Date: November 01, 2017
Principal Investigator: Marco Grados, MD
Application No.: IRB00097094

If you are using EPIC for this study, fax a copy of the signed consent form to 410-367-7382

PARENT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Breathing Retraining for Panic and Anxiety Disorder in Teens**

Application No.: **IRB00097094**

Sponsor: **Pediatric Anxiety Research internal fund**

Principal Investigator: **Marco Grados, MD, MPH**
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1. What you should know about this study:

- You are being asked to allow your child to join a research study. This consent form explains the research study and your child's part in the study. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- Joining this study is voluntary. If you allow your child to join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide not to allow your child to continue the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to allow your child to participate.
- If we think your child's participation in this study may affect your child's clinical care, information about your child's study participation will be included in your child's medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your child's doctors. When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- 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.

- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research is being done to measure the effectiveness of the Freespira Breathing System (FBS) for children and adolescents who have an anxiety disorder.

The FBS is a portable, at-home device that has been cleared by the U.S. Food and Drug Administration (FDA) for use in adults with panic disorders. The device trains users to adjust their breathing to control and normalize their breathing patterns. The objective of this study is to see if FBS decreases anxiety in children and adolescents.

Children between the ages of 9-17 years old, with an anxiety disorder may join the study.

How many people will be in this study?

Up to 60 children and adolescents and their parents will be recruited to participate in the study.

3. What will happen if you allow your child to join this study?

If you agree to allow your child to be in this study, we will ask you and your child to complete the following things:

The role of the parent in this study will be to fill out the required questionnaires, bring their child to the study visits and to monitor their child's compliance in using the Freespira Breathing System.

During this study if a study team member suspects abuse, neglect or abandonment of a child they will report it to the proper authorities.

a) Screening Visit (Week 0):

You and your child will be asked to take part in a screening visit where the study will be explained to you and your child. At this visit, you will be asked to provide your child's current medication list and confirm it has not changed in the last month.

If at any time during the study, your child is found to be depressed or exhibit severe suicidality or ideation, he/she will be referred to the study doctor, who will evaluate your child and make the appropriate treatment referral.

As part of the study, your child will be randomly (by chance, like a flip of a coin) assigned into either the Active Intervention Group or the Active Control Waitlist Group. In this visit, we will discuss the use of FBS. The FBS will be used by your child twice a day, once in the morning for 17 minutes and once in the evening for 17 minutes. During this screening visit, we will help you and your child come up with a plan to help your child use the FBS on a regular schedule.

b) Baseline Visit (Week 1)

Active Intervention Group

During a second visit, a personal interview will take place with your child, which will last about 2 hours. This visit will either take place in participant's home visit (at study doctors discretion) or will take place at the research study office. The questions will primarily address your child's anxiety and past history.

You will also be asked to complete paper-and-pencil questionnaires about your child.

We will ask about any changes to your child's medication since the last study visit. We will also ask how many therapy sessions your child has attended since they last study visit.

You and your child will receive training on how to use the FBS.

- There will be sounds emitted from the device to help your child with his/her breathing pace.
- This device will also measure breathing rates and carbon dioxide, a gas that you breath out normally..
- The device will come with a hand-held Tablet computer with the Freespira Application. The App provides easy-to-follow audio and visual instructions that guide your child through prescribed breathing sessions.
- You will then be asked to assist your child in breathing exercises for 17 minutes, twice a day, for 4 weeks.
- The FBS is loaned to you while your child is participating in the study. We will ask you to sign an Equipment Loaner Form. This form is an agreement for you to have the device as loaned, and keeping returning the Equipment will result in a charge of $500 after the study is over.

Daily panic attack diaries: Your child will be given a daily panic attack diary to track frequency, symptoms and severity of any panic attacks they may experience over the four weeks of breathing retraining. You may help your child complete the diary as needed.

Active Control Waitlist Group

You will be contacted by phone or online (SKYPE), whichever is more convenient, to fill out baseline assessments (clinical interview and pen and paper questionnaires). The waitlist participants will complete the same baseline assessments as the active intervention group. Waitlist participants will also be given daily panic attack diaries diary to track frequency, symptoms and severity of any panic attacks they may experience. You may help your child complete the diary as needed.

c) <u>Scheduled visits (Weeks 2, 3, 4 and 8):</u>

Active Intervention Group

During each study visit we will ask about any changes to your child's medication since the last study visit. We will also ask how many therapy sessions your child has attended since they last study visit.

At weeks 2 and 3, we will have a check-in with you and your child by phone or online (SKYPE), whichever is more convenient.

At weeks 4 and 8, you and your child will either have an in-home visit (at study doctors discretion) or return for a study visit with the study doctor. The interview portion can also be done by phone within a window of one week. During these visits, we will review the results of the breathing sessions, and go over any questions or concerns you or your child may have. Your child may do a four-minute breathing session at both office visits. The panic diary will be reviewed during these sessions. The device will be returned at the Week 4 visit.

During the week 8 visit you and your child will either have an in-home visit (at study doctors discretion) or come back to receive a final assessment that includes the clinical interview and paper-and-pencil questionnaires. The interview portion can also be done by phone within a window of one week. Your child will complete a four-minute breathing session with the CO2 sensor to record your child's final breathing rate. This visit will last about 45 minutes

Active Control Waitlist Group
During Weeks 2, 3, 4 and 8 the Waitlist Group be contacted for check-ins by phone or online (SKYPE), whichever is more convenient, to complete the same questionnaires as the Active Intervention Group. During weeks 4 and 8 the Waitlist Group will complete the same questioners as the Active Intervention Control Group. The panic diary will be reviewed.

Following the Week 8 visit, you and your child will follow the schedule of visits and procedures described above for the Active Intervention Group.

d) <u>Long- Term Follow-up</u>

You will also be asked to have a check-in over the phone or online (SKYPE) at six (6) and have a office or in-home visit at twelve (12) months after the study has been completed for a follow-up evaluation. This evaluation includes a clinical interview and pen-and-paper questionnaires.

Future Studies

We would like your permission to contact you about other studies that you or your child may be eligible for in the future Please check the appropriate box and sign below.

☐ Yes, I would like to be contacted for future studies

_____ _____
Signature of Parent Date

☐ No, I would not like to be contacted for future studies

_____ _____
Signature of Parent Date

4. What are the risks or discomforts of the study?

<u>Freespira Breathing System (FBS)</u>

users of the device from adult clinics. We have also conducted a small study with children and adolescents which has provided us information on side effects.

Possible side effects are: headaches, light-headedness or dizziness may occur in the first several breathing retraining sessions. These side effects typically improve during later sessions.

Questions/questionnaires:
Sometimes people find it hard to talk about their lives. If you find it too upsetting, you and your child may end the interview at any time. You and your child may refuse to answer any question you are asked.

Confidentiality:
We will keep what you tell us confidential. This means that what you or anyone else tells us will not be told to others. However, there is the risk that information about you may become known to people outside this study.

Your name and your child's name and the information that you provide will be kept completely confidential and will not be released to anyone other than for the scientific purposes of the project. These documents will be archived. They will be labeled by your subject number only, that is, it will not be labeled using your name. The linkage of your name with your child's subject number can only be accessed by members of the research team who can access the central records room for the study.

If you would like the information released to your doctor, you may sign a release form allowing us to do so.

5. Are there benefits to your child from being in the study?

There may or may not be a direct benefit to your child from being in this

study. If your child takes part in this study, your child may help others in the

future.

6. What are your options if you do not want your child to be in the study?

You do not have to allow your child to join this study. If your child does not take part in the study, your child's care at Johns Hopkins will not be affected.

If you decide not to allow your child to join this study, other options are available. You do not have to allow your child to join this study to get treatment. Treatments for anxiety disorder include cognitive behavioral therapy or medication but your child cannot start these treatments while he/she is enrolled in this trial.

7. Will it cost you anything to allow your child to be in this study?

No.

In the event of a lost/misplaced device, you will be responsible for $500 payment to the sponsor. This payment will not be requested in the event of a damaged device, and is only a small portion of

8. Will you or your child be paid if you allow your child to join this study?

Your child will be given $30 for the Consent visit, Week 4 visit, and Week 8 visit. Your parking cost will also be covered for all visits.

You may be required to provide your child's social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

9. Can your child leave the study early?

- You can agree to allow your child to be in the study now and change your mind later.
- If you wish to end your child's participation, please tell us right away.
- Leaving this study early will not stop your child from getting regular medical care.
- If your child leaves the study early, Johns Hopkins may use or give out your child's health information that it already has, if the information is needed for this study or any follow-up activities.

10. Why might we take your child out of the study early?

Your child may be taken out of the study if:

- Staying in the study would be harmful.
- Your child needs treatment not allowed in the study.
- You or your child fails to follow instructions.
- The study is cancelled.
- If they fail to complete the required breathing exercises for over 50% of the allotted time, as efficacy would not be able to be assessed.
- If during the study, participants are found to be depressed or exhibit suicidal ideation while completing surveys, they will be referred to the P.I. Dr. Marco Grados, a board-certified child and adolescent psychiatrist, who will evaluate them and make the appropriate treatment referral. Treatment failure will be assessed at the 4-week post-treatment interval (8 weeks from study initiation).
- If participant is unable to complete Week 4, Week 8, and 12 Month visits within visit windows they will be contacted by study PI, and if the issue is not able to be resolved they will receive a research study withdrawal letter in the mail explaining why they are being withdrawn from the research study.
- There may be other reasons to take your child out of the study that we do not know at this time.
- If your child is taken out of the study early, Johns Hopkins may use or give out your child's health information that it already has if the information is needed for this study or any follow-up activities.

11. How will your child's privacy be protected?

We have rules to protect information about your child. Federal and state laws and the federal medical Privacy Rule also protect your child's privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

ollect information about your child. This includes

things learned from the procedures described in this consent form. They may also collect other information including your child's name, address, date of birth, and information from your child's medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your child's identity and that your child is in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your child's information. We make this information available to your child's doctors for your child's safety.

People outside of Johns Hopkins may need to see or receive your child's information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your child's information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your child's information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your child's information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your child's information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your child's information has no time limit. You may revoke (cancel) your permission to use and disclose your child's information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your child's information, your child's part in this study will end and no further information about your child will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. What treatment costs will be paid if your child is injured in this study?

Johns Hopkins does not have a program to pay you if your child is hurt or has other bad results from being in the study. However, medical care at Johns Hopkins is open to your child as it is to all sick or injured people.

The costs for any treatment or hospital care your child receives as a result of a study-related injury that is not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

13. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you? The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- People from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your child's rights as a participant or if you think you or your child have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?
Call the principal investigator, Dr. Marco Grados at 443-287-2291. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if your child is injured or ill as a result of being in this study?
If you think your child is injured or ill because of this study, call **Dr. Marco Grados** at **443-2872291**
during regular office hours.

d. What happens to Data that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you allow your child to join this study, you should understand that you/your child will not own your child's data, and should researchers use them to create a new product or idea, you/your child will not benefit financially.

14. Assent Statement

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

15. What does your signature on this consent form mean? Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to allow your child to join the study

You and your child will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Parent (Print Name) Date/Time

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

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time **For CHILD PARTICIPANT**

Description of LAR's authority under Maryland Law to act as surrogate health care decision-maker for child research participant (for example, Legal Guardian, court-ordered representative) Date/Time

Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

Signature of Witness to Consent Procedures (Print Name) Date/Time (optional unless IRB or Sponsor required)

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS