Public Health Service



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

MEMORANDUM

To: Principal Investigator

From: David E. Kleiner, MD, PhD Joseph W. Chinquee, DHSc, MT(ASCP)

Medical Director, Tissue Procurement/Processing Facility Clinical Manager

NCI/CCR/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 OHSRP exemption approval. To obtain this approval complete a 'Request for Determination - Specimen Data Use Interview Survey or Other' which can be found at: https://federation.nih.gov/ohsr/nih/index.php (NIH login required) under "Investigator Resources" or directly at https://federation.nih.gov/Determination/Start.php (NIH login required). Please provide a copy of the OHSRP approval memo that designates your activity "EXEMPT" 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. If adequate material is available, standard recuts will be prepared by the NCI Laboratory of Pathology, Histology section. 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



Reviewed by:

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

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

PRINCIPAL INVESTIGATOR INFORMATION			
Principal Investigator (please pri	nt name legibly):		
Principal Investigator (please pri Institute: Br	anch:	Building:	Room:
Phone:	Page:	Fax:	
E-mail:			
Alternate Contact Information:			
Alternate Phone:			x:
E-mail:			
CAN number:			
DESCRIPTION OF RESOURCE NEEDS Type (must check)Linked (identifiable)Anonymized AutopsyDeceased			
Type (must check) Li	nked (identifiable)Anon	ıymized Aut	opsyDeceased
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 app Is this a request for l	oly): Fresh Frozen Parafi Fresh Tissue collection via V		
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:			
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 FO	ORMS WILL BE RETUR	NED TO PRINC	IPAL 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: chinquei@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:

Date: