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CONSENT FOR RESEARCH
The Pennsylvania State University

Title of Project: Piloting a virtual navigation (VN) system for bronchoscopic lung nodule sampling

Principal Investigator: William E. Higgins, PhD

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Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (814) 865-6512

Subject's Printed Name: _____

We are asking you to be in a research study.

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, and there will be no penalty or loss of benefits to which you are entitled.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.

Why am I being invited to take part in this research study?
We are asking you to take part in this voluntary research study because you have had a CT scan, and possibly a PET scan, and your doctor recommended that you have a bronchoscopy in order to diagnose areas of differing tissues in your lungs. These procedures are being recommended to you as part of your standard of care.

What is the purpose of this research study?
The purpose of this research is to improve the effectiveness of bronchoscopies for diagnosis, and improve the ability to get the scope to the area of interest in your lungs in order to get tissue for evaluation. Currently, doctors look at 2-dimensional CT scans and form a mental picture of how to maneuver the bronchoscope into the correct position for sampling. Doctors may also use an ultrasound device (called EBUS) to help localize the area of interest. We are testing the use of a new Virtual Navigation (VN) system that will create a 3-dimensional picture of patients' lungs based on CT and PET images. This system uses the 3-D map created from the CT images and combines them with real-time bronchoscopic images to direct the doctor to the site s/he is trying to see and/or sample. It is hoped that this system will

increase the efficiency and effectiveness of bronchoscopies. This system has been developed by Dr. William Higgins, a professor of Electrical Engineering at the Penn State University.

How long will the research study last?
Participation in this study does not require any additional time on your part.

What will I need to do?
Other than signing this consent form, you will have no other responsibilities outside of your standard of care.

What are the main risks of taking part in the study?
All procedures for this research are being performed as part of your standard care, except the use of your CT scans to produce a 3-D image of your lungs. There are no foreseen risks to you for the use of the 3-D image to help guide your bronchoscopy. Your doctor may decide to take certain biopsies while looking at the 3-D image during your bronchoscopy, however no biopsies will be taken for the research study. Because we will be using your medical records as part of this research, there is the possibility of loss of confidentiality.

What are the possible benefits to me that may reasonably be expected from being in the research?
There are no benefits to you from taking part in this research. Results of the study may benefit other people in the future by helping us learn more about improving the diagnosis of lung cancer and improve our ability to distinguish cancerous from non-cancerous lung tissues.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You can decide to participate or not to participate.

DETAILED INFORMATION
The following is more detailed information about this study in addition to the information listed above.

1. Why is this research study being done?

This research is being done to test the use of a new Virtual Navigation (VN) system during bronchoscopies. This system is being developed by Dr. William Higgins, a professor of Electrical Engineering at the Penn State University, in order to increase the efficiency and effectiveness of bronchoscopies.

Approximately 166 people will take part in this research study at Penn State.

2. What will happen in this research study?

The following procedures will take place as part of this research study:

- Consent form: This research will be thoroughly explained to you and if you decide to participate, you will first sign this consent form.

-Review of medical record information: We will look at your past medical records and any test results, such as laboratory results or CT scans, to gather information about you and your medical care up to this time. The information we gather about you will create a research record. All information that will continue to be gathered about you (such as your procedure and pathology results) will also become a part of this record. All

of your research information will be labeled with a code number in order to protect your privacy. The code key that links your data to your name will be kept locked up and will only be accessible by the investigators performing this research.

-Review of the CT scan your doctor orders: You doctor has recommended that you have a CT scan, possibly a PET scan, a bronchoscopy, and possibly another CT scan performed at 6-months as part of your standard care. We will use your CT scans to create a 3-dimensional image of your lungs to show your bronchoscopy doctor before s/he performs your procedure, and to use in combination with images s/he will take while performing your bronchoscopy to help guide the procedure.

-Review of the bronchoscopy results: The diagnostic procedures performed during the bronchoscopy will depend on the nature of the differing tissue, and will be described to you as you give consent for the clinical bronchoscopy. Participation in this research will not alter the tests that are performed. Research personnel will remain in the surgical suite while your procedure is going on in case the doctor has any questions regarding the imaging. Your doctor can decide to use or not to use the imaging during your procedure, and can conduct your bronchoscopy as per standard of care.

-Storing of CT, PET and bronchoscopy video images: Your CT/PET images will have identifying information removed and will be labeled with a code number to protect confidentiality. Your bronchoscopy will be recorded to use for additional analysis. These recordings will be labeled with code numbers to protect confidentiality. You will not be able to be identified by any of the images on the recording.

-Future Use of CT, PET and bronchoscopy video images: As part of this study, we are obtaining copies of CT scans and bronchoscopic video images from you. The National Institutes of Health, which funds this research, asks that research materials be shared with other investigators who may be able to use the materials to gain additional knowledge. We therefore will create a repository of images from this research and make it available for future studies. These future studies may provide additional information that will be helpful in understanding lung disease or developing imaging systems to help identify lung disease, but it is unlikely that these studies will have a direct benefit to you. The results of these tests will not have an effect on your care. Neither your doctor nor you will receive results of these future research tests, nor will the results be put in your health record. It is possible that your images might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur. If you have any questions, you should contact Dr. Higgins at 814-865-0186 or Dr. Bascom at 717-531-2925, Monday through Friday between 9:00AM and 5:00PM.

When your scans and images are placed in this research repository they will not be labeled with any of your personal information such as your name or a code number. Once you give your permission to have this data stored in the repository they will be available for use in future research studies indefinitely and cannot be removed due to the inability to identify them.

What are my responsibilities if I take part in this research?

If you take part in this research, you will have no major responsibilities outside of your standard of care.

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

There are no major risks outside of your standard of care. There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be

taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

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

4a. What are the possible benefits to me?

There are no benefits to you for taking part in this research.

4b. What are the possible benefits to others?

The results of this research may improve the diagnosis of lung cancer and improve our ability to distinguish cancerous from non-cancerous lung tissues.

5. What other options are available instead of being in this research study?

You may choose not to be in this research study.

6. How long will I take part in this research study?

Being in this research study does not require any time on your part.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

- A list that matches your name with your code number will be kept in a locked file in Dr. Rebecca Bascom's office.
- Your research records will be labeled with <<list all identifiers that apply: your code number, your initials, your date of birth, etc.>> and will be kept in a safe area in <<PI's name>> research office.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, the following people/groups may check and copy records about this research.

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- The Penn State Institutional Review Board (a committee that reviews and approves human research studies) and the Penn State Human Research Protection Program
- The investigator, Penn State study staff, and other Penn State professionals who may be evaluating the study or need this information to do their jobs (such as for treatment, payment (billing), or health care operations)

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable information and samples may be shared with that new institution and their oversight offices. Data will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and authorization.

The research team may use your past, present, and future medical information and records for the purpose of your participation in the research study specifically identified in this authorization. Information that will be disclosed may include information that identifies you and your medical condition, as well as information developed as a result of the research study. Your authorization will remain in effect until you revoke it. You may change your mind and revoke (take back) this authorization at any time and for any reason. However, any information previously disclosed under this authorization may not be retrieved and may no longer be protected by federal or state privacy laws. To revoke this consent and authorization, contact the Principal Investigator using the information found on the first page of this form. Revocation of, or refusal to sign, this consent and authorization will not impact the care you receive at Penn State that is not related to the research, however, you will be excluded from participation in this research study if you do not provide this consent and authorization.

7b. What will happen to my research information and/or samples after the study is completed?

We may use your research information in future studies or may share your information with other investigators for future research without your additional informed consent. Before we use or share your information or samples we will remove any information that shows your identity.

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

8a. What will I have to pay for if I take part in this research study?

There is no cost to you for taking part in this study outside of your standard of care.

9. Will I be paid to take part in this research study?

You will not receive any payment or compensation for being in this research study.

10. Who is paying for this research study?

The institution and investigators are receiving a grant from The National Institutes of Health (NIH) to support this research.

Dr. Higgins and The Pennsylvania State University have financial interests in Broncus Medical, Inc. These financial interests have been reviewed by the University's Institutional and Individual Conflict of Interest Committees and are currently being managed by the University and reported to the NIH. If you would like more information, please contact the Conflict of Interest Program at 717-531-0003, ext. 283526.

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

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study William Higgins, Ph.D. at (814) 865-6512.

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the Penn State Human Research Protection Program (HRPP) at (814) 865-1775 or visit the HRPP website at https://www.research.psu.edu/irb/participants if you:

- Have questions or want information regarding your rights as a person in a research study.
- Have concerns, complaints or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov, as required by U.S. Law or policy. 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.

INFORMED CONSENT TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

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Signature of Person Giving Informed Consent and Authorization
Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and authorize your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name