Preparation for Retrieval/Processing of Materials

When the RBCC approves the request, an information packet prepared by RBCC staff with the help of the study Principal Investigator will be sent to each Chief of Pathology at the departments where materials of interest are located. The information packet will include a letter with a brief description of the protocol, the study abstract and a listing of study subjects and pathology accession numbers.

Expectations of KPSC Principle Investigators Including Physicians, Scientists and Staff Collaborating with External Entities

- All projects for external use (e.g., research, publication, collaboration with university faculty or biotech firms) require a KPSC PI.
- KPSC PI will assume responsibility for:
  - Completing the IRB application/request for expedited review.
  - HIPAA Compliance.
  - Financial oversight for the project.
  - Initiating subcontracts (i.e., material transfer and/or data use agreements) with the external organization.
- There is an explicit expectation that the KPSC site PI will participate in the design, implementation of the research protocol, analysis and manuscript preparation for the study.
- It is expected that the study budget will provide for 5-10% FTE for the KPSC site PI, as well as funds adequate to cover staff time for specimen retrieval.

  Link to useful information and forms:
  http://researchweb.lsrs.ca.kp.org/topbar/sitemap.htm

  Webpage includes:
  - Raptor Form (for preparatory research activities, e.g. pilot studies where you will not access PHI)
  - IRB application
  - Research & Evaluation
  - Research Finance (contact Sharon Figgins, Director of Research Finance, 626.564.3135, tieline 8.338.3135 or at Sharon.M.Figgins@kp.org
    - Contracts & Grants (e.g., DUA's, confidentiality agreements, etc.)

Checklist for Biospecimen Requests

Internal Studies (SCPMG Physicians /Investigators using KPSC specimens)

- Complete and submit KPSC RBCC Application Sections 1-3 (see page 13)
  - ( ) Investigators' signatures and complete contact information.
  - ( ) Detailed protocols (i.e., use of biospecimens, safeguarding of biospecimens, data destruction plan, confidentiality protection).
  - ( ) Include approved KPSC IRB/RAPTOR form if request is for preliminary data for a grant proposal.

External Studies (specimens and/or data will be released or published outside KPSC)

- Complete and submit KPSC RBCC Application (see page 13)
  - ( ) Investigators' signatures and complete contact information.
  - ( ) Submit KPSC IRB application with detailed protocols (i.e., use of biospecimens, safeguarding of biospecimens, data destruction plan, confidentiality protection).
- Submit KPSC IRB approval/exemption letter to the RBCC coordinator.
- Submit fully executed subcontracts/agreements to the RBCC coordinator. A Material Tranfer Agreement (MTA) is required when requesting biospecimens for external use, MTA's also apply to any data, information or any product derived from the KPSC biospecimens. A Data Use Agreement (DUA) is required when KPSC data is requested for external use. Contact Research Finance for further information about which agreements are required. (http://researchweb.lsrs.ca.kp.org).
- Submit study cost center number if the cost of specimen retrieval and refilling is not covered by local medical centers (see page 11 for the cost of services).

Frequently Asked Questions*

1. **Do I need to complete the application if I am using only my medical center's specimens/slides?**

   Yes. At the March 2007 Chief's group meeting, there was an agreement to centrally track all specimens used for internal and external purposes.

2. **Do surgery patients sign any type of consent for or release of their tissue?**

   The consent form signed by patients, Consent to Operation, Administration of Anesthetics and the Render of Other Medical Services, contains the following statement: "I hereby authorize the hospital and medical group to dispose of any severed tissue or member in accordance with accustomed hospital practice."

3. **Who owns the specimens?**

   California law on ownership of specimens was extensively explained by the Supreme Court of California in Moore v. Regents of University of California (51 Cal.3d 120) Jul 9, 1990.

   The KPSC Medical Care Program owns the specimens although the patient has the right to access them. In the ordinary medical activities of the KPSC Medical Care Program regarding the financial value of tissue, we are at relatively little risk. Routinely removed tissue has no significant value. However, tissue has a significant value only if it has been passed through some research project that demon strates a unique attribute that makes it particularly valuable.

   It is exceedingly rare that human tissue has a unique attribute that makes it particularly valuable. To avoid the risk that might arise if a research project demonstrates that the specimen of a patient has a unique attribute that makes it particularly valuable, our IRB and other research compliance activities extensively address misuse of research to gain secret profits as occurred in the Moore case.

4. **Is it true that cytology specimens cannot be removed from the medical facility premises and are available only for on site review?**

   It is the practice of the KPSC Medical Care Program to retain cytology specimens on site. There are several reasons for storing biospecimens at KPSC medical facilities:
   a) Statutes exist that require that tissue be retained for a particular length of time.
   b) Tissue specimens may be valuable for the continued care of patients. To assure their availability, these tissues are kept on site rather than stored elsewhere.
   c) If litigation is in process or threatened, tissue samples that are unique and cannot be reproduced are retained rather than produced on subpoena or other legal process.

5. **What if I need to outsource pathology review (e.g., to a vendor or academic collaborator)?**

   a) A secure storage system which allows for timely retrieval of specimens when requested is required.
   b) Your IRB protocol must outline the steps that will be taken to maintain secure storage and ensure that patient identification information linked with specimens are kept separately.
   c) If specimens are to be sent outside the KPSC organization, you will need: 1. Business Associate Agreement, or 2. Data Use Agreement (contact Research Finance for assistance).

*Responses to questions 2-5 provided by: Dr. Paul Deiter, M.D., LL.B. Counsel, Southern California Permanente Medical Group. Personal communication, May, 2007.

KAISER PERMANENTE®

KPSC Regional Biospecimen Coordinating Committee
Application to Obtain Pathology Materials

Is the project:

Internal (within KPSC region only)

External (non KPSC, including other KP regions)

SECTION 1

Project Title:

KPSC IRB Approval #:

Funding Source and Status:

Submit study cost center number if the cost of specimen retrieval and refilling is not covered by local medical centers (see pg 11 for the cost of services)

Number of accessions requested:

KPSC Principal Investigator:

Printed Name	Signature	Date

Phone	Fax	Email

Principal Investigator affiliation and title:

Non-KPSC Collaborators:

Name	Affiliation	Email

(Insert names of additional collaborators & contact information here)

SECTION 2

Timeline, Data Retention/Destruction:

When do you need the tissue?
Anticipated timeline

- Project start date
- Number of months to complete the project
- Date when access to specimens will no longer be required
- Date when specimens will be returned
- Date when data (electronic or hardcopy) will be destroyed

SECTION 3

1. Data Linkages: Please complete if results of biospecimen assays will be linked to other KPSC databases (e.g., pharmacy, outpatient, inpatient, etc.).

   Databases to which linkage is planned:

   _____

   _____

   _____

   _____

   _____

2. Detailed description of the material(s) requested (e.g., diagnostic years of interest, type of materials needed (pathology reports, slides, blocks)
3. Detailed description of protocols that will use pathology materials (e.g. specific tumor marker assays)
4. Procedures to ensure specimens are not exhausted

APPEND LIST OF MRNS AND ACCESSION NUMBERS AND LOCATIONS OF BIOSPECIMENS SECTION 4 (FOR EXTERNAL PROJECTS)

Provide the following information on a separate sheet:

1. Status of funding (specify agency):
2. Statistical power/ number of subjects (Kaiser and non-Kaiser, separately)
3. Procedures to ensure specimens are safely returned to Kaiser Permanente

Statement by Requestor

1. Requestor agrees that she/he will not pass PHI, or derivative files (i.e., de-identified data sets) on to any other party without the express written consent of the KPSC IRB and approval by the RBCC Committee.
2. Requestor will bear all risks resulting from its publication or presentation.
3. Requestor agrees to destroy all files, documents or other records containing KPSC data in their custody at the earliest opportunity consistent with the conduct of the proposed use unless there is a health or research justification for retention or retention is required by law. Notwithstanding the foregoing, requestor agrees to destroy all files, documents or other records containing KPSC data in their custody no later than necessary to complete the work, but no longer than the end of the study; unless the RBCC Committee, at its sole discretion, extends the deadline for destruction after consideration. The Requestor is responsible for submitting a request for such an extension by written notice to the RBCC Coordinator.

Destruction means physical destruction of files or deletion of electronic data related to the specimens, documents or other records. De-Identification shall not be considered destruction.

4. All reasonable efforts will be made to limit the use or disclosure of PHI to only that which is necessary to accomplish the intended purpose.
5. The Researcher understands that some data may contain confidential information about individual patients and other identifiers such as names of physicians, hospitals and laboratories or may otherwise be in a form (pathology report) where individual patients may be identifiable. The Requestor agrees to ensure security and protection of identifiable record level data as follows:

   - Biospecimens (blocks, slides) and related paper copies of records will be kept in access-protected premises.
   - Access to the computers and records stored in them will be restricted through use of passwords and other appropriate access control procedures.
   - If photocopied, identifiers will be obliterated completely.
   - Electronic files containing PHI (e.g. magnetic and optic disks, CDs and cartridges) will be destroyed at the end of the study.
   - All study related electronic files will be transferred through secure electronic file transfer methods.

6. If the Requestor is working with external collaborators (e.g., universities or other institutions), the Requestor will be responsible for having each of these persons sign Confidentiality Agreements. In addition, the Requestor is responsible for establishing a Data Use Agreement/Material Transfer Agreement with each external institution. The Requestor is responsible for sending these documents to the KPSC RBCC prior to committee review. No other person shall have access to the records in a form where individuals may be identifiable.

Contact Research Finance to initiate these agreements (Sharon Figgins, 626.564.3135 or tie 8.338.3135, Sharon.M.Figgins@kp.org).

7. Append IRB application. A copy of the IRB approval letter must be provided to the RBCC Coordinator prior to the retrieval and release of any specimens.

8. If KPSC specimens or data will be released or published outside KPSC, append legal subcontracts and study budget or cost center to be charged (see #6 above).

The Principal Investigator certifies that the information reported in this form and the Research Project Proposal is accurate and agree to comply with the terms and conditions contained in this form.

KPSC Principal Investigator:

Signature

Printed Name

Date

Principal Investigator's affiliation and title

Cost Center to be charged for retrieval of specimens

Please send completed applications to:

Kaiser Permanente Southern California
Department of Research & Evaluation
100 S. Los Robles, 2nd Floor, Pasadena, CA 91101

Attention:

Michelle McGuire, MA, RBCC Coordinator
& Reina Haque, PhD

Email: michelle.m.mcguire@kp.org
Email: reina.haque@kp.org
Fax: 626.564.3409

Appendix 7:
Best Practices Guidelines

Biorepositories Best Practices Resource List

1) International Society for Biological and Environmental Repositories http://www.isber.org/
   a. 2008 Best Practices for Repositories http://www.isber.org/Pubs/BestPractices2008.pdf

2) National Cancer Institute Office of Biorepositories and Biospecimen Research
   http://biospecimens.cancer.gov/default.asp
   a. Best Practices for Biospecimen Resources
      http://biospecimens.cancer.gov/global/pdfs/NCI_Best_Practices_060507.pdf
   b. How to Establish and Manage a Tissue Bank or Other Specimen Resource
      http://www.cancerdiagnosis.nci.nih.gov/specimens/establish.htm
   c. NCI Specimen Resource Locator http://pluto3.nci.nih.gov/tissue/default.htm

3) Australasian Biospecimen Network http://www.abrn.net/
   a. Australasian Biospecimen Network Biorepository Protocols—Revision 4
      http://www.abrn.net/pdf/ABN_SOPs_Review_Mar07_final.pdf

4) RAND http://biospecimens.rand.org/
   a. Case Studies of Existing Human Tissue Repositories: “Best Practices” for a Biospecimen Resource for the Genomic and Proteomic Era
      http://www.rand.org/pubs/monographs/MG120/index.html

5) Public Population Project in Genomics (P3G) Observatory
   a. http://www.p3gobservatory.org

6) Organization for Economic Cooperation and Development
   a. Guidelines for Human Biobanks and Genetic Research Databases
      www.oecd.org/sti/biotechnology/hbgrd
   b. Creation and Governance of Human Genetic Research Databases
      http://www.oecd.org/document/50/0,3343,en_2649_34537_37646258_1_1_1_1,00.html