

Clinicians Survey

1. Information Sheet

Assessing Medication Responsiveness in Persons with Autism Spectrum Disorders (ASD)
[IRB#: 091045] The George Washington University
(Information about this study for prescribing doctors of patients with ASD)

You are asked to complete a survey on the medication responsiveness of one of your patients towards medication prescribed to treat symptoms of autism spectrum disorder. The participant (or parent/guardian) has reviewed an Authorization for the Use and Disclosure of Protected Health Information (PHI) and has given consent for the disclosure of their PHI for this research study. However, you may decide to have the participant (or parent/guardian) sign another release form that is consistent with your office's standard operating procedure. This study is under the direction of Dr. Valerie Hu of the Department of Biochemistry and Molecular Biology, The George Washington University Medical Center (GWUMC), and paid for by The George Washington University. Taking part in this research is entirely voluntary.

Introduction: Many different medications are prescribed to individuals with autism spectrum disorders (ASD) without explicit knowledge of the biological deficits associated with the symptoms in any given individual. Because many medications are prescribed based on "trial-and-error," some people don't experience any benefits at all while others experience a major improvement.

The study: Through participant/parent/guardian and clinician surveys, we are studying the effectiveness of various medications that are prescribed to improve the symptoms of ASD by analyzing the information provided on the surveys. We hope that the results of this study will be used to better design studies with subgroups of individuals with ASD based on their response to specific medications which will aid in identifying genes that associate with the effectiveness of a particular medication. The long-range goal of these studies is to identify genetic profiles that would help clinicians prescribe medications more accurately based on their patients' unique biology.

YOUR ROLE IN THIS STUDY AS THE PATIENT'S CLINICIAN

You are being asked to complete a brief survey about the medication(s) that you have prescribed to the patient with ASD and to provide information on the effectiveness of the prescribed medication(s) for that individual. You may complete the survey online at www.surveymonkey.com/GWautismstudy-clinician or print a hard copy (from the PDF attachment in the recruitment email sent to your patient) and mail the completed form back to us at the address given at the end of the survey. All personal information on the patient will be deleted once we are able to match the clinician's survey with the patient's survey and art task. We will be happy to compensate you for the postage.

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2. Information Sheet (cont.)

The total amount of time you will spend in connection with this study is estimated to be approximately 10-15 minutes. You may refuse to answer any of the questions and you may stop your participation in this study at any time.

Possible risks or discomforts you could experience during this study include possible loss of confidentiality although no information is being asked about you personally.

Note: The patients or their parents/guardians have agreed to have the protected health information of the patients released by their prescribing doctors by checking a consent box on the information sheet about the study for patients or parents/guardians prior to engaging in this study.

You will not benefit directly from your participation in this study. The benefits to science and humankind that might result from this study are:

- 1) The ability to design studies using distinct biological subtypes of individuals with ASD based upon medication responsiveness (which will aid in obtaining more specific genomic information pertinent to the ASD subtype)
- 2) The development of better predictors of positive response to a given medication (that is, better treatment options) based upon the pharmacogenomic profile of an individual with ASD.

Privacy of information: Every effort will be made to keep the personal information of the patient confidential; however, this cannot be guaranteed. If results of this research study are reported in journals or at scientific meetings, the people who participated in this study will not be named or identified. Your records for the study may be reviewed by representatives at The George Washington University (sponsor of this study) and by departments of The George Washington University responsible for overseeing research and compliance.

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3. Information Sheet (cont.)

Who to contact: The Office of Human Research of George Washington University, at telephone number (202) 994-2715, can provide further information about your rights as a research participant. Further information regarding this study may be obtained by contacting Study Coordinator at autismstudy@gwumc.edu or at telephone number (202) 994-5042.

*Please keep a copy of this document in case you want to read it again.

*** 1. By clicking on the “I agree” button below you authorize the Study Investigator and members of the research team to use and share with others (disclose) your patient’s PHI provided for the purpose of this study.**

I agree

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4. Patient Information

Survey: Assessing Medication Responsiveness in Persons with Autism Spectrum Disorders (ASD) [IRB#: 091045] (To be completed by clinician of patient with an ASD)

Information about this study: Through patient/parent/guardian and clinician surveys, we are studying the effectiveness of the various medications that are prescribed to improve the symptoms of ASD by analyzing the information provided on the surveys. The results of this study will be used to better design studies with subgroups of individuals with ASD based on their response to specific medications which will aid in identifying genetic variants or genes that associate with the effectiveness of a particular medication. The long-range goal of these studies is to identify pharmacogenomic profiles that would help in prescribing medications more accurately based on the patients' unique biological makeup. All patient information will be de-identified for this study.

* 1. Today's Date

Date: MM DD YYYY
 / /

2. Demographic information of patient

Name:

Date of Birth:

Diagnosis:

Comorbity(ies):

3. Gender

Male

Female

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5. Information about current medications

Please list each medication that your patient with ASD is currently taking, the symptom(s) you originally intended to target, and the overall benefit of each medication according to the following scores:

0 – none to uncertain benefit; 1 – mild to moderate benefit; 2 – clearly positive or substantial benefit

1. Medication (dose)

1.
2.
3.
4.
5.

2. Targeted symptoms

1.
2.
3.
4.
5.

3. Result (score)

1.
2.
3.
4.
5.

* 4. Do you have more medications to list?

Yes

No

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6. Additional Current Medications

Please list each medication that your patient with ASD is currently taking, the symptom(s) you originally intended to target, and the overall benefit of each medication according to the following scores:

0 – none to uncertain benefit; 1 – mild to moderate benefit; 2 – clearly positive or substantial benefit

If there are additional current medications, please list them on this sheet.

1. Medication (dose)

- 6.
- 7.
- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.

2. Targeted symptoms

- 6.
- 7.
- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.

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3. Result (score)

- 6.
- 7.
- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.

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7. Medication History

List any previously prescribed medication(s) that had a clear and substantial benefit, and the reason for discontinuation

1. Medication

1.
2.
3.

2. Reason for discontinuation

1.
2.
3.

8. Mailing Information

If you choose to mail in the completed survey, please use the address:

Autism Study, c/o Dr. Valerie Hu, Department of Biochemistry and Molecular Biology, The George Washington University Medical Center, 2300 Eye Street NW, Washington, D.C., 20037

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