DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
http://www.nih.gov

MEMORANDUM

To: Principal Investigator

From: David E. Kleiner, MD, PhD
Medical Director, Tissue Procurement/Processing Facility
NCI/CCR/Laboratory of Pathology

Joseph W. Chinquee, DHSc, MT(ASCP),DLM
Clinical Manager, Laboratory of Pathology

Subject: **Tissue Resource Committee (TRC) request for Human Biological Materials for Research**

Thank you for your inquiry into Laboratory of Pathology for Human Biological Materials. This TRC form is to request archived paraffin-embedded biomaterial from clinical cases, and for anonymized fresh frozen biomaterial waste tissues. Your proposed experiment must be covered either by an existing IRB-approved protocol or exemption from the requirement for IRB review.

> *Note*: Do not use the attached form to request fresh tissues approved by an IRB protocol; rather, please use the NIH-2803 Medical Record form, which is available in the TPPF or electronically in the Clinical Research Information System (CRIS) as the Research Tissue Procurement Request form.

Biological material from autopsy cases or deceased patients do not require IRB approval or an exemption from the NIH Office of Human Subjects Research Protections (OSHRP); however, release of biological material from deceased patients without an OHSR exemption requires certification or proof that the patient has expired, if material is not from an autopsy case. Requests for other anonymous tissues require approval from OHSRP. To obtain this approval, requests should be submitted through OSHRP's web-based request for determination system: https://federation.nih.gov/Determination/start.php (NIH Login required). Please provide a copy of the OHSRP approval email that designates your activity "Excluded from IRB review" with the TRC request form.

Where necessary, include information on IRB approval or exemption, protocol requirements, and patient name, medical record number, pathology case number, and block number - if known. Requests should be submitted to Ms. Silke Williams, Bldg 10, Room 2S249, MSC 1500. Requests will be reviewed by the LP Tissue Resource Committee (TRC) and forwarded to the Laboratory of Pathology clinical manager and clinical section head for review as quickly as possible. Requests are generally reviewed within 3 days after receipt. Approval notification or request for additional information will be made through e-mail. Turnaround time for processing the biomaterial usually takes between 5-15 working days (3 weeks) for simple requests; but, larger requests could take several weeks, up to two months to complete.

Materials cannot be released unless sufficient diagnostic material is available for NIH archives (SI & SB cases). If adequate material is available, standard recuts will be prepared by the NCI Laboratory of Pathology, Histology section. Requests for recuts from non-NIH consultation (SS) cases can be processed through the TRC program if the Histology laboratory can accommodate based on workload.

If a request cannot be accommodated based on the workload or complexity, it will be sent out to our designated reference laboratory at the requestor's expense. Current reference laboratory costs run from $5.50 to $9.30 per slide (subject to change). All requests must include a Common Accounting Number (CAN) to cover the cost of such request(s).

For additional information about:

- Application process; contact Dr. Joseph Chinquee (DHSc) at (301) 480-7177
- Status of requests under committee review –or- Status of approved request; contact Ms. Silke Williams, at (301) 480-7189 or email: williamss4@mail.nih.gov
- For Fresh Tissue collections via the Walter Reed MCC / NCI collaboration; contact Dr. David Kleiner (301) 480-8487 and specify this request on the TRC form under Description of Resource Needs.
- Use of NIH-2803 for IRB approved fresh tissue or questions about the WRMCC/NCI tissue collaboration, please contact Ms. Sarah Young (301) 480-7182 or Dr. Mohammad Mahboob (301) 480-7181

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NCI LABORATORY OF PATHOLOGY
INTRAMURAL REQUEST FOR HUMAN BIOLOGICAL MATERIALS FOR RESEARCH PURPOSES

PRINCIPAL INVESTIGATOR INFORMATION

Principal Investigator (please print name legibly): _____
Institute: _____ Branch: _____Building: _____ Room: _____
Phone: _____ Page: _____ Fax: _____
E-mail: _____
Alternate Contact Information: _____
Alternate Phone: _____ Page: _____ Fax: _____
E-mail: _____
CAN number: _____

DESCRIPTION OF RESOURCE NEEDS

Type (must check) __ Linked (identifiable) __Anonymized ___ Autopsy __Deceased

Tissue source requested: _____
__ Normal tissue
__ Abnormal tissue. Indicate key diagnostic terminology for database search.

Recuts: __ Recuts only (please attach list with patient name, NIH patient number, path number, block #)
__ Recuts with pathology review (attach list)

Tissue Type (circle all that apply): Fresh Frozen Paraffin Autopsy Cytology Other:_____
__ Is this a request for Fresh Tissue collection via Walter Reed MCC / NCI collaboration

Circle recut slide type : Regular/untreated Charged Other/specify: _____
# of slide recuts: _____ ___ **check if recuts should be made using Rnase precautions. Tubes must be provided.**

Other: _____

NOTE: Materials cannot be released unless sufficient diagnostic material is available for NIH archives. Tissues and slides from non-NIH consultation cases are not typically eligible for TRC requests.

INTENDED USE & METHODOLOGY (Attach additional pages if necessary)

Please include a list of any special requirements or exclusions, and include and expiration date of request if applicable.

OSHR EXEMPTION FORM or IRB APPROVAL NUMBER MUST BE PROVIDED

Attach OHSR Exemption Form or provide IRB Protocol #: _____
Note: An OSHR exemption is not required for Autopsy material. For release of material from non-living patients, please attach certification or proof that the patient has expired.

CERTIFICATION BY PRINCIPAL INVESTIGATOR

The approval provided covers both the protocol and patient-executed consent, and the research proposed is specified within the approved protocol and consent or IRB waiver of consent.
Signature of Principal Investigator of the specified protocol or waiver:

X _____Date: _____

***** INCOMPLETE FORMS WILL BE RETURNED TO PRINCIPAL INVESTIGATOR *****

For more information contact: Joseph Chinquee, DHSc, MBA, MT(ASCP)DLM, Clinical Manager
(301) 480-7177 or NIH page 102-10321 or e-mail: chinquej@mail.nih.gov
Return form and attachments to: Laboratory of Pathology, Tissue Resource Committee
10 Center Drive, Room 10/2S249, MSC 1151
Attn: Ms. Silke Williams (williamss4@mail.nih.gov)

Laboratory of Pathology-Internal Use	Processing notes:
Reviewed by:_____Date:_____	