Adult Consent Form (includes HIPAA Authorization)

Title of Research Study: ***Teen Brain Training (TBT)***

Investigator Team Contact Information:
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Researcher: Karina Quevedo, PhD, L.P. Department of Psychiatry Phone (mobile): _____ Phone (landline): 612-273-9761 we seldom reply Email: queve001@umn.edu non-emergency, fast reply.	TBT Study Staff: _____ Phone (mobile): _____ Phone (landline): 612-626-6952 reply within business hours. Email: _____ non-emergency, fast reply.

If your doctor is also the person responsible for this research study, please note that they are interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: This research is supported by the National Institute of Mental Health (NIMH).

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- **The goal of research** is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- **The goal of clinical care** is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are 18 years old and have had a suicide attempt at some point in your life **OR** you became 18 while enrolled in the study after starting the study as a child/teenager.

What should I know about a research study?

- Someone will explain this research study to you.
- 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.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to examine a new, experimental treatment for adolescents at risk for suicide attempts called **neurofeedback training**. In neurofeedback training, you are trying to control your brain function on purpose. You will see your brain activity (displayed like a thermometer) and recall positive memories to try to change your levels of brain activity as shown on the visual thermometer. If this study is successful, it may result in new treatments for suicide risks.

How long will the research last?

We expect that you will be in this study for about 5 to 12 months. During this time, you will have a minimum of 5 study visits.

What will I need to do to participate?

You may be asked to attend at least 5 study visits, which involve completing questionnaires about your medical and psychiatric history, personality, and habits. You will also complete diagnostic interviews and

computerized tasks. Additionally, you will have two magnetic resonance imaging (MRI) scans of your brain, during which you will have the neurofeedback training.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

You may be asked about your personal experiences and psychiatric history. These questions may cause you to feel discomfort or/and distress. Please tell the research team if at any time you would like to temporarily pass on questions and/or discontinue participation in the study.

Neurofeedback is not easy to accomplish. You may feel frustrated because of your perceived inability to complete the task.

If we think that you are at high risk of suicide, we may bring you to the emergency room for assessment (or call 911 on your behalf). There is a risk that you could be admitted to the hospital if the emergency room physician also thinks that your safety is at risk.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section***

Will being in this study help me in any way?

We cannot promise any benefits to you from taking part in this research. Neurofeedback has lessened depression, emotion dysregulation, and dissociation among depressed adults who underwent a similar procedure as the one proposed in this study. We don't know if it will result in similar benefits for adolescents and young adults, but we have some early data that suggest that it may alleviate those symptoms in youth.

This study may benefit other people in the future by providing a better understanding of how adolescents with risks of suicide process self-relevant information and their emotions. And whether they can change the parts of their brain that are involved in those processes. If this neurofeedback training is effective, it may result in new treatments for suicide risks.

What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this research study. If you do not wish to participate in this study, that is fine. You may continue to receive mental health care with your current outpatient provider(s) or seek additional support on your own, if this is applicable.

Detailed Information About This Research Study

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

How many people will be studied?

We expect about a minimum of 1100 people will be screened for this research study.

What happens if I say "*Yes, I want to be in this research*"?

This study has two phases. If you are participating during the **1st phase**, you will receive neurofeedback from areas of the brain that enable memory recall. If you are participating in the **2nd phase**, you will receive neurofeedback from areas of the brain that are either related or unrelated to memory recall. Those participating in the 2nd phase will not know whether the brain activity they see is their actual brain activity or not or if it's linked to memory recall. All study activities remain the same between the two phases, except for the area of training. **We will inform you if you are participating in the 1st or the 2nd phase.**

Visit 1:

This visit may last about 5 hours. This visit may be in person or online via Zoom or other video conferencing platforms.

- You may fill out questionnaires about yourself, your life events, and your mental health.
- You may also complete cognitive assessments and diagnostic interviews.
- We may take pictures of your face with happy, sad, and neutral expressions to use during your MRI scan or instruct you on how to take and send us the pictures.
    - You will be asked to upload pictures of your face via a secure platform (such as REDCAP) but the option of emailing or texting will be offered as not everyone is familiar with such platforms. Sending pictured through unsecured email or text can present an additional risk for the pictured to be seen by people outside of the study. All necessary precautions will be made to keep the pictures stored safely and to protect your privacy.

Visit 2 and 3:

These visits may last about 5-8 hours each at the Center for Magnetic Resonance Research (CMRR).

- In these visits, you will have an MRI scan of their brain done. The scan will take approximately 1-2 hours. During this time, you will complete Neurofeedback Training and separate activities where you will be looking at different pictures (ugly, scary, nice or neutral) or human faces and following instructions. For a portion of the scan, you will also be asked to rest without sleeping.
- During **Neurofeedback Training** you will see your brain activity (shown like a thermometer). This will allow you to know how you are changing your brain function. You will recall positive memories to try to change the levels of the visual thermometer while you see pictures of your own smiling face. We can help you identify and remember those positive memories.
- After and/or before the brain scan, you will be asked to fill out some questionnaires and answer questions about your experience in the scanner and complete tasks (e.g. identifying faces or words) that measure emotion regulation and self-processing.
- Specific CMRR procedures may include: Screening procedures, including testing procedures needed before participation in MRI (e.g. pregnancy testing, x-ray to determine location of shrapnel); MRI screening procedures and duration of scanning (e.g. remove all metallic objects, wear hospital gown, etc.); whether study specific positioners like bite bars will be used or additional devices will be placed to communicate with or monitor the subject (e.g. heart rate or respiration monitoring, headphones) or conduct imaging (endo coils, etc.); additional procedures subjects will be asked to perform in this study while in the MRI scanner (e.g. perform tasks while lying in the scanner); and procedures associated with completion of the study (e.g. completion of exit questionnaires, etc.).
- If you get very tired or something is wrong with the research procedures, we may need to have more than two visits to the CMRR for the scanning and the Neurofeedback Training.

Visit 4 and 5:
The 4th visit may last about 3-4 hours and the 5th visit may last about 4-5 hours. These visits may be in-person or online via Zoom or other video conferencing platforms.

- You will repeat some of the questionnaires, assessments, and computerized tasks that you completed at the previous three study visits.

Additional Visits:
If additional time is needed to complete tasks from previous visits, additional visits may be done.

- Repeat tasks, scanning or questionnaires.
- Complete missing visits and additional phone, remote or in person visits as needed

We will video or audio record your diagnostic interviews, and possibly the scanning sessions, to help with data analysis and to help train our research staff how to conduct these interviews.

Communications:
You have the option to receive updates related to appointment reminders and updates via text message and/or email message (Standard text messaging rates will apply). For your safety, we will need to have your cellphone, email, current residence information, and your location if we are interviewing you remotely. We will be asking you for your current address to send you short written communications while you are enrolled in the study. You will have the opportunity to opt-in to receive those communications and you can change your mind even if you agree now. We will also ask you to program our main numbers in your phone as **Teen Brain Training** so that you can quickly identify us when we call you.

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

If you take part in this research, you will be responsible for: attending the study visits agreed upon with the research team and following instructions given to you by the research team.

What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student, or your present or future employment. Deciding to not participate will not harm your relationship with the doctors and the hospital staff, nor will it prejudice future treatment.

If you stop being in the research, information about you that has already been collected may not be removed from the study database. You will be asked whether the investigator can collect information from your routine medical care, such as your medical records after you leave the study. If you agree, you will be asked to sign an additional consent form (i.e. Clinical Data Collection after Withdrawal Consent Addendum) and HIPAA authorization to document your agreement to participate in ongoing data collection.

Can I be removed from the research?

It's possible that we may have to ask you to leave the study before you finish it. If this happens, we will tell you why. We may also help arrange other care for you if needed. Possible reasons for removal include:

- Claustrophobia resulting in intense discomfort in the scanner that cannot be lessened with brief anxiety decreasing interventions.
- Refusal to cooperate with study procedures.
- High risk of imminent suicide attempt (for example, there is intent, and a plan is in place). It is possible to re-enroll in the study after level of care is adjusted if approved by the PI and an independent medical monitor.
- Onset of psychotic symptoms that clearly impair judgment and ability to assent.
- Onset of neurological or metabolic illness known to significantly affect brain function and structure.
- Onset of substance dependency disorder or new evidence that symptoms are linked to substance use.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

Privacy and Confidentiality

We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of some risk of a data breach involving the information we have about you. This include communications between you and the research team via unencrypted phone calls, emails or text. **Email, letters, and text communications that are not-encrypted always carry the risk of been accidentally read by others not part of the study team. This is a risk of any non-encrypted communication**. For the purposes of this research, we must remain it touch with you via such means. While we will always exercise caution, you have the right to be aware of these risks.

MRIs

MRI machines use a strong magnet and radio frequency magnetic fields to take images of your body. The scanning process is similar to an x-ray or CT scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like x-rays or CT scans. The risks associated with MRI scans are:

Projectiles: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and by controlling access to the scanner.

Claustrophobia: The scanner is a long narrow tube that may cause some people to feel claustrophobic.

Hearing Damage: The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if you do not wear hearing protection. Hearing protection is required and is provided by the investigator.

Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable please notify the investigator.

Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If you have any implanted device notify the investigator.

Heating of Devices: The radio frequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You will be asked to remove these items if possible. If

they cannot be removed you will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. You will be in constant contact with the investigator and should notify the investigator immediately, via the squeeze ball, if you notice anything unusual, become claustrophobic, think that your hearing protection is not adequate, or if you experience nerve stimulation that is uncomfortable.

In addition, there is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after leaving the magnet. If any sensations experienced during participation cause discomfort or pain, notify the researcher right away and your participation will stop and you will be taken out of the magnetic field.

Will I receive any imaging results after an MRI?

The images or pictures created during this study are for research purposes only and are not intended to provide health care to you. However, if the results from the magnetic resonance imaging show something unusual in the pictures, we will provide you a copy of your brain pictures that will not contain any personal information. You will then decide whether to contact a radiologist, neurologist or your own physician. However, further medical follow up is not a part of this study and the study does not have funds set aside for this purpose. Therefore, if the results do show something unusual, any medical follow up cost will be your responsibility and/or the responsibility of your health insurance carrier.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

The risks of exposure to high magnetic fields are unknown for fetuses. Therefore, if you are a female who is capable of becoming pregnant, and you have any reason to believe that you might be pregnant, you should not participate in this study.

Will I know about any new information about the effects of MRIs on human health? Notification of Significant New Findings

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you. If you come to the Ambulatory Research Center (ARC) for a visit, your parking will be reimbursed up to $15.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☒ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☒ My HIV/AIDS testing records _____ (initial)

☒ My genetic testing records _____ (initial)

☒ My mental health diagnosis/treatment records ____ (initial)

☒ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data and specimens when this study is over?

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who

you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results with you. With our questionnaires, we may identify symptoms that meet the criteria for mental health diagnoses. These diagnoses will be for research purposes only. We will not provide treatment or information about these diagnoses However, if you wish to receive a brief summary assessment you are welcome to request so from the research team via an email to Dr. Karina Quevedo. We will send you, via the listed email, a summary of (i.e. one paragraph) findings.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous. If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury

let the study physicians know right away. Given that the neurofeedback and other procedures involved entail minimal risks there is no available compensation for research-related injuries.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you up to $485 for your time and effort. If you do not complete the study, you will be paid for the visits you complete.

- Visit 1: $60 + $15 for parking if the visit is in-person
- Visit 2: $90
- Visit 3: $90
- Visit 4: $100 + $15 for parking if the visit is in-person
- Visit 5: $100 + $15 for parking if the visit is in-person

Your will also receive $10 for a snack at Visits 2 and 3 in cash or as part of the payment. If you cannot complete the entire protocol (e.g., problems with the computer task at the time of the scan, excessive movement that make the scanning unusable), you will be invited for an additional visit and paid an additional $40.

Payment may be made in cash or check or using a pre-paid debit card called Greenphire ClinCard.

The Greenphire ClinCard works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit. You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees. The debit card system is administered by an outside company. The company, Greenphire, will be given your name and social security number. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equal or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	While I am enrolled in the research, the research team can send me letters or written communications at my current place of residence.
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Dr. Quevedo or collaborating researchers.
_____	_____	The researcher may use my pictures in future studies where participants could see my face among many others for 2 seconds.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent