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 are an exceptional responder, a person who has had a unique response to cancer treatments that are not effective for most other patients. 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: Exceptional Responders) is a project of the Department of Biomedical Informatics at Harvard Medical School to collect data on approximately 100 participants who are exceptional responders to cancer treatments. Through this study, we will create a registry of data from individuals who are exceptional responders. In doing so, we also hope to understand the effort required to (i) recruit participants; (ii) obtain and curate the data (meaning to organize, sort, and categorize data); (iii) make that data available to the participant or their legal caregiver, and (iv) make this registry of data, all de-identified, available to qualified researchers who are approved to use the data for research on exceptional responders. We hope that the knowledge we gain during this study will not only help us to create additional long-term studies in the future, but will also help researchers to identify commonalities among exceptional responders and, ultimately, benefit others battling cancer who may have similar characteristics.

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.

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 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 blood sample, if you provide it) through the time of the additional questionnaires. 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 publicly-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 questionnaires, 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 may 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 blood sample, we will work with you to have a blood sample obtained at

a laboratory local to you. The amount of blood taken will be approximately 2 teaspoons. 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 analyzed for their genetic information.

- We will ask you for permission to access any tumor samples (for example, from biopsies that you may have had done in the past) that might be available so that we can look at the genetics of the tumor.
- 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. To do this, in most cases we will use the services of PicnicHealth, a company that specializes in obtaining medical records and digitizing them. We will also obtain records from clinical or pre-clinical trials that you have participated in, whenever possible. 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 additional questionnaires related to this study. These will take no longer than 10-15 minutes each and you may choose whether you wish to answer each questionnaire as you receive it. Questionnaires will be emailed to you with an explanation and a link to access the questionnaire online.
- In addition to this consent, participants may be asked to wear a Fitbit® for the purposes of this study. Those who agree to wear one must agree to the Fitbit® terms of service, end user license agreement, and privacy policy. If you choose to wear a Fitbit®, you 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 (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 you grant us permission, we will obtain the data from Fitbit® servers on your behalf and store it alongside the other data we have collected for you.
    - You will be allowed to keep the Fitbit® after your participation has ended.
- Data obtained from you for this study will be de-identified (all identifying information will be removed, and it will be given a study ID number) and combined with the de-identified data from other exceptional responders who are part of this study into a single database. The database will then be accessible to qualified investigators approved to do research using the data. The use of this database will be overseen by the Department of Biomedical Informatics.

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. Additionally, some of the data that you provide may be sensitive. We take the privacy and security of your data seriously, and we will implement robust data protection measures to safeguard the data, but we cannot guarantee complete privacy and confidentiality. As with any study involving genetic testing, there is a risk of social and economic disadvantages if genetic information is disclosed to the wrong source.

Additionally, there are risks associated with any blood draw. If you choose to provide a blood sample, these risks may include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting.

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 "closed group" will be created for study participants who wish to converse about the study. This group will be viewable to public users, but individuals must request to join and be accepted by group administrators before they can view posts and members. Only individuals who are participants of the study will be accepted into the closed group. However, 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.
- 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 and samples 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.
- Study staff 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.
- Oncologists approved by study staff may be enlisted as expert advisors to assist with determining eligibility of registrants. Only de-identified data will be made available to the advisors, and only when necessary to determine exceptional response status.
- 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.
- Outside investigators approved by the Department of Biomedical Informatics to access de-identified data contained in the registry for research purposes.
- 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.

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 1-866-606-0573) 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 blood sample for this study. Saliva samples will be stored and later analyzed for genetic data.

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

Please indicate if you DO NOT give us permission to access samples from your tumor that may be stored (for instance, from previous biopsies).

- [ ] I DO NOT GIVE PERMISSION FOR MY EXISTING TUMOR SAMPLES TO BE USED 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 and to be contacted in the future for additional information.

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

Name of participant

Jane Smith

Signature of participant (Please type your name)

Jane Smith

Date

02/12/2021