ADVISORY FOR BIOSPECIMENS COMMITTEE
ACCESS POLICY FOR THE USE OF KPNW SPECIMENS IN RESEARCH

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I. **KPNW SPECIMENS AND DATA AVAILABLE FOR RESEARCH**

**Blood Derived Specimens**  
The Northwest Research Laboratory (NWRL) houses more than 30,000 Kaiser Permanente Northwest (KPNW) health plan members’ specimens to be used and shared for research. This repository was created to supply the scientific community with samples and associated data to uncover the genetic basis of disease, study drug response, and develop genetic diagnostics to predict and monitor disease. The goal of the NWRL is to support research studies in collaboration with investigators at the Center for Health Research (CHR).

The Northwest Biobank (NWBB) is a collection of blood-derived samples housed at the NWRL that were collected after receiving consent from subjects to use their samples for genetic research and to share these specimens with other researchers, including genomic databases such as the National Institutes of Health database of Genotypes and Phenotypes (dbGaP). The specimens available for research include blood-derived DNA collected from healthy adults or adults with a known history of disease. These samples are blood that would be otherwise discarded after a patient had these samples collected for clinical purposes. Acquisition DNA used for research purposes is extracted from whole blood, buffy coat or GenVault specimens. GenVault is a proprietary dry-state storage platform that enables the extraction, preservation, recovery and distribution of DNA at room temperature.

**Tissue Resource**  
Tissue specimens are also available to research collaborators of CHR investigators. Formalin fixed paraffin-embedded (FFPE) tissues specimens are collected at KPNW as part of routine clinical care.
In most cases, consent has not been collected from KPNW members in the tissue resource, but research studies can access these specimens as long as they adhere to IRB, HIPAA, State of Oregon, and Kaiser Permanente regulations. For more information on usage of these specimens, please refer to the KPNW compliance website. KPNW has retained FFPE tissue blocks and clinical H&E slides on procedures as far back as 1971 for tissue collected in a KPNW owned facility. A minority of KPNW members, particularly members living in Southwest Washington or regions south of Portland (such as Salem and Eugene), have procedures conducted at non-KPNW institutions.

Tissue specimens available for research include FFPE tissue slides, FFPE tissue sections in tubes and FFPE tissue blocks (only in limited circumstances would the block be available for research). Tissue slides can be sectioned to meet the thickness, slide type, and staining required for the research study. H&E slides can be created for research studies from the tissue blocks.

**Data Available for Research**

KPNW’s specimen resources can be linked with extensive longitudinal electronic medical records (EMR) data on diagnoses, clinical or laboratory measurements, and treatments. These data are well organized for research, which enables easy collaboration and harmonization, especially with other large-scale biobanks. These data can be shared with research collaborators in the form of deidentified or limited datasets.

Types of data available:

- **Clinical and administrative data from electronic health system databases**: This includes data from the EMR, as well as data that have been extracted from these data sources and placed into the Virtual Data Warehouse (details below*);

- **Clinical pathology reports**: Clinical pathology reports can be deidentified and sent to research collaborators for studies using tissue specimens. Data can also be abstracted from these reports by CHR’s data coordination department;

- **Genomic data**: Data resulting from genotyping assays conducted on specimens described in this document. These data are not currently available but may be collected prospectively pending subject consent and IRB approval.

*Information on the Virtual Data Warehouse*: The Virtual Data Warehouse (VDW) consists of clinical and administrative data that have been extracted from source databases and transformed into a common data model. The common data model facilitates research that utilizes combinations of data from multiple source databases, or includes combinations of data across multiple institutions.

**II. KPNW LABORATORY RESOURCES**

**Airport Way Laboratory**

Investigators need to partner with the KPNW clinical pathology and histopathology departments to support tissue research studies. A minimum pathology review is required on all specimens.
dispatched for research to ensure that clinical specimens are not depleted. Research studies can create a customized pathology review to be conducted by KPNW pathologist. All sectioning is conducted by highly trained KPNW clinical histotechs.

**Northwest Research Laboratory**
The Northwest Research Laboratory (NWRL) is a state-of-the-art laboratory and biorepository in Portland, Oregon, administered by the CHR. The NWRL houses all specimens described in the *Blood Derived Specimens* section, processes all new specimens, performs DNA extractions from blood and tissue derived specimens (see note above), and distributes DNA and other specimens.

The NWRL is equipped with automated DNA extractors, gel electrophoresis equipment, imaging system, thermal cycler, spectrophotometer, Nanodrop, and RealTime PCR detection system. The NWRL’s expert staff have optimized extraction protocols for the use of samples on genomic platforms. In addition to quantifying and dispatching specimens, NWRL can perform limited genotyping such as TaqMan assays, limited ELISA assays, and assist in the design and execution of bio-assays on newly collected bodily fluid specimens, including DNA, metabolic, or hormonal measurements.

### III. ADVISORY FOR BIOSPECIMENS COMMITTEE

The Advisory for Biospecimens Committee (ABC) is the governing body for the existing specimen resources and the research data derived from these specimens at KPNW. The purpose of this committee includes the following:

- Provide fair, equitable access to data and specimens for research;
- Ensure careful stewardship and management of KPNW’s biospecimen collections used for research purposes;
- Maintain a centralized organizational structure and standardized protocols to minimize the burden of research requests on the pathology department and NWRL staff;
- Establish policies and protocols to support patient rights, progress in medical science and the research agenda of KPNW and CHR;
- Guarantee that the costs of research are borne by study budgets and not by the pathology or other KPNW departments.

Approval by the ABC is required for any researcher interested in accessing existing data and biospecimens (see [Access to NWBB, NWRL, and NWTL Biospecimens and Data Derived from these Resources](#) for more information).

Prospective studies involving *de novo* sample collection do not require ABC approval to initiate the study. However, coordination with the ABC is strongly encouraged because the committee can provide resources, such as lessons learned and protocols, from previous research studies completing *de novo* sample collection. Please contact the [ABC Administrator](#) for more information.

**Advisory for Biospecimens Committee (ABC) Selection and Composition**
The ABC consists of core members elected by the leadership team at CHR. These members were selected based on their ability to provide strong scientific and ethics review of a variety of areas related to biospecimen research.

**Subject Matter Experts**
Occasionally, the ABC may not have the specific subject matter expertise to comprehensively review a proposal. The ABC retains the right to ask subject matter experts to review the proposal. Please note: subject matter experts may be other researchers in the applicant’s specific scientific field.

**Conflict of Interest/Excused from Review**
ABC members will be excused from review for various reasons including:
- ABC members will not review their own submitted initial requests or applications.
- ABC members will recuse themselves from the review of proposals where they perceive there may be a conflict of interest or an unbiased review cannot be offered. ABC members are required to declare this conflict of interest to the ABC Administrator.

### IV. ACCESS TO NWBB, NWRL, AND NWTL BIOSPECIMENS AND DATA DERIVED FROM THESE RESOURCES

The process required to access these resources includes the following steps:

1. **Partner with a CHR investigator on your research project:** The ABC requires investigators applying from other institutions to collaborate with a CHR investigator on all studies using the biospecimen samples and data managed by the ABC. Interested parties can contact our ABC Administrator at CHR_Biospecimen@kpchr.org for assistance in identifying an interested CHR collaborator. Investigators from other institutions can also contact CHR investigators directly.

   One of the most valuable assets of Kaiser Permanente is our internal investigators. The CHR investigator will be the research projects’ advocate to ensure all pre-award work is completed according to Kaiser Permanente’s regulations. With the help of a CHR investigator’s expertise, investigators from outside institutions will have assistance in navigating the KP electronic health record data and can gain a deeper understanding of the biospecimen resources available for research collaborations.

2. **Submit an Application to the ABC:** All requests for biospecimens must undergo a review process. Requests to use biospecimens for research purposes are made directly to the ABC. With the assistance of the CHR research collaborator, an application will be completed and submitted to the ABC for review. For more information on the ABC application process, see ABC Specimen and Specimen Data Application Process.

   To start the process of learning more about the KPNW biospecimen resources available for research and the application process, we strongly suggest contacting our ABC administrator.
V. STUDY FEASIBILITY AND PRE-AWARD TASKS

In order to evaluate the feasibility of a study, investigators often undergo a prep-to-research process in coordination with staff at CHR. This process includes defining scope of the study, applying study criteria to identify the number of subjects and samples that meet the criteria, and developing a budget. The CHR investigator will assist the research collaborator in this process. This step should be completed after investigators from outside institutions have identified a CHR research collaborator and before the investigator submits a request application to the ABC.

VI. ABC SPECIMEN AND SPECIMEN DATA APPLICATION PROCESS

ABC Specimen and Specimen Data Request Application

The investigator requesting specimens will need to complete an ABC Specimen and Specimen Data Request Application. Information required to complete the application includes:

- Basic information about the study (including PI and research collaborators contact information, funding source(s), start and end dates, IRB status);
- Description of how the study will establish safeguards to prevent exhausting of biospecimens;
- Number of samples and type of data requested;
- Quantity of specimens requested;
- Statistical power and feasibility of the project;
- Description of specific testing performed on specimens requested;
- Description of quality assurance procedures;
- If the study is using samples from the NWBB (i.e., a blood-derived resource), the investigator will need to disclose if there is a chance medically actionable results will be found. If there is a chance of medically actionable results, the investigator will need to describe the procedures for releasing results or justification for why results cannot be released to study participants;
- Study overview (summary of specific aims, significance, and methods).

ABC specimen request applications can be found here: [Hyperlink to PDF form].

Applications will be reviewed by the ABC, which will evaluate the applications using four guidelines:

1. Scientific Merit;
2. Ethical, Social, and Legal Implications (including IRB approval, MDTA, and appropriateness in the context of the consent form signed by the participant);
3. Technical Assessment;
4. Organizational Risk.

Each proposal will be reviewed and scored by individual ABC members, after ABC group discussion. Reviewers will consider four of the review criteria above and give one of three designations (Meets criteria, Does not meet criteria, Criteria not applicable) to score the proposal. Each of the four designated areas must be scored as “Meets Criteria” by the majority of ABC reviewers in order for
the project to be approved. Proposals that do not meet this threshold will be returned for revisions or declined access.

All applications will undergo non-scored review by the Executive Director/CHR Chief Operating Officer (COO) to assess organizational risks to Kaiser Permanente as a whole.

If a request for specimens or specimen data conflicts with an existing study (such as the study aims of two studies overlap), the ABC has the authority to deny applications due to these conflicts. It is strongly encouraged that applicants start coordinating with the ABC Administrator early in the proposal and ABC application process to ensure potential conflicts are identified and resolved before study proposals seeking funding is submitted.

Participation in consortiums using specimens and data governed by the ABC will be discouraged unless there is a KPNW or CHR researcher contributing a significant scientific role in the project.

**Data Only Studies**
Data only studies must first obtain approval from the ABC if accessing existing data derived from specimens governed by the ABC. This process only applies to data derived from specimens in a research setting (e.g., whole genome sequencing data collected for research). Therefore, any data collected during clinical care does not require ABC approval. Applicants should fill out the ABC Specimen and Specimen Data Request Application and write “not applicable” for sections that do not apply to data only studies.

**Timing of ABC Specimen Request Applications**
The ABC reviews all applications during their monthly meetings. Applications need to be submitted two weeks prior to the next ABC meeting to ensure review at the upcoming meeting. Contact the ABC administrator for a schedule of upcoming ABC meetings.

We recommend listing more than one contact person to represent the proposed study in case any questions arise from the ABC. Between submitting the application and leading to the ABC meeting, committee members will often have follow up questions to the applicant, which will be submitted via email. Unanswered questions before the ABC meeting may result in a delayed decision from the ABC.

**Assistance with ABC Application Process**
If you have any questions about the application or the review process, please contact the ABC administrator.

Table 1. ABC Application Review Criteria
Reviewers will consider four of the review criteria below and give one of three designations (Meets Criteria, Does not meet criteria, Criteria not applicable) to score the proposal.

**Review Criterion #1: Scientific Merit.**
If the aims of the project are achieved, will scientific knowledge, technical capability, and/or clinical practice be informed or improved?

Will successful completion of the aims inform or improve the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field?

Are the research team and Kaiser Permanente collaborator qualified to conduct the proposed research?

**Review Criterion #2: Ethical, Legal and Social Implications (ELSI).**
Has the applicant effectively outlined the potential ethical, legal, and/or social implications of the proposed study?

Has the applicant proposed sufficient strategies for mitigating those potential harms?

Is there a way to ensure that the proposal is consistent with the prior consent associated with the samples?

**Review Criterion #3: Technical Assessment.**
- Have appropriate samples been requested?
- Is the number/volume of samples justified to meet the standards for appropriate statistical power without unnecessarily depleting sample availability?
- Are the samples available?
- Have the appropriate data been requested?
- Are the data available?
- Has the applicant committed to returning generated data back to KPNW?

**Review Criterion #4: Organizational Risk.**
*Kaiser Permanente’s highest priority is the protection of members. The Executive Director & COO of the Center for Health Research, or a designated proxy, will review all proposals to identify potential risks for Kaiser Permanente health plan members, or reputational risks to the Kaiser Permanente organization as a whole. The review will include assessment and feedback from the ABC.*

**VII. ABC REVIEW OUTCOMES**
The ABC Administrator will inform applicants of the ABC’s decision, with one of four decisions:
• **Approved** – the Application has been approved to use the resources.

• **Contingent Approval** - The Application has been accepted, contingent upon results from feasibility studies, pilot assays, or sample assays. In some incidences, approval may be contingent on the return of outstanding specimens sent to the applicant’s institution for a previous study before new specimens can be shared. Applicants will receive guidance from the ABC Administrator on next steps on applications with contingent approval.

• **Resubmit Requested** - Applications may fall into this category because additional information is required for ABC to make a decision. The ABC Administrator will outline the concerns and recommendations of the committee and the applicant will need to resubmit an application that addresses these specific concerns and recommendations before approval can be obtained.

• **Denied** - Application was rejected. Applicants whose Initial Request was denied will receive information from the ABC Administrator that summarizes the specific reasons for rejection.

**Appeals Process**
Applicants may contact the ABC Administrator within 3 months of a disputed ABC decision if they wish to appeal the decision. When contacting the ABC Administrator, applicants will need to submit a written request which includes reasons why the decision should be reviewed. Within 4-6 weeks of receiving the request, the ABC Chairperson will review the request, and respond to the applicant with a decision. If considered necessary, the ABC may seek additional advice from administrative, bioethics, or scientific experts.

**Study Changes**
Substantial changes to studies already reviewed by the ABC will result in the necessity to submit a new ABC Specimen and Specimen Data Request Application [insert link to application pdf or website] so that the changes can be reviewed by the ABC. Changes that would be considered substantial would include changes to the study aims or scope, the number of samples requested, the quantity of samples requested, protocols for protecting patient information, the type of biospecimen data requested, and specific testing performed on specimens. If you are unsure of what changes constitute a substantial change, please contact the ABC Administrator.

**Approval Validity Term for Projects Without Funding**
If ABC approval has been granted before funding is secured, then the approved application will be held for 12 months until funding is secured. This eliminates the need for an applicant to resubmit the same proposal to the ABC, but it is not a guarantee of availability of biospecimens. If funding is not secured after 12 months, the application will be considered withdrawn unless the investigator requests an extension by emailing ABC Administrator. The length of the extension will vary due to the circumstances under which it is requested.
VIII. ADDITIONAL STEPS TO CONSIDER IN THE PLANNING PROCESS

ABC approval is always contingent on the research study completing the necessary IRB, compliance, and other patient protection steps before sending specimens and data. It is the responsibility of the applicant to make sure all of these steps are completed. Investigators from outside institutions should coordinate with their CHR research collaborator to complete these tasks.

Most studies accessing the biospecimens and data governed by the ABC are required to complete the following tasks before any specimens or data can be dispatched. These tasks can be completed before or after the ABC review.

1. **IRB approval:** IRB approval is often required at both KPNW and outside institutions participating in the research. Additional information about the KPNW’s IRB can be found on the KPNW Research Compliance website: [https://research.kpchr.org/research-compliance/](https://research.kpchr.org/research-compliance/)

2. **Execute HIPAA Compliant Agreements:** Generally a Material and Data Transfer Agreement (MDTA) or a Data Use Agreement (DUA) between institutions is required if KPNW will be sending data and/or materials to an institution outside of the KPNW region. These agreements ensure that the project is compliant with HIPAA regulations.

   Additional information about HIPAA regulations and MDTAs and DUAs can be found on the KPNW Research Compliance website: [https://research.kpchr.org/research-compliance/](https://research.kpchr.org/research-compliance/)

3. **Other Compliance and IRB Requirements:** Other compliance or IRB requirements may include making sure no subjects involved in the research study are on the research and genetic exclusion list, obtaining approval to send limited or deidentified datasets, completing a data transfer request, and setting up a new study account on the CHRsecure data transfer site.

4. **Budget/Contract approval:** The applicant will need to go through the standard CHR budgeting procedure to determine project costs and timeline. Note that the biospecimen resources at KPNW are for use in research collaborations and are not available on a fee-for-service basis.

IX. ABC POLICY ON DATA

This section applies to any data, datasets, laboratory analysis, or results collected during research studies in association with specimens governed by the ABC. This includes, but is not limited to, variables regarding health or disease status, laboratory results derived from specimens governed by the ABC, and data added as part of prior studies conducted using data and biospecimens.

**Personal Health Information (PHI) Restrictions**

Investigators must use the minimum identifiers necessary and any use of limited datasets with PHI needs to comply with HIPAA requirements that can be approved by the IRB. For more information on PHI and limited datasets, navigate to the KPNW Compliance website at: [https://research.kpchr.org/research-compliance/For-Researchers/Protect-PHI-HIPAA](https://research.kpchr.org/research-compliance/For-Researchers/Protect-PHI-HIPAA)
Unless PHI is required to re-contact participants in very specific situations (see *Medically Actionable Results (NWBB specimens only)* below for a description), only deidentified datasets can be shared with research studies using NWBB specimens. For more information on PHI and deidentified datasets, navigate to the KPNW Compliance website at: [https://research.kpchr.org/research-compliance/For-Researchers/Protect-PHI-HIPAA](https://research.kpchr.org/research-compliance/For-Researchers/Protect-PHI-HIPAA)

*Medically Actionable Results (NWBB specimens only)*

If the study is using the NWBB resource, the investigator will need to coordinate with CHR staff to disclose results of substantial medical importance to KPNW study participants. This procedure is required for studies using this resource because KPNW subjects with NWBB specimens signed a consent form stating that if a result of medical importance was discovered, the KPNW participant would have the option of learning of the result. Such disclosure will be carried out on a case-by-case basis.

The cost and coordination required for contacting participants, asking for their preference of learning results, disclosing medically actionable results, and retesting new samples using clinically appropriate protocols will be the responsibility of the study requesting these specimens from the ABC. The approval process required before contacting participants includes following the *Re-contact of Participants* (NWBB specimens only) procedures described below, and obtaining IRB and ABC approval of the study protocol associated with disclosing results to participants.

If a study does not disclose genetic results to study participants, justification will need to be provided. Cost is not a justifiable reason for not disclosing results.

*Re-contact of Participants (NWBB specimens only)*

In limited situations, a research study may need to re-contact consented participants with blood-derived specimens in the NWBB (not applicable to the tissue resource). Reasons for re-contact may include collecting prospective data on these subjects or disclosure of laboratory findings that are determined to be of medical importance. The collection of participant information for re-contact is not governed by the ABC and will need to be approved and coordinated through the IRB and CHR investigator managing the NWBB, Sheila Weinmann.

*Returning Specimens and Data to KPNW*

Under limited circumstances, tissue blocks may be dispatched to research collaborators located at another institution. KPNW CHR requires that all tissue blocks dispatched to other institutions be returned to KPNW in a timely manner. The exact timeline for return should be outlined in the MDTA agreed to by all involved parties. In addition, KPNW reserves the right to request that tissue blocks be returned in an expeditious manner.

ABC also requires sharing of laboratory results with KPNW after the completion of data analysis. Examples of results include (but are not limited to) genetic or genomic sequencing (raw data and variant-interpreted), immunohistochemistry, and other laboratory results. Details of data sharing should be described in the ABC Specimen and Specimen Data Application and in the MDTA before project work begins.
Protocols surrounding the destruction of specimen and data at the conclusion of projects should also be described in the MDTA and approved by the IRB before project work begins.

**Acknowledging NW Biobank Resource**
If blood-derived specimens from the NW Biobank are used, please use the following language to acknowledge the resource:

The NW Biobank resource was made possible with support from the Oregon Clinical and Translational Research Institute (OCTRI), grant number UL1 RR024140 from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH), NIH Roadmap for Medical Research; the MJ Murdock Charitable Trust, and institutional support from the Center for Health Research (CHR), and Kaiser Permanente Northwest (KPNW).

X. **ABC CONTACT INFORMATION**
If you have questions or would like to start coordinating with KPNW to access biospecimens available at CHR, please contact our ABC Administrator or ABC Chair.