Sheet 17: PROCUREMENT AND USE OF HUMAN BIOLOGICAL MATERIALS FOR RESEARCH

This Information Sheet is posted on the OHSR Web Site at the request of the Tissue Research Committee. Questions about it should be directed to the NCI Laboratory of Pathology (see web site address below).

1. INTRODUCTION

In June 2000, the Medical Executive Committee (MEC) constituted the Tissue Research Committee (TRC) to formulate guidance about the procurement and use of human tissues for research and to standardize procedures for the acquisition, documentation, tracking, and transfer of tissue for research purposes. The final recommendations of the TRC were approved by the MEC in September 2001 and the policies resulting from these recommendations are set forth in the Medical Administrative Series (MAS) #M01-2 entitled "Procurement and Use of Human Biological Materials for Research", see <http://push.cc.nih.gov/policies/PDF/M01-2.pdf>

This Information Sheet provides a brief summary of the TRC's recommendations and the policies and procedures contained in the MAS. The two most important reasons for the new policies are:

- To prevent unauthorized use of human tissue in research, and
- To track tissue that is legitimately obtained and is sent to NIH laboratories for research purposes.

Investigators and IRBs should familiarize themselves with the documentation involved in these policies and procedures, and in particular with the requirements of the NCI's Laboratory of Pathology.

2. DEFINITIONS

(a) "Human biological materials" are defined as all tissues and fluids obtained from living individuals, with the exception of blood. The collection of blood is addressed in MAS M95-9, "Guidelines for Blood Drawn for Research Purposes in the Clinical Center" (see http://push.cc.nih.gov/policies/show_policy.asp?pol_number=M95-9).

(b) “CLIA Certified Laboratories” are defined as clinical diagnostic laboratories certified by the DHHS Health Care Financing Administration pursuant to Section 353 of the Public Health Service Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA). These laboratories may accept human specimens for the purposes of performing procedures that have been approved by the DHHS. The NCI/CCR/Laboratory of Pathology is designated as

the CLIA certified Anatomic Pathology laboratory for patients being treated at the Clinical Center.

3. THE TISSUE RESOURCE COMMITTEE'S RECOMMENDATIONS

(a) Human subject protections

• Human tissues from living individuals may be used for research only after obtaining IRB review and approval, **or** an exemption from IRB approval from the Office of Human Subjects Research (OHSR). Use OHSR's "Request for Review of Research Activity" form to obtain an exemption. The form is available on OHSR's web site at <http://ohsr/od/nih./gov/>. Biological material from autopsy cases or deceased patients does not require an OHSR exemption or IRB approval, but certification or proof that the patient is deceased is required.

• All new protocols must contain a section in the body of the protocol that defines and justifies the planned acquisition and use of tissues. (See OHSR Information Sheet #5, "Guidelines for Writing Research Protocols"; Information Sheet #6, "Guidelines for Writing Informed Consent Documents" and Information Sheet #14, "Guidance on the Research Use of Stored Samples or Data."

• All current protocols that involve tissue acquisition must be amended to contain such a justification no later than at the time of continuing review.

• Informed consent documents must also state if tissue is to be obtained for research purposes and if the tissue will be reviewed for clinical diagnostic purposes by a CLIA-certified laboratory.

• A CLIA certified laboratory must receive at least a portion of all tissue specimens for diagnosis unless the IRB approves a waiver of such review.

(b) Required Forms

• IRB-approved protocol or exemption. An IRB-approved protocol or OHSR exemption is required before any tissue may be removed for research purposes (see 3(a), above). The intent to collect tissue for research must be noted on the initial protocol review application form (NIH 1195), in the body of the protocol and in the consent document. (The CC Protocol Coordination Service Center's database will include this information, which will enable the

Laboratory of Pathology to track protocols that involve collection of human tissues.)

• "Request for Human Biological Materials /Tissue Procurement and Transfer" This form must be completed by the Principal Investigator or a member of the research team at the time of tissue *removal.* The three-part form includes the number of the protocol, information about the research subject, the type of material being acquired, and who is authorized to obtain and receive it. A copy of this form accompanies the tissue when it is transferred to a CLIA certified laboratory for review, storage and distribution. A copy of the form is also routed to the Medical Record Department. If tissue is to be *transferred* to an intramural site other than a CLIA certified Laboratory (i.e., the IRB has waived the need for pathology review), the Principal Investigator must complete this form. The form is designed to document authorized, i.e., protocol approved, procurement of tissue and to track where the tissue is sent. Records may be subject to audit at any time.

• "Intramural Request for Human Biologic Materials for Research Purposes" Intramural investigators, including the Principal Investigator or members of the research team, must use this form to *obtain* human biological materials from the Laboratory of Pathology.

• "Extramural Request for Human Biologic Materials for Research Purposes" Extramural investigators must use this form to obtain tissue from the Laboratory of Pathology.

The forms noted above were developed by the TRC, in cooperation with the Laboratory of Pathology. They are attached to MAS #M01-2. The "Request for Human Biological Materials /Tissue Procurement and Transfer" can be obtained from Medical Records. All other forms can be obtained from Laboratory of Pathology web site http://dcs.nci.nih.gov/branches/lop/labres/index.html

4. RESPONSIBILITIES OF THE NCI/CCR LABORATORY OF PATHOLOGY

The Laboratory of Pathology is legally accountable for storing and protecting in its archive a sufficient amount of tissue specimens obtained from CC patients for *diagnostic purposes.*

The Laboratory of Pathology also stores and protects human tissue obtained under an approved protocol for *research* purposes. It processes requests for acquisition of human biologic materials from its archive as a service and provides

other services, including anonymizing tissue, but does not review the proposed science or prioritize requests by their perceived scientific merit. Copies of the Laboratory of Pathology's standard operating procedures are available upon request.

5. DISTRIBUTION OF HUMAN BIOLOGICAL MATERIALS BY THE LABORATORY OF PATHOLOGY (LP)

The Laboratory of Pathology will not release any human biological materials in its custody without authorization documented by a protocol or an exemption and with one of the forms listed in section 3 (b) above.

- The LP will provide human biological materials first to the Principal Investigator or research team whose protocol authorized the tissue acquisition.

- Annonymized tissue will be released to other intramural investigators or to extramural investigators only if a sufficient amount is available for distribution after the needs of the protocol and the LP archive have been met.

- The LP will not release tissue specimens to an extramural investigator for research without the authorization of the intramural Principal Investigator and the permission of the patient.

For additional details about the policies, procedures and documents required for obtaining and using human biological materials, please refer to MAS# M01-2 or visit the Laboratory of Pathology web site at http://dcs.nci.nih.gov/branches/lop/labres/index.html.