HealthPartners, Inc.
Consent to Participate in a Research Study

Study Title	Personalized Smoking Cessation Tool Based on Lung CT Image
Study Investigator	Charlene McEvoy, MD, MPH 651-254-7670 (daytime)
Study Team Coordinator	Linda Loes 763-377-5827

You are being asked to participate in a research study to help assess the clinical effectiveness of a personalized patient report tool in helping people to quit smoking. The personalized Patient Report Tool is based on Imbio's Lung Density Analysis.

The Imbio analysis uses a CT image to create a visual profile of a specific person's lung health, which is then compared to the lung health of other people of the same gender and similar age who have never smoked.

This study involves one or more of the following:

- Receiving a personalized patient report tool based on your lung screening CT images
- Receiving a telephone counseling session from a tobacco cessation specialist
- Usual care

The principal investigator of this study at HealthPartners is: Charlene E. McEvoy, MD, MPH a clinical pulmonologist and researcher with the HealthPartners Institute for Education and Research. Harry Lando, PhD, a researcher within the Division of Epidemiology and Community Health, School of Public Health at the University of Minnesota, Lauren Keith, PhD, IMBIO, LLC., Michael Burke, PhD at the Mayo Clinic in Rochester, MN, and Ella Kazerooni, MD at the University of Michigan Medical School will also be involved in this research activity.

What is the purpose of this study?

To assess the clinical effectiveness of the Imbio personalized Patient Report Tool in helping people to quit smoking.

Where will this study take place?

This study will take place at HealthPartners Institute and at the University of Michigan, Ann Arbor. We expect to enroll about 300 subjects at HealthPartners Institute. The total number of subjects to be enrolled in the United States is expected to be 400.

What is involved?

If you agree to take part in this study, you will review this consent form over the phone with a member of the study staff within 72 hours of your screening CT, before you know the results of your scan. The research team will ask you questions to see if you qualify to be in the study and go over the consent form with you verbally, before attesting to your consent to participate or not. You will then need to mail the signed Consent Form to the study offices in the postage-paid envelope provided to you.

If you meet all criteria to be in this study, you will be randomized to one of four groups. Randomized means being assigned to a group by chance, like flipping a coin or drawing names out of a hat. You have a 1 in 4 chance of being assigned to one of the groups listed below.

The different groups are as follows:

- Group 1: usual care
- Group 2: Imbio Report
- Group 3: Usual care and 45 minute counseling session; and
- Group 4: Imbio Report and 45 minute counseling session.

You cannot choose which group you will be in.

Within a week of your CT scan you will receive the standard CT letter (usual care) or the Imbio Report in the mail. Depending on your group, you may then receive a phone call from a Mayo Tobacco specialist who will provide a 45 minute smoking cessation counseling session. Regardless of your group, you will receive a total of three follow-up phone calls from the University of Minnesota Measurement Services who will ask you questions to assess readiness to quit, motivation to make a quit attempt, use of a smoking cessation quitline, quit attempts and long-term smoking abstinence. The three phone calls from the University of Minnesota Measurement Services will occur at the following timepoints:

- three weeks post CT results
- 3 months post CT results, and
- 6 months post CT results.

If you report to the University of Minnesota that you have quit smoking, you will be invited to send a saliva sample to the University of Minnesota to analyze your saliva for cotinine (a nicotine byproduct present in the saliva of persons who are actively smoking.) A separate consent form for this testing will be sent to you along with the sample kit and instructions.

As a subject, you will be responsible for:

- answering call from counselors, if applicable
- answering follow-up calls and responding to questions
- following the directions of the investigator and research team

Risks and Benefits of being in the Study

Risks of being in this study are minimal and include the potential loss of confidentiality. We will do our best to keep your health information confidential. All research staff have been thoroughly trained and maintain current certification in the protection of privacy and confidentiality of research subjects. All study data are kept in secure, password protected data files behind secure institutional firewalls.

Are there any benefits to me?

You may or may not benefit from being in this study. Participating in this study may increase your general knowledge regarding motivation and barriers for tobacco cessation.

It is also possible that your condition could stay the same or even get worse. We hope the information learned will help other patients in the future.

Will I be paid to participate?

You will be paid for $20 after the first follow-up call, and $20 after the second follow-up call. You will be paid $70 after the third follow-up call, for a total of $110 if you respond to all follow-up calls. If you do not complete the study, you will only be paid for the follow up calls you completed.

How long will I be in the study?

You will be in the study for approximately 7 months.

Do I have to be in this study?

You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your regular medical care.

You may decide to participate now, but change your mind and withdraw from the study anytime without penalty or loss of benefits. If you decide to withdraw before the last study visit, let the investigator or study staff know.

Will my records be kept confidential?

Your study records will be kept as confidential as possible. If you are in Group 3 or Group 4, your CT scan results or Imbio Report will be provided to the Mayo Smoking Cessation counselors prior to your counseling session. This is further described in the HIPAA Authorization.

What if there is new information about this study?

If we learn any new information about this study that might make you change your mind about participating, we will tell you.

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. The NCT number for this study is: NCT03087617

Who oversees this study?

HealthPartners Institutional Review Board (IRB) has approved this study. The IRB is a group of people who review all research studies at HealthPartners to check that they meet federal laws and ethical standards.

IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision for you. Feel free to talk about this study with your family, friends and personal doctor before you decide.

Who do I contact?

If …	You should contact	Contact information
You are harmed by the research or have a questions about clinical procedures in the study	Charlene McEvoy, MD	651-254-7670
You have questions about your rights as a research subject	IRB office	952-967-5025

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.

Subject Name (Printed): _____

Subject Signature: _____ Date: _____

For Site Use only:

- I have carefully explained to the subject the nature and purpose of this study.
- The subject and I have read and reviewed this consent form over the telephone together.
- The subject has had a chance to ask questions and receive answers about this study.
- I have explained and discussed the nature of the research.
- I have explained and discussed potential risks and benefits.
- The alternate treatments available to the subject and the benefits and risks of each have been outlined to the subject.

_____

Name of person providing Attestation of telephone consent Title

_____

Signature of person providing Attestation of telephone consent Date

Information about Confidentiality and HIPAA Authorization

The Privacy Rule of the federal Health Insurance Portability & Accountability Act (HIPAA) is a law that protects the confidentiality of your personal health information. This Authorization describes your rights and explains how your health information will be used and disclosed.

Why is access to my health information being requested?

To help answer the research questions, the investigator and research team will use and store personal health information about you. We are asking your permission to use and share it with others, as explained below. If you don't give this permission, you won't be able to take part in the research study.

What information will be collected and used?

When you are a subject, we will collect health information about you that also includes your name, address, telephone number, or other data that could identify the health information as yours. Under HIPAA, this health information is protected and can't be used without your permission, unless otherwise permitted by law. If you sign this authorization, you are giving permission for HealthPartners Institute to use and disclose your personal health information as described below.

The following are examples of personal health information that may be collected for this study:

- results of tests and procedures
- information about your medical conditions and history

The collected information may contain your name, address, telephone number, social security number, health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

Who will see my protected health information?

By signing this Authorization, you allow the HealthPartners, the University of Minnesota, IMBIO, LLC, and the Mayo Clinic research team to use your personal health information to carry out and evaluate this study. You also allow access to your personal health information (including direct access to your medical records at HealthPartners) to the following:

Who may have access:	Purpose:
HealthPartners consultants and employees, including IRB members	To protect the rights and safety of subjects and make sure the study information is correct
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries)	To make sure applicable laws are being followed
Organizations that grant accreditation to hospitals and research programs	For HealthPartners to remain accredited

Will you keep my health information confidential?

We will keep your personal health information as confidential as possible. We will only share it as described above or if required or permitted by law. It is not likely your information will be given to

others without your permission. However, once your information leaves HealthPartners, we can't control how it is used, and it will no longer be covered by the HIPAA Privacy Rule.

Will other people know that I was in this study?

If the results of this study are published, your name or other personal information will not be included.

How long will my personal health information be used?

Access to your personal health information begins as soon as you sign this form. This authorization expires when the study is finished, data analysis is complete, and the study records have been destroyed. This is expected to be approximately 12/31/2020.

What if I change my mind?

If you don't want us to use and disclose your personal health information anymore, you must let the investigator know in writing. If you need help with this, you can ask the research team or call the HealthPartners IRB office at 952-967-5025.

If you withdraw permission for us to use your personal health information:

- you can't continue in the research study
- we will stop collecting health information from you
- we will still use and disclose any information that we gathered while you were a subject
- there will not be any penalty or loss of benefits to which you are otherwise entitled

Can I see my study records?

You can see your study records at any time.

Printed Name of Subject: _____ Date: _____

Signature of Subject: _____

FOR SITE USE ONLY:

- The subject and I have read and reviewed this authorization form over the telephone together.
- The subject has had a chance to ask questions and receive answers about their authorization.

_____

Name of person providing Attestation of telephone HIPPA Authorization Title

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Signature of person providing Attestation of telephone HIPPA Authorization Date