Consent Form

Please read, initial, and sign the consent form.

Thank you!

Please read the following consent form and enter your name, date and signature at the bottom of this page if you would like to continue as a part of the study.

Study #:20-00130
Version date: 7-18-24

NYU Langone Health

Research Subject
Key Information Form Instructions

Title of Study:	Verbal Working Memory and Attention Remediation for Adults with TBI
Principal Investigator:	Gerald Voelbel, Ph.D. Department of Occupational Therapy 212-998-5827

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

Purpose of the Research Study
The purpose of this study is to see if computerized mental training exercises can improve thinking ability and memory in individuals with a traumatic brain injury. You are being asked to participate in this study because you have experienced traumatic brain injury. Another part of the study is examine if light therapy, called photobiomodulation, with the computerized cognitive training improves thinking and memory.

Other Key Information
This study will last about 3 months and will involve about 33 visits. While in this study you will be asked to complete three cognitive assessments for your short-term memory, attention, memory, and answer some questionnaires about your health. Some people will be asked to be part of the light therapy part of the study.

Foreseeable Risk and Benefits
A comprehensive list of all possible risk and discomforts related to this research is included in the full consent, the most common risk experienced include fatigue and frustration. If this happens just let us know.

You may benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because computerized cognitive training and the light therapy may be a prescribed to them as treatment for their cognitive difficulties.

Alternatives to Participation
Should you choose not to participate, it is your choice and participation is voluntary.

For in-depth details regarding this study, please refer to the full informed consent document attached. For questions and concerns regarding any of this information, contact Gerald Voelbel, Ph.D. at 212-998-5827 or gv23@nyu.edu

NOTE: This Document Should Not Exceed 2 Pages In Length

NYU Langone Health

Research Subject Informed Consent Form

Title of Study:	Verbal Working Memory and Attention Remediation for Adults with Traumatic Brain Injury
Principal Investigator:	Gerald Voelbel, Ph.D. Department of Occupational Therapy Steinhardt School 82 Washington Square East 6th Floor New York, NY 10003 (212) 998-5827

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called "subjects" or "research subjects". These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will send you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to examine if cognition in individuals with a traumatic brain injury can be improved with computerized cognitive training and light therapy. This study will explore if cognitive training and low laser light therapy applied to the top of the head and the nostrils helps the brain recover from brain injuries. This kind of information may provide doctors, scientists, and sports medicine staff a better understanding of the possible ways to improve recovery from brain injuries.

3. How long will I be in the study? How many other people will be in the study?

Your participation will involve 3 cognitive assessments and 30 cognitive training sessions for a period of up to 12 weeks. Individuals interested will be offered to take part of the light therapy that will occur simultaneously with cognitive training for the 30 cognitive training sessions.

Each of these visits will take the following amount of time:

- The assessments will take approximately 3 hours each plus online surveys about your health.

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- The training sessions will last approximately 30 minutes each.
- The light therapy therapy is 20 minutes at the same times as the cognitive training.
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4. What will I be asked to do in the study?

There will be four parts to the research study. First part, you will undergo neurocognitive assessment that will assess attention, short-term memory and verbal memory. You will also complete some online surveys about your health.

Second part, you will be asked if you would like to take part of the light therapy with cognitive training. If you are willing to take part of the light therapy part of the study, you may be assigned to the light therapy experimental group or sham light therapy group. The light therepay group will wear a head gear similar to the one in the picture the left with a light attached to the nostril for the light therapy sessions. Each light therepay session is 20 minutes and occur simultenously with the computerized cognitive training. If you are assigned to the sham light therapy group, you will wear the headgear but will not get light modulation.

There are two cognitive training training groups, you may be assigned to one of the computerized cognitive training groups. Each group will undergo 30 computerized training for attention and short-term memory or recognizing faces and facial expressions.

Third and fourth parts, at the end of the training sessions and one month later you will be undergo another neurocognitive assessment.

5. What are the possible risks or discomforts?

Risk of Study

There are no anticipated risks to you participating in this study other than those encountered in day-to-day life. No anticipated risks from receiving the light therapy, but the pressure of having the headgear on top the head may be annoying.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

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There is no direct benefit expected from your participation in this study. It is hoped the knowledge gained will be of benefit to others in the future. The results of this study may lead to better or more effective ways to treat people with head injuries.

8. What other choices do I have if I do not participate?

Participation is voluntary.

9. Will I be paid for being in this study?

There will be no cost to you, but you understand that you will be reimbursed after each neurocognitive assessment with a $25 Amazon gift card.

In order to receive payments for your participation in research, you may need to provide your Social Security number and email address. This is because NYU is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00, and you may be taxed on these research payments above $600.00.

10. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

11. When is the study over? Can I leave the Study before it ends?

If you decide to take part in the study, you may withdraw from participation at any time without penalty or loss of benefits to which you would otherwise be entitled. You may also withdraw your Authorization for us to use or disclose your protected health information for the study. If you do decide to withdraw your consent, we ask that you contact Dr. Voelbel and let him know that you are withdrawing from the study. His mailing address is 82 Washington Square East, 6th Floor, New York, NY 10003. If you wish to withdraw your Authorization as well you must contact Dr. Voelbel in writing to Gerald Voelbel, Ph.D. 82 Washington Square East, 6th Floor, New York, NY 10003. Remember that withdrawing your Authorization only affects uses and sharing of information after your written request has been received, and you may not withdraw your Authorization for uses or disclosures that we have previously made or must continue to make to complete analyses or report data from the research.

The Principal Investigator or another member of the study team will discuss with you any considerations involved in discontinuing your participation in the study. You will be told how to withdraw from the study.

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You understand that the investigator has the right to withdraw you from the study at any time. You may be withdrawn from the study for failure to keep appointments or follow protocol directions as instructed.

12. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

13. Permission to contact you about future research:

I authorize the principal investigator and his co-investigators to contact me about future research on head injuries within the Department of Occupational Therapy provided that this future research is approved by the original IRB of record and that the principal investigator and co-investigator are affiliated with the research protocol.

If I agree, then someone from Dr. Voelbel's research staff might contact me in the future and he will tell me about a research study. At that time, I can decide whether or not I am interested in participating in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

☐ I agree to be contacted by the Principal Investigator or Co-Investigators of the research study titled: Verbal Working Memory and Attention Remediation for Adults with Traumatic Brain Injury.

☐ I do not want to be contacted by the Principal Investigator or Co-Investigator of the research study titled: Speed of Processing Training in Traumatic Brian Injury

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1)	Permission to contact you about future research	◯ I agree to be contacted by the Principal Investigator or Co-Investigators of the research study titled: Verbal Working Memory and Attention Remediation for Adults with Traumatic Brain Injury: A pilot, randomized, placebo-controlled study. ◯ I do not want to be contacted by the Principal Investigator or Co-Investigator of the research study titled: Verbal Working Memory and Attention Remediation for Adults with Traumatic Brain Injury: A pilot, randomized, placebo-controlled study.
2)	Initials of participant	_____

Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your care at any of the NYULH facilities. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for one of our future research studies. It does not mean that you must join in any study.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

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15. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

16. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

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3) First Name of Subject

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4) Last Name of Subject

_____

5) Signature of Subject

_____

6) Date

_____

7) Name of Research Personnel Obtaining Consent

_____

8) Signature of Person Obtaining Consent

_____

9) Date

_____

Copy of Informed Consent for Download

[Attachment: "consent form.pdf"]