

## **Information Sheet for Consent of an Adult to Be in a Research Study**

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study. In this form "we" means the researchers and staff involved in running this study at the University of Virginia.

### **What is the purpose of this form?**

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. You may print this page if you would like to keep a copy of this form.

### **Who is funding this study?**

This study is being funded by the University of Virginia's Strategic Investment Fund through the Supporting Transformative Autism Research (STAR) Initiative.

### **Key Information About This Research Study**

You are being asked to take part in a research study. The goal of this study is to create an autism research registry through the Autism DRIVE (Data System for Research Integration, Visualization & Exchange), an online data system designed for individuals with autism, their families, and professionals. By joining this research registry, you will have a chance to join and learn about current and future autism-focused research studies being conducted at the University of Virginia. By completing the registration process, we will also be able to connect you to autism resources within the "Resources and Trainings" portion of the DRIVE that are specific to your specific interests and needs.

You do not have to take part in this study. You should only agree to take part in this study after reading this consent form. You may also discuss this with your family, friends, health care providers or others before you make a decision.

If you no longer wish to be part of the registry, you can cancel your account at any time. We do not anticipate that anything negative will happen to you by joining the autism research registry.

In order to join the registry, you will be asked to complete some questions about yourself. Questions will focus on your contact information, current home and work or school environment, diagnoses, and services. It will take approximately 10 -15 minutes to complete these questions. If you do not want to answer them all at one time, you can save your progress and return to complete remaining questions at a later time.

You may find that you are unfamiliar with some of the terms used in questions that you are being asked as part of the registration process. If this is the case, you are welcome to contact us through our website to request clarification. If you do not feel comfortable answering any questions, you do not have to answer them.

UVA researchers conducting autism research studies may contact you at a later date about a research study you are eligible for – if you agree to participate in those studies, a separate study team will work with you to complete their own consent form.

<b>Principal Investigator:</b>	Rose Nevill, 417 Emmet Street South, PO Box 400260 Charlottesville, VA 22904-4260
<b>Sponsor:</b>	University of Virginia Strategic Investment Fund

**What problem is this study trying to solve?**

This study is trying to establish a network of a large number of individuals with autism, their families and professionals across the state of Virginia to connect with research studies being conducted through the University of Virginia. This will address a major limitation of progress within the autism research field, which is that most research is being conducted with small groups of participants and in individual labs and clinics. This means that we may be missing out key insights about autism. Finding ways to engage more individuals with autism and their families in research will help us learn more about their experiences and challenges, and will help us develop better interventions and supports. You are being asked to take part in this study because you or someone in your family has autism.

**Why would you want to take part in this study?**

You might like to take part in this study because you want to help us find new discoveries about autism through engagement in scientific research. Providing information about you and/or your family also allows you to be matched with autism resources and trainings that might be a good fit for you.

**Why would you NOT want to take part in this study?**

You might not want to take part in this study if you do not feel comfortable sharing information about yourself with University of Virginia researchers.

**What will I have to do if I take part in this study?**

If you take part in this study you will:

- create a login account on the Autism DRIVE website
- answer questions about your demographic information, educational background, services, medical history, and diagnoses.

This process will take approximately 15 to 20 minutes.

**What is the difference between being in this study and getting usual care?**

Participating in this study will not have an effect on the usual care or supports you are currently or plan to receive.

**Could you be helped by being in this study?**

You may or may not directly benefit from being in the Autism Registry. Possible benefits include: being matched with research studies of interest, and access to a number of Autism-specific resources. In addition, information researchers get from this study may help others in the future.

**What are your other choices if you do not join this study?**

You/your child do(es) not have to be in the Autism Registry to continue to receive treatment and/or services at University of Virginia. You/your child will continue to receive the same care at University of Virginia whether or not you decide to participate in the Autism Registry.

If you are an employee of UVA your job will not be affected if you decide not to participate in this study. If you are a student at UVA, your grades will not be affected if you decide not to participate in this study.

**Will you be paid for being in this study?**

You will not be paid for enrolling in the study.

**Will being in this study cost you any money?**

There are no costs associated with joining the Autism Registry.

**What if you are hurt in this study?**

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

**What happens if you leave the study early?**

You can change your mind about your child's participation in the Autism Registry any time. You can agree to your child's participation in the Autism Registry now and change your mind later. Your child does not have to be in this Autism DRIVE to get services they can normally get at the University of Virginia. If you decide to stop your child's participation in the study, we will ask you to cancel your account under the "Your Profile" page of the Autism DRIVE website. Even if you do not change your mind, the study leader can take your child out of the study.

## **How will your personal information be shared?**

The UVA researchers are asking for your permission to gather, use and securely share information about you/your child for the Autism Registry. If you decide not to give your permission, you cannot be connected to resources and opportunities through the Autism DRIVE, but you can continue to receive regular medical care and services at UVA.

## **If you sign this form, we may collect any or all of the following information about you:**

- ☐ Personal information such as name, address and date of birth
- ☐ Your health information. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

## **Who will see your private information?**

- ☐ The researchers to make sure you/your child are matched with potential studies and resources
- ☐ People or groups that oversee the study to make sure it is done correctly
- ☐ People who evaluate study results, which can government agencies that provide oversight
- ☐ If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Information obtained from you during this study may be used in future research. Your information may be shared with other researchers inside the University of Virginia. They will not be sent with information that could identify you such as name, address or phone number.

## **What if you sign the form but then decide you don't want your private information shared?**

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, you can cancel your account under the "Your Profile" page on the Autism DRIVE website. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

## **Please contact the Principal Investigator listed earlier in this form to:**

- Obtain more information about the study
- Ask a question about the study procedures or treatments

- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Rose Nevill, PhD, BCBA  
417 Emmet Street South, PO Box 400260  
Charlottesville, VA 22904-4260  
Telephone: (434)243-1718

### **What if you have a concern about this study?**

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research  
PO Box 800483  
Charlottesville, Virginia 22908  
Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.