopsy samples are used to secure the diagnosis, and determine the extent of the cancer (stage). There is an increasing amount of tests that are performed on the biopsy

sampled, to help gain information on the cancer itself, which helps to find the best treatment for the individual patient.

You are asked to participate in this study, which compares two different ways to obtain the lymph node samples, by either using suction on the needle, or using no suction. Your doctor performing the surgery would use both ways to sample your lymph nodes. This research will help determine which way will provide more lymph node material by weighing the biopsy samples. The risk of the bronchoscopy and (EBUS-TBNA) procedure is not increased by either applying suction or no suction to the biopsy needle, and overall minimal. Both ways are often performed at Ohio State and other institutions across the world. This research will help determine which biopsy technique results in more material. We hope that the results can help doctors to get the best possible biopsy results and guide the treatment for future patients.

1. Why is this study being done?

As more and more tests are needed from these samples to allow the best treatment for patients including you, we want to study if using additional suction when sampling provides more tissue. Therefore, we plan to take take samples with and without additional suction from each participant, and will compare both weights and blood contents. We will not collect samples specifically for research purposes and we will not collect any other samples such as blood samples. There is only one group, that all participants of the study will be in, and in this one group we will take some of the clinically indicated lymph node samples with and some without suction.

2. How many people will take part in this study?

We anticipate to sample 263 lymph nodes of up to 120 patients at the James.

3. What will happen if I take part in this study?

When you take part in this study, you will let us analyze the weight and blood content of lymph node samples taken bronchoscopically applying additional suction and not applying suction. The use of suction when sampling is part of the standard of care procedure and routinely performed at OSU. It is unclear if using suction provides significantly more tissue or only more blood. Therefore, we aim to sample both with suction and without, weigh each sample and analyze each samples blood content and then compare both samples.

Before an EBUS-TBNA a pregnancy test is routinely performed at OSU and this is part of the eligibility screening.

Review your medical records: This includes your health information as well as your answers to any medical and health questionnaires you complete as part of your standard medical visit. This will help researchers study what you and other patients who have a lung lesion suspicious for lung cancer have in common.

What will the data be used for?
The clinical data you donate to the James will be used to conduct the current lung cancer-related medical research. By signing this research described in this form. You will not be provided any of the test results from the research.

When the research staff at the James receives a request for use of your donated data, it can only be released to researchers with the approval of an Institutional Review Board, which is a committee of health care providers at an institution that reviews plans for research to ensure the rights and welfare of the people who enroll in the study, or as otherwise permitted by law.

4. How long will I be in the study?

The actual time required to enroll in the study will be about 15 minutes when the study is explained and you provide informed consent. All of the data and samples will be collected as part of your routine medical care when you are already having samples collected through biopsy.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

You have the right to stop the future collection of your health information at any time. If you decide to stop, no additional information will be collected for use in this study. The James will keep the results of any research that has been performed prior to withdrawal of your consent.

Your decision will apply from the time you provide written notice. All study data collected will be destroyed when you withdraw from the study.

To notify the study team that you no longer want to participate, please write to the James Cancer Hospital and Solove Research Institute, Inc. (Attention: Peter Kneuertz, MD, Division of Thoracic Surgery, 410 W 10th Avenue, 8 North Doan Hall, 43210 Columbus, Ohio or email Filiz Oezkan, MD (Filiz.Oezkan@osumc.edu)).

6. What risks, side effects or discomforts can I expect from being in the study?

The overall risk of EBUS is minimal, common complications include bleeding, post-interventional cough, soreness of throat, mediastinitis and pneumothorax, all of them are very rare (<1-2%). The procedure does not bear any significant additional risk and is a standard of care.

There is the potential for unknown risks to a foetus or newborn if a participant becomes pregnant

Risks associated with loss of privacy: Your personal health information will be used and disclosed as provided in this form. The risks associated with this part of the study are low. The risk relates to the chance that your personal information could be given to someone who is not permitted to see it. Many steps are in place, however, to prevent this. The electronic medical record system and tissue tracking data base is password protected and can only be accessed by authorized people to perform their job duties.

There is a risk of breach of confidentiality.

7. What benefits can I expect from being in the study?

There may be no direct benefit to you if you take part in this study. We hope the information learned from this study will benefit others with lung cancer in the future. By studying clinical data and sample processing up to 120 patients will be enrolled and up to 263 lymph nodes will be sampled. We hope that we might learn more about how to best sample lymph node and tumor using endobronchial ultrasound-guided transbronchial needle aspiration.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

Your bronchoscopy with EBUS-TBNA and following testing on your tissue will be billed to you or your insurance in the usual manner. You will be responsible for any deductibles, coinsurance or copayments required by your particular health plan. There is no cost to you or your insurance for the data collection on your samples and from your medical record.

10. Will I be paid for taking part in this study?

You will not be paid to take part in this study.

We hope this study will help doctors find new ways to take better care of lung cancer patients.

If you agree to participate, your sample-related information will be considered a gift to the James. The James may sell or share your samples and personal information with others, such as private companies, government agencies, or other universities. The university will be paid if your samples and information are sold.

- Your samples and personal information may be used to make new products or technologies. You will not be paid even if these new products or technologies are sold or make money.
- You cannot choose how your personal information will be used. If you do not want to let others decide how your information will be used, then you should not donate your samples.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

This is not a treatment study. The medical treatment you receive will not be affected if you take part in this study. You and your doctor will always decide on the best treatment for you.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information (and bio-specimens) be used or shared for future research? *(*

Yes, it may be used or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of

federal law, we must obtain your written authorization before we use or disclose your information for this study.

By signing this form, you are permitting researchers at the James to use persona health information for research purposes. You are also allowing the James to disclose your personal health information to any organization participating in a research-related data or information exchange in connection with this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

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

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

The James will keep your information in password protected databases and locked research files in a secure environment and will protect it to the full extent of the law. Some of these are traditional databases that are only accessible to the researchers and collaborators that are part of this study. Sometimes, however, researchers are required to submit de-identified data to publically-accessible databases. This means that other researchers that are not involved in this particular study would have access to the results. Although only experts who apply for access will be allowed and will know how to interpret this information, there is a very small chance that someone could connect you with information from this study since your genetic makeup is unique to you. This is very unlikely to occur.

Your samples will be kept in freezers in locked laboratories in a secure environment and will only be labeled with a code number and not any of your personally identifiable information.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
    - working for or with the sponsor; or
    - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- Others:
    - Researchers in the field of lung cancer
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IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and

- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact Peter Kneuertz, MD, peter.kneuertz@osumc.edu or Filiz Oezkan, MD at filiz.oezkan@osumc.edu

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact OSU HIPAA Privacy Officer at 614-293-4477.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Filiz Oezkan at filiz.oezkan@osumc.edu or 614-366-2223.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time