Official Title:	Urban Zen Integrative Therapy for Person with Pulmonary Hypertension
NCT Number:	NCT03194438
Document Name:	Informed Consent Form
Document Date:	April 25, 2017

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

Study Title:	**Feasibility and Acceptability of Integrative Therapy in Symptom Management for Persons with Pulmonary Hypertension**
Principal Investigator:	**Mary Elizabeth Happ, Ph.D., RN, FGSA, FAAN**
Sponsor:	The Ohio State University College of Nursing

- **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.

1. Why is this study being done?

This study is being done to evaluate if a type of integrative therapy called Urban Zen Integrative Therapy (UZIT) is feasible and acceptable for patients with Pulmonary Hypertension. We also would like to observe what impact this therapy may have for patients dealing with a chronic condition such as Pulmonary Hypertension.

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

Twenty patients will be asked to take part in this study.

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

If you agree to take part in this study, you will receive six, individual, weekly sessions of UZIT which will be videotaped. Some of the video recordings will be reviewed to make sure that each UZIT session is provided in a consistent manner throughout the study. After most UZIT sessions, we will ask you to describe about how the session went (semi-structured interview). You will complete questionnaires about your symptoms, activity level, and your quality of life. You will also complete a home practice diary to record how and how long you practice UZIT at home.

UZIT will include the use of 3 essential oils (lavender, lemon, or peppermint), and gentle body movement. It also includes restorative pose which includes light twists, seated forward folds and gentle backward bends. There will also be body-awareness meditation (guided meditation) and energy healing therapy (therapeutic touch). UZIT is a free service and currently available for hospitalized patients at the Ohio State University Wexner Medical Center.

Before each scheduled UZIT study visit, a research staff will remind you of your appointment through a phone call or a text message. We will call/ text you through the preferred method of contact as indicated by you.

4. How long will I be in the study?

If you choose to participate, you will be in the study for the period of 6-8 weeks. Each study session will last about 60-90 minutes. Home diary completion will take about 5-10 minutes per week.

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.

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

There is a potential risk of allergic reaction to inhalation of essential oil during the UZIT session, but is considered to be rare. We will take this precaution by having you smell a very small amount of each oil while sitting quietly before you are enrolled in the study.

Some changes in your blood pressure and heart rate related to position change during UZIT practice may occur. Since UZIT is not an exercise program, but rather a mind-body practice with gradual body position change, this risk is small.

When answering survey questions about symptoms or feelings, there is also a potential risk of emotional distress.

There is a small risk of confidentiality breach. We will follow the Institutional Review Board (IRB) guidelines in protecting your privacy pertaining to electronic, hard copy data collection as well as video recording of the sessions.

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

There may be no direct benefit to you from being in the study. However, possible benefit may include relaxation and/or symptom relief.

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?

There is no additional costs to you in taking part in this study. UZIT session will be provided to you free of charge. You do not have to pay for parking to attend the UZIT session.

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

Study participants will be paid in the form of $5.00 grocery store gift cards at the end of each UZIT session. The total amount for the entire study is $30.00.

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 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?

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 participants in research.

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

Every effort 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.

14. 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;

- Information gathered for this research about:
  - Cardiac Catheterization result
  - Pulmonary Hypertension medications and other medications
  - Video- recording of UZIT sessions
  - Diaries and questionnaires
  - The diagnosis and treatment of a mental health condition
  - Hospitalization encounters

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

Researchers and study staff.

III. Who might get this information?

- 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: The Dissertation committee members who collaborate in this project, healthcare providers who manage your care, data safety monitoring board that review safety data.

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 specified date at which your permission ends unless you withdraw consent. 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

Dr. Mary Beth Happ, Ohio State University College of Nursing, 1585 Neil Ave., Columbus, OH 43210 USA. Phone: 1-614-292-8336 Fax: 1-614-292-7976 Email: Happ.3@osu.edu.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact

HIPAA Privacy Manager, the Ohio State University Medical Center, 140 Doan Hall, 410 W. Tenth Avenue, Columbus OH 43210 Tel: 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 Ms. Sandra Meadows in 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

Dr. Mary Beth Happ, Ohio State University College of Nursing, 1585 Neil Ave., Columbus, OH 43210 USA. Phone: 1-614-292-8336 Fax: 1-614-292-7976 Email: Happ.3@osu.edu.

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