IRB APPROVED
AS MODIFIED
Jun 01, 2023

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Data Consent– Parent/LAR and Child

TITLE: SPARK: Simons Foundation Powering Autism Research for Knowledge, a national cohort of individuals and families affected by Autism Spectrum Disorder

PROTOCOL NO.: None

WCG IRB Protocol #20151664

SPONSOR: Simons Foundation

INVESTIGATOR:
Wendy Chung, MD, PhD
Boston Children's Hospital
300 Longwood Avenue
Mailstop #BCH3218
Boston, MA 02115
United States

STUDY-RELATED PHONE NUMBER(S):
SPARK Study Staff
1-844-54-SPARK
info@SPARKforAutism.org

Wendy Chung, M.D., Ph.D.
1-844-54-SPARK

SUMMARY

The purpose of this consent form is to **help you decide if you want to take part in this research study**. If you decide not to join, it will not affect your medical care.

The study is called SPARK: Simons Foundation Powering Autism Research for Knowledge.

Why are we doing this research?

- This study will form a group of over 50,000 people with autism spectrum disorder (ASD) and their families, to **learn more about autism.**
- A coded data set from this study, without names or identifiable information, will be shared with approved researchers to power new research.

What will you do?

- You can participate in SPARK if:
    1. You live in the United States.
    2. You are a person with ASD or you are a parent or legal guardian (legally authorized representative or LAR) or full biological sibling of a person with ASD.
    3. You read and understand English or Spanish.

- You will complete surveys and other tasks about your and your child/dependent's health, thoughts, behaviors, and ASD diagnosis. You will provide new information over several years.
- You will be asked to share your name and other information to make a code called a Global Unique Identifier (GUID) (see https://nda.nih.gov/tools_guid_tool.html). The GUID allows researchers to share and match up data without identifying who you are.
- You may be able to share medical records and reports with SPARK, which will become part of your data.
- You may get emails, text messages, or other contacts from SPARK to remind you of study tasks, gather more information or updates from you, ask for feedback, or send other invitations or news.
- You will be told any information that might change your decision to be in the study and you may be asked to sign updated consent forms.
- You may be asked if you would like to participate in other research studies. Some studies may be sponsored by companies trying to develop new supports and treatments for autism or other conditions. You are not required to do this.
- You will also be asked if you want to give permission to provide a saliva sample. You are not required to do this.

Providing Consent on Behalf of a Child or Dependent Adult

To sign someone up for this study, you must be the parent or legal guardian (LAR) with primary legal custody and the right to medical decision-making. If they are over 18, you must be court appointed LAR or power of attorney (or proxy by state law).

- When a child in SPARK turns 18, we will contact you, and you will need to verify legal guardianship with us.
    - If the child is now an independent adult with no legal guardian, they will need to sign a new consent. They will have their own account and you will no longer be able to see their information on your SPARK account or fill out surveys about them, unless they give permission.
- You must tell us about any changes in guardianship.

What are the risks and discomforts?

- There are no major risks to participate in SPARK.
- It is possible that a question could make you feel uncomfortable. You can choose to not answer any question.
- You may receive information from surveys that you complete. It is possible that this information could be upsetting. If this happens, you should call your doctor or therapist to discuss your concerns.
- The information we return from surveys is not a clinical evaluation and we are not able to monitor your responses: if you have concerns about the behavior or safety of individuals in your family, contact your doctor or other professional. If you or someone else is at risk of harm to self or others, call 911 or go to the emergency room.

Confidentiality

Your data are kept safe and private, but a possible risk is that it could be seen by someone who was not supposed to see it. We believe our security measures make it unlikely that this will happen.

What are the benefits?

- There are likely no direct benefits for being in SPARK.
- You may receive individual results about your child/dependent from some surveys.
- You may be able to read articles that describe research results of SPARK or other related studies that you participated in.
- You may be able to connect with other people and communities.
- You may benefit from hearing about other research studies. Some of these studies may have their own incentives or benefits.
- The major benefit will be to the community of individuals with autism because we will learn more about the causes of autism and try to develop better treatments and supports.
- **Payment**
  - Your family will receive a $50 gift card code if the individual with autism and their parents give usable saliva samples. The details of this will be in a separate Genetic Consent form.
  - You may be entered into a drawing for an iPad or other item(s) if your family completes study tasks or sends in samples within a certain time.
  - Some surveys may have incentives. We will tell you which surveys will receive payment and what the payment will be.

What are the costs?

There are no costs to be in SPARK – it is free.

Other options for treatment

This is not a treatment study. You can choose to not be in SPARK.

What do we do with your Data?

Authorization to Use and Share Data:
What Information will be Given to Others

Identified data (including surveys, records, lab results, contact information):

- The SPARK team and Simons Foundation staff will be able to see your personal, medical, and genetic information.
- If you or one of your family members are connected in registration or in another way to a SPARK Clinical Site (hospital or university) or to one of our partner research studies, we will share your information and data with them. They will also share your information, such as your medical and testing records with us.
- If you were invited to SPARK by a family member, they may receive reminders about your study steps if we cannot reach you.
- We will share some of your information with the computer consultants that we work with. These contractors are also required to keep all your information confidential.
- We may ask you if you would like your contact information to be shared with new research studies. You are not required to do this.
- If an audit, review, or investigation is required, the Department of Health and Human Services (DHHS) agencies or WCG Institutional Review Board (WCG IRB) may ask to see our records. They are groups that check research.

De-identified data:

- We will store your information and share it with approved researchers, but your information will NOT be identified with your name or any other identifiable information. It will be labeled with a code (number).
- Some researchers may be from companies making treatments.
- We may send your coded data to the National Database of Autism Research (NDAR) in the National Institute of Mental Health Data Archive (NDA), for researchers to use. This data will have no identifying information and is protected by an NIH Certificate of Confidentiality (see below).
- When a child turns 18, we will continue to store and share their coded data.

Why do we share your data?

We need to share your data to do the research, help return your results, and make sure the research is right.

How to take away permission to use and share your identified information

- You may take away your permission for us to use and share your identified health information. To do this, contact SPARK at the email address below in the questions section.
- If your information was already sent to researchers or your Clinical Site, it cannot be taken back from them. But no new information will be asked for or shared.

When does your permission to share your identified information expire?

Your permission for us to use and share your identified information will expire at the end of the analysis of the study data or December 31, 2050, whichever is sooner.

How do we keep your information confidential?

- Confidentiality is keeping personal information like your name and address safe and not showing it to others, unless you give us permission. We will take steps to keep your personal information private, but we cannot promise total confidentiality.
- All data will be encrypted (re-coded) and stored in a secure password-protected database to help prevent unauthorized access to your information.
- We will never use your contact or personal information for publications or to share with anyone else besides the people explained above without your permission.
- All identifiable information about you, like your name, will be replaced with a study code (number). The study code is kept separate from your personal information.

- Your information could be shared again by the people we share it with, but that is against the law – these groups are required to keep your information confidential.
- Your data will never be sold for profit.
- This research is covered by a Certificate of Confidentiality from the National Institutes of Health.
    - This means that we cannot release or use information or documents that may identify you in any action or suit unless you say it is okay.
    - We cannot provide your information as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.
    - The Certificate DOES NOT stop: reporting that is required by federal, state, or local laws (for example, reporting child or elder abuse, some communicable diseases, and threats to harm yourself or others); or being used for other research if allowed by federal regulations.
    - It does not stop you from giving permission to release your information from this research to others (such as your doctor) or to access your own information.

How to withdraw (leave) the study

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you.
- You may take away your permission to be in the study by contacting us at the email address below in the questions section.
- If you leave the study, we will not ask for new information from you, but data already used by researchers cannot be taken back from them.

Who pays for the study?

The sponsor, the Simons Foundation, is paying for this research study.

QUESTIONS

Contact SPARK at 1-844-54-SPARK or info@SPARKforAutism.org or Wendy Chung, M.D., Ph.D. at 1-844-54-SPARK for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury or problem, or
- if you have questions, concerns, or complaints about the research.

If you have questions about your rights as a research participant or if you have questions, concerns, or complaints about the research, you may contact:

WCG IRB
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 855-818-2289
E-mail: researchquestions@wcgirb.com.

WCG IRB is a group of people who check research studies. WCG IRB will not be able to answer some study-specific questions. But you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

A copy of this consent form will be on your dashboard and you can print it for your records.

CONSENT FOR MYSELF AND MY CHILDREN/DEPENDENTS

- I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.
- I understand that I will be asked to choose individuals to fill out certain kinds of information about me, such as surveys, and authorize SPARK to obtain this information from the individuals that I choose.

I agree to participate in SPARK.

I agree for my children/dependents indicated below to participate in SPARK.

I give permission to share my and my children/dependents' information with the people listed in the authorization section of this consent, for the reasons listed there.

Yes, I consent **No,** I do not consent

_____ _____

BY SIGNING THIS DOCUMENT, I CERTIFY THAT I AM THE LEGAL GUARDIAN/LEGALLY AUTHORIZED REPRESENTATIVE OF THE CHILD/CHILDREN/DEPENDENT/S LISTED ABOVE.

By choosing "Yes, I Consent" and pressing "SAVE & CONTINUE" below, you agree you are electronically signing this document.

A copy of the final consent will be in your dashboard on the website.

Your SPARK participation begins when you click SAVE & CONTINUE below!