

## RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

### *Data Consent Parent/LAR & Child*

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

**PROTOCOL NO.:** None  
WIRB® Protocol #20151664

**Sponsor:** Simons Foundation

**Investigator:** Wendy Chung, MD, PhD  
160 Fifth Avenue  
New York, New York 10010  
United States

#### STUDY-RELATED

**PHONE NUMBER(S):** SPARK Study Staff  
1-844-54-SPARK

Wendy Chung, MD, PhD  
(212) 524-1611

A person who takes part in a research study is called a research or study participant. In this consent form, "you" and "your" may refer either to you, the parent or guardian/ legally authorized representative (LAR) of an individual with an Autism Spectrum Disorder (ASD) or to the minor child/dependent adult for whom you are providing consent. If your child/dependent is now 18 or older and you were not appointed by the court as his/her legal guardian or not designated power of attorney (or representative/proxy per the laws of your state), you may not complete this consent form. Independent adults over 18 years must register and consent themselves.

#### SUMMARY

You are being asked to take part in a research study called SPARK: Simons Foundation Powering Autism Research for Knowledge, a national cohort of individuals and families affected by ASD

(hereinafter referred to as SPARK). The purpose of this consent form is to help you decide if you want to take part in this research study.

You should not join this research study until all of your questions are answered.

Things to know before deciding whether or not to take part in this research study:

- The main goal of a research study is to learn things to help individuals in the future.
- The decision to join or not join the research study will not cause you to lose any medical benefits or insurance. If you decide not to take part in this study, your doctor will continue to treat you the same.
- Your information from your participation in SPARK will become part of a research study. Your responses may be viewed and/or copied by the sponsor of this study and other research groups associated with the study.

If you take part in this research study, you will be able to print this consent form.

## **PURPOSE OF THE STUDY**

You are being asked to enroll in a study called SPARK. The purpose of this study is to form a group of 50,000 individuals with ASD and their family members, to identify the causes of autism and to accelerate future clinical research on ASD. The information from this study will help to identify genetic and non-genetic factors that contribute to ASD. A limited data set from this study, which removes information that may directly identify you, your relatives, or your household members, will be made available to qualified researchers, which may include researchers who may be sponsored by companies who are trying to develop new supports and treatments for autism or other conditions.

This consent form covers providing and sharing information about individuals with ASD, their parents and siblings, completing surveys, and being contacted with requests to join additional research studies. In a separate biospecimen consent form, you will be asked to agree to submit saliva for yourself and your children for DNA analysis. You may join SPARK even if you indicate on that consent form that you do not consent to submit a saliva sample. You can decide at any point in the future that you would like to consent to submit a saliva sample. If there is difficulty in providing a saliva sample, you will be asked to agree to submit a blood or other sample for DNA analysis.

## **PROCEDURES**

Participants joining SPARK live in the United States, are able to read and understand English to consent and complete online questionnaires, and are individuals with ASD, their parents or LAR's, and their biological full siblings.

Signing this consent form means that you agree to enroll in the study and that through a secure online site you will:

- Register one non-ASD full biological sibling if available. We will provide additional guidance on how to do so during registration. If that sibling is an adult, you will be able to invite that sibling to register. For families in which more than one child has ASD, register all biological siblings and invite all adult siblings to register.
- Invite other adult biological family members to join SPARK, such as your independent adult child with ASD or the other biological parent of the child with ASD (if available). Invitations to biological parents will show your child(ren)'s names.
- If you have ASD, you will also invite your biological parents and sibling if they are available.
- Provide information about medical and psychiatric history and/or ASD diagnosis, for yourself, your child/ren / dependent/s with ASD and their sibling/s. If you are a parent of a legally independent adult, he or she may consent and ask you to complete surveys about him/her.
- Complete a questionnaire about social communication for children with ASD aged 2 to 18.
- For all participants, share personally identifying information (Full legal name of participant at birth, participant date of birth, gender, and place of birth to generate a special code called a Globally Unique Identifier (GUID) (for more information about GUIDs, please see [https://ndar.nih.gov/tools\\_guid\\_tool.html](https://ndar.nih.gov/tools_guid_tool.html)). A GUID serves as a universal identifier that allows researchers to share data about you and your children, as study participants, with other researchers without identifying who you are to anyone.
- For all participants, agree to be contacted about opportunities for future research studies (described below).

After enrollment, you will be asked to:

- Indicate if you are willing to provide a saliva sample.
- Complete additional surveys about yourself and members of your family. When certain surveys are sent, legally independent adult participants will be asked to designate another individual, who knows them well, to fill out the survey about them.
- Complete your / your child's biological extended family history of medical and psychiatric conditions.
- Indicate whether you would like results from particular surveys.
- On your personal "dashboard" on the website, indicate your permissions for who may share or receive certain types of information about you at your request.
- Choose if you would like to use an optional mobile app designed for families affected by ASD.
- Choose to upload your / your child/dependent's medical records and reports. SPARK researchers will extract information from these reports and store this information in a central database. You may be able to store, organize and access these reports securely at any time. We may also ask you in the future if you would provide specific medical records, to follow up on certain medical or other conditions.

You may be contacted via email or other means for reminders, including for registration or study procedures; invitations, registrations and/or study procedures of your family members; requests for feedback about the study; invitation to share your experience on social media or to participate in community outreach and for other announcements including research and other opportunities. If you were invited to SPARK by a family member, they may receive notifications and reminders about your registration and study procedures. You also will be automatically enrolled for our SPARK newsletter containing information about ASD and other opportunities and research for families with ASD.

As part of your participation in this study, you may be given access to a family-friendly mobile app that you can use to enter and organize information about the individual with ASD. Use of this mobile app is optional. The app has features that enable tracking of ASD behaviors. In the app, you also will be given the option to identify your providers (such as therapists), who may enter certain kinds of information about you/ your child/dependent, and with whom you may share some of your mobile app data. All data collected through the app will be encrypted and stored in a database administered by the Simons Foundation. This database enables the scoring of your information, to provide results to you. In the app, you will be given the choice to share the data you enter to approved outside researchers, without any personally identifying information. If you do not agree to share your mobile app data with researchers, you may still use the app to record data for your own use.

All participants will be contacted periodically and asked to update their contact information, provide medical and educational updates, and complete surveys online on themselves and/or their family members. These annual updates and surveys are anticipated to take you approximately 30 minutes or less to complete.

For a ward under guardianship who is under age 18, or an adult over 18 who cannot make legal decisions independently: to participate in this study, a legally authorized representative (LAR; legal guardian of a child/ dependent) must provide consent on his/her behalf. The LAR must be the individual who was appointed by the court to have legal authority to consent to the dependent's general medical care, and can consent him or her into research, or representative/proxy recognized by laws of the state of residence as able to do the same. In cases where one parent was granted primary legal custody (rights to medical decision making) by the court, he/she must be the one to consent the child into research.

If a child (with or without ASD) who reaches the age of 18 years during the study wishes to continue to participate in SPARK, he/she will need to provide consent if an independent adult, or his/her legally authorized representative (LAR) will need to verify guardianship. We will notify you and ask you questions to determine if the individual is an independent adult. No new data will be collected from participants who reach the age of 18 years until they consent as independent adults or guardianship is verified. If an individual was previously consented by a LAR and gains the legal right to provide his/her own consent according to the court, the LAR must indicate a change in guardianship in the website account dashboard. After a child turns 18 and is indicated not to have a guardian, or an adult gains legal independence, and he or she consents, that individual will be given access to their own account, and parents/guardians will no longer have access to that individual's account or results. For any updated surveys to be completed by parents/guardians, the individual will

have to consent for them to do so.

You will be able to update your permissions for who may receive or enter information about you/ your child/dependent, by contacting SPARK or going through your website account dashboard at any time.

It is possible that SPARK researchers will contact you and ask you for additional information to further understand your/your family's genetic findings or other medical/behavioral data provided by you or your provider.

In addition to providing information, by joining SPARK you are agreeing to be contacted by SPARK about opportunities to participate in research studies about autism for which you qualify, including those based upon your genetic findings. Some studies may be sponsored by companies who are trying to develop new supports and treatments for autism or other conditions. It is up to you to decide whether or not you want to participate in these research studies.

SPARK does not have an end date. We will inform you if SPARK will close in the future.

## **RISKS AND DISCOMFORTS**

There are no anticipated risks or discomforts associated with joining SPARK except a possible loss of confidentiality. Your personal data will be protected, but loss of confidentiality is possible. Loss of confidentiality means that personal information is unintentionally seen by someone who is not on the study team and was not supposed to see or know about your information. Plans for keeping your information private are described in the "confidentiality" section of this consent form.

It is possible a questionnaire may occasionally contain a question that makes you feel uncomfortable. You can choose not to answer any question.

You will be given the option to receive results of some surveys. Results may include information about your/your child/dependent's behavior and/or development. It is possible you may find results of some surveys upsetting. If this occurs, you should call your doctor or mental health provider to discuss your concerns.

You should know the information we return is not a substitute for a clinical evaluation or feedback and we are not able to monitor responses to surveys. If you have concerns about your spouse's, child's, relative's or your own thoughts, behavior or safety, contact your physician and seek a professional clinical evaluation, or help them to do the same. If you ever have concerns that someone is at risk of harming themselves or others, you should call 911 or take them to the nearest emergency room.

## **NEW INFORMATION**

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

## **BENEFITS**

There are no direct benefits related to participation in SPARK. By joining SPARK, you may have the benefit of hearing about research studies for which you qualify. Some of these studies may have incentives/benefits. Through the web portal, you may be able to read articles that describe results of studies in which you have participated, or other information of interest to you, and you may be able to connect with other families and communities. The information you provide may help others with ASD in the future.

We will return to you overall study results. If you agree, we may return to you limited information about the research results of questionnaires you complete about yourself and/or your minor children/dependents. We will not return adults' results from surveys filled out by others (such as parents or spouses). You may find this information useful for sharing with schools or medical professionals.

## **COSTS**

You are not expected to incur any costs for participation in SPARK.

## **PAYMENT FOR PARTICIPATION**

We are asking that the individual with ASD and both biological parents (if they are available) give sufficient saliva (spit), for you to receive \$50 in gift cards.

Samples from the individual with ASD **and** both parents will be checked to make sure there is enough saliva to study, before sending you the gift card(s). If you are the biological parent: you will receive \$25 for complete samples from yourself and your child(ren)/dependent(s) with ASD, and \$25 for a complete sample from the invited biological parent.

If you are the adoptive parent or guardian: you will receive \$25 for a complete sample(s) from your child(ren)/dependent(s) with ASD, and \$25 for complete samples from the invited biological parents (if applicable; if biological parents are not available to participate, you will still receive a \$50 gift card).

If any of you gives a saliva sample that is not sufficient to study, that person will have to send another sample, and then we will send you the gift card(s). We will send a maximum of \$50 in gift cards per family. However, if you were invited to SPARK by a family who has a member with ASD, and you have your own child(ren) with ASD completing SPARK, you also will receive a separate gift card.

If the second saliva sample is also too small to study, we may ask for another type of sample. Some families or individuals may give blood as their first sample instead of saliva, and the family will receive \$50 for the individual with ASD. We will send a maximum of \$50 in gift cards per family for saliva and/or blood samples.

You and the invited parent may be contacted with reminders, and may be entered into a drawing for an iPad or other item(s) of similar value as long as you, your child(ren)/dependent(s) and the invited parent all finish registration and send saliva kits back within a specified timeframe.

It may take several months for you to receive your gift card(s).

When you complete certain surveys about yourself or your child/dependent, you could receive up to \$25 in gift cards, earn points toward gift cards, or be entered into a drawing to win an iPad or other item of similar value. Individuals you authorize to complete surveys about you may receive the same or similar types of compensation. We will tell you which surveys will receive payment, and what the payment will be.

We will contact you periodically to check if your information has changed and you will be asked to complete some surveys online. If you sign up for more research studies in the future, there may be other additional compensation.

## **ALTERNATIVE TREATMENT**

This is not a treatment study. Your alternative is not to participate in SPARK.

## **AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

### **What information may be used and given to others?**

The study investigator Wendy Chung, MD, PhD and the study team will have access to your / your child/ dependent's personal and medical information that are provided and that result from the study. For example:

- Past and present medical records
- Research records and laboratory test results
- Survey answers
- Records about email correspondence, phone calls made as part of this research
- Personally identifying information such as name, address and email address

### **Who may use and give out information about you/ your child/ dependent?**

- The study investigators and the study staff.

### **Who might get this information?**

The Sponsor of this research, the Simons Foundation. "Sponsor" also means any persons or companies that are:

- working for or with the sponsor, such as our data consultants and contractors, or

- owned by the sponsor.

Your / your child/ dependent's information may be given to:

- Department of Health and Human Services (DHHS) agencies,
- Western Institutional Review Board® (WIRB®),
- Your or your family's SPARK Clinical Site or partner research cohort/consortium or partner organization (if applicable),
- Your clinical care providers (if you authorize them to receive it).

### **Why will this information be used and/or given to others?**

- to do the research,
- to study the results, and
- to see if the research was done right.

When the results of this study are made public, information that identifies you/ your child/ dependent will not be used. All the information you enter, and information others enter about you/ your child/ dependent, including personally identifying information, will be stored in a central database. The Simons Foundation will share some of your information with approved outside researchers after removing all information that identifies who you/ your child/ dependent are (such as name, address, and phone numbers). Information shared in this way will be associated with a unique code which may be used to link together information about you collected over time. Outside researchers will not be able to identify you / your child/ dependent using this code.

By participating in this study, you will be allowing the Simons Foundation to provide your/ your child/ dependent's research data to the National Database for Autism Research (NDAR). NDAR is a data repository for use by and for researchers from around the country. Data in NDAR will be kept without names or other identifying information and will be coded by a study ID only.

### **Additional individuals or groups who may see or receive information about you:**

SPARK study staff will share your contact information with researchers only if you give permission for us to do so and if you indicate that you want more information about an additional research study.

When you invite your child/dependent's biological parent to participate as a secondary account holder, you may give permission for them to see certain information about your shared children/dependents, such as contact information, medical records and individual results. They will not be able to see your own information about yourself. For legally independent adult individuals with ASD and adult biological siblings, no other family members will be able to see their information.



If you OR ANY of your family members were referred to SPARK by one of our designated SPARK Clinical Sites or a partner research cohort/consortium or other partner organization: This project is a multi-site collaboration among designated clinical research centers, hospitals and universities in our SPARK Clinical Site Network and other partner research cohorts/consortia and organizations (hereafter referred to as "Site"). By agreeing to participate in this study, you give us permission to obtain and use information about you and your child(ren)/dependent(s), such as psychological testing scores, medical records or genetic results, from the Site that you OR your family (primary registrant) is affiliated with (via registration, notification to SPARK or other means), AND to share your and your child(ren)/dependent(s)' data from the study (such as registration and contact information and survey results) back with that Site. This applies EVEN IF you and your child(ren)/dependent(s) are invited into SPARK or are linked by another family member and you and your child(ren)/dependent(s) were not directly seen by that Site. This is because the whole family's data is linked together. You are linked in the dataset to your registered relatives even if you did not invite them directly but they were invited by another family member. Your Site also may require a separate HIPAA Authorization form at the Site in order to share information back and forth with SPARK.

You also will have the ability to give us permission to receive information about you/ your child/ dependent such as test scores and reports from your/ your child/ dependent's other care providers. You also may give us permission to share identified data we collected about you/ your child/ dependent, such as test results, with your/ your child/ dependent's care providers (for example, your doctor).

If you choose to use the mobile app, you can choose in the app to share specific types of information with your/ your child/ dependent's providers (such as therapists). Information entered or seen on the app will be sent to the individuals you designate, and this information will be identifiable.

You will have the ability to check and change your permission for others (such as the Clinical Site) to see your information by contacting SPARK using the number or email below, or you will be able to go to your dashboard page for sharing data/authorizations on the website. You may add permission for a new Site or provider, and with your permission that Site/Provider's information will be sent to the child/dependent's other parent/guardian.

### **Is my health information protected after it has been given to others?**

Your/ your child/ dependent's health information may be further shared by the groups listed above. If shared by them, the information will no longer be covered by this Authorization. These groups are committed to keeping your health information confidential.

### **What if I decide not to give permission to use and give out my health information?**

Then you will not be able to be in this research study.

### **May I withdraw or revoke (cancel) my permission to use and disclose information?**

You may withdraw or take away your permission to use and disclose your/ your child/ dependent's identified information at any time. To change permissions for specific disclosures, such as to a Clinical Site, research cohort, partner organization or care provider, you may contact SPARK using the number or email below, or you will be able to go to your dashboard page for sharing data/ authorizations within your account on the website. If you revoke authorization only for yourself from a Site or provider, your minor child or dependent's contacts from the Site will still go to you, as the guardian. If your Site required you to sign an Authorization form, you also will have to revoke your authorization with that site.

When you withdraw your permission for a specific use or disclosure of your/your child/ dependent's identified information, for example with your Clinical Site, information that has already been gathered and used by researchers including links to your/your child/dependent's identity, cannot be taken back from them. New information will not be sent with your identity. However, if you continue in SPARK, non-identified (anonymous) datasets will be available to the Site, and it is possible the Site may be able to re-identify your data in the future.

To withdraw or cancel permission for *all* use of identified information indicated above, you must send this in writing to SPARK study staff. If you withdraw your permission for *all* use of information, you will not be able to stay in this study.

### **When does my permission expire?**

Your permission to use and disclose your/your child/dependent's information will expire at the end of the analysis of the study data.

## **VOLUNTARY PARTICIPATION AND STUDY WITHDRAWAL**

Your participation in this study is voluntary. You may decide not to participate or you may leave the study, or may decide for your child/ dependent not to participate, or to leave the study, at any time. You do this by sending written notice to SPARK. Your decision will not result in any penalty or loss of benefits to which you are entitled.

When you withdraw from the study, data that has already been used by researchers or others cannot be taken back from them, but your information will not be included in future research.

Your/ your child/ dependent's participation in this study may be stopped at any time by the study researcher or the sponsor without your consent for any reason, including:

- If it is in your / your child/ dependent's best interest.
- You do not consent to continue in the study after being told of changes in the research that may affect you.

## **CONFIDENTIALITY OF INFORMATION COLLECTED FOR RESEARCH PURPOSES**

We will take steps to keep your personal information private, but we cannot guarantee total confidentiality. All identifiable information about you/ your child/ dependent will be replaced with a study code. A list linking the code and your identifiable information will be kept separate from the research data. All research data and records will be stored electronically on a secure database with encryption and password protection to help prevent unauthorized access to your personal information. We will not release information about you/ your child/ dependent to others not listed above. Our contracting third party online survey and database service providers and consultants have agreements with us that they will keep all information confidential. We will not use your/ your child/ dependent's name or your identity for publication purposes, unless we have your special permission. Your research data and records may be kept indefinitely by the study Sponsor.

To help us protect your privacy, *we have obtained a Certificate of Confidentiality from the National Institutes of Mental Health*. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below:

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from **voluntarily** releasing information about your child, yourself, or your involvement in this research. Note also, that if an insurer or employer learns about you and/or your child's participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

You have been asked to provide information to create a unique identifier for the National Database for Autism Research (NDAR). As a reminder, NDAR is a biomedical informatics system and data repository, created by the National Institutes of Health to assist biomedical researchers working to develop a better understanding of autism and/or to develop more effective methods to diagnose, treat and prevent autism spectrum disorders. Data entered into NDAR will be kept confidential, with NDAR being designed for access by researchers only. Data provided to NDAR as part of you and/or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to NDAR will retain individually identifying information related to the data they provide, NIH has issued a legislatively authorized certificate of confidentiality that will help NDAR and participating institutions avoid being forced to disclose information that may identify you as an NDAR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Finally, you should understand that we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you, your child, or others. With respect to you and/or your child's participation in NDAR, we do not plan to make voluntary disclosures except

if there were severe threats to the public health or safety.

## **SOURCE OF FUNDING FOR THE STUDY**

The sponsor, the Simons Foundation, will pay for this research study.

## **QUESTIONS**

Contact SPARK at 1-844-54-SPARK or [info@SPARKforAutism.org](mailto:info@SPARKforAutism.org) 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.
- 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:

Western Institutional Review Board® (WIRB®)  
1019 39th Avenue SE Suite 120  
Puyallup, Washington 98374-2115  
Telephone: 1-800-562-4789 or 360-252-2500  
E-mail: [Help@wirb.com](mailto:Help@wirb.com)

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

If you agree to be in this study, you will have the opportunity to print this consent form for your records.

## **CONSENT FOR MYSELF AND MY CHILDREN**

I have read this consent form (or it has been read to me). 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 authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

I agree to participate in SPARK.

**I agree for my children indicated below to participate in SPARK.** I authorize the use and disclosure of my child's health information to the parties listed in the authorization section of this consent for the purposes described above.

**ASSENT, for Children age 10-17 or Dependents with a Legally Authorized Representative**

Statement of parent/ guardian/ LAR:

- I have explained all aspects of the research to the best of his or her ability to understand.
- I have answered all his or her questions relating to this research.
- My child/ dependent agrees to be in the research.
- I believe his or her decision to enroll is voluntary.
- I agree to respect my child/ dependent's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

**OR**

- My child/dependent is not able to assent due to lack of mental capacity.

My minor child/ren or the adult/s for whom I am the legally authorized representative appears to understand the research to the best of his or her ability and has agreed to participate.

BY SIGNING THIS DOCUMENT, I CERTIFY THAT I AM THE COURT-APPOINTED LEGAL GUARDIAN (OR POWER OF ATTORNEY OR PROXY PERMITTED BY LAWS OF MY STATE) 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.**

By signing this document I certify that I am the legal guardian of the child/children/dependent/s listed above.

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