PEOPLE-POWERED MEDICINE

About this consent form

Please read this form carefully. This form provides important information about participating in research. You have the right to take your time in making decisions about your participation in this research. You may discuss the decision with your family, friends, and/or your doctor. If you have any questions about the research or any portion of this form, please ask us. If you decide to participate in this research, you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

All forms, including this one, are available on the project website. They are intended to help you make an informed decision about your participation. The website will be updated regularly, so you should check the site often to obtain the most current information about the study.

Participation is voluntary

You are invited to take part in this research because you have autism or autism spectrum disorder (ASD). It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping participation will involve no penalty or loss of benefits to which you are otherwise entitled.

What you should know about a research study:

- A research study is something you volunteer for.
- Whether or not you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide, it will not be held against you.
- Feel free to ask all the questions you want before you decide. A member of our research team is available to communicate with you about taking part in this research study if you have questions. Contact information can be found at the end of this consent form.

What is the purpose of this research?

An ongoing barrier to understanding and treating medical conditions is obtaining information that goes beyond what we normally collect during a clinical evaluation at a doctor's office, hospital, or with a developmental specialist. This information can include environmental exposures, treatments at home, other medical conditions, activities, and literally hundreds of other facts. There has been a shift in the amount of health data coming from healthcare institutions in relation to data gathered from "extra-institutional" efforts that are led by companies, patient advocacy organizations, or self-motivated individuals using consumer web applications and devices that connect to the Internet. Examples may include data sent to or processed by web applications, internet-connected devices like wearable fitness wrist-bands (e.g., Fitbit™), and social media websites like Facebook and Twitter.

This study (People-Powered Medicine) is a pilot project of the Department of Biomedical Informatics at Harvard Medical School to collect data on a small group of approximately 100 participants to understand

the usefulness of this data for scientific research and to determine its quality. Through this study, we hope to understand the effort required to (i) recruit participants; (ii) obtain and curate data (meaning to organize, sort, and categorize data); and (iii) make that data available to the participant or their legal caregiver. We hope that the knowledge we gain during this pilot study will help us to develop long-term studies in the future, through which data collected could be used by researchers to study particular medical conditions. However, the data provided for this study will not currently be available to other researchers for studies. We only wish to understand the process and feasibility, as well as the quality of data that we obtain.

Recruiting participants

Through this study, we will test the idea that social media (such as Facebook and Twitter) and the internet can be used to recruit, consent (obtain permission), and enroll individuals in a research study. Because this study is a pilot project, we have decided to focus on individuals with one common medical condition. As a result of our extensive expertise and previous research experience with autism and ASD, we chose to focus our recruitment on individuals with autism or ASD for the purposes of this study.

Obtaining and collecting data

We will combine, sort, and categorize data collected by institutions in healthcare settings such as hospitals, clinics, doctor's offices, or other places of care. In order to do this, we will create and test a computer model for storing and analyzing this data in a secure database. By doing this, we hope to better understand the scientific value of data that comes from a wide variety of sources related to people with a particular medical condition.

Making data available to the participant

Another goal of the People-Powered Medicine study is to collect and combine as much data as possible about you so that participants can have access to this data all in one secure location. This will allow you to have access to your combined medical information so that you can easily share it with anyone, including clinicians and other researchers, as you see fit.

How many people will take part in this research?

About 100 people will take part in this pilot research study.

How long will I take part in this research?

Your active participation in the study will last approximately 6 months, from the time of initial consent and obtaining data (including saliva sample, if you provide one) through the time of the follow-up questionnaire. The duration of the entire observational study will be 3 years.

What can I expect if I take part in this research?

As a participant, you can expect the following:

- We will ask for permission to access your public social web presence on Facebook and Twitter, if you have accounts.
  We will only access publically-available data from these accounts. The Facebook 'Settings' option (accessed in the dropdown menu under the down arrow at the right top of the page) allows users to check and change general settings for the account, security options, privacy settings,

including which posts are seen by the public, as well as public post specific options. Posting options that are set to be seen by “Everyone” are considered public posts and will be accessed for the purposes of this study. Because Facebook is frequently updated, we recommend routinely checking your privacy settings.

- We will request the zip code where you primarily live to determine potential environmental risks and exposures that you may have.
- We will collect data through internet applications, specifically by means of software (web pages backed by computer code) to administer a questionnaire, or through networked hardware devices (specifically your smartphone and/or Fitbit™) that gather data from the individual and also can feed information back to the individual. Information collected include profile information (such as height, weight, stride length, time zone, location), activity information (such as steps, distance, calories burned, active minutes), heart rate, nutrition, sleep, and information about weight.
- If you agree to provide a saliva sample, we will send you a kit and instructions for obtaining and returning this sample. Because this study aims to understand what is involved in collecting and analyzing data of all types in one location, including genetic (DNA) data to better understand and study particular medical conditions, samples we collect will be stored initially and later analyzed. In doing so, we hope to understand the quality of genetic data that comes from the saliva samples and the process required for obtaining and analyzing it. . You will have access to the raw genetic testing results (just the genetic code), but you will not receive any interpretation of this data. This is because the analysis being done is only good for research purposes and is not reliable for clinical or diagnostic purposes.
- We will ask you to give us permission to obtain a copy of your electronic health record (also known as an “EHR”) from the hospital systems or practices where you have obtained care. This copy can be in the form of a fax, pdf, or other format. Regardless of the format, a digital form of the data will be entered into the study database.
- We will ask you to complete an online questionnaire about your family medical history and other conditions you may have.
- We will ask you if you are willing to participate in future surveys/questionnaires and seek your permission to contact you with occasional questionnaires. These will never occur more frequently than twice a year and will be no longer than 10 questions each.
- In addition to this consent, participants who wear a Fitbit™ for the purposes of this study must agree to the Fitbit™ terms of service, end user license agreement, and privacy policy. Participants who choose to wear a Fitbit™ will be required to create a Fitbit™ account on Fitbit.com and agree to the terms of service listed (https://www.fitbit.com/legal/terms-of-service). If you do not agree to the terms of service, please opt out of wearing the Fitbit™ at the end of this consent form. ++ An account is required in order to gather the data from the Fitbit. The data is stored in the Fitbit™ as it is being collected until it is uploaded to the Fitbit™ servers using the web application. After the participant grants us permission, we will obtain the data from Fitbit™ servers on their behalf and store it alongside the other data we have collected for that participant. ++ You will be allowed to keep the Fitbit™ after your participation has ended.

What are the risks and possible discomforts?

There are possible risks, discomforts, and inconveniences associated with any research study. This study does not involve testing any new drugs or therapies, so we do not expect any medical side effects from participating. However, you may feel inconvenienced by having to enter information into an application or website, or seeing the reminders or messages sent through an application or website. Also, some of the data that you provide may be sensitive, such as medical information and genetic information. While it is unlikely that someone outside this study could gain access to this information, if it were to happen, there could be disadvantages, such as social stigma related to certain medical diagnoses, that occur. This risk is something that we deal with and manage routinely in the projects we are involved with. Therefore, we take extreme measures to help ensure the privacy and security of your data. Your data is only

accessible to trained staff approved to work on this project and an agreement is in place between Amazon Web Services (the cloud environment where your data is stored) and Harvard Medical School to help protect personal health information.

This study involves third parties such as Facebook and Twitter for recruitment and for obtaining data. Therefore, interest in this study (through visiting our public Facebook page or viewing our public tweets) may be viewable to Facebook and Twitter administrators. Additionally, if an individual chooses to "Like" our public Facebook page, this may be viewable to other Facebook users in addition to Facebook administrators. Finally, an optional Facebook "secret group" will be created for study participants who wish to converse about the study. While this group is not viewable to public users and is only able to be viewed by individuals who are part of the group (invited to join by the group administrators), it may be possible for Facebook administrators to see who is interested in the study and who is part of the Facebook group.

Are there any benefits from being in this research study?

- One benefit of this effort is that we will organize your data into a single electronic package, making it available to anyone you choose to designate. This will make it easier to use your data however you wish, including sharing it to support other research efforts.
- You receive occasional updates about research results in autism and ASD that may be relevant to you.
- Participants who agree to wear a Fitbit for this study will be allowed to keep the Fitbit after their participation has ended.
- Apart from direct benefits to you, society and the community at large may benefit from knowledge obtained in the research.

What are my alternatives to participation in this research?

The alternative to participating in this research study is not to participate. You may also withdraw your consent and discontinue participation at any time. If you choose to withdraw we will destroy all data provided by you since enrollment in this study.

Will I be compensated for participating in this research?

You will not be compensated for participating in this research.

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

What happens if I am injured as a result of participating in this research study?

Although we do not expect any physical injuries from participation in this study, should physical injury occur resulting from participation in this research, Harvard's policy is not to provide compensation, but medical treatment will be available including first aid, emergency treatment, and follow-up care as

needed, and your insurance carrier may be billed for the cost of such treatment. In making such medical treatment available, or providing it, the persons conducting this research project are not admitting that the injury in question was their fault.

Can my participation in the research end early?

You may decide not to continue in the research at any time without it being held against you. The person in charge of the research can remove you from the research at any time, for any reason, without your approval.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

We take several steps in our commitment to protect the privacy and security of your data:

- Data will be held in secure physical structures that have guarded and credentialed access.
- Researchers must be approved by the Harvard Medical School (HMS) Institutional Review Board (IRB) prior to being able to see identifiable data. AWS administrators may also have access to the data. Amazon Web Services (AWS) administrators are under contract and bound by policy to not examine data without specific permissions from HMS or Harvard. However, the data may be subject to subpoena without Harvard's knowledge.
- We apply policies that ensure that only authorized people associated with research related activities will have access to the data.
- We will never sell your data to third parties.
- Your data is overseen by staff trained in applying leading data privacy and security frameworks.
- Under the U.S. Health Insurance Portability and Accountability Act of 1996, a HIPAA business associate agreement (BAA) is a contract between a HIPAA-covered entity and a HIPAA business associate (BA). The contract protects personal health information (PHI) in accordance with HIPAA guidelines. A BAA is in place between HMS and AWS to help ensure privacy and HIPAA-level security of the data we store in their cloud. We will also adhere to other professional, ethical, and federal regulatory standards protecting health information and research data.
- Your data will not be shared with your health care provider without your permission and will not become a part of your medical record.
- The results of this research may be published in a scientific or medical research journal or at conferences so that others can learn from this study. Results will never be published in a way that would allow data to be associated with individual participants.

The following people might see information about you:

- Research staff and study administrators approved by the IRB to work with the data.
- People or groups that are hired to provide services related to this research, such as obtaining your medical records for us.
- Federal and/or state agencies that oversee research or others as required by law.
- Data collected, including identifiable information, may be seen by the Harvard Institutional Review Board (IRB) that oversees the research and/or the Quality Improvement Program.

If the quality of data that we obtain through this study is such that we wish to allow researchers to use the data for future study on autism and ASD, we may seek out additional funding to do so. However, we will contact you to discuss and obtain your permission at that time, and you will have the option of requesting that your data not be included in other studies.

Because you will have access to your consolidated participant profile, we must retain your information in order to enable this access. If for any reason we can no longer support this access, we will offer you the opportunity to request and receive a hard copy of your entire profile. If you decide to share private

information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have any questions about this, please contact us.

If I have any questions, concerns, or complaints about this research study, who can I talk to?

A member of our research team is available to communicate with you about taking part in this research study if you have questions. You can contact Cassandra Perry, People-Powered Medicine (PPM) Project Manager, at 617-432-5484 or at Cassandra_Perry@hms.harvard.edu.

The Principal Investigator of this study is *Isaac Kohane, MD, PhD*. He can be reached at *617-432- 2145*:

- If you have questions, concerns, or complaints,
- If you would like to talk to the research team,
- If you think the research has hurt you, or
- If you wish to withdraw from the study.

This research has been reviewed by a Harvard Longwood Medical Area Institutional Review Board (Harvard Faculty of Medicine or Harvard T.H. Chan School of Public Health). If you wish to speak with someone from the IRB, please contact the Office of Human Research Administration (OHRA) at 617-432- 2157 (or toll-free at 1-866- 606-

573. or 90 Smith Street, Boston, Massachusetts 02120 for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Authorization to Use and/or Share Protected Health Information (PHI)

Federal law requires Harvard Medical School to protect the privacy of health information that identifies you. This information is called Protected Health Information. In the rest of this section, we refer to this simply as “health information.”

If you decide to take part in this research study, your health information may be used within Harvard Medical School and may be shared with others outside of Harvard Medical School.

We have marked with a ☒ how we plan to use and share your health information. If a box is not checked ☐, it means that type of use or sharing is not planned for this research study.

- **Health information about you that might be used or shared during this research**

  x Information from your hospital/clinic records within this institution or elsewhere, that may be reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside this institution, you will be asked to give permission for these records to be sent to researcher(s) conducting this study.

  x New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

- **Why health information about you might be used or shared with others**

  The reasons we might use or share your health information are:

  - To do the research described above
  - To make sure we do the research according to certain standards – standards set by ethics and law, and by quality groups
  - For public health and safety – for example, if we learn new health information that could mean harm to you or others, we may need to report this to a public health or a public safety authority
  - For treatment, payment, or health card operations
- **People and groups that may use or share your health information**

  1. **People or groups within this institution**

     x Researchers and the staff involved in this research study

     x Harvard review board that oversees the research

     ☐ Staff within this institution who need the information to do their jobs (such as billing, or for overseeing quality of care or research)

  2. **People or groups outside the institution**

     x People or groups that we hire to do certain work for us, such as data storage companies, our insurers, or our lawyers

     x Federal and state agencies such as the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protection, and other U.S. or foreign government bodies, if required by law or involved in overseeing the research

     ☐ Organizations that make sure hospital/clinic standards are met

     ☐ The sponsor(s) of the research study, and people or groups it hires to help perform this research study

     ☐ Other researchers and medical centers that are part of this research study

     ☐ A group that oversees the data (study information) and safety of this research study

     ☐ Other:

- **Time period during which your health information might be used or shared with others**

  Because you will have access to your consolidated participant profile, we must retain your information in order to enable this access. Thus, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your Privacy Rights

- You have the right **not** to sign this form permitting us to use and share your private information for research. If you **do not** sign this form you cannot take part in this research study. This is because we need the private information of everyone who takes part.
- You have the right to withdraw your permission for us to use or share your private information for this research study. If you would like to withdraw your permission, you must notify the person in charge of this research study in writing.

- If you withdraw your permission, we will not be able to take back any information that has already been used or shared with others. This includes information used or shared to carry out the research study or to be sure the research is safe and of high quality.
- If you withdraw your permission you cannot continue to take part in this research study.
- You have the right to see and get a copy of your private information. To ask for this information, please contact the person in charge of this research study.

Signature

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

Please indicate if you DO NOT wish to provide a saliva sample for this study. Saliva samples will be stored and later analyzed for genetic data.

- [ ] I DO NOT WISH TO PROVIDE A SALIVA SAMPLE FOR THIS STUDY.

Please indicate if you DO NOT wish to wear a Fitbit™ for this study.

- [ ] I DO NOT WISH TO WEAR A FITBIT™ FOR THIS STUDY.

Please indicate if you DO NOT wish to be contacted with additional questionnaires for this study.

- [ ] I DO NOT WISH TO BE CONTACTED WITH ADDITIONAL QUESTIONNAIRES FOR THIS STUDY.

I agree to participate in the study.

(Typing your name below acts as your signature and indicates your permission to take part in this research.)

Name of participant

Signature of participant (Please type your name)

Date