TO: Faculty and Administrative Officers

Earlier this year, the campus Human Research Policy Board (HRPB) discussed existing policy on use of residual human materials. Because of new technologies, current regulations, and a sense that campus guidance on the matter may be dated, the HRPB felt that the policy should be reexamined. As a result, Alan Robinson, Executive Associate Dean, David Geffen School of Medicine has agreed to convene and chair a group that is now reviewing campus policy on use of human materials and make recommendations for revisions.

While awaiting the recommendations of Dr. Robinson’s work group, we want to remind you of the following:

The Office of Protection for Research Subjects (OPRS) will continue to accept requests for Institutional Review Board (IRB) review of research protocols involving the acquisition and sharing of human materials. Additionally, the Office of Contract and Grant Administration (OCGA), the Office of Intellectual Property Administration (OIPA) and the Office of Clinical Trials (OCT) will continue to review requests for material transfer agreements, sponsored research agreements and clinical trial agreements that may involve the collection and/or sharing of residual human materials.

Researchers should not independently enter into agreements to share surplus tissue. The transfer of human tissue to a third party should be accomplished by means of a written Material Transfer Agreement (MTA) negotiated by OIPA, or incorporated into a research contract or grant. Research contracts or grants are negotiated by OIPA if the work is sponsored by a Government or non-profit agency. Research contracts are negotiated by OIPA if sponsored by industry. Clinical Trial agreements are negotiated by the OCT.

It is appropriate to collect nominal fees to cover the actual costs of tissue acquisition, storage, preparation and shipping. Human materials themselves may not be sold. Additionally, under UCLA policy, surplus tissue may not be transferred to third parties including commercial entities, for non-research purposes or for a commercial entity’s independent research use. These materials may, however, be shared for the purposes of collaborative UCLA-industry research. Tissues specifically collected for one research project that remain unused at the completion of the project may not be transferred into a new project or tissue bank without IRB approval. Finally, it is important to note that no agreements for the transfer of human tissue will be signed absent appropriate IRB approval.

The following policies, regulations and guidance on this matter are now in place and govern the way in which human materials (e.g. cells, tissue, blood, urine, and residual diagnostic specimens) are acquired, shared and used for research:
California law regarding hospitals and their clinics requires that all routine tissue specimens must be delivered to pathology for diagnosis and identification.

The campus’ legal obligations to protect human research subjects extends to research that uses human materials including specimens obtained in the course of treatment, surgery or routine patient care. This obligation applies to all specimens, even those that might have been discarded if not used for research. Therefore, all research involving the acquisition, sharing and/or use of human materials requires prior review and approval by a UCLA IRB. Investigators who anticipate collecting tissue for research purposes must create an informed consent document for prospective donors. This consent must be specific. It must include explicit permission for banking tissue, current or future use of tissue for research purposes, and possible transfer to third parties. Further, the consent must include specific language regarding commercial products and/or cell lines developed from the research project. Guidance provided in November 1998 by then-Executive Vice Chancellor Rory Hume indicates that template consent form (HS-2a) is to be used in studies involving human tissue samples or genetic materials with identified tissue or genetic materials. Form HS–2b is to be used for research that involves anonymous or anonymized (de-identified) tissue or genetic materials.

Additionally, the IRB has specific requirements for the storage and sharing of biological and genetic materials (http://www.oprs.ucla.edu/human/documents/pdf/Tissue%20SOPs%202005.pdf). Once campus investigators have received IRB approval to maintain tissue banks then they can bank and store the “surplus” tissue. Otherwise surplus material is either discarded, or maintained by the Pathology Department’s Tissue Procurement Core Laboratory (TPCL).

To receive tissue from TPCL each investigator must first obtain human subjects approval (IRB approval). The TPCL only obtains tissues from routine surgery or autopsies that are not needed for diagnostic purposes. Tissue obtained from a patient is assigned an identification number. The patient’s identity is kept strictly confidential and will never be released to researchers unless the acquisition of such information is approved by the IRB.

A final reminder: Certification in packing and shipping regulations is required for anyone who packages and ships biological materials including human materials. The Biosafety Division of the campus Office of Environmental Health and Safety (EHS) offers a certification class that covers packaging and shipping regulations that meets the federal Department of Transportation training requirements.

If during this interim period you have questions, please direct them to Claudia Modlin, Research Policy and Compliance Coordinator at extension 42642.

Sincerely,

Roberto Peccei
Vice Chancellor for Research