

Working Toward Wellness Parent Consent Form for Physiological Data Collection

A little over a year ago, you spoke with someone from United Behavioral Health about a project called Working Toward Wellness. The purpose of the study is to learn how to help people who might be feeling depressed. At the time you enrolled in the study, you may have become eligible for extra services, or you may have been told about services available to you in your community. We also mentioned that we may be contacting you for future interviews.

Learning about responses to stress

In addition to asking you some questions, we are also interested in learning from you and your child(ren) how daily experiences affect how stressed you feel. One way for us to learn about this is to ask you questions, but another way is to measure a stress hormone your body produces called cortisol. Cortisol is released into your body when you experience stress, and it also is produced at other times of the day as well. Cortisol can be measured in your saliva or spit.

In order to learn more about this, we would like to collect your saliva and saliva from your child(ren) using a simple procedure of spitting through a vial that we will demonstrate with you. The purpose of collecting your saliva is *only* to measure the levels of cortisol in your body. We will not be measuring anything else in these saliva samples. The time spent on the saliva collection should only take about 5 minutes per person.

Unique and different ID numbers will be created for each of your samples and this data will be kept in a location separate from your identifying information. All samples will be destroyed as soon as the data is collected and checked for errors. The samples will only be used for this study and related research. By related research, we mean research that might address such questions as the relation between cortisol levels and levels of depression across time, or how levels of cortisol are related to other aspects of your behavior and well-being.

Learning about genes and the environment

In addition to measuring your level of cortisol, we are also interested in understanding more about the link between your genes, the inherited characteristics that distinguish one person from another, and depression. Some people think that there may be some relationship between genes and depression. While we know that what a person is born with does *not* determine whether or not he/she will get depressed, sometimes genetic characteristics can make some people more or less likely to experience depression than others. This kind of information can be really important to learning more about depression. For this reason, we'd like to collect a sample of your genetic material, or DNA, from you. The procedure is very simple: we would only need you to spit into a small container to collect this information from you.

We would *only* look at things in your DNA that are related to family risk for depression and nothing else. We would not be measuring anything drug-related in the samples. The time spent on the DNA collection should only take about 5 minutes per person. And, as with the cortisol samples collected, each DNA sample will be marked with a unique identification number that will be kept separate from your identifying information. These samples will be destroyed as soon as the data is collected and checked for errors. The samples will only be used for this study and related research. By related research, we

mean that we might be interested in how your genes affect how you respond to differences in your environment.

Because we are also interested in how what children are born with may affect how they are doing, we are also interested in collecting this same genetic information from your child(ren). As with your sample, we would *only* look at things in your child's DNA that are related to family risk for depression and nothing else. Like your samples, these DNA samples will be labeled with a unique identification, stored separate from any identifying information. All samples will be destroyed as soon as the data is collected and checked for errors. The samples will only be used for this study and related research.

Collecting additional samples

Finally, we are interested in seeing what the levels of cortisol are over the course of two full days. Understanding how cortisol levels vary over the course of the day can tell us even more about how people experience stress. For this portion, we will leave you with a home kit for collecting saliva samples to conduct yourself and for your child(ren) (if applicable). We will also ask you to complete one brief daily diary asking you questions about your and your child(ren)'s day, for each day that you collect these follow-up saliva samples. You will be asked to mail the samples and the diaries to us and once we receive them, we will send your family a \$20 gift card for the samples collected from you and a \$10 gift card for the samples collected from each of your child(ren) (if applicable).

Summary of data collection

In summary, we are seeking your permission to collect the following information:

- two saliva samples that we would collect from you (and each child) now, one to assess cortisol level, and one to assess several genetic biomarkers
- three saliva samples collected on two follow-up days for a total of 6 additional saliva samples for each of you and your child(ren's), to assess cortisol levels. These samples we will ask you to mail back to us.
- one daily diary on each of two follow-up days, for a total of 2 diaries for each of you and your child(ren). These diaries you will mail to us with the 6 samples.

Risks of participation

There are no known risks to collecting these samples. To avoid the risk of choking, we will only do the saliva collection with child(ren) over the age of two. We use an extra long cotton roll (approximately 3 inches in length) so that it will not get caught in the child's mouth. The child will also be seated during the saliva collection and we will supervise the first procedure carefully. You will always be present during the saliva collection of your young child(ren) (if applicable).

Participation is voluntary

The results of this study can help us understand better how to help people who might be depressed, along with their families and their child(ren). However, it is important that you understand that participation in this study is completely voluntary for you and your child(ren). You can choose to participate in the saliva collection, the DNA collection, or both. The same applies for the consent you provide for your child(ren). You and your child(ren) may also stop the data collection at any time without penalty. Your decision will not affect any services or benefits you might receive now or in the future.

Protecting your information

All the information you and your child(ren) provide will be kept confidential. All study staff are trained to protect privacy and sign a privacy pledge. Your answers will be recorded with an identification number and your names will be kept in a location separate from your answers. No reports will describe you in a way that would allow you to be identified either.

We will do everything we can to keep others from learning about your participation in the research. We have a Confidentiality Certificate from the U.S. government that adds special protection for the research information that identifies you. It says we do not have to identify you, even under a court order or subpoena. You should know, however, that we may tell someone if harm to you, harm to others, or child abuse becomes a concern (this report would not be based on any information that comes out of any of your saliva samples). Also, the federal agency that pays for this study may see your information in an audit, but it too will protect your privacy. This Certificate does not mean the government approves or disapproves of our project.

If you have questions at any time during the study, please call Francisca Azocar or Kathy Sweet at United Behavior Health toll-free at (800) 207-0084. You can also call David Butler or Pamela Morris at MDRC using the toll-free number (800) 221-3165.

Consent for Myself

By my signature, I agree to have the following data collection occur:

Saliva collection to measure stress:

CHECK ONE: YES NO

Saliva collection of DNA to understand family risk for depression:

CHECK ONE: YES NO

Additionally, I agree to have my saliva samples be used in future related research studies as long as my identifying (i.e. name, address, etc) information is not linked to my saliva samples:

CHECK ONE: YES NO

(SIGNATURE)

(INTERVIEWER'S SIGNATURE)

(DATE)

Consent for Children

By my signature, I agree to allow the following child(ren) to participate in the following data collection procedures. A copy of the study description given to my child(ren) will be provided to me.

_____ Saliva collection to measure stress:
 (CHILD'S NAME) CHECK ONE: YES NO

Saliva collection of DNA to understand family risk for depression:
 CHECK ONE: YES NO

_____ Saliva collection to measure stress:
 (CHILD'S NAME) CHECK ONE: YES NO

Saliva collection of DNA to understand family risk for depression:
 CHECK ONE: YES NO

Additionally, I agree to have my children's saliva samples be used in future related research studies as long as their identifying (i.e. name, address, etc) information is not linked to their saliva samples:

CHECK ONE: YES NO

 (SIGNATURE OF PRIMARY CAREGIVER)

 (INTERVIEWER'S SIGNATURE)

 (DATE)