CONSENT TO BE A PARTICIPANT IN A RESEARCH STUDY

[Parental permission and assent for participants under 18]

PROJECT: EASE UP: Therapies for Emotion Dysregulation in Autistic Teens and Young Adults

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SOURCE OF SUPPORT: Patient Centered Outcomes Research Institute (PCORI)

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WHO IS DOING THIS RESEARCH?

This research study is a collaboration between researchers at the University of Pittsburgh and The University of Alabama.

WHAT IS THIS STUDY ABOUT?

You and your child are being asked to take part in a research study. It is your choice to join this research study. The researchers will explain the study to both of you. They will answer any questions either of you might have. You are encouraged to take your time to make your decision.

We are doing this study to compare two therapies, the Emotion Awareness and Skills Enhancement (EASE) Program and the Unified Protocol (UP). This research study will measure potential changes in your child's ability to manage their emotions. EASE and the UP are therapies that help people learn how to manage emotions. Both therapies have research to show that they are helpful. EASE uses mindfulness to help people manage their emotions and was designed for autistic people. The UP helps people manage their emotions by focusing on changing their thoughts. The UP was developed for many mental health challenges and was not designed specifically for autism. The goal of this project is to find out which one is more helpful for autistic people.

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WHAT WILL HAPPEN IF I DECIDE TO BE IN THE RESEARCH STUDY?

If you both choose to take part in this study, the child will do several things:

16 to 20 weeks of therapy: Your child will be assigned to either EASE or the UP therapy based on the agency where your services are provided. The sessions will be held at one of our community partner agencies. Your child will complete approximately 16 weekly therapy sessions. The therapy should be completed within 20 weeks. The therapy programs will total 16 to 20 hours of therapy sessions.

The therapy sessions can be in person or remote, via telehealth conferencing software. We do strongly encourage in-person therapy sessions because we believe it is more effective. Your child will meet with their provider from the agency for their scheduled sessions. It will be your child's choice to involve you in their therapy sessions. These are not parent training or family therapy programs. You may be asked to join some or all of your child's sessions, but it is their choice.

- **EASE:** In the EASE program, your child will learn about ways to manage emotions In EASE, clients practice mindfulness meditations to help manage emotions. Mindfulness meditations are brief practices (2-15min) where participants focus on their breathing, body sensations, thoughts, and emotions. You may be asked to attend some of the sessions. You will be given summaries of the sessions as well, so you can support your child throughout the therapy.

- **UP:** In the UP program, your child will learn strategies to manage emotions, such as reducing use of avoidance. Like EASE, the UP is delivered primarily one on one (your child and their provider), but you may be asked to attend some sessions.

Surveys and Interviews: Your child and you will complete surveys and interviews if you join the study. The surveys and interviews can be completed virtually or in person. Your child will be interviewed by someone on our team before they start therapy and after the end of therapy. This interview will take about 1 hour. We will record the interview for later coding; please see below.

You both will be asked to complete surveys online on a secure website. The survey questions will be about your child's feelings, behavior, and quality of life. You both will be able to take breaks if you cannot complete them all at once.

You will complete these surveys four times:

- Before your child begins EASE or the UP therapy
- Half-way through the therapy

- After the therapy ends
- Three months after completion

Most of the surveys will take between 30 and 90 minutes. The length of time will differ between people. We think that it will be about 2 to 6 hours of surveys total over the entire study.

WHAT ARE THE STUDY RISKS?

The risks for being in this research study are minimal.

- You both could spend your time and feel that you did not benefit from the therapy
  - It is our hope that both of these therapies will help your child better manage their emotions.
- It is possible that you both may become upset when asked to talk about thoughts, feelings, and actions related to problems with managing emotions.
  - You both can choose not to answer any questions or discuss any topics that make you uncomfortable.
  - You can stop the research study at any time.
- All providers in this study are trained in the EASE and UP therapies. The providers working on this project have experience working with individuals and families. It is possible that there could be a breach of confidentiality. This means someone could see your surveys or interviews who is not permitted.
  - We take steps to protect your privacy and confidentiality, like using private ID numbers instead of names on anything saved from the study.

WHAT ARE THE BENEFITS FROM DOING THIS STUDY?

Both therapies (EASE and the UP) were developed to help people handle their emotions better. It is possible that your child will feel better from completing the therapy.

Results of this study may help us know if one therapy is better for autistic people who struggle with their emotions. We will share what we learn with other mental health professions, which could improve therapies and services for autistic people.

HOW WILL OUR INFORMATION BE KEPT PRIVATE?

We will keep files with our recordings and notes on a computer that is **secure**. Secure means the files are stored where only our study team can access them, and only our study team will know the passwords to open the files.

We will not have your name written anywhere on the file. We will use a random number. So instead of having a file, for example, that is called “John Smith Interview,” it might be called “#101 Interview.” Only people working on this research study will have access to you and your child’s name information. This will include the Principal Investigator, research personnel, consultants, students affiliated with the project, or

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trained research assistants.

Your files during this study will remain private. Your files will only be shared with your permission or as required by U.S. or State law. This may happen if we are legally required to share because of concerns of abuse of a child or if your child is having thoughts of self-harm or intent to harm others. If this happens, this information will be reported to local child and youth services or to emergency health and safety providers.

Designated people from The University of Alabama Research Conduct and Compliance Office, the University of Pittsburgh Office of Research Protections, and/or PCORI may access and review your data.

Therapy sessions, surveys, and interviews will be video/audio recorded for data analysis and provider training. The recordings are done solely for research purposes and are not for clinical use. We will not give you a copy of or access to the recordings of your sessions.

We will also keep notes that your provider writes about the session. These tapes and notes will only be seen by the research team at the University of Pittsburgh and The University of Alabama. Someone could listen to the session or see the notes who has not been given permission. This is possible any time files are stored on computers. Here is what we will do to try to prevent that from happening:

- Video and audio recordings of sessions and the interviews will be kept on a computer that is secure. Secure means that the files are stored where only our study team can access them. Only our study team will know the password to open the file.
- All secure files will be stored at The University of Alabama and shared with the University of Pittsburgh. The team will password protect the files and share them across secure servers.
- We will not have your name written anywhere on the file that we save. We will use a random number that is saved in a different place from the surveys. The primary investigators in charge of this study will limit who can see that file.

Research records will be maintained for at least 7 years following final reporting or publication of a project.

WILL IT COST US ANYTHING TO DO THIS STUDY?

There is no cost for completing the surveys in this study. You must pay for the therapy at the community agency. You will know the costs in advance. There is no financial cost for joining this study to complete surveys and interviews.

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You will spend a lot of time in therapy sessions during this study. You will also spend time traveling to therapy and completing surveys.

WILL WE BE PAID FOR PARTICIPATION?

Only your child will be paid for this study. Please let us know before the first payment if you and your child decide the payments should be issued to you (caregiver) instead. The payment is a token of appreciation for the time to complete the surveys. They will be paid with a gift card after each time they complete the surveys. There are four times that you will be asked to complete the surveys. Your child may receive a maximum of $170. The payments are given after the surveys are done on time. We cannot pay for surveys that are completed too late.

- First time: $50 for surveys and interviews
- Second time: $20 for surveys
- Third time: $50 for surveys and interviews
- Fourth time: $50 for surveys

All payments in this study are taxable income regardless of the amount. The universities are required by law to file a Form 1099 – Miscellaneous with the IRS if you receive $600 or more in a calendar year. You will then receive a 1099. You can still join the study if you don't provide a social security number. But, the IRS requires that 24% of the payment be sent by the university to the IRS for 'backup withholding' and you will then only receive 76% of each payment.

IS THERE ANOTHER OPTION TO RECEIVE THERAPY?

You can talk to other mental health professionals about other options for therapy. You do not need to join this study to have counseling services. This will not prevent you from receiving any counseling services from either university or any affiliated providers. It will not prevent you from joining other studies with the University of Pittsburgh, UPMC, or The University of Alabama.

WHAT IF WE WANT TO STOP?

It is your choice to be in the study. You can change your mind about being in this study at any time. You can stop being in this study at any time. Stopping this study will not impact your relationship with anyone at the University of Pittsburgh or The University of Alabama. You can also tell us to stop using your information. If you tell us to do that, we will also take you out of the study. We will still use any information about you that we already collected. You will not be paid for the surveys you do not complete.

You will need to talk to your provider if you choose to stop the research study and want to keep seeing your provider for therapy. It is possible that stopping the study may change the cost you have to pay for sessions if you are receiving financial assistance from your provider. It is important to talk to your provider about this if it is your choice.

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It is possible that we could ask your child to stop the study. This would happen if:

- We feel that it is unsafe for your child to stay in the study.
- Your child is at risk of hurting him or herself or someone else.
- Your child misses 3 or more weeks in a row of your counseling sessions.
- Your child "no shows" for 3 or more counseling sessions. That means you don't tell your provider that you are missing the session.
- Your child is not completing their surveys.

WHAT ARE YOU DOING WITH THE RESULTS?

The findings from this research study may be used for scientific or educational purposes. Results will be shared at scientific meetings and/or published in professional journals or books. The University of Pittsburgh Department of Psychiatry or The University of Alabama Department of Psychology could also use the results for education, knowledge, or research. A summary of this research study will be shared on http://www.clinicaltrials.gov, as required by US Law. Results from this study will be shared online once the study is over. This website will not include your name or any other information that can identify you. The website will just include a summary of the results. You can search this website at any time. Data sharing can help speed up research. PCORI, who is funding this project, requires that we share our data with other researchers upon request. We are also required to submit it to a PCORI-designated data sharing repository. This data will be shared without information that could identify you. All researchers and their institutions who request your de-identified data must promise to keep your data safe and will not try to learn your identity.

WHAT ARE MY CHOICES?

1. Think about it. (Take more time. Talk to friends, family, providers, etc.)
2. Learn more. (Ask and talk about more questions)
3. Yes, I want to join the study
4. No, I do not want to join the study

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VOLUNTARY CONSENT

It is your choice to be in this study. You may want to discuss it with your family, friends, or your doctor before you decide. If there is information on this form that doesn't make sense, please ask us to explain. Always contact the study team if you have questions at any time.

Your care from UPMC will stay the same, whether you decide to be in the study or not. Your decision will have no effect on care you receive from a UPMC facility, provider, or health insurance plan.

This study is separate from any benefit you receive from the University of Pittsburgh or UPMC. Benefits are things like education, health insurance, or other services. Any decision you make about being in this study will not change any of those benefits.

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I have read the details of the research study. I have asked all the questions that I have. The research team has answered them. I acknowledge that I am the legal guardian of the person whose name appears below. I understand that as a minor, they are not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for their participation in this research study. I also give my consent for the use of information about myself that I provide to be included in the study. I understand that if we join the study that we can stop the study at any time without consequences.

If you have questions about your rights as a participant in a research study or would like to make suggestions or file complaints and concerns about the research study, please contact:

The University of Alabama Office for Research Compliance (205) 348-8461 or toll-free at 1-877-820-3066. You may also ask questions, make suggestions, or file complaints and concerns through the IRB Outreach Website at https://research.ua.edu/compliance/irb/. You may email the Office for Research Compliance at rscompliance@ua.edu.

_____
Printed Name of Participant

_____
Printed Name of Support Person

_____ _____
Signature of Support Person Date

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VOLUNTARY ASSENT

I have asked all the questions I have. The research team has answered them. I understand I can stop the study at any time and no one will be upset. I can change my mind later and that is okay as well. By signing this form, I give my consent for the use of my information that my caregiver and I provide to be included in the study.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

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REQUIRED FOR PARTICIPATION IN PROJECT: PERMISSION TO RECORD AUDIO & VIDEO

Therapy sessions, surveys, and interviews will be video/audio recorded for data analysis and provider training. The recordings are done solely for research purposes and are not for clinical use. We will not give you a copy of or access to the recordings of your sessions. These tapes will only be seen by the research team at the University of Pittsburgh and The University of Alabama. We will not have your name written anywhere on the file that we save. We will use a random number. **Do you agree to be audio and video recorded for this purpose? If yes, check the box and initial in the space provided.**

☐ Yes _____

☐ No

**** "YES" MUST BE CHECKED IN ORDER TO PROCEED ****

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CERTIFICATION OF INFORMED CONSENT

I certify that I explained the nature and purpose of this research study to the above-named individual(s). I discussed the potential benefits and risks of study participation. All questions about this study are answered. We will be available to address future questions as they arise. I certify that no research component of this protocol was done until after this consent form was signed.

_____	_____
Name of Person Obtaining Consent	Role in Study
_____	_____
Signature of Person Obtaining Consent	Date

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