INFORMATION FOR THE APPLICANT:

This Pre-application document is provided as a REFERENCE for investigators seeking to use samples and/or data from the Kaiser Permanente Research Bank (KPRB). 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 KPRB Access Review Committee (ARC).

The purpose of the Pre-Application is to:

- Outline the proposed project, including requested samples and/or data
- Provide a brief lay summary of the proposed research project that can be understood by members of the public
- Outline the credentials of the applicant
- Request Kaiser Permanente collaborators if needed

In the Pre-Application review phase, the Access Review Committee will:

- Confirm the scientific qualifications of the applicant
- Determine feasibility of the proposed project given the KPRB resource; this includes an assessment of sample and data availability
- Ensure alignment with KPRB access policies, which can be requested from the Access Administrator at ResearchBankAccess@kp.org)
- Help applicants identify Kaiser Permanente collaborators, if needed and if a match can be found

Pre-Applications will be reviewed by the Access Review Committee (ARC) within 4 weeks of submission. If the Pre-Application is approved, the applicant will be invited to submit an Application.

The KPRB also welcomes potential applicants to schedule a scientific or technical consult to assess the feasibility of the proposal and answer applicant questions, prior to submitting a Pre-Application.

DIRECTIONS:

- Pre-applications should be submitted electronically through the KPRB Access Portal. To do so, go to the "For Researchers" page on the KPRB website (kp.org/researchbank/researchers), click on "Apply to Use Resource," and complete the "KPRB Researcher Registration" form. After doing so, you will receive two emails – one with a link to your researcher dashboard, and one with a password to log in.
- In order to support the rapid and comprehensive processing of your Pre-Application, additional details are requested in certain sections. If information is not available for any specific field in the Pre-Application, please write N/A.
- During the Pre-Application stage, applicants may request preliminary, preparatory-to-research (PTR) data to determine whether the KPRB resource can answer the proposed scientific question. If preliminary data is needed, please choose the "pre-application with PTR data request" option in the Access Portal and complete and submit the KPRB Preparatory to Research Attestation, which can be requested from the Access Administrator.
- During the Pre-Application stage, applicants must declare the intent to collect additional information from KPRB participants—for example, re-contacting participants with a survey. If recontact is planned, you will be asked to complete the "Additional Collections" section of the pre-application.

CHECKLIST:

- ☐ Pre-Application
- ☐ Preparatory to Research (or RAPToR) form
- ☐ (optional) Preparatory to Research Data Request Addendum
- ☐ (optional) Additional Collections Addendum

PRE-APPLICATION

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

ABSTRACT

1. Please copy/paste an abstract (1 page limit) for the proposed study. Include:
    a. Specific aims
    b. Significance
    c. Materials Requested. Please include:
        i. Type of data/specimens requested (including brief overview of Preliminary Data if being requested)
        ii. Why KPRB data/specimens are key to answering questions
    d. Methods. Please include:
        i. Study type
        ii. The minimum sample size necessary to carry out this study
        iii. Planned analyses and data to be generated.
            1. Please describe the assays and/or genetic analysis that will be performed on the requested specimens.
            2. Investigators intending to conduct biological assays should introduce them here, but will be required to describe the proposed assay in more detail during the Application phase
        iv. Highlight whether this is a Genome-wide Association Study (GWAS) and whether there are any plans for data sharing.

INSERT ABSTRACT HERE

LAY SUMMARY

2. 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

3. 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:

4. 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: _____)

REQUEST FOR PREPARATORY TO RESEARCH DATA (OPTIONAL)

Applicants may request preparatory to research data, e.g. preliminary data, prior to submitting an Application, to determine whether the KPRB resource can answer their proposed scientific question. If requesting summary data, derived by accessing participant MRNs, the Kaiser Permanente collaborator should complete and submit the "KPRB Preparatory to Research Attestation" form (see #6 below).

If Preliminary Data is needed:

√ Please complete and submit the PREPARATORY TO RESEARCH DATA REQUEST ADDENDUM found after the signature page below

5. Are you requesting preliminary data?
   - □ YES (email Access Administrator at ResearchBankAccess@kp.org with questions)
   - ➢ Specify date by which preliminary data are needed:_____
   - □ NO

6. The "KPRB Preparatory to Research Attestation" form must be submitted with the Pre-Application if Personal Health Information (PHI) will be accessed for activities preparatory to research (As mandated per the HIPAA Privacy Rule).

   - □ I will submit this Preparatory to Research form with this Pre-Application. Please contact the KPRB Access Administrator to request the form, and complete and upload it with your electronic submission
   - □ I have already submitted this Preparatory to Research form for this project. Please upload a copy with your electronic submission.
   - □ Submission of this Preparatory to Research form for this project is pending identification of a Kaiser Permanente collaborator. Please upload a blank copy of the form with your electronic submission to be completed by the Kaiser Permanente collaborator, once identified.

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 provided.

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

7. DATA □ YES □ NO (If No, skip this section, move to section 8. Biospecimens)
   - Indicate where datasets will be sent for analysis (Institution): _____

   a. SURVEY DATA
      - □ Survey Data
        - Specify survey variables needed for analysis, if known (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.

8. 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.

9. 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: If you will request participant recontact, you will be asked to provide a study description in the Application, to estimate whether the number of participants are available for re-contact, based upon their contact history.

      □ NO

FUNDING

10. 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.

11. Is peer review anticipated? □ YES □ NO

TIMELINE

12. Please copy and paste a timeline below. The Timeline should include two components:
    - □ Project Timeline
      a. Include timeline by which preliminary (e.g. preparatory to research) data is needed.
      c. Include timeline to complete biospecimen and data analysis
      d. 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:_____

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.
    _____

My signature below indicates my agreement that:

- The information I have submitted in this Pre-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 4), I agree to having my pre-application circulated to interested KP investigators in all regions. If I have not selected that box, I understand that my pre-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 Pre-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 #9b, 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.
- 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

PREPARATORY TO RESEARCH DATA REQUEST ADDENDUM

Applicants may request preparatory to research, e.g. preliminary data, prior to submitting an Application, to determine whether the KPRB resource can answer their proposed scientific question.

Before completing this addendum, please review/complete Section 9 to determine if the ADDITIONAL COLLECTIONS ADDENDUM needs to be completed, as well.

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

PRELIMINARY DATA MAY INCLUDE:

- Description of the numbers of specimens/specimen-derived data of different types available for research
- Description of the numbers and types of specimens/specimen-derived data available for specific phenotypes specified in the Pre-Application
- Numbers and demographic characteristics of participants with specimens/specimen-derived data available
- Numbers and demographic characteristics of participants excluded by criteria specified in the Pre-Application.

DO NOT USE THIS ADDENDUM to request or describe the final amount of data/samples needed for the proposed work. A complete description of the data/samples requested should be included in the Application.

1. The KPRB Preparatory to Research Attestation form must be submitted/uploaded with the Pre-Application if Personal Health Information (PHI) will be accessed for activities preparatory to research. This is mandated by the HIPAA Privacy Rule.

   □ I will submit this Preparatory to Research form with this Pre-Application. Please contact the KPRB Access Administrator to request the form , and complete and upload it with your electronic submission
   □ I have already submitted this Preparatory to Research form for this project. Please upload a copy with your electronic submission.
   □ Submission of this Preparatory to Research form for this project is pending identification of a Kaiser Permanente collaborator. Please upload a blank copy of the form with your electronic submission to be completed by the Kaiser Permanente collaborator, once identified.

Please indicate the type of preliminary data you are requesting and include draft results tables, if needed:

2. **DATA** □ YES □ NO (If No, skip this section, move to section 4. Samples)

   a. **SURVEY DATA**
      □ Survey Data
         √ Specify survey variables needed for preliminary analysis, if known (copy/paste below):
         _____

      NOTE: For reference, see the Men's and Women's Health Survey Questionnaires associated with the various samples within the KPRB.

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
- □ Mitochondrial data
- □ 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): _____

3. SAMPLES □ YES □ NO

√ Estimated number of samples needed by participant phenotype:_____

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.

4. DRAFT RESULTS TABLES

ATTACH DRAFT RESULTS TABLES TO ELECTRONIC SUBMISSION VIA THE ACCESS PORTAL

5. TIMELINE

Please include the following information from your Pre-Application Project Timeline:

- □ Date by which preliminary data is needed:_____
- □ Timeline to analyze preliminary data:

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.