

# Partners HealthCare System Research Consent Form

Certificate of Confidentiality Template  
Version Date: January 2018

Subject Identification

Protocol Title: Participant Database for Persons Interested in Research  
Studies of Developmental Disorders

Principal Investigator: Tal Kenet, PhD

Site Principal Investigator:

Description of Subject Population: Healthy adults and adults with developmental  
disorders (ages 18-45)

## About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

## Why is this research study being done?

Our research group studies brain development and associated medical conditions in healthy adults and adults with developmental disorders such as autism, an autism spectrum disorder, language impairments or attention deficit disorders. You have shown interest in being part of our research studies. As a result, we are asking you to take part in this screening assessment which involves taking tests and answering questions. The information from these tests and your answers will help us decide which studies you can be in, either now or in the future.

## How long will I take part in this research study?

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We will ask you to come in to our research office for one or more visits to complete assessments and questionnaires. Each visit will last about 2 or 3 hours. The number of visits and how long the visits take will depend on the specific studies. It will also depend on the time you need to complete the assessments and questionnaires.

## What will happen in this research study?

You have been asked to sign this consent form because you are potentially eligible for one or more of our studies. If you are eligible for any studies, we will tell you about those studies and answer any questions you may have. We will ask you to sign a separate consent form for each research study in which you wish to enroll.

To further determine eligibility and to participate, you will be asked to complete some assessments and questionnaires. We may ask you (and/or your parent or legal guardian) questions about your behavioral and social skills, your handedness, and your medical and family history including any illegal drug use. A licensed neurologist or neurodevelopmentally trained licensed physician may also perform a neurological examination. A neurological exam is a standard physical exam that focuses on how the brain and nervous system work by looking at findings such as strength, coordination and reflexes. During the COVID-19 pandemic, we may also check your temperature with a non-contact thermometer to screen for COVID-19.

*Videotaping:* We will videotape the testing that we do with you. Once our team has reviewed and scored the tests, these tapes will be erased.

One of the tests we may do with you, however, is the ADOS test. ADOS stands for “Autism Diagnostic Observation Schedule.” The ADOS is an interview that is used to see if people have autism, an autism spectrum disorder or do not have an autism spectrum disorder. The person in charge of this study would like to keep the videotape of your ADOS to use for research studies in the future. If you agree, we will keep your tape. The tape will NOT have your name on it. Instead, it will be labeled with a study code number. The tape will be kept in a locked cabinet. Only qualified staff from our research group will see the tape.

Please indicate if you give us permission to keep your ADOS videotape in our database.

**YES:** \_\_\_\_ **NO:** \_\_\_\_ **INITIALS:** \_\_\_\_\_ **DATE** \_\_\_\_\_

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If you may be eligible for one of our MRI studies, we may choose to first train you in the mock scanner. This training will be short (about 15-30 minutes or so usually) and is meant to get you familiar with the MRI. A “mock scanner” is a fake scanner that looks like an MRI machine but does not have any magnets. The “mock scanner” will be used to show you what will happen during the MRI scan and allows you to practice staying still. The real MRI scanner makes different sounds as it takes pictures of your brain, so we will play you some of these sounds during the mock scanner session so you know what to expect if you come back for a real MRI. The most important part of the mock scanner session is for you to practice lying on your back and staying still while you go into the scanner tunnel. If you come back for one of our MRI studies, you will need to stay still while we are taking pictures of your brain in the real scanner in order for the brain pictures to come out clearly.

We are asking your consent to share any raw data we collect, in a de-identified form, to be shared on the National Database for Autism Research (NDAR). NDAR is an NIH-funded research data repository that aims to accelerate progress in ASD research through data sharing. Data is made available, on appropriate terms and conditions as specified by the NIH, to qualified investigators.

As part of your participation in the study, a unique subject number, called a GUID, will be assigned to you that will allow researchers to see if you have been involved in more than one study or database used to study ASD. If you have participated in more than one study or database, this unique subject number will help connect information across studies. This subject number will also allow your de-identified data to be combined with data from other research studies to increase the likelihood of meaningful analysis. Only this subject number, and not your personal identifiable information, will be accessible to other investigators. This unique subject number may make it possible for a researcher who used this unique subject number in another study that you took part in to identify you.

## What are the risks and possible discomforts from being in this research study?

The questionnaires, interviews, mock scanner training, and/or tests may cause you (and/or your parent or legal guardian) to become bored, frustrated, or uncomfortable. We hope that you will complete everything. However, you (and/or your parent or legal guardian) can skip anything you don't want to complete.

If the testing uncovers any neurological or psychiatric problems, we will tell you. With your written permission, we will contact your doctor or clinician by phone and/or by mail or email to

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alert them. If it is necessary, we will offer you (and/or your parent or legal guardian) help in locating the appropriate referrals to follow up on this information.

## What are the possible benefits from being in this research study?

You will not receive treatments or any other direct benefits from taking part in this study. In general, we hope that what we learn from our studies will help researchers understand developmental disorders better.

## Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

## What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

## Will I be paid to take part in this research study?

Yes, you (or your legal guardian) will receive payment for participating in our study. For the time you spend completing the screening tests and questionnaires, you will receive \$30 per hour. Should you complete less than an hour of testing and questionnaires, you will receive a minimum of \$30 for your time. For questionnaires that are completed remotely, you will receive \$50 upon completion of self-questionnaires and an additional \$50 upon completion of parental

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questionnaires. If you or your parent complete some but not all questionnaires, you will receive \$25 for the incomplete assessments. Before you sign the consent form, the research staff will tell you which questionnaires they would like you (or your legal guardian) to complete.

You will be reimbursed for transportation at the current government rate for mileage if driving or for your Uber/Lyft expenses, up to \$80 total per visit (\$40 each way). The transportation allowance will also apply to public transportation or taxi services.

## What will I have to pay for if I take part in this research study?

There will be no costs to you or your health insurance company from taking part in this research study. All of the study visits and all study procedures and tests will be provided at no cost to you.

## What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

## If I have questions or concerns about this research study, whom can I call?

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You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Tal Kenet, PhD is the person in charge of this research study. You can call her at 617-643-6732 where you can leave a message and Dr. Kenet will return your call.

If you have questions about the scheduling of appointments or study visits, call our research coordinator at 617-966-9766.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

## If I take part in this research study, how will you protect my privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as “identifiable information.”

### In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

### Who may see, use, and share your identifiable information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research

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- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections) state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

## Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

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Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

## Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

## Informed Consent and Authorization

### Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

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**Signature of Subject:**

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

\_\_\_\_\_  
Adults or Minors, ages 14-17

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

**Signature of Parent(s)/Guardian for Child:**

I give my consent for my child to take part in this research study and agree to allow his/her identifiable information to be used and shared as described above.

\_\_\_\_\_  
Parent(s)/Guardian of Minor

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

**Signature of Guardian or Authorized Representative for Adult:**

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her identifiable information to be used and shared as described above.

\_\_\_\_\_  
Print Name (check applicable box below)

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time (optional)

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Relationship to Subject: \_\_\_\_\_

**Signature of Study Doctor or Person Obtaining Consent:**

**Statement of Study Doctor or Person Obtaining Consent**

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

\_\_\_\_\_  
Study Doctor or Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

**Subject Advocate**

In certain situations, the Partners Human Research Committee (PHRC) will require that a subject advocate also be involved in the consent process. The subject advocate is a person who looks out for the interests of the study subject. This person is not directly involved in carrying out the research. By signing and dating below, the subject advocate represents (or “says”) that the subject has given meaningful consent to take part in the research study.

**Statement of Subject Advocate**

I represent that the subject or authorized individual signing above has given meaningful consent.

\_\_\_\_\_  
Subject Advocate (when required)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

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Consent Form Version Date: February 15<sup>th</sup> 2022