CONSENT FORM

Title of this Research Study
Holotropic Breathwork for Nursing Students

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Nebraska (CN).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

The purpose of this study is to examine how Holotropic Breathwork might impact the mental health of nursing students. You will be asked to complete five surveys. You will participate in one day of holotropic breathwork.
Holotropic Breathwork is a group experience of guided hyperventilation that can induce states of expanded consciousness.
This experience may lead to improved mental health.

Why are you being asked to be in this research study?
You are being asked to participate in this study because you 19 years of age or older and are a student in a nursing program at the UNMC College of Nursing.

People who have been diagnosed with a bipolar disorder or a psychotic disorder or have had psychotic symptoms at any point in life, diagnosed with a cardiac condition, received care for a cardiac condition, or have current cardiac symptoms, ever diagnosed with a seizure disorder, have current uncontrolled hypertension (140/90 or greater), have been diagnosed with glaucoma or retinal detachment, recent surgeries, or currently pregnant will not be allowed to participate for their own safety.

What is the reason for doing this research study?
We are conducting this study to see if and how holotropic breathwork impacts mental health.

What will be done during this research study?

In this study, you will be asked to fill out five surveys about your mental health and your experience in the breathwork. The first survey will take place shortly before your breathwork and the second shortly after your breathwork. We will then ask you to complete additional surveys 1, 3, and 6 months after the breathwork. Each of the surveys is expected to take approximately 7 minutes.

On the day of the breathwork, you will be asked to arrive in the morning. All individuals capable of becoming pregnant will be asked to submit a urine sample for a pregnancy screen. People with a positive test will not be allowed to participate.

We will then have an opening circle and then a 1-hour presentation on breathwork. You will then find a partner. One of you will be the "breather" first while the second will be the "sitter." You will switch roles for the afternoon session.

As a breather, you will be asked to lie on a mat with eye shades. Music will be played to support your experience. You will be led through a guided relaxation or body scan which helps you focus on and relax various parts of your body and mind to help prepare you for the breathwork. You will then be asked to breathe more quickly and deeper until you notice something shift in your consciousness. The session will last 2-3 hours.

In addition to your sitter, facilitators will be in the room the entire time to support you.

If you agree to participate in this study, we ask you to make a commitment to participate as a breather and also as a sitter for someone else. As a sitter, your role will be to stay with your breather and help them with small tasks such as handing them water or a tissue. If anything more comes up for the breather, we ask you to get the attention of a facilitator so they can assess and address the needs of the breather.

After the second breathwork session, a closing circle will be held where you can discuss your experience if you would like. Lastly, a 1-hour presentation will be held on integrating your experience into your daily life.

The activities may last approximately 8 hours.

Five facilitators will be present during the entire day of breathwork to answer any questions or to help you with anything you need.

Complete consent	With PI in-person or over Zoom
Baseline survey	Completed online within one week befo
Preparation talk, breathwork, integration talk	Will take approximately 8 hours
Complete post-survey	Before you leave campus the day of bre
One month after breathwork	Complete online survey
Three months after breathwork	Complete online survey
Six months after breathwork	Complete online survey

What are the possible risks of being in this research study?
During the breathwork, you may experience temporary dizziness/light-headedness, headaches, or numbness in your hands and feet.
You may experience powerful emotions during breathwork.
You may also remember or re-experience traumatic events.
Breathwork can be psychologically uncomfortable for some people but experiences can be similar to other forms or breathwork, deep meditation, or some forms of psychotherapy.

If you have experienced unprocessed trauma, you may experience effects from this during breathwork in ways that might be similar to processing the trauma in various forms of psychotherapy. You may have a re-experiencing of the events, an "out of body" experience, or dissociate. If you have past experiences and are not sure you would tolerate these potential events during breathwork, please talk with a member of the facilitator team.

In most cases, you will be allowed to carry through with your process. However, you will be prevented from acting out in situations when you may harm yourself or someone else, damage property, or engage in interactions which could be construed as sexual in nature.

As a sitter, you may become bored or uncomfortable as a result of seeing the emotional process of breathers (e.g. crying).

You may become upset as a result of an unexpected positive pregnancy test.

You may become upset as a result of questions you are asked in the surveys.

What are the possible benefits to you?
You may not get any benefit from being in this research study.
You may experience improvements in your mood, anxiety, and make progress in existential questions. Some people experience a degree of resolution in their past trauma.

What are the possible benefits to other people?
If this study has positive results, this study could help encourage a wider offering of Holotropic Breathwork to nursing students.

What are the alternatives to being in this research study?

Instead of being in this research study, you can choose not to take part.

What will being in this research study cost you?
There is no cost to you to be in this research study.

Will you be paid for being in this research study?
You will not be paid to be in this research study.

Who is paying for this research?
The researcher's development account is being used to pay for this study.

What should you do if you are injured or have a medical problem during this research study?
Your health and safety is our main concern. If you are injured or have a medical problem or some other kind of problem because of the study call someone listed at the end of this consent form.

How will information about you be protected?
In the course of this research, we will collect information about you. This will include your name, age, and e-mail address. We call this "identifiable private information". We will keep this information as confidential as possible.
Your information will be stored on an encrypted UNMC cloud server designed for sensitive information.

Who can see information about you?
By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) to have access to your research data. Your research data will be used only for the purpose(s) described in the section "What is the reason for doing this research study?".

You can change your mind and tell us to stop collecting further research data for use in this research at any time by contacting the principal investigator or any of the study personnel listed at the end of the consent form. However, the information which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to take part in this research.

We may share your research data with other groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)

How will results of the research be made available to you during and after the study is finished?
In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address: nguenzel@unmc.edu

A description of this clinical trial will be available on 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 this website at any time.

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your relationship with the investigator or the organization. You will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this research (withdraw) at any time. If you decide to stop being in the research, please let us know.
If you stop being in the research study it will not affect your care or your relationship with the investigator or the organization. You will not lose any benefits to which you are entitled.
Your studies, grades, and progression in your program will be unaffected.

Will you be given any important information during the study?
We will tell you right away if we get any new information that might make you change your mind about being in the study.

What should you do if you have any questions about the study?
We gave you a copy of *"What Do I Need to Know Before Being in a Research Study?"*

If you ever have any questions about this study, call the Principal Investigator.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463.
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Documentation of informed consent
You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects You have had your questions answered.
- You have decided to be in the research study.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Subject Name_____

Signature of Subject_____Date_____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate

Signature of Person Obtaining Consent_____Date_____

Authorized Study Personnel

Principal
* Guenzel, Nick (Nick)
alt email: nguenzel@unmc.edu
phone: 402-472-7391
alt #: 402-472-4000
degree: PhD/APRN

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn't in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I've started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830
402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT ...

... to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

... to freely decide whether or not to take part in the research.

... to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

... to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

... to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

... to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

... to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.