

INFORMATION FOR THE APPLICANT:

This Application document is provided as a REFERENCE for investigators who have a Kaiser Permanente Research Bank (KPRB) Access Review Committee (ARC)-approved Pre-application. It should NOT be completed or submitted to the KPRB, but can be used to prepare for the electronic submission. Please read this cover page in entirety for instructions on how to submit a proposal for review by the ARC.

The purpose of the Application is to:

- Confirm feasibility of the proposed project given the KPRB resource; this includes an assessment of sample and data availability
- Assess scientific value of the proposed project
- Ensure alignment with KPRB access policies (which can be requested from the Access Administrator at ResearchBankAccess@kp.org)

Review Criteria:

The ARC will use the criteria tabulated in **Attachment B** to review Applications.

Deadlines:

There are 6 deadlines to submit an Application – February 15th, April 15th, June 15th, August 15th, October 15th, and December 15th. Applications will be reviewed at the next scheduled ARC meeting after the deadline. The Access Administrator will inform applicants of the ARC's decision within one week of review.

DIRECTIONS:

- If your Pre-application is approved by the ARC, you will receive two emails – one with a link to your researcher dashboard and one with your password to log in. Once in your researcher dashboard, you will need to click on the link to your active and approved Pre-application, to launch it and convert it into a full Application, thus completing the submission process.
- For information that has not changed, please copy/paste responses from your Pre-Application into your Application. If information has changed, please input new information into your Application. If information is not available, please write N/A.
- Before filling out this full-length Application, applicants are encouraged to read “KPRB Policy on Data” and “Confidentiality” sections in the KPRB Access Policy document.

CHECKLIST:

- Application
- IRB approval documentation
- Preparatory to Research (or RAPTtoR) form
- (optional) Additional Collections Addendum

APPLICATION

Today's Date:	
Project Title:	
Principal Investigator:	
Affiliation:	
Phone:	
Email:	
Fax:	

PRE-APPLICATION FEEDBACK

The Pre-Application reviewers identified area(s) in which additional information or details was needed. Please address this specific feedback as part of your Research Plan – either within the Research Strategy or in a separate section (see item “i” below).

ABSTRACT

1. Please copy/paste the same version from your Pre-Application (1 page limit, 10 point font minimum). If the Abstract has changed, please use a revised version.

RESEARCH PLAN

2. Please include a detailed research plan with the following sections included:

- a. Introduction
- b. Specific aims
- c. Research Strategy

Note: Describe any bioassays that will be used (these include assays completed by non-commercial labs, or assays completed with non-commercial materials). Please submit questions about biospecimen assays to ResearchBankAccess@kp.org. Please include a detailed plan if conducting pilot assays—including the suitability and reproducibility of the chosen approach.

- d. Subject eligibility criteria
- e. Measurements/Analytic methods
Note: Describe analyses that will be completed
- f. Sample size estimates
- g. Power calculation methodology
- h. Data collection methods
- i. Response to specific feedback from the Pre-Application

INSERT ABSTRACT AND RESEARCH PLAN HERE

LAY SUMMARY

3. Provide a brief lay summary (200 words), at a 7th grade reading level, of the proposed project, copied/pasted below. It should not exceed 200 words and should be understood by members of the general public. This lay summary may be posted on the KPRB website for the purpose of educating the general public about the types of projects that use this type of resource. This includes the following: What scientific problem will be solved; why is it important to solve this problem and who will benefit from the solution; how the applicant will solve the problem and what this breakthrough will mean for patients, Kaiser Permanente members, researchers, physicians, etc.

INSERT LAY SUMMARY HERE

SCIENTIFIC EXPERTISE

4. Please provide a Biosketch, including a Personal Statement, for each investigator on this project. NIH biosketches are preferred.

ATTACH BIOSKETCH AS SEPARATE DOCUMENT IN ELECTRONIC SUBMISSION VIA THE ACCESS PORTAL

PLEASE ANSWER THE FOLLOWING QUESTION:

5. A Kaiser Permanente investigator is required to collaborate on projects proposed by external groups, except in unusual circumstances. To learn more, or to access help finding a Kaiser Permanente collaborator, please contact the Access Administrator.

Are you a Kaiser Permanente investigator?

- YES NO

For applicants external to Kaiser Permanente, is a Kaiser Permanente investigator collaborating on this project?

- YES, Please name: _____
- NO, I would like assistance identifying a Kaiser Permanente collaborator. (Please list suggestions for possible KP collaborators, if known: _____)

REFERENCE

PLEASE ANSWER THE FOLLOWING QUESTIONS:

Before filling out this section, we advise applicants to review the “KPRB Policy on Data,” included in the KPRB Access Policy, to learn more about KPRB’s policies on: Data & Materials Use & Protection, Biospecimen Analysis, Data analysis, and Data Sharing.

MATERIALS REQUESTED

Indicate which of the following materials (DATA, BIOSPECIMENS or ADDITIONAL COLLECTIONS) are being requested by checking the appropriate boxes and providing information below. All use of data and/or samples requested should be substantiated in the abstract or research plan.

For reference, see the [Description of Data and Specimens Available for Research](#), which can be found on the KPRB website (kp.org/researchbank/researchers).

6. **DATA** YES NO (If No, skip this section, move to section 7. Biospecimens)

➤ Indicate where datasets will be sent for analysis (Institution): _____

a. **SURVEY DATA**

Survey Data

➤ Specify survey variables needed for analysis (copy/paste below):

NOTE: For reference, you may request copies of the [Men’s and Women’s Health Survey Questionnaires](#) associated with the various samples within the KPRB from the Access Administrator.

b. **GENOMIC DATA**

Genome-wide genotypic data (includes Principal Components)

Imputed genotype data

Full dataset (~1.2 TB)

Subset of imputed genotype data (If known, specify SNPs of interest, or provide separate list, for validation in our genetic datasets)

Y chromosome data (Justification: _____)

Mitochondrial data (Justification: _____)

Telomere length measurement data

Sequence data

c. **ELECTRONIC MEDICAL RECORD DATA**

Electronic Medical Record (EMR) Data

Regions:

KPSC

KPNC

KPNW

KPHI

KPCO

KPMAS

KPWA

KPGA

ALL

➤ Specify variables, inclusion/exclusion criteria if known (copy/paste below):

d. **ENVIRONMENTAL AND OTHER DATA**

Census data

➤ Specify date(s) and area(s): _____

NOTE: We can link to the 2000 Census and the 2010 Census via KP clinical records to derive variables of interest, but we cannot offer specific location information in a de-identified dataset, including zip code.

7. **BIOSPECIMENS** YES NO

- Indicate where samples will be sent for analysis (Institution): _____
- Estimated number of samples needed by participant phenotype: _____
- Cases/Controls required: YES NO

a. Indicate type of sample and volume needed for analysis, if known:

- Plasma _____ mL
- Serum _____ uL
- DNA amount requested (Extracted from: blood/buffy coat saliva both) _____ mcg
 - Specify DNA concentration and volume requirements _____ ng/uL

Note: Whole blood (frozen) has limited availability and may be provided, on a case by case basis.

b. Which assays and/or genetic analyses do you anticipate performing on the samples requested?

NOTE: The KPRB may require that genotyping/sequencing be conducted at a specific site to ensure the quality of data generated. If appropriate data are not available, KPRB may require that a pilot study be conducted to ensure that analytes of interest can be measured with adequate validity and variation in the KPRB population.

8. **ADDITIONAL COLLECTIONS ADDENDUM** (if additional collections or KPRB participant contact is needed)

- a. Do you anticipate using only KPRB samples for your project or are you combining data/specimens from other sources as well?
- KPRB only
 - Other existing or planned collection (please describe):

b. Does your project require that you collect additional data from KPRB participants?

- YES – please complete the **ADDITIONAL COLLECTIONS ADDENDUM** found after the signature page below.

NOTE: The KPRB limits the number of times participants can be contacted. Please describe in detail the recontact strategy and recontact information being requested. This information is used to estimate whether the number of KPRB participants are available for re-contact, based upon their contact history.

- NO

FUNDING (*Please update this section if funding status has changed since the Pre-Application was submitted*)

9. Is this proposed project funded?

- YES
 - Funding entity: _____
 - Anticipated start and completion dates for research project: _____
- NO, Please provide a timeline for submission to funding agencies in the TIMELINE section below.

10. Is peer review anticipated? YES NO

TIMELINE *Please update this section if timeline has changed since the Pre-Application was submitted*

11. Please copy and paste a timeline below. The Timeline should include two components:

- Project Timeline
 - a. Include timeline to complete biospecimen and data analysis
 - b. Include estimated timeline to complete work outlined in specific aims.

- Funding Timeline
 - a. Where the Application was/will be submitted for funding: _____
 - b. Timeline/dates of submission or planned submission to funding agency: _____
 - c. Key return dates for funding decisions: _____

IRB

12. Status of Investigator's IRB approval:

- IRB approval still needed
- IRB approval obtained (IRB approval date: _____)

NOTE: If IRB approval has already been obtained, attach the IRB approval notification. If not, proof of IRB Approval is required prior to receipt of data/materials.

ETHICAL LEGAL, SOCIAL IMPLICATIONS (ELSI)

13. Ethical, legal, or social implications for individual research participants could include problems arising from re-identification or loss of confidentiality, or other considerations that might be covered in a consent form. Ethical, legal, or social implications for a group might occur as the result of interpretation or misinterpretation of results, dissemination of controversial findings, and could involve stigmatization of a group or groups. Please provide answers to all questions below.

- a. What are the potential ethical, legal, and/or social implications of the proposed study?

- b. Please discuss any potential individual or social/group harm that might occur as a result of conducting this research, or interpreting or disseminating research findings.

- c. Please suggest some potential strategies for mitigating those harms.

CONFLICT OF INTEREST

14. Does your institution have a written Conflict of Interest (COI) policy that complies with federal COI regulations in 42 CFR Part 50, Subpart F?

- YES
- NO

15. Do you or your spouse/domestic partner or any dependent children have a Significant Financial Interest, or Significant Non-Financial Interest Related to the subject matter or outcome of this research? Please see **Attachment A** for definitions of these terms.

- YES (see below)
- NO

If YES, please describe the nature of your interest:

- If you checked YES and are a Kaiser Permanente Investigator, please submit an Investigator COI Attestation Form and accompanying disclosure of interests to the designated Conflict of Interest Officer for your region. Please promptly inform the KPRB of the Committee's decision.
- If you checked YES and are not employed by Kaiser Permanente, then please submit the matter to your institutional Conflict of Interest Committee. Please promptly inform the KPRB of the Committee's decision.

REFERRER

My signature below indicates my agreement that:

- ◆ The information I have submitted in this Application is accurate and complete to the best of my knowledge and belief.
- ◆ The following information provided by me to the KPRB as part of the application process may be disclosed to the public on the KPRB website (or elsewhere) or distributed to Kaiser Permanente Researchers and staff, as needed: General topic area, study title, name of PI, name of Kaiser Permanente collaborator, name of institution to serve as prime contractor, type of KPRB materials requested for the study, whether participant contact is proposed, dates of study, funding source and status, and lay summary.
- ◆ If I have selected the box indicating that I would like assistance identifying a Kaiser Permanente collaborator (Question 5), I agree to having my application circulated to interested KP investigators in all regions. If I have not selected that box, I understand that my application will not be circulated to other KP investigators.
- ◆ All other information provided by me to the KPRB will be treated as confidential and will only be used or disclosed as necessary for purposes related to KPRB application activities and operations including reports to KPRB sponsors. This restriction will not apply to information that is: (i) not treated by me as confidential or is otherwise available to the public, (ii) known to or developed by Kaiser Permanente personnel independently of this Application, (iii) approved for disclosure by me, or (iv) received by Kaiser Permanente from a third party without restriction on disclosure.
- ◆ I will comply with KPRB Access Policies and Procedures for requesting and accessing KPRB Materials
- ◆ If direct participant contact has been requested in item #8b, my signature below also indicates my agreement that:
 - I will obtain approval from the KPRB of all written materials to be provided to participants prior to the study implementation.
 - Any recontact of KPRB participants must be initiated and managed by KPRB staff only, as described in the Material and Data Transfer Agreement (MDTA).
 - I will return all data/samples obtained from contacting KPRB participants.
 - I will provide information requested by the KPRB in order to track study participants in the KPRB information systems.
- ◆ I understand that if I acquire a Significant Financial Interest or Significant Non-Financial Interest during the course of the research which is the subject of this application, I must promptly disclose this interest in writing to the KPRB.
- ◆ There may be use fees for data and materials that I have requested, which will be provided upon request. Transfer of data and materials to me will be conditioned on my agreement to pay such fees.
- ◆ If my study aims change at any time I will promptly notify the KPRB in writing of such changes.

Signature of PI

Date

For questions about the forms or application process, please contact:

Kaiser Permanente Research Bank
Inga Wagar
Access Administrator
Email: ResearchBankAccess@kp.org
Phone: (510) 625-3346

ADDITIONAL COLLECTIONS ADDENDUM

If your project requires that you collect additional data from KPRB participants, please complete this form.

DIRECT PARTICIPANT RECONTACT REQUESTED YES NO

If YES,

1. Specify type of participant contact proposed:

- Mail
- On-line
- Telephone
- Personal Interview
- Physical Examination
- New Biospecimen

a. For each box checked above, please provide the type of data that will be collected and the reason for collecting:

- Mail:
- On-line:
- Telephone:
- Personal Interview:
- Physical Examination:
- New Biospecimen:

2. Please describe the study cohort. This is required for the KPRB to estimate whether enough participants are available for re-contact, based upon their contact history.

3. Data/biospecimens to be collected (instruments/questions, measurements, etc):

4. Number of participants to be re-contacted or newly contacted:

5. Estimated unit time required/participant:

6. Number of re-contacts/participant:

7. Approximate date(s) when re-contact will occur:

8. Alternative(s) in study design and data collection to re-contacting KPRB participants:

NOTE: If your study involves a new participant consent form, the KPRB will require that the participant be offered the option of having his/her data and/or biospecimens used for future research.

Attachment A: Definitions for Conflict of Interest

Definition of Significant Financial Interest:

(1) Anything of monetary value, whether or not the value is readily ascertainable, consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse/ domestic partner and dependent children) that reasonably appears to be related to the Investigator's proposed role in the research which is the subject of this Application:

(i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

(3) The term *significant financial interest* does not include the following types of financial interests:

- i. salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- ii. any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- iii. income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- iv. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- v. income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Definition of Institution: Any domestic or foreign, public or private, entity or organization that is applying for or that receives research funding. Note: For purposes of this Application, an Investigator's Institution cannot be (or include) the sponsor of the research or any organization that provides funding for the research.

Definition of “Related to”: Whenever it could reasonably appear that the research could be affected by or have an effect on an investigator’s financial or non-financial interests. The following are examples:

- results of the research could be relevant to the development, production, sale, marketing or improvement of a product or service by an entity in which the investigator has a Significant Financial or Significant Non-financial Interest;
- the investigator receives income or other remuneration from an entity for consulting or other activities that reasonably appear to be related to the research;
- the investigator has an interest in intellectual property (patent, copyright or other rights) that could be relevant to the research project;
- the investigator has a Significant Financial or Significant Non-financial Interest in an entity that will be a party to a subcontract for a portion of the work or will supply products or services for the research; or
- patients or subjects will be referred to or evaluated in the research by an entity in which the investigator has a Significant Financial or Significant Non-financial Interest.

Definition of Significant Non-financial Interest: Any Significant Leadership Interest (as defined below) or any current and/or recent (preceding 12-month period) involvement by the individual, his or her spouse/ domestic partner or dependent children that might create a divided loyalty, or give the appearance of a divided loyalty, which is not disclosed above, such as involvement in a pending lawsuit related to the subject matter or outcome of the research which is the subject of this Application.

Definition of Significant Leadership Interest: Any relationship or role in which the individual (or the individual’s spouse/domestic partner or dependent children) participates with decision-making authority on a board, committee, professional society or association, or process regarding the subject matter or research which is the subject of this Application.

Attachment B: KPRB Application Review Criteria

The KPRB Pre-Application and Application review criteria is outlined below, and is based on the NIH review criteria. *The KPRB strives for transparency in the review process. For a more detailed crosswalk outlining which NIH review criteria will and will not be used to assess KPRB Applications, please email ResearchBankAccess@kp.org.*

<p>Review Criteria. Reviewers will consider the <u>four review criteria below</u> (Significance, Investigators, Approach, ELSI) and <u>select one of three designations</u> (Meets criteria, Does not meet criteria, Criteria not applicable) to score the proposal. Additional notes (if needed) will be provided below the score. All Applications will undergo non-scored review by the Executive Director to assess organizational risks to KP as a whole.</p>	
<p>Review Criteria #1: Significance. If the aims of the project are achieved, will scientific knowledge, technical capability, and/or clinical practice be informed or improved?</p> <p>Will successful completion of the aims inform or improve the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?</p>	<p>Meets criteria</p> <p>Does not meet criteria</p> <p>Criteria not applicable</p> <p><u>Notes (if needed):</u></p>
<p>Review Criteria #2: Investigator(s).</p> <p><i>Assessed at the Pre-Application stage</i> Is the research team and KP collaborator well suited to the project?</p>	<p>Meets criteria</p> <p>Does not meet criteria</p> <p>Criteria not applicable</p> <p><u>Notes (if needed):</u></p>
<p>Review Criteria #3: Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?</p> <p><i>Assessed at the Pre-Application and Application stage</i></p> <ul style="list-style-type: none"> • Have appropriate samples been requested? • Are the samples available? • Has the appropriate data been requested? • Is the data available? <p>If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?</p> <p>Has the applicant committed to providing generated data to the KPRB?</p>	<p>Meets criteria</p> <p>Does not meet criteria</p> <p>Criteria not applicable</p> <p><u>Notes (if needed):</u></p>
<p>Review Criteria #4: Ethical, Legal and Social Implications (ELSI). Has the applicant effectively outlined the potential ethical, legal, and/or social implications of the proposed study?</p> <p>Has the applicant proposed sufficient strategies for mitigating those potential harms?</p>	<p>Meets criteria</p> <p>Does not meet criteria</p> <p>Criteria not applicable</p> <p><u>Notes (if needed):</u></p>
<p>Organizational Risk. <i>KP's highest priority is the protection of members. The Executive Director of the KPRB will review all proposals to identify potential risks for KP health plan members, or reputational risks to the KP organization as a whole.</i></p>	