

Patient or Parent-Guardian Survey

1. Information Sheet

Information about the Research Study entitled:

“Assessing Medication Responsiveness in Persons with Autism Spectrum Disorders (ASD)”
[IRB#: 091045] The George Washington University

You are invited to participate in a research study 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 knowing the biological causes of autism. Because many prescriptions are based upon “trial-and-error”, there are people who don’t experience any benefits at all while others experience a substantial improvement. Many parents of children with ASD have referred to this substantial and noticeable improvement as a “Wow!” effect.

The purpose of this study is to find out how persons with ASD respond to certain medications and whether or not these medications help make their symptoms better. We would also like to have your (or your child’s) treating doctor answer a survey on how s/he thinks you (or your child) is responding to these medications. There is no age-limit or age-range specified for subjects enrolled in this study.

Long-range goals: By doing this study, we hope to learn information that may help doctors better prescribe medications to their patients. It may also help us design future research studies.

YOUR ROLE IN THIS STUDY

If you choose to take part in this study, you will be asked to:

1) Complete a survey which asks for information about the medication(s) you (or your child) are taking and your personal opinion as to whether the medication is effective in reducing the symptoms for which the medication was prescribed; You may complete the survey online or print a hard copy (from the PDF attachment in the recruitment email) which may be completed and mailed directly to us at the address given at the end of the survey. We will be happy to compensate you for postage.

2) Request that your (or your child’s) treating doctor complete a brief survey about the medication(s) that you (or your child) are currently taking; You may forward the weblink (www.surveymonkey.com/GWautismstudy-clinician) containing the description of the study and survey to the doctor where s/he may complete the survey online. Alternatively, your doctor may print a hard copy (from the PDF attachment in the recruitment email) and, after filling it out, mail it directly to us at the address given in the survey. [We will ask your (or your child’s) doctor questions about how well the medication is working.]

3) Complete a simple drawing task. If you (or your child) elect to participate in this study, you will be provided with the necessary materials and instructions by mail. The drawings will provide us with information about your (or your child’s) strengths, abilities and current performance level.

The total amount of time you will spend in connection with this study is estimated to be 1 hr to fill out the questionnaire, 20 minutes to complete the drawing task, and the time it takes to request and to obtain a completed questionnaire from your (or your child’s) clinician. You may refuse to answer any of

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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, anxiety over answering questions related to medications or your feelings about their effectiveness, risk of eating non-toxic crayons, particularly for children. Therefore, we ask that minors be supervised by an adult during the coloring activity. Participating in this study poses no risks that are not ordinarily encountered in daily life.

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2. Confidentiality

PARTICIPANT COMPENSATION

A \$20 Gift card from Amazon.com will be sent to the participant upon completion of the participant's survey and receipt of the drawings. Compensation is not dependent on receipt of the clinician's survey.

The benefits to science and humankind that might result from this study are:

- 1) The ability to design studies using distinct groups of people with ASD based upon their response to medication (which will aid in obtaining more specific genomic information relevant to the ASD subtype);
- 2) The development of better medication based upon the genetic profile of a person with ASD.

Confidentiality: The information collected in the questionnaires will be "de-identified" once we have received all of your (or your child's) study material. That is, your (or your child's) name, address, respondent's name (if not the participant), and e-mail address will be removed from the information and the art task provided. Your records for the study may be reviewed by officials at The George Washington University (sponsor of this study) and by departments of the George Washington University responsible for overseeing research safety and compliance.

HOW IS YOUR PRIVACY PROTECTED?

Federal law requires that hospitals, researchers and other healthcare providers (like physicians and labs) protect the privacy of health information that identifies you. This kind of information is known as "protected health information" or "PHI." This section tells you your rights about your protected health information in the study. This section also lists who you let use, release, and get your protected health information. You are free to not allow these uses and releases by not signing this form. If you do that though, you cannot participate in the study.

Because of the need to release information, complete confidentiality cannot be promised. The results of this research study may be presented at meetings or in publications. If this is done, your identity will not be disclosed in those presentations.

Protected health information that may be used and released (disclosed) in this study includes information such as:

- Demographic information (e.g., date of birth, gender, geographic location). This information could be used to identify you.
- Information about your medical history (ASD diagnosis and associated disorders; current and past medications and your response to these medications)

You also allow the Study Investigator and her research team who are part of the study to release your health information to:

- GWU Institutional Review Board ("IRB") or its authorized representatives
- Accrediting agencies and legal counsel.

By signing this form, you allow the use, sharing, copying, and release of your protected health information to carry out the study by:

- your prescribing doctor(s) who is/are not part of the study

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- the Study Investigator and her research team.

This permission does not end unless you cancel it, even if you leave the study. You can cancel this permission any time except where the investigator and research team have already used or released your health information, or relied on your permission to do something. Even if you cancel this authorization, the researchers may still use and disclose protected health information they already have obtained about you as necessary to maintain the integrity or reliability of the research. However, no new PHI will be collected from you after you revoke your authorization.

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3. Implied Consent to Participate

To cancel your authorization, you will need to send a letter to: Dr. Valerie Hu, Dept. of Biochemistry and Molecular Biology, The George Washington University Medical Center, 2300 Eye St., NW; Washington, DC 20037, or send an e-mail to Study Coordinator at autismstudy@gwumc.edu

This Authorization does not have an expiration date.

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits.

Your protected health information will be treated confidentially to the extent permitted by applicable laws and regulations. Federal law may allow someone who gets your health information from this study to use or release it in some way not discussed in this section and no longer be protected by the HIPAA Privacy Rule.

Implied consent to participate: Your signature is not required in this document. Your willingness to participate in this research study is indicated by clicking on the "I agree" button online before taking the survey, or implied if you proceed with completing and submitting the paper survey.

If you prefer to complete a paper survey, you may request a survey together with the art materials by contacting Study Coordinator at autismstudy@gwumc.edu or by calling 202-994-5042 and leaving your name and complete address. We will then send you all the necessary materials together with a self-addressed stamped envelope for the return of the materials. We will also provide a separate self-addressed, stamped envelope for your doctor to return the clinician's survey.

We also ask for your consent to use the information collected in this study for any future studies relevant to medications used for ASD. You may choose not to participate in this study at any time before submitting the questionnaire.

Who to contact: The Office of Human Research of The 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 PHI for the purpose of this study. If you do not wish to authorize the use or disclosure of your PHI, you cannot participate in this study because your PHI is necessary to conduct this study.

I agree

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4. Patient Information

Subject or Parent/Guardian Survey
Assessing Medication Responsiveness in Persons with Autism Spectrum Disorder (ASD)
[IRB#: 091045]

1. Please enter today's date.

MM DD YYYY

Today's Date: / /

2. Name of individual (person) with autism:

First

Last

3. Home zipcode

ZIP:

4. Date of Birth

MM DD YYYY

D.O.B. / /

5. Gender

Male

Female

6. Race: Please check all that apply

- American Indian/Alaska Native
- Asian
- Black or African American
- Caucasian/White
- Native Hawaiian or other Pacific Islander

7. Ethnicity

Hispanic/Latino

Not Hispanic/Latino

8. Education of person with autism (current grade or highest level completed)

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5. Respondent Information

1. Relationship of person completing questionnaire to individual with autism

Self

Parent/Guardian

Other (please specify)

2. Respondent's name and email (if not the affected individual)

Name:

Email Address:

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6. Information about current medications

We are interested in the prescribed medications that have produced a range of results from no effect at all to a clear and substantial improvement (sometimes referred to as a "Wow! effect") in your (or your child's) symptoms or behaviors.

Please list each medication that you (or your child) are currently taking, and, if known, the symptom(s) for which it was prescribed. Indicate how long you have been taking the medication in days, weeks, months, or years (approx.)

1. Medication

1.
2.
3.
4.
5.

2. Approx. length of time

1.
2.
3.
4.
5.

3. Symptom(s) targeted

1.
2.
3.
4.
5.

For each medication, please give your opinion of its effect on the targeted symptoms by checking the appropriate number. 0 – No effect to Uncertain; 1 – Mildly to moderately helpful; 2 – Very helpful (substantial improvement - "Wow" effect)
(correspond numbers with medication name entered previously)

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4. Effectiveness

	0 - No effect/Uncertain	1 - Mildly to moderately helpful	2 - Very helpful
1.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5. If a medication has been ranked as “very helpful”, please check below if the significant improvement has been noticed or commented on by:

- Family members outside the home
- Friends
- Teachers
- Casual acquaintances
- Peers (other students, co-workers, etc.)

Other (please specify)

6. Are you (or your child) still taking the medication(s) that you indicated as being “very helpful”?

Yes

No

If not, why not?

Please list any non-prescription supplements or alternative therapies you (or your child) are currently taking as well as the symptoms or behaviors that these are hoped to address.

For each supplement or alternative therapy, please rate its effectiveness using the following scores: 0 – No effect or Uncertain; 1 – Mildly to moderately helpful; 2 – Very helpful (substantial improvement - “Wow” effect)

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7. Supplement or therapy

- 1.
- 2.
- 3.
- 4.

8. Targeted symptom or behavior

- 1.
- 2.
- 3.
- 4.

9. Effectiveness (score as 0, 1, or 2)

	0	1	2
1.	<input type="text"/>	<input type="text"/>	<input type="text"/>
2.	<input type="text"/>	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>	<input type="text"/>

10. Do you have more current medications or supplements/therapies to list?

Yes

No

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7. Current Medications (continued)

Below is additional space to continue listing current medications or supplements/therapies.

Please list each medication that you (or your child) are currently taking, and, if known, the symptom(s) for which it was prescribed. Indicate how long you have been taking the medication in days, weeks, months, or years (approx.)

1. Medication (cont.)

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

2. Approx. length of time

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

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3. Symptom(s) targeted

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

For each medication, please give your opinion of its effect on the targeted symptoms by checking the appropriate number. 0 – No effect to Uncertain; 1 – Mildly to moderately helpful; 2 – Very helpful (substantial improvement - “Wow” effect)
 (correspond numbers with medication name entered previously)

4. Effectiveness

	0 - No effect/Uncertain	1 - Mildly to moderately helpful	2 - Very helpful
6.	jñ	jñ	jñ
7.	jñ	jñ	jñ
8.	jñ	jñ	jñ
9.	jñ	jñ	jñ
10.	jñ	jñ	jñ
11.	jñ	jñ	jñ
12.	jñ	jñ	jñ
13.	jñ	jñ	jñ
14.	jñ	jñ	jñ
15.	jñ	jñ	jñ

Please list any non-prescription supplements or alternative therapies you (or your child) are currently taking as well as the symptoms or behaviors that these are hoped to address.

For each supplement or alternative therapy, please rate its effectiveness using the following scores: 0 – No effect or Uncertain; 1 – Mildly to moderately helpful; 2 – Very helpful (substantial improvement - “Wow” effect)

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5. Supplement or therapy

- 5.
- 6.
- 7.
- 8.
- 9.
- 10.

6. Targeted symptom or behavior

- 5.
- 6.
- 7.
- 8.
- 9.
- 10.

7. Effectiveness (score as 0, 1, or 2)

	0	1	2
5.	€	€	€
6.	€	€	€
7.	€	€	€
8.	€	€	€
9.	€	€	€
10.	€	€	€

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8. Medication history

Have you (or your child) ever taken any medication that has been very helpful in improving an ASD-associated symptom? If so, please list the medication(s), the improved symptom(s), the reason discontinued.

1. Medication

- 1.
- 2.
- 3.
- 4.

2. Improved symptom(s)

- 1.
- 2.
- 3.
- 4.

3. Reason for discontinuation

- 1.
- 2.
- 3.
- 4.

4. List one medication, if any, that has been most helpful

The following 2 questions are to be asked of (or answered by) the person with ASD.

5. Do you think this medication has been helpful?

- Yes
- No
- Don't know

6. Do you remember how you felt before you started to take this medication and, if so, how do you feel now?

	Worse	The same	Better	Don't know (or not sure)
Response:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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9. ASD Characteristics

1. Please indicate the degree to which the following ASD characteristics apply to you (or your child) by checking a number that best describes your characteristics:

Not at all (0); A little (1,2,3); Moderately (4,5,6); A lot (7)

	0	1	2	3	4	5	6	7
Impairment in social interactions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Impairment in language/communication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Repetitive or stereotyped actions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Restricted interests/activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Obsessive thoughts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Associated symptoms or problems:

Please check if you (or your child) currently experience any of the following conditions on a chronic or recurring basis.

- Epilepsy (seizures, fits, convulsions)
- Sleep disturbances (examples: difficulty falling or staying asleep; nightmares)
- Gastrointestinal (digestive/stomach) problems (examples: diarrhea, constipation, colitis)
- Immune system problems (examples: chronic infection, inflammation)
- Cognitive impairment (example: IQ less than 70)
- Other chronic problems (please specify)

3. Information about assessment for autism spectrum disorder

At what age were you (or your child) diagnosed with an autism spectrum disorder?

4. Please check the following to indicate the initial diagnosis

- Autism Disorder
- Pervasive developmental disorder-not otherwise specified (PDD-NOS)
- Asperger's Syndrome

Other (please specify)

5. If the diagnosis has changed over time, please indicate the most recent diagnosis

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**6. The diagnosis was made by:
(Check all that apply)**

- Pediatrician
- Psychiatrist
- Psychologist
- Neurologist
- Psychological/Developmental Testing
- Speech Pathologist
- School system

Other (please specify)

7. Have you (or your child) been given any of the following standardized tests for autism spectrum disorders?

Please check all that apply. Don't worry if you don't know.

- Autism Diagnostic Observation Schedule (ADOS)
- Autism Diagnostic Interview-Revised (ADI-R)
- Childhood Autism Rating Scales (CARS)
- Checklist for Autism & Toddlers (CHAT)
- Autism Screening Questionnaire
- Don't know

Other (please specify)

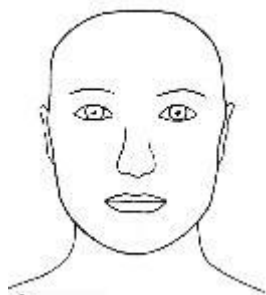
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10. Assessment through drawing task

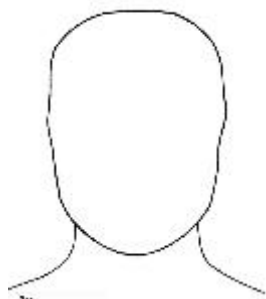
We are using a simple drawing task to find out more about the strengths, abilities and current performance level of the person with ASD who is being described in this questionnaire. For this task, we will be sending you two simple drawings to be completed by the person with ASD, a box of non-toxic crayons to be used in this task, and brief instructions on completing the drawing task.

Below are the two drawings included in the packet.
(printed on 8.5 x 11inch pieces of paper)

Drawing 1



Drawing 2



1. In order to receive this material, please provide the name of the recipient as well as an address where the materials should be sent. We will include a self-addressed stamped envelope for the return of the completed drawings. Please do not send the crayons back.

Name:

Address:

Address 2:

City/Town:

State:

ZIP:

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11. Feedback to study investigators

1. Please add any comments you think might be helpful for us to know regarding the medication treatment you (or your child) has received to address autism spectrum disorder.

2. What improvements would you like to see with regard to medication therapy for autism spectrum disorders?

3. May we contact you to let you know about any follow-up studies that are planned as a result of this study?

Yes

No

4. If yes, please include your email and/or phone number.

Email Address:

Phone Number:

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12. 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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