RUTGERS
School of Arts and Sciences

Department of Psychology
Psychology Building, Room 113
Rutgers, The State University of New Jersey
152 Frelinghuysen Road
Piscataway, NJ 08854-8019

ebtorres@psych.rutgers.edu
p. 732-208-3158

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: A pilot project to validate digital biomarkers as a tool to measure improvement in core symptoms of autism during sulforaphane treatment.
Principal Investigator: Elizabeth Torres, PhD.

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research is to**: determine if changes seen during sulforaphane treatment (a compound that comes from eating certain vegetables) can better be understood using digital biomarkers. These digital biomarkers are things like heart rate, muscle movement etc. and are measured using non-invasive devices (like a watch and like a Band-aid).

If you take part in the research, you will be asked to undergo 5 visits over 16 weeks. All study subjects will take the study medicine for this timeframe. At each visit the study doctor will evaluate you. The study Coordinator will assist your parent/legal guardian in filling out the standard tests (used in the previous study) and digital biomarker data will be measured using non-invasive wearable devices (like a watch and like a Band-aid).

Your time in the study will take: Following this informed consent visit, we anticipate the initial visit to teach you how to use the devices will be less than an hour. The Baseline and follow up visits will take 1.5 and a half hours. including time with study doctor and assessment by standard tools (~ 30 minutes) and digital biomarker assessment (~ 1 hour).

Possible harms or burdens of taking part in the study may be;
- Possible side effects of sulforaphane include flatulence (gas), weight gain, gastrointestinal disturbances (large bowel movement, soft stool), and increased urination. These effects are expected to be minor if they occur.
- Possible Loss of Confidentiality. As with all studies there is a small chance of loss of confidentiality.

The benefits of taking part in this study may be: that sulforaphane treatment influences social interaction, abnormal behavior, and verbal communication in male individuals with autistic disorder without serious side effects and if so may benefit the subject directly. However, it is possible that you might receive no direct personal benefit from taking part in this study.

A possible indirect benefit is that If digital biomarkers are shown to be able to measure improvement during sulforaphane treatment they may become a valuable tool in future studies and help us understand the nature of the underlying improvements observed.

An alternative to taking part in the research study Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you

choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Elizabeth Torres, PhD is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Elizabeth Torres, PhD may be reached at 732-208-3158.
Her mailing address is:
Rutgers, The State University of New Jersey
Department of Psychology
Psychology Building, Room 113
152 Frelinghuysen Road
Piscataway, NJ 08854-8019

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

SPONSOR OF THE STUDY: Busch Biomedical Grant Program.

Why is this study being done? To determine if changes seen during sulforaphane treatment (a compound that comes from eating certain vegetables) can better be understood using digital biomarkers. These digital biomarkers are things like heart rate, muscle movement etc. and are measured using non-invasive devices (like a watch and like a Band-aid). It may also help us to understand differences in response to this compound.

Who may take part in this study?
You may take part in this study if:

- If you have autistic disorder
- You are male.
- You are between the ages of 13 – 30 years old.

Why have I been asked to take part in this study?
You have been asked to join this study because you have completed our double-blind study (where neither the study subject or the investigators know who is taking medicine and who is taking placebo) with sulforaphane, meet the criteria for this study and you expressed interest in being part of future studies.

How long will the study take and how many subjects will take part?
This study is for 10 subjects. Each will take the study medicine for 12 weeks. We anticipate this project will be completed by July 2023.

What will I be asked to do if I take part in this study?
Those that decide to enter the study will be interviewed by the study doctor, Dr. Traeger and as in our pervious trial, fill out the Aberrant Behavior Checklist (ABC), Social Responsiveness Scale (SRS). Last, we will measure “digital biomarkers” using wearable devices (like a watch and like a Band-aid). These digital biomarkers measure unnoticeable or hard to notice movements in your body.

All subjects in this study will receive the study medicine and as before, the number of pills depends on body weight. The capsule may be swallowed whole or crushed and mixed with food.

Following this informed consent process, each subject will undergo 5 visits over 16 weeks. The initial visit to teach you how to use the devices will be less than an hour. We anticipate the Baseline and follow up visits will take 1.5 hours .For each visit the study doctor will do a screening and ask questions to see if there are any adverse effects; we will fill out the ABC and SRS and perform the digital biomarker measures where you will be asked to do things like walking, pointing and reaching for things to see if sulforaphane treatment changes these digital biomarkers.

What are the risks of harm or discomforts I might experience if I take part in this study?
You should not take any over-the-counter medicines, herbal products, vitamins or food supplements while taking part in this study, unless you tell the study doctor and get permission from the study doctor to go on taking these medicines. You will follow the instructions of the study doctor about the use of any of these products.

You should also tell the study doctor about all medicines that other doctors may have prescribed for you to take.

Risk of the supplement: One risk to subjects is the potential side effects of the study medicine. The study medicine comes from eating cruciferous vegetables (like broccoli). The form used in this study is called Avmacol® and is commercially available, well tolerated and has not been shown to cause damage in other studies or by people that purchase and take as a dietary supplement at similar doses. Side effects of sulforaphane can include flatulence (gas), weight gain, gastrointestinal disturbances (large bowel movement, soft stool), and increased urination. These effects are expected to be minor if they occur.

Loss of Confidentiality: As with all studies there is a small chance of loss of confidentiality.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be: that sulforaphane treatment influences social interaction, abnormal behavior, and verbal communication in male individuals with autistic disorder without serious side effects and if so may benefit the subject directly. However, it is possible that you might receive no direct personal benefit from taking part in this study.

A possible indirect benefit is that If digital biomarkers are shown to be able to measure improvement during sulforaphane treatment they may become a valuable tool in future studies and help us understand the nature of the underlying improvements observed.

What are my alternatives if I do not want to take part in this study?
There are no alternative treatments available. Your alternative is not to take part in this study or to purchase Avmacol®.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
The results of this study will be published in an appropriate scientific journal. At the end of the study. We do not anticipate sharing other results.

Will there be any cost to me to take Part in this study?
There will be no costs to you to take part in this study.

Will I be paid to take part in this study?
You will not be paid to take part in this study.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

Those that wish to enter the study will be given a participant number (described below) which will be used on all study related documents during the study.

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

All data including screening data, assessment of core symptoms of autism and test results will be securely sent to or brought to the study coordinator. Data will be stored in both electronic files and hard copy source documents. The source documents will be coded and will be stored in locked file cabinets in a locked room. Any electronic data will be stored on password protected computers on a secure network within the University and not accessible by outside individuals. Data analysis and reporting will be done with the NDAR GUID as the only identifier, names etc. will not be used.

The NDAR GUID helps to ensure that this information can be sent and stored securely, protecting your privacy and the confidentiality of the data. Using the NDAR GUID allows data collected on an individual from one study or site to be associated with the data from another study or site without the risk of exposing your identity. The identifying information used to generate the ID is encrypted. Only data from those that indicate on the consent form that their data may be sent to NDAR will be uploaded to NDAR.

Clinicaltrials.gov:
A description of this clinical trial is available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

National Database for Autism Research (NDAR):
Data from this study may be submitted to the National Database for Autism Research (NDAR). NDAR is a computer system run by the National Institutes of Health that allows researchers studying autism to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about autism more quickly than before.

During and after the study, the researchers will send information about your health and behavior to NDAR. However, before they send it to NDAR, they will remove information such as name, address, and phone number, and replace that information with a code number. Other researchers nationwide can then file an application with the National Institutes of Health to obtain access to your study data for research purposes. Experts at the National Institutes of Health who know how to protect health and science information will look at every request carefully to minimize risks to you and your privacy.

You may not benefit directly from allowing your information to be shared with NDAR. The information provided to NDAR might help researchers around the world treat future children and adults with autism spectrum disorders so that they have better outcomes. NDAR will report to Congress and on its website about the different studies that researchers are conducting using NDAR data; however, NDAR will not be able to contact you individually about specific studies.

You may decide now or later that you do not want to share your information using NDAR. If so, contact Elizabeth Torres, the researcher who is conducting this study, and he will tell NDAR and stop sharing the research information. However, NDAR cannot take back information that was shared before you changed your mind. If you would like more information about NDAR, this is available on-line at http://ndar.nih.gov.

Do you give permission to send your data to NDAR (check one)?
Yes_____ No_____ Initials:_____

Will I be informed about future research projects?
If you wish to be informed about future research projects, you must give permission.

Do you give permission to be contacted about future research?
Yes_____ No_____ Initials:_____

What will happen to my information or biospecimens collected for this research after the study is over?
The information collected about you for this research will not be used by or distributed to investigators for other research except for the de-identified data shared with NDAR.

What will happen if I am injured during this study?
Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include: flatulence (gas), weight gain, gastrointestinal disturbances (large bowel movement, soft stool), and increased urination. In addition, it is possible that during the course of this study, new adverse effects of Avmacol® that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether you take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, their relationship with the study staff will not change, and he may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your permission for the use of data already collected about you, but you must do this in writing to:
Elizabeth Torres, PhD
Her mailing address is:

Rutgers, The State University of New Jersey
Department of Psychology
Psychology Building, Room 113
152 Frelinghuysen Road
Piscataway, NJ 08854-8019

However, NDAR cannot take back information that was shared before you changed your mind. If you would like more information about NDAR, this is available on-line at http://ndar.nih.gov.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I contact if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can call Elizabeth Torres
Department of Psychology
732-208-3158.

If you have questions about your rights as a research subject, you can contact the Rutgers IRB Director at: New Brunswick/Piscataway HealthSci IRB 335 George St., Liberty Plaza Ste. 3100, New Brunswick, NJ 08901, (732)235-9806 or the Rutgers Human Subjects Protection Program at (973) 972-1149, email us at humansubjects@ored.rutgers.edu., or write us at 65 Bergen St., Suite 507, Newark, NJ 07107..

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?
The following data may be used.

- Medical history or treatment.
- Psychological testing, surveys or questionnaires.

Who May Use, Share or Receive My Information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators involved in the Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision:
Elizabeth Torres, PhD
Her mailing address is:
Rutgers, The State University of New Jersey

Department of Psychology
Psychology Building, Room 113
152 Frelinghuysen Road
Piscataway, NJ 08854-8019

How Long Will My Permission Last?
"There is no set date when your permission will end. Your health information may be studied for many years."

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____