Laboratory of Pathology
Center for Cancer Research
National Cancer Institute
National Institutes of Health

Clinical Services

Request for Human Biological Materials for Research Purposes

2002

ACKNOWLEDGEMENTS

This procedure was created under the direction of the Tissue Resource Committee (TRC). The National Cancer Institute, Center for Cancer Research, Laboratory of Pathology (LP) acknowledges the hard work and dedication of this multi-institute team, which helped develop this procedure. Members of the committee include:

Tissue Resource Committee Chair
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Tissue Resource Committee Members
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Sam Hwang, MD, PhD, NCI
Kim Jarema, RHIA, CC
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PURPOSE AND GUIDELINES

This procedure is written under the direction of the Tissue Research Committee (TRC). In June 2000, the Medical Executive Committee constituted a Tissue Resource Committee to formulate guidance regarding the procurement and use of human tissues for research. The committee was charged to address issues of human subjects protections, implementation of tissue acquisition, transfer and documentation in the Clinical Center (CC), and implementation of tissue transfer to non-NIH investigators. Additionally, the committee sought to delineate the differences in handling tissue specimens obtained for clinical care as opposed to research, and to protect investigators' access to tissues collected under protocols, while providing access of others to the archival CC specimen collection (the Archive) curated by LP.

The Committee's broad recommendations are intended to provide human subjects protection, provide a method of documentation, balance the clinical needs of the patient and the protection of the research interests of the investigator, provide a mechanism for LP to facilitate acquisition of human tissues from the Archive, and educate the NIH community. See appendix for guidance document for additional information.

It is not the purpose of the TRC to review the scientific merit or ethics of any proposal. Proposals must have proper Institutional Review Board (IRB) approval or Office of Human Subjects Research (OHSR) exemption. IRB approval is necessary if the request requires samples linked to patient identification. It is the responsibility of the requestor to obtain the appropriate approval before requesting resources through LP. Neither IRB approval or OHSR exemption is required for materials from deceased patients.

LP is responsible and accountable by law for the use and protection of patient materials that are in its archive. By law, LP is accountable for patient materials and proof of diagnosis, (e.g., slides, blocks). If the requested material is in danger of being exhausted, the Pathologist and original Principal Investigator (PI) in charge must be consulted to determine if the request can be fulfilled.

Specimens prospectively collected for particular protocols are protected from non-protocol specific research. General policies are listed below to provide general guidance.

1. All specimens that are collected for protocol purposes but for which limited material is available will be unavailable for any research (linked or unlinked) without the consent/collaboration of the PI. Limited material is defined as a single block specimen (includes cytologies and surgicals). Such specimens will be flagged in the SoftPath™ Laboratory Information System (LIS) along with the protocol number.
2. Limited medical specimens collected as part of medical care of the patient, but not part of the protocol (e.g. stomach biopsy on a hepatitis patient), will be available for research with the proper ethical approval.
3. Non-limited specimens collected for a protocol will be available for research without the consent or collaboration with the principal investigator with the proviso that at least one representative block is set aside and preserved for diagnostic purposes.

4. More restrictive use could be flagged on larger (less limited) cases on a protocol-by-protocol basis if the principal investigator notifies LP or notates this on each specimen requisition.
5. Restrictions on uses of limited specimens would be lifted 5 years after the protocol has closed, unless otherwise requested by the PI.
6. Investigators placing MIS orders for our services will have to answer a yes/no question about whether the specimen they are collecting is required or specified by the ordering protocol. (All MIS orders that non-pathology personnel place already have to be linked to a protocol number). This information will come over to the LIS via the computer interface between the MIS and LIS. If the specimen is being collected for the protocol, the tech who accessions the case will retype the protocol number in the "F.case#" field on the Specimen Registration screen, which is a searchable alphanumeric field. There are multiple benefits to collecting this information. First, it should reassure investigators worried about their protocol biopsies. Second, it will permit us to easily track these specimens and link specimens to PIs. We will also be able to extract information about which protocols require the most technical work. Right now, this only affects in-house specimens; however, placing this question and a place for protocol number on the paper request forms for submitted cases are under consideration.
7. Also under evaluation is the recommendation that aggressive, anonymized, tissue collection be implemented on all large specimens and autopsies with the idea of collecting both frozen and fixed tissue. Fixed tissue collection could take place after all routine blocks have been prepared. Some further thought needs to be given to how fresh frozen tissues should be collected, but on very large specimens selection of tissues to be frozen should not be controversial. A system for anonymizing specimens in the LIS has already been implemented. Only the patient age, sex, and diagnosis will be recorded for each tissue.

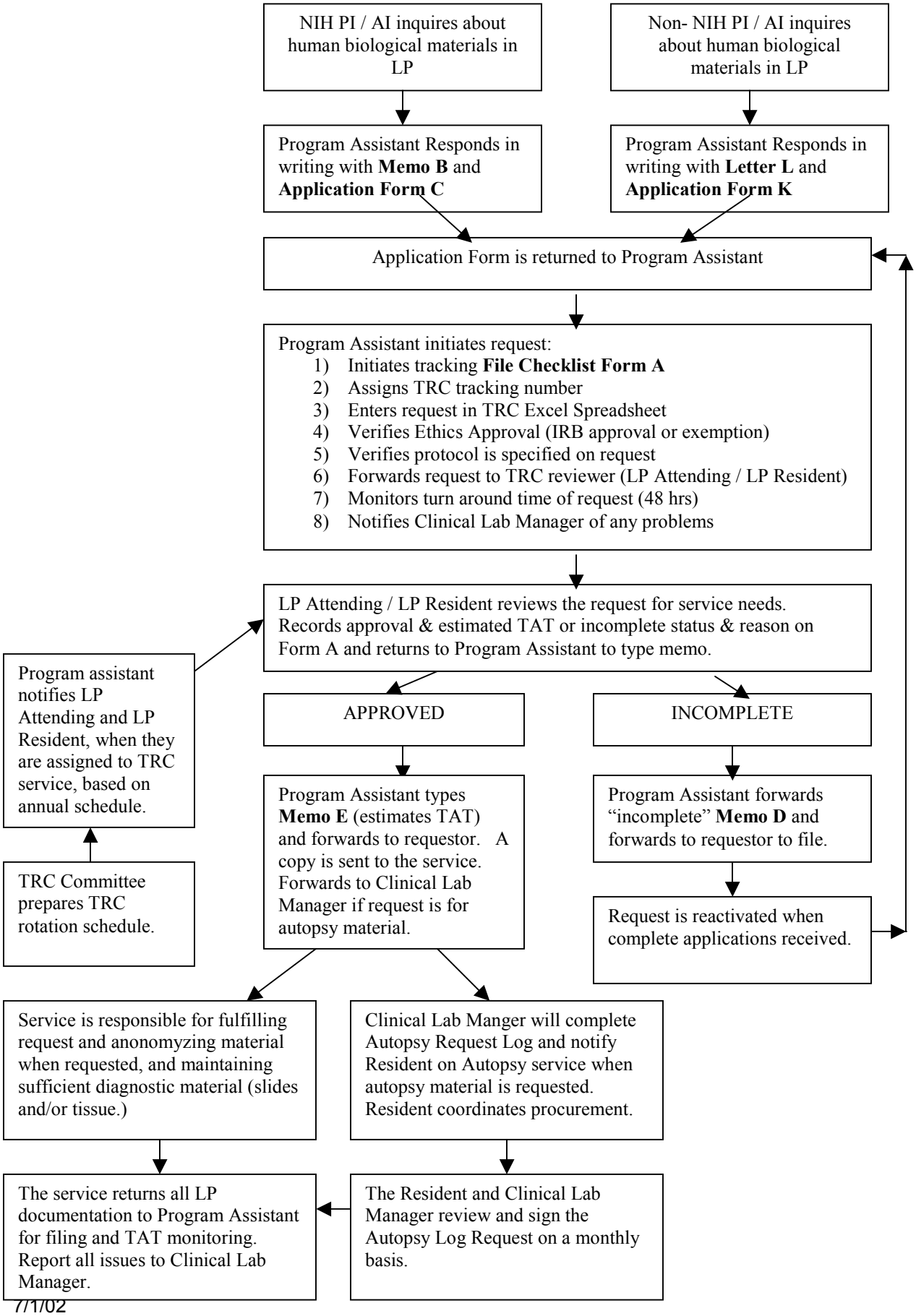
The TRC may question the technical approach of any request and may contact the requestor for additional information to justify or modify the request.

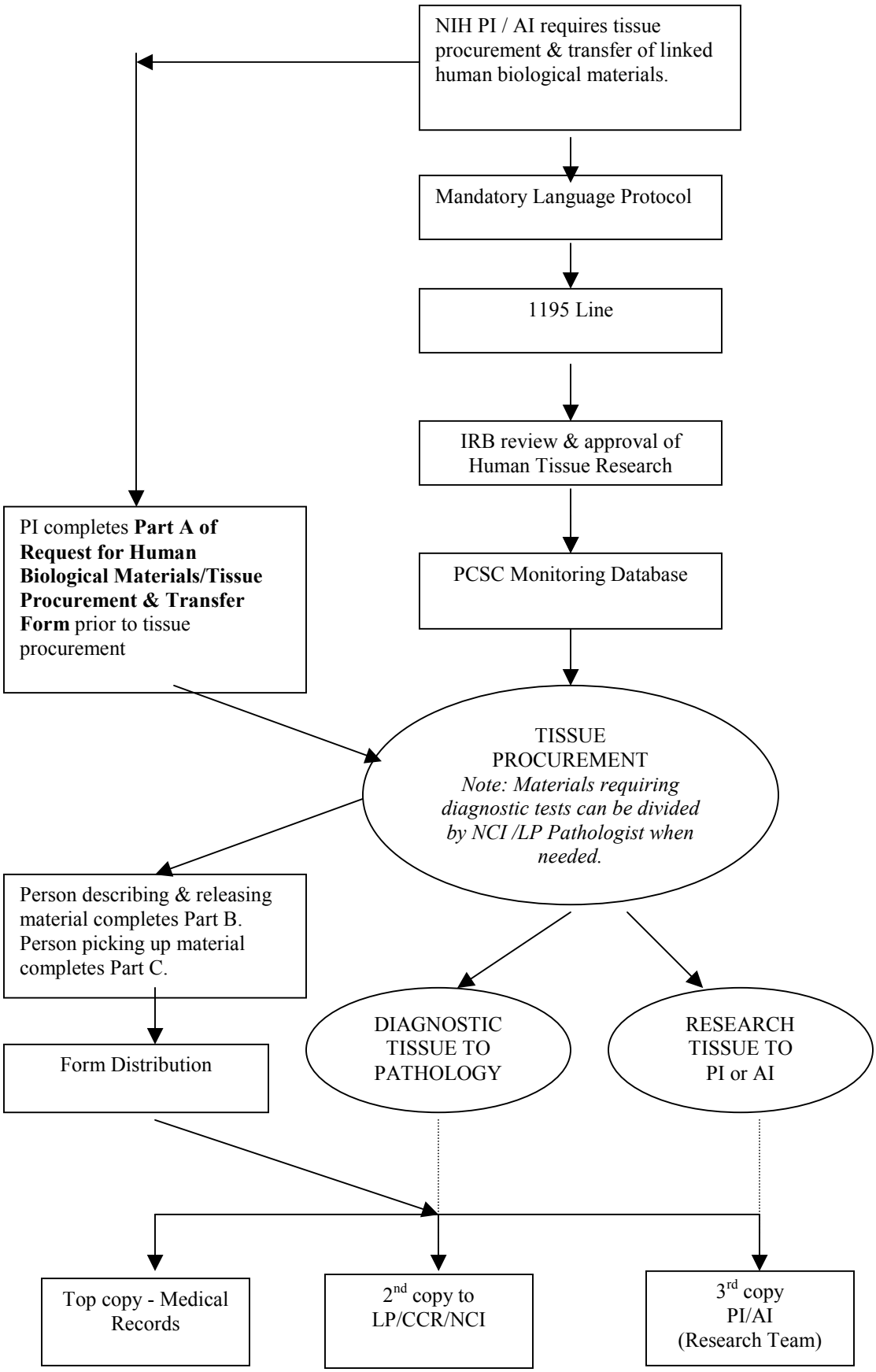
All non-protocol use of patient tissues must be submitted to the TRC for approval. Use of tissues for controls in diagnostics tests is exempted (e.g., block used as a control for an immunoperoxidase stain). Tests performed for diagnosis (tests performed in a CLIA or CAP approved laboratory) are exempted from this process.

The requestor must specify whether or not the request is linked (identifiable) or anonymized (unlinked, with no patient identifiers and therefore cannot be correlated with patient's clinical course or clinical outcomes, etc). All studies using tissues from living patients must be either IRB approved or OSHR exempted. The investigator doing the study cannot perform the unlinking. A technologist within LP will be responsible for unlinking all tissues for anonymized studies. Any study that uses patient information other than age, sex and diagnosis (i.e. clinical outcome) must be IRB approved. Age, sex and diagnosis (i.e. clinical outcome) may be provided for OHSR exempted requests. An OHSR is not required for Autopsy material. For release of material from non-living patients, the requester must attach certification that the patient has expired. All studies need to be approved by the TRC.

Request for Human Biological Materials for Research Purposes

Tissue Resource Committee Flow Chart





TISSUE PROCUREMENT AND TRANSFER FLOW CHART

Flow Chart for Request for Human Biological Materials Tissue Procurement & Transfer Form (Parts A & B)

Protocol

↓

Tissue Need

↓

Schedule Procedure → Notify Research Team

↓

Complete Part A.
Send form with medical record with patient to procedure.

↓

Procuring physician/team: Verify completeness of Part A of the Form
Note: May be more than one tissue or pass.
(e.g., one for pathology and one for investigator)

↓

Procedure

↓

Person describing and releasing material/tissue completes Part B.
Note: Pathologist can divide materials requiring diagnostic tests, when needed.

↓

Person picking up material completes Part C.

Copies of form should be distributed at time of tissue transfer:
Top copy: Medical Records
2nd Copy: Laboratory of Pathology (LP)/CCR/NCI
3rd Copy: Research Team

PROCEDURE (REQUEST FLOW)

A. Request for archived human biological material

1. Any new questions regarding how to complete a TRC request should be directed to program assistant assigned to the TRC. The program assistant will respond in writing with a cover letter (TRC B, or TRC L for non-NIH requests) and a Request for Human Biological Materials application form (TRC C, or TRC K for non-NIH requests).
2. The requestor must complete TRC C/K and return.
3. The LP program assistant assigned to the TRC will log the request into the TRC Excel file, and assign the TRC number on the applications. A file is created and a checklist (TRC A) is placed in the file. A resident or fellow will work with an attending according to the monthly TRC schedule to review the request. The LP Program Assistant delivers the application to the assigned TRC member covering for that month, within 24 hours of receipt.
4. The TRC member reviews the application and takes action within 48 hours of receipt based on the following categories:
   a. ***Incomplete application –***
      - The TRC signs the “INCOMPLETE” SIGNATURE line and specifies why the application is incomplete or cannot be fulfilled (e.g., specific technical reason, inadequate information, etc), by checking the reason(s) the application is incomplete and returns to the program assistant.
      - The program assistant notifies the requestor in writing or e-mail using “TRC D” as a template, records the date of the FAX or e-mail on file checklist (Form A) and in the Excel file.
      - The request will remain on file until additional information is received.

   b. ***Complete application –***
      - The TRC signs the “APPROVED ” SIGNATURE line and estimate the turn around time for completion.
      - The program assistant notifies the requestor in writing or e-mail using the acceptance letter and letter to the section chief using “TRC E” and “TRC F” as templates, and records the date of the FAX or e-mail on file checklist (Form A) and in the Excel file.
      - The request will remain on file in LP.

5. The section chief is then responsible for fulfilling the request assigning the request to a technologist to complete. When possible, recuts will be performed in-house. All recuts that are sent to a reference lab will be charged to the requesting PI’s CAN#. NCI PIs are not charged for work. If the material is in danger of being exhausted, the Pathologist and original PI for the material must be consulted to determine if the request can be fulfilled.
   a. If anonymized (unlinked) material is requested, a technologist or archivist will unlink the source. For example, if anonymized recuts are sent to a reference lab for cutting, a random number will be

assigned to the block before the blocks are sent out. Slides will be labeled with the random number. The label will be removed from the block before it is returned to the file.

b. The technologist or archivist will order "research recuts" in the Laboratory Information System (LIS) indicating the amount of slides given for research.

c. Records of the source will not be documented in a way that the material can be linked to the patient. Any interim documentation created in organizing the request will be destroyed at the time of releasing the material or shortly thereafter.

B. Request to obtain human biological material at the time of autopsy

1 Follow steps 1-5 in Section A, above.

2 The section chief reviews the request and forwards to the Clinical Lab Manager to record on the Autopsy Request Log (TRC G). The Clinical Lab Manager will also notify the resident on the autopsy service.

3 The resident will coordinate autopsy tissue procurement. Proper authorization for autopsy consent must be obtained for all cases. Tissue will not be procured on autopsy cases that occur after hours, weekend, or holidays unless special arrangements are made to pickup the specimen. The resident on the current month of service notifies the resident on next month of service of any pending requests. The log is reviewed and signed by both the resident and the manager on a monthly basis.

C. **Tissue procurement and transfer of human biological material at time of collection (e.g., surgical procedure, skin biopsy, lymph node biopsy, fine needle aspirate, etc) for research use only and/or diagnostic purposes.**
Note: Separate standard operating procedures are necessary for the operating room and other venues.

1. Documentation that tissue can be removed for research purposes must be in place prior to tissue removal, acquisition, and transfer. The Medical Record's Form "Request for Human Biological Materials Tissue Procurement & Transfer Form" must be submitted to the Operating Room, Pathology, or appropriate acquisition and disposition group. Materials cannot be collected with out the completed form. The completed form is placed in the permanent Medical Record

2. General instructions are as follows:

Note: This form is used when tissue is obtained for research. Do not use this form if materials are only obtained for pathology lab (NCI/CCR/LP) for clinical diagnostic purposes.

PART A: REQUEST & CERTIFICATION BY PRINCIPAL INVESTIGATOR

All information in part A must be completed by the Principal/Associate Investigator prior to procurement of biological materials (tissues, fluids, etc) for research purposes.

- Complete the patient identification information (Last name, First name, Middle initial, NIH Medical Record #) located in the lower left hand corner of the form.
- Print the name of the principal investigator requiring tissue procurement and transfer of linked human biological materials for research purposes.
- Complete the information principal investigator or associate investigator
    - Institute/Branch of the PI

- Building/room number
- Phone and pager of the PI

- Indicate date of request
- Indicate whether the material is for
  - Research use only (will not receive pathology review)
  - Diagnostic purposes and research purposes (Laboratory of Pathology can be involved in the division of the material, when needed)
- Provide the IRB Protocol # for this request.
- Provide the name of the physician performing the procedure (person responsible for collecting the material (e.g., surgeon's name)
- List the research material and the recipient of the material designated in the IRB approved protocol.
- Obtain the signature of the Principal Investigator/Associate Investigator and date to certify the request.

PART B: DESCRIPTION OF TRANSFER

Part B is to be completed by the person describing and releasing the material.

- Describe tissue source (specify number of pieces, organ, left vs. right, anterior vs. posterior, etc where appropriate):
- *Example: Pelvic lymph node, left*
- Describe Measurements, quantity, and description of material/tissue procured.
- *Example: Single pass aspirate.*
- Record name of person describing and releasing material after procurement (e.g., pathologist, surgeon, nurse).
- The person describing and releasing the material must sign and date at the bottom of section B on the form.

PART C: DESCRIPTION OF TRANSFER

Part C is to be completed by the person picking up the research material.

- The person picking up the material must sign and date the form.

3. Materials removed for research are not available for diagnosis.
4. The appropriate physician or surgeon must document in the Medical Record the nature and description of the material removed, purpose of removal, destination of tissue (name of institute laboratory, including building and room number).
5. If fresh material requires division between samples for research and diagnosis, LP will do this so that adequate tissue for clinical diagnosis is ascertained. This division will be done by a staff pathologist or designate. Documentation of samples removed will be recorded on The Tissue Procurement & Transfer Form and in the gross description of the SoftPath™ LIS report.
6. Where research mandates frozen tissue, the research samples will be held as a frozen block in pathology pending clearance of the diagnosis in case further material is required for diagnosis.
7. The distribution of the material is documented by the staff pathologist or designate in the LIS Path report.
8. The distribution of the form is as follows:
   a. Original (white): Medical Records
   b. Yellow copy: NCI/LP

c. Pink copy: Designated Principle Investigator or Associate Investigator specified on the form.

D. Request from extramural (outside NIH) organization.

1. If LP receives a request from outside the NIH the program assistant responds with letter L and the Extramural Request for Human Biological Materials For Research Purposes (Medical Record Form # NIH-2803-2, appendix K).
   Note: Anonymized tissue will not be released because it is not within our mission to function as a tissue bank.
2. The requestor must provide billing information on the request form so that the reference lab may bill for the service. Shipping will be billed to the requestor's account specified on the request.
3. The program assistant records the date the completed form is received and forwards it to the TRC reviewer.
4. To obtain linked material, the PI must have an IRB approved protocol and consent for this acquisition. The TRC reviewer must verify the form is complete. The patient (or guardian) signature is required. Because of the Privacy Act, no personally identified (linked) samples (materials) can be shared even if the outside IRB has waived consent. The Privacy Act does not apply if the patient is deceased. The extramural principal investigator must certify this request.
5. Materials cannot be released unless sufficient diagnostic material is available for NIH archives.
6. In accordance with the CC Medical Administrative Policy M01-2 (http://push.cc.nih.gov/policies/PDF/M01-2.pdf), these requests require approval by the PI of the protocol under which the tissue was collected or the institute Clinical Director.
7. The TRC reviewer reviews the request and records the outcome (e.g., recuts will be sent on XX/XX/XX, denied/incomplete form, etc) and signs the form. The Clinical Laboratory Manager and archivist will coordinate release of patient material.
8. The program assistant will make a copy of the completed form for the TRC files and the original will be forwarded to the patient's medical record at NIH, after the request has been fulfilled. LP is obligated by law to forward all requests (even if incomplete) to the Medical Record. A follow-up letter will be return to the extramural principle investigator at the time of release of materials or denial of request.

References

Clinical Center. Policy and Communications Bulletin. Medical Administrative Series. M01-2. SUBJECT: Procurement and Use of Human Biological Materials for Research. November 2, 2001.

Clinical Center. Policy and Communications Bulletin. Medical Administrative Series. M77-2 (rev.). SUBJECT: Informed Consent. May 30, 2001

Clinical Center. POLICY: Guidelines for Blood Drawn for Research Purposes in the Clinical Center. October 1, 1995.

Code of Federal Regulations. Title 42, --Public Health, Chapter IV –Health Care Financing Administration, Department of Health and Human Services, Part 493— Laboratory Requirements, Revised, October 1, 2000.

Code of Federal Regulations. Title 45, Public Welfare; Department of Health and Human Services National Institutes of Health Office for Protection from Research Risks; Part 46, Protection of Human Subjects. Revised, June 18, 1991. Effective August 19, 1991.

Code of Federal Regulations. Title 45, Standards for Privacy of Individually Identifiable Health Information; Final Rule Parts 160 and 164. (Implementation of Health Insurance Portability and Accountability Act of 1996) Final Rule, December 28, 2000. Effective April 14, 2001.

H.R. 3569. Human research protection and promotion act of 2000 (Introduced in the House, February 2, 2000 & referred to the Subcommittee on Health and Environment, February 7, 2000)

NCI. Confidentiality, data security, and cancer research: perspectives form the national cancer institute. March 23, 1999.

NCI. Uses of Human Tissues. August 28, 1996.

The National Commission for the Protection of Human Subjects. The Belmont Report; Office of the Secretary; Ethical Principles and Guidelines for the Protection of Human Subjects Research. April 18, 1979.

The Warren Grant Magnuson, Clinical Center. The Medical Record Handbook. October, 2000.

Tissue Resource Committee, Ongoing.

APPENDIX:

FORMS

AND

SAMPLE MEMOS

Request for Human Biological Materials for Research Purposes
FILE CHECKLIST

(THIS SECTION IS COMPLETED BY THE PROGRAM ASSISTANT)

Request #_____ Date received: ____/_____/____ Date sent to Resident Fellow ____/_____/____

TRC Review members Resident/Fellow _____ Attending _____

(THIS SECTION IS COMPLETED BY RESIDENT/FELLOW)

1. Appropriate Ethics Approval (IRB approval or exemption)
   ___Yes ___ No

2. Required as part of ongoing clinical protocol (#_____)
   ___Yes ___ No

3. Resource availability (Forwarded to Section or Unit Chief)

   _____ Autopsy (David Kleiner, MD, PhD, Chief, Post Mortem Services)

   _____ Cytology (Andrea Abati, MD, Chief, Cytology)

   _____ Cytogenetics (Diane Arthur, MD, Chief, Clinical Cytogenetics)

   _____ Hematopathology (Elaine Jaffe, Chief, Hematopathology)

   _____ Histopathology (David Kleiner, MD, PhD, Director, Clinical Operations)
   (REQUESTS FOR RECUTS)

   _____ Immunohistochemistry (Mark Raffeld, MD, Chief, Immunohistochemistry Unit)

   _____ Flow cytometry (Maryalice Stetler-Stevenson, MD. PhD, Chief Flow Cytometry Section)

   _____ Molecular Diagnostics (Mark Raffeld, MD, Chief, Molecular Diagnostics Unit)

   _____ Surgical pathology (Maria Merino, MD, Chief, Surgical Pathology)
   (Note: Request for recuts only should go to Histopathology)

(THIS SECTION IS COMPLETED BY THE RESIDENT/FELLOW & ATTENDING)

4. **INCOMPLETE**
   Reason (will be typed in letter)
   ___ IRB Protocol#
   ___ OHSR Exemption
   ___ CAN number
   ___ Intended Use and Methodology
   ___ Patient list (include NIH patient number)
   ___ Must indicate if request is linked (identifiable) or anonymized
   ___ Other: Specify: _____
   by TRC _____ ___/___/___ _____ ___/___/___
   (Resident/Fellow) (Attending)

5. **APPROVED**
   Estimate of TAT for completion _____ days (to be included in letter)
   Other information to include (will be typed in letter): _____
   _____
   by TRC _____ ___/___/___ _____ ___/___/___
   (Resident/Fellow) (Attending)

6. **LETTER FAXED OR E-MAIL SENT ____/____/_____ BY _____**
   (COMPLETED BY PRORAM ASSISTANT) (Place document in file)

TRC-A

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

MEMORANDUM

To: _____

From: Laboratory of Pathology

Date: _____

Subject: Laboratory of Pathology Research Development and Support Request

Thank you for your inquiry into Laboratory of Pathology Support Services. Please fill out the attached request form. Your proposed experiment must be covered either by an existing IRB-approved protocol or exemption from the requirement for IRB review. You can contact the Office of Human Subjects Research for the exemption form. Refer to web site: http://ohsr.od.nih.gov/

Where necessary include information on IRB approval or exemption, protocol requirements, and patient name, CC number, pathology number, and block number if known. Support requests should be submitted to Mrs. Susan Gantz, Bldg 10, Room 2N212. Requests will be reviewed by the LP Tissue Resource Committee and forwarded to the Laboratory of Pathology Service Chief as quickly as possible.

All requests for recuts of paraffin blocks without pathologic review will receive expedited review. Materials cannot be released unless sufficient diagnostic material is available for NIH archives. For those requests where adequate material is remaining, upon receipt of a completed form, the NCI Laboratory of Pathology, Histology section will oversee the preparation of the material. If a request cannot be accommodated based on the workload, it will be sent out to a reference laboratory chosen by NCI/LP at the requestor's expense. Current costs run from $2.95 per untreated, unstained slide to $3.35 per gelatin, lysine, or silanated slides and $7.35 per hematoxylin and eosin stained slides. Please include your CAN number to cover the cost of such request.

TRC-B

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

TISSUE RESOURCE COMMITTEE

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 one option): __ Linked (identifiable) -*OR*- __Anonymized
Tissue source requested: _____
__ Normal tissue
__ Abnormal tissue. Indicate key diagnostic terminology for database search.
Service: __ Autopsy __ Cytogenetics __ Cytopathology __ Flow cytometry
__ Hematopathology __ Immunohistochemistry __ Laser capture microdissection
__ Molecular diagnostics __ Surgical Pathology __ Other (specify): _____
Recuts: __ Recuts only (attach list with patient name, NIH patient number, path number, block if known)
__ Recuts with pathology review (attach list with patient name, NIH patient number, path number, block)
Tissue Type (circle all that apply): Fresh Frozen Paraffin Autopsy Cytology Other/specify:_____
Circle recut slide type : Regular/untreated Gelatin Poly-L-Lysine Silanated Other/specify: _____
# of slide recuts: _____ **___ check if recuts should be made using Rnase precautions.**
Other: _____
NOTE: Materials cannot be released unless sufficient diagnostic material is available for NIH archives.

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 #:_____

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: Kevin Nellis, MT(ASCP), Clinical Lab Manager
(301) 594-9532 or NIH page 104-4613 or e-mail: nellisk@mail.nih.gov
Return form and attachments to: Laboratory of Pathology, Tissue Resource Committee
10 Center Drive, Room 10/2N212
Attn: Ms. Susan Gantz (gantzs@pop.nci.nih.gov)

TRC-C

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

MEMORANDUM

To: _____

From: Laboratory of Pathology Tissue Resource Committee

Date: _____

Re: Proposal for _____

Thank you for your interest in using Laboratory of Pathology Research Development and Support Resources. Your proposal was reviewed and was found to be incomplete. Your proposed experiment must be covered either by an exiting IRB-approved protocol or an exemption from the requirement for IRB review for the use of human tissue. You can contact the Office of Human Subjects Research for the exemption form. Refer to web site: http://ohsr.od.nih.gov/

Please submit the following information:

___ IRB Protocol#
___ OHSR Exemption
___ CAN number
___ Intended Use and Methodology
___ Patient list (include NIH patient number)
___ Indicate if request is linked (identifiable) or anonymized

Completed requests should be submitted to Ms. Susan Gantz, Bldg 10, Room 2N212. Requests will be reviewed by the LP Tissue Resource Committee and forwarded to the Laboratory of Pathology Service Chief as quickly as possible.

All requests for recuts of paraffin blocks without pathologic review will receive expedited review. Materials cannot be released unless sufficient diagnostic material is available for NIH archives. For those requests where adequate material is remaining, upon receipt of a completed form, the NCI Laboratory of Pathology, Histology section will oversee the preparation of the material. If a request cannot be accommodated based on the workload, it will be sent out to a reference laboratory chosen by NCI/LP at the requestor's expense. Current costs run from $2.95 per untreated, unstained slide to $3.35 per gelatin, lysine, or silanated slides and $7.35 per hematoxylin and eosin stained slides. Please include your CAN number to cover the cost of such request.

Your proposed experiment must be covered either by an existing IRB approved protocol or an exemption from the requirement for IRB review for the use of human tissue.

TRC-D

APPROVAL SENT VIA E-Mail:

TO: All requestors listed on form and anyone mentioned on request form

CC: Chief of Service, Clinical Laboratory Manager, Archivist, TRC Reviewer
Note: Print copy of e-mail for the TRC file folder.

SUBJECT: Approval for Request for Human Biological Materials <INSERT TRC #>

INTRODUCTORY TEXT:
Thank you for your interest in using Laboratory of Pathology to request for human biological materials.

FOR REQUESTS WITH IRB APPROVAL, USE THE FOLLOWING TEXT:
Your proposal was reviewed and was found to have appropriate human subjects' protection use of patient materials. It is understood that the IRB approval you have provided covers both the protocol and patient-executed consent and that the research you propose is specified within the approved protocol and consent.

FOR REQUESTS WITH OHSR EXEMPTION, USE THE FOLLOWING TEXT:
Your proposal was reviewed and was found to have appropriate human subjects' protection or exemption documentation for use of patient materials. It is understood that the activity is designated as "EXEMPT" from the OHSR and that the research you propose is specified within the Request for Review of Research Activity Involving Human Subjects.

FOR REQUESTS OF MATERIALS FROM AUTOPSY OR DECEASED CASES, USE THE FOLLOWING TEXT:
Your proposal and research request was reviewed and the activity is designated as "EXEMPT" since the materials will be from deceased patients.

ADD STATEMENT FOR TURN AROUND TIME:
Based on current resource, the estimated turn around time to complete this request is approximately _____ days.

OR (FOR AUTOPSY OR DECEASED CASES), USE THE FOLLOWING TEXT:
The turn around time is dependent on availability of autopsy case.

ADD STATEMENT FOR WHO THEY MAY CONTACT FOR FOLLOW-UP, IF NEEDED:
Your request will be forwarded to David Kleiner, MD, PhD, Director of Clinical Operations. Please contact Dr. Kleiner for further arrangements (301-594-2942).

OR FOR OTHER SERVICE:
Your request will be forwarded to Dr. _____, chief of the Surgical Pathology. Please contact ____ for further arrangements (301-____-_____).

TRC E

TISSUE RESOURCE COMMITTEE
NCI LABORATORY OF PATHOLOGY
REQUEST FOR HUMAN BIOLOGICAL MATERIALS
Autopsy Request Log

Date / by	TRC #	Type of tissue	Special requirements/ Exclusions (e.g. size, collection within X hrs of expiration, other)	Contact Person Phone /pager (required)	Notification for pick-up List person contacted, date, & time	Picked up by	Is this an ongoing request? Yes/No *If yes, please enter new line for future request.*	Comments / Corrective Actions

Notes:
1) Proper authorization for autopsy consent must be obtained for all cases.
2) Do not procure tissue on autopsy cases that occur after hours, weekends, or holidays unless special arrangements are made to pick up the specimen.
3) Resident on current month of service will notify resident on next month of service of any incomplete cases.

Monthly Autopsy Resident Review			Monthly Clinical Lab Manager Review		
___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___
___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___
___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___
___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___
___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___
___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___
___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___	___ ___/___/___

TRC-G

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

MEMORANDUM

To: Dr. _____

From: Laboratory of Pathology Tissue Resource Committee

Date: _____

Re: TRC schedule

For the month of _____you are the scheduled (attending/staff/resident/fellow) for the incoming TRC request forms. I am sending you this package of information to help you understand the TRC process. Per your request, I can e-mail you the sample memos. Please contact Kevin Nellis if you require additional information at 301-594-9532 or nellisk@mail.nih.gov.

Thank you,

TRC Program Assistant

Laboratory of Pathology, Tissue Research Committee
10 Center Drive, Room 10/2A33
Attn: Ms. Susan Gantz,
e-mail: (gantz@pop.nci.nih.gov)

TRC-H

TRC ROTATION 2001 ACADEMIC SCHEDULE

MONTH	RESIDENT/FELLOW	ATTENDING
July 2001	Dr. Berman	Dr. M. Stetler-Stevenson
August 2001	Dr. Feldman	Dr. Quezado
September 2001	Dr. Auerbach	Dr. Kleiner
October 2001	Dr. Rosenblatt	Dr. Hewitt
November 2001	Dr. Herrmann	Dr. Jaffe (1st half) Dr. Duray (2nd half)
December 2001	Dr. Bryant-Greenwood	Dr. Abati
January 2002	Dr. Cassarino (1st half) Dr. Todd Barry (2nd half)	Dr. Filie
February 2002	Dr. Schrager	Dr. Raffeld
March 2002	Dr. Taddesse-Heath	Dr. Pittaluga
April 2002	Dr. Zha	Dr. Kingma
May 2002	Dr. Clark	Dr. Tsokos
June 2002	Dr. Myrick	Dr. Merino

Please notify Kevin Nellis of any changes (trades) to the schedule.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

National Cancer Institute
Laboratory of Pathology
Building 10 / Room 2N218
Besthesda, Maryland 20892
(301) 594-9532

American HistoLabs, Inc
7605-F Airpark Road
Gaithersburg, Maryland 20879
(301) 330-1200

July 19, 2000

Re: Order # _____

Enclosed are ___ #___blocks re-labeled as _____ , and _____. From these blocks, please cut a total of _____sections on ___(type)____ slides.

Please use RNase precautions when preparing the slides.

Please label all slides using the identifier on the white label placed on the back of the block.

Please return all material to:

DHHS/NIH/NCI/Lab of Pathology
Histology Branch, Building 10, Room 2N218 or 2N212
Besthesda, Maryland 20892
Attn: Kevin Nellis
(301) 594-9532

Respectfully,

Kevin Nellis, MT(ASCP)
Clinical Laboratory Manager

TRC-I

INSERT
REQUEST FOR HUMAN BIOLOGICAL MATERIALS TISSUE PROCUREMENT
& TRANSFER FORM

INSERT
EXTRAMURAL REQUEST FOR HUMAN
BIOLOGICAL MATERIALS FOR RESEARCH PURPOSES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

http://www.nih.gov

DHHS/NIH/NCI/DCS/LP
9000 Rockville Pike
Bethesda, Maryland 20892
Bldg 10 Rm 2N212, MSC 1516
Attn: Kevin Nellis / Susan Gantz

<INSERT DATE>

<INSERT NAME OF REQUESTOR>
<INSERT ADDRESS>

Subject: Request for human biological materials for research purposes

Dear Dr. <INSERT NAME OF REQUESTOR>:

Thank you for your inquiry about the National Cancer Institute Laboratory of Pathology (LP) Support Services. The NCI/LP Tissue Resource Committee (TRC) will evaluate requests as quickly as possible. All requests for paraffin block recuts without pathologic review will receive expedited review.

To obtain material, you must have an IRB approved protocol and consent for this acquisition. The patient's (or Guardian's) authorization for release of the sample is also required. The principal investigator must certify the research use of the requested human biological material will be in accordance with the IRB's determinations or that use has been determined to be exempt for IRB review and approval. This form will be added to the patient's medical record at NIH, even if the request is incomplete or denied.

It is the responsibility of the requestor to obtain the appropriate approval before requesting resources through NIH. LP is responsible and accountable by law for the use and protection of patient materials that are in its archive. By law, LP is accountable for patient materials and proof of diagnosis, (e.g., slides, blocks). If the requested material is in danger of being exhausted, the pathologist and the NIH PI under whose protocol the sample was originally collected must be consulted to determine if the request can be fulfilled. The TRC may question the technical approach of any request and may contact the requestor for additional information to justify or modify the request

Materials will not be released unless sufficient diagnostic material is available for NIH archives. For those requests where adequate material is remaining, upon receipt of a completed form, the NCI Laboratory of Pathology, Histology section will oversee the preparation of the material. It will be sent out to a reference laboratory chosen by NCI/LP at the requestor's expense. Current costs run from $2.95 per untreated, unstained slide to $3.35 per gelatin, lysine, or silanated slides and $7.35 per hematoxylin and eosin stained slides. Please provide billing information on the request form so that the reference lab may bill you for the service. Shipping will be billed to your Fed Ex account on your request or you may specify alternate shipping arrangements.

Respectfully,

Tissue Resource Committee

Enclosure (1)

TRC-L

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

http://www.nih.gov

DHHS/NIH/NCI/DCS/LP
9000 Rockville Pike
Bethesda, Maryland 20892
Bldg 10 Rm 2N212, MSC 1516
Attn: Kevin Nellis / Susan Gantz

July 1, 2002

<INSERT PI NAME>
<INSERT MAIL LOCATION>

Subject: Extramural Request for Human Biological Materials for Research Purposes
<INSERT PT NAME & MEDICAL RECORD #>
<INSERT CASE #>

Dear Dr. Rosenberg:

Dr. <INSERT REQUESTOR INFORMATION> has requested human biological materials on the above patient. In accordance with the CC Medical Administrative Policy M01-2 (http://push.cc.nih.gov/policies/PDF/M01-2.pdf), this request requires approval by the PI of the protocol under which the tissue was collected or the institute Clinical Director.

Please review the enclosed request and complete the “Approval by Intramural Principal Investigator/Clinical Director” section to indicate approval. Please return original package to Susan Gantz (Bldg 10 Rm 2N212, MSC 1516).

The medical record form will be added to the patient’s medical record even if the request is incomplete or denied.

Respectfully,

NCI/LP Tissue Resource Committee

Enclosures

Checklist for release of limited material

TRC Request #: _____ Protocol #: _____ Block #: _____

___ 1. Does this block request have a TRC approved request?
YES NO If No, notify Clinical Lab Manger.

___ 2. Is there more than a single diagnostic block? **YES NO**
YES NO If "Yes," verify that a remaining representative block is set aside and preserved for diagnostic purposes, and release the requested block. It is not necessary to complete items #3- 5.
If "NO" continue checklist.

___ 3. Is the requested material is in danger of being exhausted, based on request?
YES NO (e.g., limited tissue remaining in block, or very small section)
If yes, consult with the Pathologist and original Principal Investigator (PI):
Name of pathologist approving release _____ Date _____
Signature of Pathologist _____ Date _____
Name of PI approving release _____ Date _____
(ATTACHE MEMO OR E-MAIL CONFIRMATION)

___ 4. Is the specimen flagged in the SoftPath™ (LIS) along with the protocol number?
YES NO
If Yes,
Protocol # _____ LIS flag ___/___/___ Protocol closed: ___/___/___

If yes, release material for only the protocol specified in LIS, or if protocol has been closed for 5 years, or contact the Pathologist and original Principal Investigator (PI) to obtain approval:
Name of pathologist approving release _____ Date _____
Signature of Pathologist _____ Date _____
Name of PI approving release _____ Date _____
(ATTACHE MEMO OR E-MAIL CONFIRMATION)

___ 5. Was specimen collected as part of medical care of the patient, but not part
YES NO of protocol (e.g. stomach biopsy on a hepatitis patient)?
If no, retain block in archive. Notify, Clinical Lab Manager.

Comments/Corrective actions:

Was block released? No / Yes

Complete and verified by _____ Date ___/___/____

Replaces: Request for Patient Related Materials

Written by:

_____ Date : ___/___/___

Kevin L. Nellis, M.T. (A.S.C.P.)

Approved by:

_____ Date : ___/___/___

David E. Kleiner, M.D., Ph.D.

Revised or Reviewed?	Date	Signature
Revised Reviewed	___/___/___	
Revised Reviewed	___/___/___	
Revised Reviewed	___/___/___	
Revised Reviewed	___/___/___	
Revised Reviewed	___/___/___	
Revised Reviewed	___/___/___	
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Revised Reviewed	___/___/___	