OREGON CLINICAL + TRANSLATIONAL RESEARCH INSTITUTE

Center for Health Research

Request for Proposal:

Specimen Retrieval Opportunity with the NW Biobank at Kaiser Permanente Northwest
www.octri.org/nwbiobank

KEY DATES FOR APPLICANTS

Meet with Kaiser Investigator deadline	October 23, 2014
Proposal deadline	November 3, 2014
Proposal decision	November 20, 2014
Submit IRB protocol and Material Data Transfer Agreement	By December 1, 2014
Specimen Retrieval	By June 30, 2015

PROGRAM OVERVIEW

The Oregon Clinical & Translational Research Institute (OCTRI) is now accepting proposal for Specimen Retrieval with the NW Biobank at Kaiser Permanente. With this announcement, we are inviting investigators to submit a proposal for specimen retrieval and use.

This is an opportunity for investigators at OHSU to have their own research ideas supported through the Kaiser Permanente resource.

Samples will be retrieved from the Kaiser Permanente Northwest Biobank (NWBB). Specimens currently in storage are stabilized buffy coat or DNA at -80C. Buffy coat samples will have DNA extracted before transfer to the selected investigator for use in research. The NWBB currently has over 14,500 samples on hand for this use.

Collection of samples began in 2009 with a cohort of hypertensive patients invited to participate by mail (N=524). Over the years we have collected samples from members with other conditions such as breast cancer, prostate cancer and lung cancer (N~=3,500), people who had diabetes diagnosed at KP (N~=5,000), members with diagnosis of depression (N~=1,000), women at increased risk for ovarian cancer (N~=1,000), members 80 years of age and older (N~=1,200), and members with a cardiovascular diagnosis (N~=1,000). We have also had members join the NW Biobank who heard by word of mouth, or were invited as healthy controls, or had other conditions (N~=800). Some subjects have multiple conditions, but are counted only once in the category where they were identified for recruitment.

- 58% of the samples are from female members
- 98% are 40 years of age or older
- 93% are white

Samples from the Tissue Clinical Library may also be available. The Kaiser Permanente Northwest pathology department currently holds more than 3.5 million blocks and associate slides dating back to 1971 in a clinical tissue library. The Tissue Clinical Library consists of archival paraffin-embedded tissue samples that were originally collected for clinical diagnostic purposes. The blocks contain both normal and tumor tissue. The majority of the specimens have been fixed in 10% neutral buffered formalin and

then embedded in paraffin blocks. These specimens have been successfully accessed for numerous research studies.

All specimen retrieval costs will be supported by OCTRI. This RFP supports the retrieval of approximately 125 tissue specimens or 500 buffy coat specimens for a single project for which specimen retrieval can be completed by June 15, 2015. Specimens will include a limited amount of clinical annotation from the electronic medical record. All variables will need to be electronically available (e.g., not requiring manual chart review or natural language processing) and well defined by the researcher (e.g., based on standard codes such as ICD9 or NDC codes). Scope will be limited by available programmer time. Investigative teams will be responsible for supporting costs associated with any assays performed on the specimen or analysis of the specimen and clinical data.

Who benefits?

Grant applications often fail because investigators lack access to the needed biological samples or because the cost of acquiring samples is prohibitive. A researcher taking advantage of this opportunity could be in the position to submit a very compelling application (learn more about the NW Biobank at Kaiser Permanente and associated data resources.) Similarly, researchers with existing programs of funded research could benefit significantly by augmenting their existing sample resources with a new collection.

> Examples: Specimen-retrieval efforts could focus on KPNW members with prostate cancer, hypertension, colon cancer, ovarian cancer, diabetes, or other prevalent conditions, including KPNW members who are very long-lived.

Return of Data and Materials

Kaiser will retain ownership of all biobank biological material and data. In accordance with the time frame specified by the MDTA, Recipient shall return to Kaiser (or, if Kaiser so requests, destroy) all unused Kaiser Specimens, including any data and materials provided by Kaiser with the Kaiser specimens. Upon request by Kaiser, Recipient shall provide certification that all unused specimens and other Kaiser data and materials have been returned to Kaiser or, if Kaiser so requested, destroyed. The MDTA template can be found here.

PROPOSAL

Principal investigators must fit the OHSU guidelines for eligibility http://www.ohsu.edu/research/rda/documents/PI_Eligibility_Awards.pdf. Investigators must meet with the Kaiser liaison Sheila Weinmann, PhD, to obtain further information about the current capabilities, and discuss the scientific potential and feasibility of proposals for specimen retrieval. She can also help investigators evaluate the available data from the electronic medical record. (Read more about the KPCHR Data Warehouse.) Individual appointments can be scheduled by contacting Debra Burch (Debra.Burch@kpchr.org)) prior to the deadline of October 23, 2014. A Kaiser Permanente Investigator will supervise the preparation and delivery of data and will collaborate on the study. This person's effort in preparing the specimens is provided as part of the award. Please contact Dr. Weinmann to help identify the appropriate expert.

Proposal Outline (3 page maximum for sections 1-5) Proposal should include the following elements:

Abstract: Provide a 250-word paragraph with a clear and concise description of the project's objectives, proposed methodology and anticipated results. The abstract should clearly indicate a start and end date for the project. As a general guideline, the completion of the project should be no longer than twelve months from the proposed start date.

Proposal Narrative (Please adhere to the following outline):

1. Background, context and long-term goals: What is the major opportunity that drives the proposal? Highlight any unique combination of background, prior experience and capabilities that are being brought to bear on the project. Briefly describe the current status of related research at OHSU, including existing strengths and opportunities. Finally, explain how the requested specimens will allow the research team to move to the next stage of research success, with the objective being sustained research support.
2. Specimen Request: Please provide details on the specimen request including data requirements (phenotype), sample size justification, sample type (DNA, tissue) and sample processing requirements (slides, staining, DNA concentration Specimens will remain the property of Kaiser Permanente. Use of Kaiser specimens and data, including any microarrays provided by Kaiser, will be restricted to the specified project only and are subject to Kaiser IRB approval.
3. Project plan: Against the background provided in the previous sections, describe the work you plan to undertake and its expected outcomes. Make it clear to reviewers that you have devised a well-crafted plan that makes good use of the specimen resource.
4. Timeline: Provide a timeline for completion of the OHSU and KP IRB protocol and the proposed work in a simple format such as a short paragraph or simple diagram. Please contact Bridget Adams 503-494-5077 or adamsb@ohsu.edu if you have questions regarding IRB requirements for your proposal. Unless justified based on the nature of the work involved, the specimens should be provided by June 30th, 2015.
5. Plans for continuation: **This is a key section**. Describe plans for how the proposed work will yield ongoing research with independent funding. Identify specific and expected sources of extramural support. For each source, include the agency or organization and any recurring or special program to which you plan to apply, and any known submission deadlines.
6. References cited (not included in page limit).
7. Biosketches for key personnel (not included in page limit).

REVIEW AND SELECTION

The proposals for specimen retrieval will be evaluated by a small committee of scientists from OHSU and KPNW. These proposals will be evaluated alongside other proposals for investment in the NW Biobank at Kaiser Permanente. The Director of OCTRI will make a final investment decision.

1) Proposals for specimen retrieval will be evaluated based on the following criteria:
    a. What is the significance of the research, and how will it impact human health?
    b. What resources are available already to the investigator to complete the research proposed with the specimens retrieved from the NW Biobank?
    c. How will the proposed studies yield further funding?
    d. What is the likelihood that the investment will help the research agenda of the proposing investigator (i.e. lead to new grants and publications)?
    e. What is the feasibility of the proposed specimen retrieval?

RETRIEVAL OF SPECIMENS

The Investigator will be expected to take advantage of the new specimens in his or her own research. As noted above, however, all individual research will require *separate funding* through NIH or another sponsor to cover study expenses, including those for specimen processing or analysis. Investigators will need to satisfy all relevant IRB and compliance regulations at both institutions before sample transfer and sample transfer must take place before the end of the fiscal year.

PROPOSAL SUBMISSION AND QUESTIONS

Submit your proposal to OCTRI via a redcap survey at:
https://octri.ohsu.edu/redcap/surveys/?s=99IQYKAJ67

Please direct all questions related to the submission process to the OCTRI Research Navigator Program (503-418-9790, octri@ohsu.edu).

For scientific questions and to learn further information about the current capabilities and discuss the feasibility of proposals for specimen retrieval please contact Debra Burch (Debra.Burch@kpchr.org) to schedule a meeting with the **Dr. Sheila Weinmann, PhD**. She can also help investigators evaluate the available data from the electronic medical record.