

Kaiser Permanente Research Bank Consent Form

Kaiser Permanente (KP) is committed to using research to help improve the health of KP members. If you decide to join the KP Research Bank:

1. You will be asked to fill out a health survey, give a blood sample, and allow us access to your health record at KP.
2. We will store your data indefinitely. Your blood sample may be used for genetic research. Only research projects approved by the KP Research Bank can use the data and samples you share.
3. You can help researchers make discoveries to improve the health of people in the future. But you should not expect any personal health benefits from joining.
4. We will do everything we can to protect your privacy. But there is still a very small chance that an unauthorized person could access your information.
5. Your participation is voluntary. You can withdraw (quit) at any time.

This form gives information to help you decide if you want to join. You should read the form carefully. You can find more details on our website at kp.org/researchbank. Please let us know if you have any questions. You can call us (844-248-2447) or email us (ResearchBank@kp.org).

1. WHAT IS THE KAISER PERMANENTE RESEARCH BANK?

The KP Research Bank collects and stores blood samples and health data from KP members who join. Researchers can use these samples and health data for many studies. By looking for patterns, researchers can learn more about how genes (DNA), lifestyle, and the environment affect health. The goal is to improve the health of KP members and the community.

We are inviting all adult members of KP to join.

2. WHAT WILL WE ASK YOU TO DO?

If you agree to join, please sign this consent form on paper or online. We will give you a copy to keep. Here is what will happen after you sign this form:

1. We will ask you to give us permission to collect data from your medical record. There is another form called “Authorization to Use Health Data for Research” for you to sign.
2. We will ask you to fill out a health survey. The survey will take about 20 minutes. You can do it now or come back and finish it later.

3. We will ask you to give us a blood sample. We will send you instructions for giving the sample. After you get the instructions, your blood can be drawn during a regular KP lab visit. A KP lab staff will draw about 2 tablespoons of blood from your arm.

3. WHAT DATA WILL WE COLLECT FROM YOU?

- **Electronic medical records.** We will collect data from your electronic medical records at KP. For example, we may get data about your health problems, test results, medical procedures, images (such as X-rays), and medicines. We will access your medical record from time to time to get the most updated data.
- **Survey Data.** In the health survey, we will ask you questions about your health, habits, family, home, and work. You do not have to answer any question you do not want to answer. We will not share your answers with your doctors.
- **Samples.** Researchers may use your sample to study many things about you including your genes (DNA). For example, we may use genome sequencing or other genetic analyses to turn your sample into genetic data. Genome sequencing is a way to map out a person's entire genetic code. We may also collect leftover samples taken from you during the normal care that you get at KP. These samples might include tissue removed during surgeries, biopsies, or blood from routine lab tests.
- **Other Data.** We will add data from other sources based on the information you give us. For example, based on where you live and work, we may add data about the number of people that live in your area and air pollution data.

4. WHAT WILL WE DO WITH YOUR DATA AND SAMPLE?

- We will store your data and samples securely, along with the data and samples from all the other people who take part in KP Research Bank. We plan to store your data and samples indefinitely unless you withdraw.
- Researchers may apply to use data and samples in the KP Research Bank for their health research projects. These researchers might work at KP, universities, the government, non-profit companies, or for-profit companies (such as drug companies). A group of scientists, ethicists, and community members at the KP Research Bank will review each project request. We will only share data and samples with researchers if a project is approved by the review group.
- Scientists may link your genetic data to your medical records and survey data to study how genetic differences between people are linked to health problems like cancer, heart disease, diabetes, and other conditions that many people have.
- Some of your data (along with data from many other people) may be put into health research databases (such as the National Institute of Health's [dbGaP](#)). Many researchers and research banks add to these databases. By combining data from many places and sharing data with each other, these databases let more researchers study and find ways

to improve health. Any data added to these databases will not have your name or other information about your identity connected to them.

5. WHAT ARE THE BENEFITS OF THE RESEARCH BANK?

You can help researchers make discoveries to improve the health of people in the future. You most likely will not get direct personal benefit from joining the KP Research Bank.

6. ARE THERE ANY COSTS OR PAYMENTS?

- There are no costs to you or your insurance for joining.
- You will not be paid for joining KP Research Bank.
- KP will not sell or trade any samples or data gathered for the KP Research Bank for profit. If research results someday lead to the development of a test, drug, or other commercial product, any financial benefits to KP will be used to support research in the public interest. You will not be paid, and neither will KP employees.

7. WILL I GET PERSONAL RESULTS FROM THE RESEARCH?

You should not expect to get personal results from research done through the KP Research Bank. Researchers study samples and data from many people over many years before they know if the results have meaning. Research is not the same as medical care. If you have any health concerns, please talk to your doctor.

There is a very small chance that researchers could discover something that might be very important to your health. If this happens, KP researchers and doctors will work together to see if this could impact your medical care. If so, we will contact you to see if you want to learn more. We will not give the results to your doctor or put them in your medical record without your permission.

8. WHAT ARE THE POSSIBLE RISKS?

The most common risk of joining is brief pain and bruising when you give your blood sample. There is also a risk that an unauthorized person could get access to the stored health data and samples. We believe the chance this will happen is very small and we will do everything we can to protect your privacy. There may also be other risks that we currently don't know about.

9. HOW WILL THE KP RESEARCH BANK PROTECT MY PRIVACY?

Your privacy is very important to us and we will make every effort to protect it. These are the ways your data and samples will be protected:

1. Your data will have the same level of protection as the data in your medical record. Your data is stored on protected computers with the most up-to-date electronic security. We regularly update our security measures.
2. We will remove your name and other information about your identity from your samples and data. We will replace them with a code. All KP Research Bank staff have privacy protection training and sign agreements to protect your privacy.
3. We will limit and track who sees your data. We will give researchers only data and samples that are needed to do the research study. We will not share your name or other information about your identity outside KP without your permission. Researchers who study your samples and health data must sign a contract to protect your privacy. They must also promise not to try to find out who you are.
4. We have a [Certificate of Confidentiality](#) from the US government. This means that any information that might identify you cannot be used in any lawsuits or as evidence unless you agree to it.
5. Your genetic information is protected by a federal law called GINA ([Genetic Information and Non-discrimination Act](#)). GINA makes it illegal for employers and health insurers to discriminate against you based on your genetic information. GINA will not protect you from discrimination if you apply for other kinds of insurance, such as life or disability insurance.

10. WILL YOU CONTACT ME AGAIN?

- We will not notify you every time your sample and data are used for research.
- We may contact you with offers to join other research studies. If you are contacted for a new study, you can decide to join or not. We will not contact you more than 4 times per year.
- Over time, some of the sample you gave us may be used up. We will let you know if another sample is needed. You can decide if you want to give another sample.

11. DO I HAVE TO PARTICIPATE IN THE KP RESEARCH BANK?

No, you do not have to. You can decide to join or not. Your decision will not affect your medical care.

12. CAN I STOP PARTICIPATING IN THE RESEARCH BANK?

Yes, you can change your mind and stop participating at any time. If you want to withdraw (quit), please let us know. You can tell us by contacting us using the information below. After you let us know you want to withdraw, we will not use or share your samples and data with anyone else in the future.

You cannot remove your samples and data from research studies that have already started. We cannot get back samples or data that have already been given out to researchers.

13. WHAT IF I HAVE QUESTIONS?

If you have questions about:	Please Contact:
The KP Research Bank, or wish to withdraw from the study	<p>The Kaiser Permanente Research Bank Michael Horberg, MD, MAS, Principal Investigator 1800 Harrison St., Oakland, CA, 94612</p> <p>The KP Research Bank Contact Center Phone: 844-268-2947 (toll free) Hours: Monday to Friday, 8am-6pm Pacific Time (11am - 9pm Eastern, 9am - 7pm Mountain, 5am - 3pm Hawaii) Email: ResearchBank@kp.org Website: https://researchbank.kaiserpermanente.org</p>
Your rights as a study participant, or if you have comments or complaints about KP Research Bank	<p>Institutional Review Board for the Protection of Human Subjects Kaiser Permanente Mid-Atlantic Permanente Medical Group 2101 East Jefferson Street, Rockville, MD 20850 Phone: 301-816-6572 or toll-free 1-877-258-0017</p>

Consent Statement: You voluntarily agree that your samples (blood, urine, tissue, saliva, etc.), survey answers, and health information can be stored in the KP Research Bank as described in this consent form.

If you sign here it means you agree to join the KP Research Bank.

Signature of participant or participant's personal representative

Date

Printed name of participant or participant's representative's personal representative

If applicable, a description of the personal authority to sign for the participant

Authorization to Use Health Data for Research

If you sign this document, you give permission to the Kaiser Permanente (KP) Research Bank to use or disclose (release) health information that identifies you for the research described below:

The KP Research Bank will be disclosing only the information that is needed for research. The health information that the KP Research Bank may use or disclose for research includes:

- Information about your health such as diagnoses, test results, health procedures, X-rays and other images, or medicines you take
- Information from health surveys and related to the samples you provide for research
- Information that uniquely identifies you, which may be used for the purpose of linking data for research.
- Samples, such as blood or cells, that were withdrawn from you and given to the lab during medical care that are left over and no longer needed

If you choose to participate, samples and information from the KP Research Bank will be shared with researchers from Kaiser Permanente (Kaiser Foundation Hospitals & Health Plan and the Medical Groups) and elsewhere (such as universities, companies, or non-profit organizations) for research studies that have been approved by an Institutional Review Board (IRB). An IRB is a committee of scientific, non-scientific, and community members who review research to protect the rights and welfare of participants.

The health information listed above may also be disclosed (released) to:

- An Institutional Review Board (IRB)
- The National Institutes of Health (NIH) to share in a research database maintained by the NIH. The database can be used by NIH-approved researchers around the world. KP is required by law to protect your health information.

By signing this document, you authorize KP to use or disclose your health information for this research. KP has agreements with other organizations to protect your health information.

In addition, KP might use and disclose your information and share your sample for future research studies as described in this document and the consent form.

You do not have to sign this Authorization. If you do not sign, you will not be included in the KP Research Bank. If you decide not to join now, or if you withdraw your consent later, your decision will not affect your routine health care or health benefits with KP.

You may change your mind and revoke (cancel) this Authorization at any time. After the KP Research Bank receives your request to revoke this Authorization, only data that has already been looked at or disclosed will continue to be used, unless there is a need to monitor your data for safety purposes.

If you wish to withdraw from your agreement, you must notify the Principal Investigator of the KP Research Bank in writing at:

Michael Horberg, MD, MAS
Principal Investigator
Kaiser Permanente Research Bank
2101 East Jefferson Street, 3E, Rockville, MD 20852

You may also withdraw by contacting the KP Research Bank by phone at 844-268-2947 or by email at ResearchBank@kp.org

This Authorization will not expire unless you cancel it. It is permissible for use in research, including the creation and maintenance of a research database or repository.

Summary of the agreement:

1. You permit the KP Research Bank and their approved research colleagues to use and disclose your protected health information (PHI) for the purpose of research.
2. You understand that if you do not approve this use, you cannot participate in the KP Research Bank.
3. KP researchers and their approved research colleagues will use your PHI, including your research and/or medical record information as well as your samples (e.g. blood, saliva, or tissue) to conduct approved research studies. This also includes information you give researchers during your participation in the KP Research Bank.
4. You understand that your health information can be stored in a data base maintained by the National Institutes of Health (NIH) and can be shared with other approved researchers.
5. If you decide that you no longer want to have your PHI used or disclosed as part of the KP Research Bank, you will write a letter stating that you want to withdraw your authorization and send it to the address provided.

You have read this authorization, all of your questions have been answered, and you agree to allow the use and disclosure of your health information for the research as described above.

Signature of participant or participant's Representative

Date

Printed name of participant or participant's personal representative

If applicable, a description of the personal representative's authority to sign for the participant



Kaiser Permanente Research Subjects Bill of Rights

Any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to be informed that they have the following rights. You have the right to:

1. Be informed of the nature and purpose of the research.
2. Be given an explanation of the procedures to be followed in the medical research, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the research.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the research if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the research if complications should arise.
7. Be given an opportunity to ask any questions concerning the research or the procedures involved.
8. Be instructed that consent to participate in the medical research may be withdrawn at any time and the subject may discontinue participation in the research without prejudice.
9. Be given a copy of the written consent form.
10. Be given the opportunity to decide to consent or not to consent to the medical research without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

California Research Subjects Bill of Rights

California law, under Health & Safety Code §24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to be informed that they have the following rights. The Bill of Rights must be written in a language in which the person is fluent. You have the right to:

1. Be informed of the nature and purpose of the research.
2. Be given an explanation of the procedures to be followed in the medical research, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the research.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the research, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the research if complications should arise.
7. Be given an opportunity to ask any questions concerning the research or the procedures involved.
8. Be instructed that consent to participate in the medical research may be withdrawn at any time and the subject may discontinue participation in the research without prejudice..
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to the medical research without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.