

Kaiser Permanente Research Bank Research Consent Form

Kaiser Permanente (KP) is committed to using research to help the health and well-being of KP members. One way to do this is to collect and store human samples, such as blood, urine, saliva, or tissue, and connect them to health information from the member's health record.

- With your permission, the KP Research Bank will “bank” your sample and health information to share with KP scientists and other researchers. To protect the privacy of our members, the KP Research Bank does not store your name, address, social security numbers, or other ways to identify you on the samples or information collected. The KP Research Bank uses a special number on the samples and information. Only KP Research Bank staff knows how to link the special number to your name or medical record number. The KP Research Bank project is funded through Kaiser Permanente.
- The KP Research Bank has been reviewed and approved by a KP Institutional Review Board (IRB). An IRB is a committee of scientific, nonscientific, and community members who review research to protect the rights and welfare of participants. This type of check makes sure that any risks are minimized and that your rights and welfare are guarded.

What is the purpose of the KP Research Bank?

The KP Research Bank aims to help scientists find new ways to prevent or treat health problems.

- Scientists will use the samples and information in the KP Research Bank to study how genes and other things, such as the environment or lifestyles and habits, are linked to specific health problems.
- Genetic research involves looking at information in your cells called DNA. Information about your genes comes from DNA, which is in the cells in your blood, your saliva, or other tissues in your body.
- Genes determine your eye color, how you respond to certain medicine, or other things that may affect your health. Future research may lead to new products, such as drugs or tests for diseases.

How many people will take part in the KP Research Bank?

The KP Research Bank is inviting all adult members of KP to take part. The KP Research Bank has a goal of getting 500,000 members to join the project. Over 200,000 members have already joined by giving a sample.

How do you participate?

If you agree to participate, here is what will happen:

- 1. The KP Research Bank will ask you to sign the Consent and the Authorization to Use or Disclose (Release) Health Information form given here.**
 - You will be sent a copy of the form if you decide to join.
 - You will have the option to print the form for your records if you sign up online.
- 2. The KP Research Bank will ask you to answer a survey.**

After giving consent, you will be asked about your lifestyle, your family's health history, and about habits that may affect your health (such as exercise and diet). The survey takes about 20 minutes and can be done online or on paper. You can take the survey at any time that works for you. You can take the survey before or after you provide a sample.

3. *The KP Research Bank will ask you to give a small sample (less than 2 tablespoons) of blood.*

- The KP Research Bank will send you a letter with instructions for getting your blood drawn when you visit your usual KP health office or lab for care, or at a time that works for you. You can provide your sample before or after you take the survey.
- The KP Research Bank can use your sample to get different parts of your blood like serum (the liquid part of the blood), white and red blood cells, and genetic information like DNA.

4. *The KP Research Bank will collect information from your health records at Kaiser Permanente.*

The KP Research Bank will link your health information (past and future) from your health record. The information used may include diagnoses, test results, procedures, images (such as X-rays) or medicine.

5. *The KP Research Bank will collect tissues and specimens that are collected during normal care that you get at Kaiser Permanente.*

Future studies may ask the KP Research Bank to collect discarded samples such as tissues removed during surgeries, biopsies of tumors, or blood, saliva, and urine leftover from routine lab tests.

What are the benefits of taking part in the KP Research Bank?

You should not expect to get direct health benefits from this research. You may be able to help scientists find new ways to prevent, find, and treat health problems.

How long will your samples and health information be stored and used in the KP Research Bank?

Your samples and health information will be stored and can be used for future research for an unlimited amount of time. It can still be used if you are no longer a KP member.

However, you can change your mind at any time; call the KP Research Bank at 844-268-2947 Monday through Friday 8am-6pm Pacific Time (11am – 9pm Eastern, 9am – 7pm Mountain, 5am – 3pm Hawaii), or email ResearchBank@kp.org to find out how to withdraw. The consent form also describes how to withdraw in the section “What are your options for joining the KP Research Bank”.

What are the risks of taking part in the KP Research Bank?

The physical risks are small. When you give your blood sample, you may feel brief pain or have some bruising from the needle. Infection, light-headedness, and fainting are possible, but not likely.

The biggest risk is that someone might get access to the data stored about you despite the KP Research Bank's best efforts to keep the information safe. The KP Research Bank believes the chance that this will happen is very small, but there is no guarantee that there is no risk. The KP

Research Bank tries to reduce this risk by removing your identifying information from the samples and surveys collected.

Protecting your privacy is very important to KP. The KP Research Bank will make every reasonable effort to protect it. The consent form describes security measures in more detail in the section “How will information about you be kept private?”.

How will your samples and health information be used?

A scientist asks to use KP Research Bank information for a research study.

A selected group of people, including KP scientists, will review studies asking to use the samples. They will decide if the request to use samples is a good idea. Information that is requested may include information from health records, surveys, blood and tissue samples, and other information collected during your participation. All information is stored using a special number instead of your name or medical record number to protect your confidentiality.

Future studies requesting to use your samples and data from the KP Research Bank may also require review and approval from another group of people on the Institutional Review Board (IRB). The job of the IRB is to protect research participants.

The KP Research Bank may share what researchers learn from studying your samples by adding some of your information (without identifying information like your name, health record number, and social security number) into databases maintained by the National Institutes of Health (NIH).

Studies that use samples from the KP Research Bank may receive grants from the government through the National Institutes of Health (NIH) and other agencies. The federal government requires that research information including genetic information that was paid for by American tax payers to be shared with other scientists. Scientists can use this information to learn even more about health and disease.

How will information about you be kept private?

Here are some ways that the KP Research Bank protects your privacy:

- Scientists who want to use data from the KP Research Bank will be given information using the special identification number assigned to you. The KP Research Bank will only provide the information needed to do the research study.
- Details that could be used to identify you will be removed from the stored data. While the KP Research Bank maintains other files with your name, address, phone number, and medical record number, the KP Research Bank will not release this information without your permission.
- The KP Research Bank keeps health information and research data on computers that are protected by the most up-to-date electronic security. Only KP Research Bank staff has access to these computers. KP Research Bank security procedures are reviewed and updated frequently.
- Samples are labeled with special numbers and are kept in locked storage areas and buildings. KP will not otherwise disclose your protected health information (PHI) [information that could identify you] unless required by law. The KP Research Bank has

obtained a **Certificate of Confidentiality** from the federal government (National Institutes of Health). You can read more about this certificate in the section “What is a Certificate of Confidentiality”.

- You will never be named in any published documents or presentations.
- No information from this project will be placed in your health record, except a note that you have given blood or some or other kind of sample for research. Research data are stored separately from health records.
- KP researchers and other approved scientists that use or share your health information for this project will sign an agreement that says they will protect your privacy and that they will never try to find out who you are.
- Although the KP Research Bank is very careful and will do everything to protect your privacy, a breach of your personal information collected for the KP Research Bank is possible, but very unlikely.

Will the KP Research Bank return study results to you?

You should not expect to get personal results from research done through the KP Research Bank. The KP Research Bank will not give results to your doctor or put results in your health record.

The KP Research Bank does not expect the KP Research Bank results to help you or your health care providers make decisions about your current health care.

What are the costs and payments of participation in the KP Research Bank?

- There are no costs for you to take part in the KP Research Bank.
- You will not be paid for participating in the KP Research Bank, including lab visits.

KP will not sell or trade any samples or data gathered for the KP Research Bank for profit. However, research results might someday lead to the development of a test, drug, or other commercial product. You will not benefit financially from any products and neither will KP employees. Any financial benefits to KP will be used to support research in the public interest.

What is a Certificate of Confidentiality?

With this certificate, the KP Research Bank cannot be forced to disclose information that might identify you, even by a court subpoena in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The KP Research Bank will use the certificate to resist any demands for information that would identify you, except as explained below.

- You or the KP Research Bank may choose to voluntarily disclose the protected health information under certain circumstances. For example, the KP Research Bank may disclose medical information in cases of medical necessity, or take steps (such as notifying authorities) to protect you or someone else from serious harm, including child or elder abuse. Federal agencies may review KP Research Bank records under limited circumstances, for example for an audit.
- Also, if you write and request that your information be released the certificate does not protect against that voluntary disclosure.

- The Certificate of Confidentiality applies only to the KP Research Bank. You can still give out information about yourself to others as you think best. This certificate does not stop you from telling a family member or others about you or your part in this research.

What federal laws protect your privacy?

State and federal laws require KP to protect the privacy and security of your personal health information. A federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law generally will protect you by prohibiting health insurance companies and group health plans including KP, from using your genetic information when making decisions regarding your eligibility or premiums.

Will the KP Research Bank contact you in the future?

- Over time, stored samples may be used up or decrease in quality. The KP Research Bank will let you know if another sample is needed, and you can decide if you want to participate further.
- The KP Research Bank may invite you in the future to take part in other research. To protect your confidentiality the KP Research Bank does not give out your name or contact information. The KP Research Bank will contact you first to see if you are interested in learning more about the new study.
- Some studies may need extra information from you. For example, a scientist might want to ask you to give another sample or to fill out a survey.

The KP Research Bank will not contact you more than four times in a year. If you change your mind in the future about being a part of the KP Research Bank, you can ask us to not contact you again.

What are your options for joining the KP Research Bank?

Your decision to take part in this study is voluntary. That means you are free to decide whether or not to participate in this study, and refusal to join will not affect your medical care or health benefits. You are also free to stop at any time and without any reason.

Please note that you cannot withdraw your samples and information from research studies that have already started. Also, the KP Research Bank cannot get back samples or information that have already been given out to scientists. But you can withdraw from any other future research.

- If you wish to withdraw from your agreement, you must notify the KP Research Bank Principal Investigator in writing at:
Michael Horberg, MD, MAS
Principal Investigator
Kaiser Permanente Research Bank
2101 East Jefferson Street, 3E, Rockville, MD 20852

What if you have questions?

- For questions about the study, please call the KP Research Bank at 844-268-2947, Monday through Friday 8am-6pm Pacific Time (11am – 9pm Eastern, 9am – 7pm Mountain, 5am – 3pm Hawaii), or email ResearchBank@kp.org.
- Questions about your rights as a study participant, comments or complaints about the study may be presented to the:

Institutional Review Board for the Protection of Human Subjects
Mid-Atlantic Permanente Medical Group
2101 East Jefferson Street, Rockville, MD 20850
Phone: 301-816-6572 or toll-free 1-877-258-0017

If you agree to take part, your signature means that you understand the following:

1. You have read this consent form and understand the program, its possible benefits and risks, and the alternatives.
2. You understand that there is some small risk someone could get access to your health information.
3. You understand that you will not receive direct health benefits from your participation.
4. You know who to contact if you have questions about the KP Research Bank
5. You agree to give a sample of your blood.
6. You understand that you may be asked to provide another blood sample sometime in the future.
7. You understand that your samples (blood, urine, tissue, saliva, etc.), and health information from the past and in the future may be used in research to learn about, prevent, or treat health problems.
8. If you change your mind, you can withdraw from the program at any time.
9. You understand that you will not receive any financial benefits from the KP Research Bank, even if results from future research lead to the development of new products.
10. You hereby voluntarily consent to participate in the KP Research Bank as described above.

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

A signature below says that you agree to join the KP Research Bank:

Use electronic buttons on
KP.org/ResearchBank to indicate
consent

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

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

You are invited to have your sample and personal information stored in the KP Research Bank. 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 this research includes:

- Information from your health record such as diagnoses, test results, health procedures, Xrays and other images, or medicines you take;
- This may also include information from surveys or information related to your sample.

If you choose to participate, samples and information from the KP Research Bank will be shared with researchers from Kaiser Permanente 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:

- The Kaiser Permanente data coordinating center in Northern California;
- 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. The federal government requires the research data that is paid for by American taxpayers be shared, so other scientists can study the combined information to learn even more about health and disease. Usually research must be reviewed by an IRB. However, if you agree to have your sample and information (without your name or health record number) posted in an NIH database, you also agree that it can be used without further review.

Kaiser Permanente 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. Kaiser Permanente has agreements with other organizations to protect your health information. However, if this information is given to an organization not covered by these policies

and laws, Kaiser Permanente can no longer guarantee the privacy and confidentiality of your information.

In addition, Kaiser Permanente 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 Kaiser Permanente.

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

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.

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. Kaiser Permanente 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.
6. 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.

Use electronic buttons on kp.org/ResearchBank to indicate consent

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.

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.