Parental Consent & Permission Document

You and your child are being asked to be in a research study. Before you decide whether to allow your child to participate, it is important that you understand why the research is being done and what it will involve. Following this summary, you will be given more detailed information.

- Participation in this research is voluntary. You do not have to allow your child to be in this study.
- This study is being conducted by researchers at the University of Utah.
- The purpose of the study is to examine how the timing of tics is related to tic characteristics, suppression abilities, and treatment response. Research shows that tics follow a specific pattern over time that relates to increases and decreases in severity throughout the lifetime, including within days, weeks, months, and years. However, more research needs to be done to see why tics follow patterns over time, and how these patterns relate to tic severity. The reason that you and your child are being asked to be in the study is because we would like to know how the timing of your child's tics relates to how well your child can suppress their tics and how much their tics improve after tic treatment.
- We are recruiting 12 parent-child dyads to participate in the study.
- If you agree to allow your child to participate in the study, you and your child will be asked to attend six study visits. All study visits will take place online via secure videoconference. The first study visit will last about 2 hours. The second, third, fourth, and fifth study visits will last between 45 minutes and 1 hour. The last study visit will last about 1 hour.
- During the first study visit, you and your child will be asked to meet with someone from the study team over videoconference. They will ask you and your child questions about your child's tics and other behaviors and symptoms. Your child's tics will then be observed for 10 minutes. Lastly, your child's tics will be observed during a 30-minute tic activity, where they will be instructed at different times to tic freely and suppress their tics.
- During the second, third, fourth, and fifth study visit, your child will participate in Habit Reversal Training (HRT), the first-line behavioral intervention for tics. These visits will focus on one of your child's tics at a time. During these meetings, you and your child will learn behavioral techniques for managing tics and reducing tic severity.
- During the sixth study visit, you and your child will meet with researchers for approximately one hour. Your child's tics will be observed during a 30-minute tic activity, where they will be instructed at different times to tic freely and suppress their tics. You and your child will then answer questions about your child's tics and other symptoms.
- There are some minimal risks to you and your child being in the study. You or your child may feel embarrassed, sad, frustrated, or uncomfortable because of the

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questions we will ask. In addition, your child may have a short-term increase in tics during the tic treatment portion of the research study, but we do not expect this to be more than what they experience on a day-to-day basis or last beyond the study period. There is also a risk of loss of confidentiality since we will be collecting information that can identify your child. These risks will be explained in detail later in this document.

- Being in this study may benefit your child's tics, but we will not know until you and your child have completed your participation in this study. Potential benefits to others will be explained later in this document.
- You can choose not to participate in this study, and you can withdraw from the study at any time for any reason without penalty or loss of benefits to which you are otherwise entitled. Your decision of whether or not to participate will not affect your current or future relations with the University of Utah.

Please take the time to read the following information carefully and discuss it with friends, relatives, and healthcare professionals, if you wish. Ask the research staff if there is anything that is not clear, or if you would like more information. Take time to decide whether or not to allow your child to be in this study.

BACKGROUND AND PURPOSE OF THE STUDY

Tic disorders (including provisional tic disorder, persistent motor/vocal tic disorder, and Tourette disorder) are a class of neurodevelopmental disorders characterized by sudden, rapid, recurrent, involuntary movements and sounds (i.e., motor and vocal tics). Tic disorders affect about 1-3% of school-aged children and wax and wane in appearance and frequency over time. Some, but not all, individuals with tics are able to suppress their tics and have specific bodily sensations that occur alongside or prior to their tics. Research suggests that behavioral treatment for tics is effective, particularly the behavioral treatment for tics with the most empirical support, Habit Reversal Training (HRT), though not all individuals or tics improve with treatment. More research is necessary to understand why certain tics have different characteristics and respond differently to treatment than others. Some recent research suggests that tics follow a specific pattern over time that relates to tic severity, though there is no research on whether tic timing patterns also relate to other characteristics of tics and how they respond to behavioral intervention. The purpose of this study is to see whether the timing of individual tics relates to different tic characteristics, like how long that tic has been going on for and how easy it is to suppress, as well as treatment response.

We are asking your child to be in this research study because they are between 8 and 12 years of age, have tics, and have not yet received 2+ sessions of a behavioral treatment for tics. We are interested in recruiting 12 parent-child dyads. You and your child will not meet any of the other children in the study.

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STUDY PROCEDURES

If you agree to allow your child to be in this study, you and your child will be asked to attend six virtual study visits, held online via secure videoconference. What will happen at each of these study visits is described below. A research staff member will contact you before each visit to remind you of the scheduled visit and to provide specific instructions for the visit. We will try to schedule the visits for times that are convenient for you and your child. All study procedures, including all study visits, will be video recorded.

Study Visit #1: During the first study visit, we will ask you and your child to meet via secure videoconferencing to complete questionnaires and answer questions about your child's background, family and medical history, and tics, feelings, moods, and behaviors. Then, your child's tics will be directly observed for 10 minutes to ensure that they meet criteria for the study. Then, your child's tics will be observed during a 30-minute tic activity, where they will be given specific instruction to tic freely or suppress their tics during different intervals. In total, this study visit should take about 2 hours.

Study Visits #2-5: Study visits two, three, four, and five will all take place via secure videoconference and follow the same general procedures. These study visits will occur approximately one week apart from one another. During study visits two, three, four, and five, your child will first be asked questions about their tics and other behaviors during the past week. Then, your child's resting tic rate will be observed through a 10-minute direct tic observation. Then, researchers will engage in Habit Reversal Training (HRT) with your child, where they will participate in activities to increase their awareness of their tics and bodily sensations, engage in behaviors that interrupt their tics, and practice using their these therapeutic techniques in different situations. Study visits two, three, four, and five will last approximately 45 minutes to 1 hour.

Study Visit #6: During the sixth study visit, you and your child will meet with a researcher via secure videoconference approximately one week following the fifth study visit. You and your child will be asked about your child's tics and behaviors throughout the past week. Then, your child's tics will be observed throughout a 30-minute tic activity, where they will be asked to follow specific instructions at different times, including to tic freely or suppress their tics.

RISKS

There may be some minimal risk from being in this study that you should be aware of. One risk is that you and your child will be asked to answer personal questions about your child's tics and behaviors. Your child may feel upset thinking or talking about personal information related to tics and other emotions and behavior. These risks are similar to those experienced when talking about personal information with others. The researchers will do their best to ask all questions in a sensitive and supportive manner and will try to help your child feel better if they become upset.

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In addition, you and your child do not have to answer any questions that you do not want to answer.

Your child may have a short-term increase in tics during the tic therapy portion of the research study, but this increase is not expected to be outside of the range of what they experience on a day-to-day basis and is not expected to extend beyond the study visit.

There is also a risk of loss of confidentiality since we will be collecting identifying information as a part of this study, including a video recording in which you or your child could be identified. Additional steps we will take to protect your confidentiality are described in the "Confidentiality" section below.

BENEFITS

Your child may directly benefit from receiving behavioral intervention for their tics throughout their participation in this study. However, we cannot guarantee this benefit, and we will not know whether they have benefited from receiving tic treatment until after your participation in this study is complete. Additionally, you and your child's participation in this study may help researchers learn more about tic disorders and potentially improve treatment for tics.

CONFIDENTIALITY

The records of this study will be kept private to the extent permitted by law, and we will do everything we can to keep participation in this study private and confidential. If results from this study are published, they will not contain your or your child's name or any additional identifying information. Your child's study record, may, however, be reviewed by the University of Utah Institutional Review Board.

In addition, if you or your child discloses actual or suspected abuse, neglect, or exploitation of a child or disabled elderly adult, the researchers and/or any member of the study staff must, and will, report this to Child and Family Services or the nearest law enforcement agency. There are also some cases in which a researcher is obligated to report issues, such as serious and/or credible threats to public health or safety. For example, if you or your child indicates that you, your child, or someone else is at imminent risk of harm (for example, suicide or serious threats toward the wellbeing of others) we will need to contact the appropriate authorities in order to protect you, your child, or the public. Doing so might require us to provide identifiable information about you or your child.

Study related records about your child will be kept in locked filing cabinets, in offices that only the research staff has access to. Study records will be kept in a secure manner, and electronic records will be password protected and stored in a secure cloud storage system. Only people

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working on the study will have access to your child's research information. To help ensure that your child's information remains private and confidential, they will be given a study identification number (for example, UT001). The only link between your child's information and their study number will be stored in a separate, secure location. All of the identifiable information that we collect in this study, including consent forms and other identifiable information will be kept for 5 years after the study is done. It will then be destroyed by shredding the hard-copy (paper copy) materials and erasing electronic copies of materials. Your information will not be kept for future research.

All parts of the study will be videotaped for study purposes. Trained and authorized study personnel will have access to video recordings. These recordings will include a view of you and your child's faces, study-related information, and possible personally identifying information (for example, your child's first name). Video recordings of you and your child will be permanently deleted when the study is done. If you or your child do not want to be videorecorded, that is okay, but you and your child will not be able to be in the study.

PERSON TO CONTACT

Investigator Contact Information

If you have questions, complaints, or concerns about this study, you can contact Kirsten Bootes at 801-585-7115 or by email at kirsten.bootes@psych.utah.edu.

If you feel your child has been harmed as a result of participation, please call Dr. Michael Himle directly or via confidential voicemail at 801-581-7529 or via email at michael.himle@utah.edu. Dr. Himle can be reached between 8:00 a.m. and 5:00 p.m., Monday-Thursday.

Institutional Review Board

Contact the Institutional Review Board (IRB) if you have questions regarding your child's rights as a research participant or have complaints or concerns which you do not feel you can discuss with study personnel. The University of Utah IRB may be reached by phone at 801-581-3655 or by email at irb@hsc.utah.edu.

Research Participant Advocate

You may also contact the Research Participant Advocate (RPA) by phone at 801-581-3803 or by email at participant.advocate@hsc.utah.edu

VOLUNTARY PARTICIPATION

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Your participation is completely voluntary. You may choose not to participate, or you may discontinue your participation or withdraw your child at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your current or future relations with the University of Utah.

If you decide to leave the study early, we ask that you call Kirsten. We may ask you to meet for a final time for a close-out visit. Whether or not you choose to meet for the close-out visit is voluntary.

You will be informed by the research investigators of this study of any significant new findings that develop during the study that might influence your willingness to continue to participate in the study.

We do not anticipate that your child will have any adverse reactions to the study procedures. However, if any adverse reactions do occur, your child will be removed from the study and referred for appropriate care. The researchers will help you to find an appropriate referral.

RIGHT OF INVESTIGATOR TO WITHDRAW

The investigator can withdraw your child from the study without your approval. Possible reasons for withdraw include: missed or cancelled study visits, inability of your child to comply with study protocol, or unexpected adverse events.

COSTS AND COMPENSATION TO PARTICIPANTS

There are no costs or compensation to you for being in this study.

PARTICIPATION IN FUTURE STUDIES

There may be additional studies in which you or your child would be eligible to participate. Please indicate if you would like to be contacted about future studies by initialing the appropriate line below:

_____ _____ Please DO contact me or my child about future studies for which I might be eligible.
(Initial) (Date)

_____ _____ Please DO NOT contact me or my child about future studies.
(Initial) (Date)

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CONSENT

I confirm that I have read this parental permission document and have had the opportunity to ask questions. I understand that taking part in this study is voluntary. I will be given a signed copy of the parental permission form to keep. **I agree to allow my child to participate in this research study and I agree to participate in this research.**

_____
Child Name

_____
Parent/Guardian Name

_____ _____
Parent/Guardian Signature Date

_____
Relationship to Child for Parent/Guardian

_____
Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

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