Principal Investigator: Dr. Joseph M. Lambert **Revision Date: 04/26/2022**
Study Title: Translational Research to Inform Interventions for Severe Challenging Behavior for Individuals with Intellectual and Developmental Disabilities
Institution/Hospital: Vanderbilt University

Name of Participant: _____ DOB: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
The purpose of the study is to help us better understand the value of rewards. Specifically, we will study how rewards support behavior. We will also study whether changes in the value of a reward will change how much behavior it can support.

If you chose to participate, we will ask you to do simple tasks during short appointments that can range from 10- to 60 min. If you don't want to work during these appointments, you can stop working and just talk to us. We'll still pay you for your time, even if you just talk to us. We hope to meet with you for between 12 and 40 appointments.

There are not many risks associated with this study. However, you may get bored if you do not like the activities we do. In that case, you can just stop doing the boring work and just talk to us.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to be in this study because you are an adult, have a disability, and expressed an interest in participating. You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Procedures to be followed and approximate duration of the study:
If you chose to participate, we will measure the number of times that you work to earn rewards. The work we give you will be simple such as flipping a switch or snapping a button. You will earn things like food, or music that you like, for working. If you agree to be in this study, you would work for as little as 10 or 15 minutes per appointment, and never more than an hour. We would expect to visit you for about 12 appointments, and not more than 40 appointments. There could be up to three appointments per day, for up to 5 days a week. The study could

be as short as 2 weeks, or as long as 2 or 3 months, depending on when you can work. Some of the appointments will be video recorded.

Expected costs:

There will be no cost to you.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

1) You may get bored if you do not like the activities we do.
2) We will do things to protect your identity like locking your data in a room. We will also give your data a pretend name. It is possible that somebody else that is not involved in this study will know that you were in this study.

Good effects that might result from this study:

a) The benefits to science and humankind that <u>might</u> result from this study.

This study will extend the research on value and reinforcement. The findings may benefit others in a different setting to decrease problem behavior.

b) The benefits you might get from being in this study.

You may not get any benefits from being in this study.

Study Results:

At the end of this study, we will show you your results and will explain what they mean. If you want to know which group you were randomized to, you can ask and we will tell you after the entire study has been completed.

Compensation for participation:

If you agree to be in this study, you would earn a $25 gift card for every 3.5 hours you spend with us.

Circumstances under which the Principal Investigator may withdraw you from study participation:

1) If you miss 2 or more appointments.
2) If the researcher decides it is best to not have you be in the study anymore.

What happens if you choose to withdraw from study participation?

Being in this study is your choice. You do not have to participate in the sessions. You can drop out of the study at any time. You will be paid for the time you spend in the study.

Contact Information.

If you have any questions at all, please feel free to contact **Bailey Copeland** at bailey.a.copeland@vanderbilt.edu. You can also contact the Principal Investigator**, Dr. Joseph Lambert** at joseph.m.lambert@vanderbilt.edu.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review

Board Office at (615) 322-2918 or toll free at (866) 224-8273. If you live in Utah, you can also contact Shauna Ayres from the Utah Department of Human Services at sayres@utah.gov.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. The following measures will be taken to decrease the possibility of breaches in confidentiality.

1) We will be very careful to keep your participation a secret. Only the investigators and research participants will know that you are in it.
2) We will destroy all documents which identify you as a participant by December 31, 2024.
3) We will keep all of your data in a locked room.
4) Your real name will not be put on any of our research documents. These documents can be kept after the study ends.
5) The videos recorded during sessions will be saved on a secure computer.
6) We will delete all videos after we are done using them.

In the event of any breach in confidentiality such as theft, the research team would be required to contact you and Vanderbilt's Institutional Review Board, and the Tennessee Privacy Office.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Your information may be shared with Vanderbilt or the government. This means Vanderbilt University Institutional Review Board or Federal Government Office for Human Research Protections will have your information if you or someone else is in danger or if we are required to do so by law.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date	Signature of volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title

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I, _____ [name of surrogate],
am the _____ [state relationship to participant]
of _____ [state participant's name]. I have read the informed consent document. It has been explained to me. I was able to ask any questions and all of my questions were answered. I know that an investigational treatment may be given to _____ [participant's name]. I believe that participation in this study is in the best interests of _____ [participant's name]. This is what he/she would say he/she wanted to do if he/she was able to do so.

Your choice to have _____ [state participant's name] participate in this study is voluntary. You may choose not to allow him/her to participate. You are also free to have him/her leave the study at any time. If new information arises that may affect the risks or benefits of this research study, you will be told so that you can make a decision whether or not to continue your family member/friend's participation in this study.

_____ [state participant's name] will be formally be asked to assent at the beginning of this study (see assent document) At the beginning of each appointment, we will informally ask for assent and will document _____ [state participant's name]'s response in our records. Continued participation in this study would only occur with continued assent.

_____ ___/___/___
Signature of Surrogate Date

_____ ___/___/___
Signature of Witness Date

_____ ___/___/___
Name and Signature of person obtaining consent Date