Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Radical Openness for Adolescents: Targeting the transdiagnostic mechanism of performance monitoring and overcontrol in adolescence, Adaptation and feasibility

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Research Team Contact: Alex Puricelli 314-747-6148

If you are the parent/guardian providing parental permission the word "you" refers to your child.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Dr. Kirsten Gilbert having to do with investigating brain differences in adolescents and young adults who differ on a characteristic of overcontrol. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to spend 2-2.5 hours in our lab on 2 separate days spaced 4 months apart. You would also have the opportunity to participate in weekly Radically Open Dialectical Behavior Therapy (RO DBT) therapy sessions (including 1-hour individual sessions and 1.5-hour skills classes) for 16 weeks. You will need to come to our lab at 4444 Forest Park Avenue in St. Louis for the lab sessions. Therapy sessions occur either in therapy offices in the St. Louis region or virtually at home (depending on safety procedures during the COVID-19 pandemic). During the lab sessions, you will have an electroencephalogram (EEG) where we will put a cap on your head and small dots of non-toxic gel in your hair which washes out with water. You will play three computer games while wearing the cap, as well as one more once the cap has been removed. We will also ask you to fill out some surveys in the EEDP office about how you usually feel, think and act. During the therapy sessions, you will receive RO DBT therapy. RO DBT helps individuals who are controlled relax rigid self-control, be receptive and open to new experiences and feedback, and increase social connectedness by helping activate the social-safety system. The main risks to you if you participate are the potential for mild boredom, fatigue, or discomfort during EEG sessions and the potential for RO DBT therapy sessions to be emotionally taxing.

You may benefit from volunteering because RO DBT therapy may help lessen psychiatric symptoms and increase adaptive functioning. By volunteering, you may help someone else in the future. There is no cost to you and you will be paid $65 per EEG session for being a volunteer participant. All of this

information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

The rest of this document provides more details about the study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are a female between the ages of 13 and 21 and because you have expressed interest in helping researchers learn more about emotions and thinking styles. The purpose of this research study is to investigate brain differences in adolescents and young adults who differ on a characteristic of overcontrol, and to provide a novel free psychosocial therapy trial of Radically Open Dialectical Behavior Therapy (RO DBT). The main goal of the study is to look at how adolescents and young adults differ on this characteristic of overcontrol and how they experience moods and thoughts and how this characteristic may lead to brain differences in responses to mistakes, reward and loss. The other main goal of this study is to test feasibility of RO DBT in adolescents. The information collected from this study may help provide valuable resources on how to identify and understand overcontrol in teens and help create more personalized mental health treatments. The information from this study may also help provide new psychosocial therapies for adolescents with mental illness.

WHAT WILL HAPPEN DURING THIS STUDY?

If you are eligible based on your phone conversation and the online questionnaire, you will come to the Early Emotional Development Program (DDP) at Washington University School of Medicine to participate in the in-person laboratory assessment.

Baseline assessment: You will have an electroencephalogram (EEG) where we will put a cap on your head and small dots of non-toxic gel in your hair which washes out with water. You will play three computer games while wearing the cap. The first will involve determining the direction arrows are pointing and the second will involve earning points by guessing doors. The third task will involve pretending that you just landed on a Hawaiian island with eleven other people. As you get to know more about the players, you will vote on each one as to whether you would like them to stay on the island with you. Each one of them will also vote whether they want to be on the island with you. The EEG portion of the task will take approximately 2 hours to complete. One additional task you will complete on the computer (although we will not monitor EEG signals during this task) is a temporal discounting task. During this task you will choose on the computer screen whether you would prefer to receive one amount of money now versus a larger amount of money later all as part of a hypothetical game as you will not receive any money. This task takes about 5 minutes to complete. After we remove the cap and you complete the EEG portion, we will collect your height and weight and then you will fill out some surveys in the EEDP office about how you usually feel, think and act. Filling out the surveys should take about 20 minutes and will generate protected health information (PHI) about your mental and physical health. The PHI generated from these questionnaires will be stored on Washington University's secure data collection website (REDCap) and will only be accessible by the research team. You are free to skip any questions you do not want to answer. The entire assessment should take approximately 2.5 hours.

Therapy portion: Interested individuals (up to eight total) will then have the opportunity to participate in approximately 16 weeks of free psychotherapy. This psychotherapy is called Radically Open Dialectical Behavior Therapy (RO DBT). RO DBT is a type of therapy that has shown to work with individuals who show behaviors of overcontrol, such as perfectionism, anxious apprehension, inflexibility and concern with making mistakes. RO DBT helps individuals who are controlled relax rigid self-control, be receptive and open to new experiences and feedback, and increase social connectedness by helping activate the social-safety system. RO DBT has been tested and shown to be effective with adults who are depressed and show symptoms of anorexia. Newer work also demonstrates preliminary support in adolescents. You have the opportunity to participate in RO DBT, which includes weekly 1-hour individual sessions and weekly 1.5-hour skills classes. These sessions will take place at therapy offices in the St. Louis region by therapists who have been highly trained in using RO DBT. You will work with the clinicians to schedule a therapy time that works for both of your schedules. Clinicians will keep notes, which will generate PHI (Protected Health Information), from your sessions in a locked file cabinet in a locked office and your name will not be linked with these notes, only your assigned ID number. Additionally, therapists will collect your height and weight at each session. Participating in RO DBT therapy will be at no cost to you.

Follow-up assessment: Four months after the baseline session, for those who participated in the therapy portion and the therapy is complete, you will return to the EEDP at Washington University School of Medicine to participate in a second in-person laboratory assessment. Additionally, eight interested individuals who do not complete the therapy portion will also have the opportunity to return to the EEDP at Washington University School of Medicine for a second in-person laboratory assessment. You will have another EEG where we will put a cap on your head and small dots of non-toxic gel in your hair whish washes out with water. You will again play the same three computer games while wearing the cap and this portion of the task will take approximately 2 hours. You will also complete the same temporal discounting computer game that will take approximately 5 minutes. After we take the cap off, we will collect your height and weight and then you will complete surveys about how you usually feel, think and act. Filling out the surveys should take about 20 minutes and will generate PHI about your mental and physical health. The PHI generated from these questionnaires will be stored on Washington University's secure data collection website (REDCap) and will only be accessible by the research team. You are free to skip any questions you do not want to answer. The entire assessment should take approximately 2.5 hours.

You will not receive the results that we obtain from our research. Nothing in regard to your participation will appear in your medical records.

Will you save my research information to use in future research studies?

As part of this study, we are obtaining data from you. We would like to use this data for studies going on right now as well as studies that are conducted in the future. However, it is unlikely that what we learn from these studies will have a direct benefit to you. There is no plan to provide financial compensation to you for use of your data. Identifiers may be removed from your private information and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

We will share your data with other researchers. They may be doing research in areas similar to this

research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or commercial sponsors of research. We may also share your data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

Your data will be stored without your name or any other kind of link that would enable us to identify what data is yours. Therefore, it will be available for use in future research studies indefinitely and cannot be removed.

Audio/Video Recording or Photographs

One aspect of this study involves making video recordings of you when you participate in the free RO DBT therapy portion of the study. The individual and skills class sessions will be video recorded so they can be supervised by the principal investigator and clinicians on this research study to ensure adherent therapy. These videos will also be viewed during meetings by Dr. Thomas Lynch, the developer of RO DBT, so that he can advise clinicians and ensure treatment fidelity. Additionally, a photograph of you will be taken for use in the Island Getaway computer task. Only the principal investigator, study clinicians and study staff have access to these videos and photographs. Videos will be destroyed immediately following your completion in the study and the photograph will be deleted at the end of the task.

While all video recordings are stored in a confidential manner, please be aware that the recording will likely contain information that would identify you.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 60 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for up to four months. All participants will come in for a baseline assessment at the EEDP, during which you will complete an EEG and fill out questionnaires. This assessment will take approximately 2.5 hours. You then will complete approximately 16 weeks of RO DBT therapy, involving weekly 1 hour individual therapy and 1.5 hour skills class. Then, you will return to the EEDP for a second follow-up assessment where you will complete an EEG and fill out questionnaires. This assessment will take approximately 2.5 hours.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

There are certain risks associated with this research, which include the potential for mild boredom or fatigue. For instance, you may experience mild boredom or fatigue while completing the questionnaires done as a part of this study. Scheduling your EEG appointment may require that you adjust your plans (work/school schedules or other activities). As a result, you may experience a loss of time and wages. If you experience any discomfort during the EEG, you will be allowed to stop at any time. We foresee these risks as minimal. During the temporal discounting task, participants could experience some mild disappointment because they are not awarded actual money.

We put a non-toxic, water-soluble gel in your hair to help the electrodes record brain waves. We wash the gel out with water afterwards, but some people do not like having gel in their hair. We also use five stickers to attach electrodes to your forehead, temples, and cheeks, and removing these stickers can feel like taking off a very small bandage. You may notice some red spots on your face afterwards, but these will soon go away.

Participating in RO DBT therapy may be emotionally taxing, as therapy requires emotional effort and you could discuss topics in therapy that make you feel uncomfortable. Additionally, attending each weekly RO DBT therapy sessions and skills classes could result in a loss of time or wages. However, we see the potential risks of participating in RO DBT therapy as minimal.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *'How will you keep my information confidential?'* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study. The RO DBT therapy may benefit you by helping lessen psychiatric symptoms and increasing adaptive functioning. You will not benefit from being in the experimental portion of the study. However, we hope that, in the future, other people might benefit from this study because we will have more knowledge of the underlying factors that contribute to overcontrol and the development of psychiatric illness and may be able to design more person-centered psychosocial treatments.

WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. You may choose not to take part in this research study or may withdraw your consent at any time. You can seek RO DBT treatment from clinicians in the community. You can also seek other forms of treatment in the community. A list of clinicians in the St. Louis region that provide RO DBT and other forms of psychological treatments can be provided to you.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will have costs for being in this research study. You will need to drive or commute to the baseline and follow-up assessments sessions at Washington University School of Medicine. For RO DBT therapy, you will need to drive or commute to weekly individual and skills class therapy sessions. Parking is free at all sessions.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

For the initial session at the Washington University School of Medicine, you will be paid up to $65. If you participate in the follow-up session four months later, you will again be paid up to $65, for a total of up to $130.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that Washington University is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The National Institutes of Health
- Hospital or University representatives to complete University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will remove identifying information from all data. We will assign you a study ID and store all data using this ID. We will keep the master list linking the code number and your identity separate from the research data. Only the PI, clinicians and people helping her will be able to see the list. This list will be kept on a password-protected computer at Washington University School of Medicine.

- For paper/hard copy records:
  - Paper/hard copy records will be stored in locked filing cabinets at the Early Emotional

Development Program, Washington University School of Medicine (WUSM) or in locked filing cabinets in clinician offices. All data collected from study procedures will be coded using an ID number, and will not include identifying information. Each participant will have a folder stored in a locked filing cabinet that contains identifying information, but not any study data or the participant's ID#. This folder will contain, for example, consent forms and contact information for the participant. Only approved research personnel will have access to the filing cabinets.

- For electronic records:
  - Most electronic records will be created and stored using REDCap, WUSM's secure data management system. REDCap will be used to collect and store data from study procedures, which will be identified via ID#. A separate REDCap database will be used to store identifying information, including (but not necessarily limited to) names, phone numbers, addresses, social security numbers, and dates of birth. Only approved research personnel will have access to the REDCap projects.
  - Electronic records not created and stored via REDCap, will be stored on secure WUSTL Box servers on password protected computers. Such files will be coded with an ID number. Only approved research personnel will have access to the server shares and password protected computers.

All of the data you provide as part of this study are confidential. We are obligated by law, however, to disclose information to the proper authorities, which may include your parents, if there is a risk of serious harm to yourself or others, for example, if you have current thoughts of suicide or a suicidal plan or if there is knowledge of ongoing abuse or neglect of a minor.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will

you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study. If you decide to leave the study early, we will ask you to attend a close out visit with your clinician if you are part of the therapy portion of the study. The close out visit with the clinician will involve closing out your treatment and ensuring you have referrals and a plan for future other treatment, if applicable. If you are not involved in the therapy portion of the study, you do not need to come to a close out visit.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because we do not think you can complete the EEG procedures, because in our judgement it would not be safe for you to continue, or because funding for the study has ended. This might also happen if because in our judgement, it would not be safe for you to continue with the RO DBT therapy and you need a higher level of clinical care if your symptoms, condition or impairment worsens.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Alex Puricelli at 314-747-6148. If you feel that you have been harmed in any way by your participation in this study, please contact Kirsten Gilbert at 314-747-0001.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 12/14/22.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Parent/Guardian Name and Relationship to Participant:

Do not sign this form if today's date is after EXPIRATION DATE: 12/14/22.

_____
(Child's name – printed)

_____ _____
(Signature of Parent/Guardian) (Date)

_____ _____
(Name of Parent/Guardian- printed) (Relationship to participant – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)