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APPROVED BY: IRB-01
IRB ID #: 202202142
APPROVAL DATE: 07/15/24

INFORMED CONSENT DOCUMENT

Project Title: **Neurodiversity Research Community: A biorepository and patient-reported outcomes study**

Principal Investigator: Jacob Michaelson, PhD

Research Team Contact: Study Coordinator: 319-335-8882

- If you are the parent/guardian of a child under 18 years old who is being invited to be in this study, the word "you" in this document refers to your child. You will be asked to read and sign this document to give permission for your child to participate.
- If you are a teenager reading this document because you are being invited to be in this study, the word "you" in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you may:

1) have a unique brain and behavior-related characteristic,
2) have a mental health-related diagnosis,
3) belong to a group or family at increased risk for mental health issues, or
4) have a job or area of study that is demanding from a cognitive or creative perspective.

The purpose of this study is to understand biological and psychological factors linked to neurodiversity. We also want to understand the positive and negative outcomes that are associated with different kinds of neurodiversity. Neurodiversity is the idea that individual brains are built and function differently. "Biological factors" include things like genetic variation, metabolism differences, or brain imaging results. "Psychological factors" are the results of surveys you fill out about your behavior and preferences. "Outcomes" can include positive events or feelings, like getting a job, graduating, excelling in your profession, or feeling safe and that you have what you need to live a meaningful life. Outcomes can also include negative experiences or feelings, like relationship stress, failing at school, or losing your job. Most people experience both positive and negative outcomes in their lives. We hope this research will improve lives by better understanding the risks and strengths associated with different neurodiverse groups.

This study is also a "repository", for which many questions related to the brain, behavior, and mental health can be answered by analyzing the data and biosamples collected through this study. Researchers

may develop other projects and contact you to study specific mental health outcomes and neurodiversity.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 50,000 people, comprising 25,000 adults and 25,000 minors, will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last indefinitely. However, you have the right to leave the Neurodiversity Research (NDVR) Community at any time. By enrolling, you will be part of ongoing health research conducted by researchers at the University of Iowa and their collaborators. Your sample and health information may be used indefinitely by researchers for many different studies, now and in the future.

Initial participation in this study will take approximately 10 minutes and may unlock additional surveys that you may complete immediately or later. You may be invited to one or more in-person visits to collect information directly from you. In-person visits usually take 1-2 hours, but depending on your availability and the number of study procedures may take as many as 4. The expected length of the visit will be discussed with you during scheduling.

WHAT WILL HAPPEN DURING THIS STUDY?

Your initial participation will involve completing a survey that collects contact information and some basic demographic information. In addition, we may collect identifying information about your family members including your parents, siblings, spouse, and any children. This will allow us to take family relationships into account during analysis of data collected in this study. Your family members may or may not have also enrolled in this study. Even if your family members don't enroll in the study, this family linkage information helps us better understand how brain-related traits run in families.

You may also be asked to complete some *optional* surveys and study procedures, at your discretion, that are detailed below. An optional in-person visit might involve any combination of the below activities, and usually lasts 1-2 hours. We may invite you to multiple in-person visits (typically no more than a 1-3 per year) to collect data over time. You may skip any question, survey, visit, or procedure that you do not wish to complete.

1. Surveys and assessments:

- Surveys that ask about information relevant to behavior and mental health.
- Mental or cognitive performance games, tests, or tasks (e.g., mental speed, problem solving skills, memory, etc.).
- Follow-up surveys: Additional surveys that are available as we learn more and develop new research questions about present abilities, interests, activities, opinions, and other information related to neurodiversity.

2. Biological data:

- Saliva donation (spit tube) **or** a blood sample (optional). These will be used to extract DNA and potentially other molecules.
- "leftover" portion of blood or other biosamples taken as part of your routine clinical care at UIHC.

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- Data from Direct to Consumer (DTC) DNA testing, such as 23andMe or Ancestry.com

3. Non-invasive (e.g., MRI) scan.

- An MRI scanner takes pictures of the inside of your brain by sending out a magnetic field and radio waves.
- The MRI scanner is a large machine that contains a hollow tube. You will be asked to lie on your back on a special table that slides into the tube. The sides of the tube will be fairly close to your body and the scanner makes a loud hammering noise while you are inside. You will be able to talk to people in the room through a speaker system. Our current protocol takes about an hour.
- New non-invasive technologies/ investigational software may become available to image the brain and body, which would be a similar experience and comparable in terms of safety to a general MRI. Such similar technologies might be used in an in-person visit, but this would be explained to you during scheduling and again before the scan.
- Participants who have trouble tolerating the 7T MRI scanner will be scanned using the 3T MRI scanner.

4. Bodily Measurements: Vital signs (e.g., blood pressure, pulse, etc.) and other bodily measures (e.g., height, weight, head circumference, etc.).

5. Medical Record Data biomedical data already collected during clinical care, including but not limited to demographic variables, vital signs (e.g., blood pressure, pulse, etc.), lab ., diagnoses, prescribed medications, procedures performed, results of psychological testing, notes related to your visits, family history, diagnoses, brain imaging (i.e. MRI- if available).

6. Other data sources:

- Results from your prenatal screening test and your neonatal metabolic newborn screening. These results were collected during and after your mother's pregnancy.
- Academic achievement scores: Results from academic, standardized tests as they may become available (e.g., Iowa Test of Basic Skills, the Iowa Assessments, etc).
- Affiliated research studies at the University of Iowa or other collaborating institutions

Photograph, video and audio recordings: During the study, you may participate in taking a photo, video and/or audio recording. This data may include but is not limited to: a conventional photograph of your face to measure your head, a motion-detecting video of your walking gait, additional audio and/or video recordings during interactions with members of the research team, such as an interview over videoconferencing platforms like Zoom. In addition to the photograph and video, we may ask to take a scanned photograph of your hands, as some developmental markers can be observed in the relative lengths of your fingers. By consenting to this research, you give permission to take photographs and/or video and audio recordings during this study as described above. Only research team members will have access to these original recordings, which will be retained for the duration of the study.

Recontacting you for future research opportunities: We will keep a secure database of your contact information for the purpose of contacting you about future studies. Agreeing to this current study does not obligate you to participate in future studies, and a separate Consent Document would need to be signed for participation in future studies. If you cannot be found with the contact information we have on file, our research team will attempt to find current contact information, e.g., through a web search,

consulting your medical record, or reaching out to family members who are involved in the study.

Tissue/Blood/Data Storage for Future Use

As part of this study, we are obtaining saliva, blood, or other clinical tissue samples from you. We would like to study your saliva, blood, or other clinical tissue samples in the future, after this study is over. Your sample, information, and/or data may be placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, it may be stripped of identifiers (such as name, date of birth, address, etc.). Other qualified researchers who obtain proper permission may gain access to your sample and/or data for use in approved research studies that may or may not be related to in the purpose of this study. DNA from tissue samples you provide or otherwise give us permission to use will be used to conduct whole genome sequencing. The tissue and data will be made available to researchers trying to learn more about the cause of diseases.

IMPORTANT DETAILS ABOUT GENETIC RESEARCH

One purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for the body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

Overview of DNA sequencing: Each of the cells in your body contains DNA. DNA is the instruction manual that determines your appearance in things like eye color or how tall you can be. Your DNA may also lead to higher or lower risk of certain diseases or disorders. Your environment will also determine some of your risk.

Your DNA is a string of four building blocks, called "bases." These bases are represented by the letters G, A, T, and C. There are billions of these letters strung together in every human's DNA and they are arranged in packages like words. Each of these "words" have specific jobs in the body. Most of the time the letters are the same in everyone. But about 1% of the population might have an "A" where someone else has a "G." This difference can explain why some people have blue eyes and others brown eyes, or why some have a high risk for a certain cancer and others a low risk. All these letters come together to create your "genome sequence", a kind of book of your genetics. It now possible to read off each of these letters and read your complete genome sequence. Your DNA sequence is unique to you. You inherit your DNA in almost equal parts from each of your parents. In very rare cases, your genome can also change through "mutations." A mutation is like if you tried to copy a page from a book, but misspelled some words. Mutations usually result from copying errors that occur in certain letters when being passed from parent to child.

When we take a sample of your blood/tissue for this study, it will go to a lab to read off those letters and give us a report on your genome. This information will then be compared with other genomes to see how they may be the same or different. It is our hope this will help us to better understand how the human body works and/or what causes it to not work well, such as when someone has a disease.

You are being asked to give a saliva, blood, or other tissue sample (biosample) for genetic research. What we learn about you from this sample will **not** be put in your health record.

If you opt to give a saliva sample, we will collect about two teaspoons of saliva in a tube. If you opt to

give a blood sample in place of a saliva sample, we will (at your discretion) 1) collect a small paper card will be spotted with blood from your fingertip. This involves a finger poke similar to a blood glucose monitor, and the pain involved is similar to a static electricity shock or 2) collect blood from the vein as would be done at a doctor's office.This will take less than 5 minutes of your time.

Genetic Information Nondiscrimination Act (GINA)

A federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more persons to discriminate against you based on your genetic information. Based on this law, health insurance companies and group health plans are prohibited from requesting your genetic information that we get from this research. This means that they may not use your genetic information when making decisions regarding your eligibility for insurance coverage or the amount of your insurance premiums. Be aware that this new federal law will not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. The law also does not prohibit discrimination if you are already known to have a genetic disease or disorder.

Future tests on your samples: The tests we might want to use to study your biosample may not even exist at this time. Therefore, we are asking for your permission to store your biosample and associated data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding the brain, neurodiversity, and mental health, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your biosample might be used to develop products tests, or discoveries that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, biosample donors do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you should this occur.

Your biosample will be stored with a code which may be linked to your name or date of birth that would enable us to identify which sample(s) are yours. If you agree now to future use of your biosample but decide in the future that you would like to have it removed from future research, you should contact Dr. Jacob Michaelson at 319-335-8066. However, if some research with your biosample has already been completed, the information from that research may still be used.

WILL I BE NOTIFIED IF MY DATA RESULT IN AN UNEXPECTED FINDING?

The results from biosamples and imaging collected in this research study are not the same quality as what you would receive as part of your routine health care. Results related to your biosample and imaging will not be reviewed by a physician who normally reads such results. Because of this, we do not routinely examine the results for medically relevant unexpected findings. Images or genetic results related to your biosample will not be placed in your medical record with your primary care physician or otherwise, without your consent. If you believe you are having symptoms that may require care, you should contact your primary care physician.

We acknowledge and respect your autonomy and your right to access information derived from this research that pertains to you. Should you request to receive certain findings from the study, your request will be considered as your consent to receive these results. The decision to return results will be made

with careful consideration of the relevance and potential impact on your well-being. It is important to note that the research findings are provided for informational purposes only, are not clinically validated, and should not be used as a basis for changing your health routines. Always consult with your healthcare provider before making any changes to your current health routines. Additionally, we may require you to demonstrate your understanding of the research findings' limitations and implications, possibly through an educational quiz, to ensure informed engagement with the returned results.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

- You may experience dry mouth by donating a saliva sample.
- You may experience brief, minor pain if you opt for blood sample donation either through a "finger poke" or through a draw from a vein.
- One risk of providing your genetic data for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. To prevent this, these samples will be given a code to identify the sample. Only the study staff will know the code. The name that belongs to the code will be kept in a secure database protected by limited access and a password only available to research team members. Only research team members associated with this project will have access to your name. There is a risk of loss of confidentiality of non-genetic data as well.
- You may be uncomfortable inside the MRI scanner if you do not like to be in closed spaces ("claustrophobia"). The MRI scanner produces loud noises (e.g., buzzing, banging), which has produced hearing loss in a very small number of patients. You will be given earplugs to reduce this risk.

WHAT ARE THE BENEFITS OF THIS STUDY?

There are no direct benefits to you from being in this study. However, we hope that, in the future, other people might benefit from the discoveries related to how genes impact neurodiversity and mental illness. This knowledge may lead to a better understanding and characterization neurodiversity and mental illness, which may be used someday to develop more effective diagnostic tests and treatments.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study.

You may receive compensation in the form of a check or gift card. Participants who 1) complete initial surveys and 2) provide a saliva or blood DNA sample will receive a gift card or check valued at $20. If an MRI scan is completed, you will be compensated an additional $95 in the form of a check or gift card. Gift cards for participants who are minors or legally dependent adults will have the gift card forwarded to the primary account holder or legally authorized representative.

In addition, to encourage retention over time, the study will hold an annual drawing for five $100 Amazon gift cards. Probability of selection will be proportional to participation in follow-up activities,

i.e., if a participant has completed five surveys, they will be entered five times in the drawing. Only participants who complete intake (intake surveys plus DNA sample) will be eligible for the annual drawing.

WHO IS FUNDING THIS STUDY?

This study is being conducted using discretionary funds in the department of psychiatry at the University of Iowa.

WILL YOU KEEP MY NAME ON FILE TO GIVE TO OTHERS?

We will keep information about you in a special kind of computer listing called a registry. A registry keeps information about you on file so that *other* researchers, not involved in this particular study, may contact you in the future about whether you are interested in being in *different* research studies. The registry will contain information such as your name, address, age, and selected medical information such as diagnosis and treatment. We will keep the information in this registry on a secure, access-controlled database. You may request that your personal information be removed from this database at any time by contacting Dr. Jacob Michaelson at 319-335-8066.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you:

- federal government regulatory agencies,
- scientists who use the registry,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To protect your privacy interests, you will be able to complete the entire consent and study process from the privacy of your own home. To help protect your confidentiality, we will keep all information you provide us in a password protected database that is only accessible to research team members. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

To help protect your confidentiality, a record of your participation will be maintained, but your biomedical and genetic data will be directly identified only by a number. It will be very unlikely for anyone working with your genetic data to know that this DNA or biomedical data belongs to you unless they access the access-restricted and password protected database and link the sample number to your name. Electronically stored genetic data will be kept in password protected files on protected computers in locked offices accessible only by research team members who are associated with this project. Should you wish to have your genetic data deleted from our database, please contact Jacob Michaelson, PhD at (319) 335-8066.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are

participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your healthcare provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, federal funding agency, and scientists using the registry.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to **Dr. Jacob Michaelson, Medical Laboratories B020/B030, 25 S. Grand Avenue, Iowa City, IA 52242.** However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Jacob Michaelson or the study coordinator at 319-335-8882. If you experience a research-related injury, please contact: Dr. Jacob Michaelson at 319-335-8066.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences,

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600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

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This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

_____ _____
(Signature of Subject) (Date)