

POLICY AND COMMUNICATIONS BULLETIN THE CLINICAL CENTER

Medical Administrative Series

M01-2 (rev.)

22 April 2003

MANUAL TRANSMITTAL SHEET

SUBJECT: Procurement and Use of Human Biological Materials
for Research

1. Explanation of Material Transmitted: This issuance transmits the policy of the Clinical Center on the collection and use of human tissue samples in research. This policy was approved by the Medical Executive Committee on 4 March 2003.
2. Material Superseded: No. M01-2, dated 2 November 2001
3. Filing Instructions: Informed Consent

Remove: No. M01-2, dated 2 November 2001

Insert: No. M01-2 (rev.), dated 22 April 2003

Distribution:

Physicians, Dentists and Other Practitioners Participating in
Patient Care
IRB Chairs

POLICY AND COMMUNICATIONS BULLETIN

THE CLINICAL CENTER

Medical Administrative Series

M01-2 (rev.)

22 April 2003

SUBJECT: Procurement and Use of Human Biological Materials
for Research

PURPOSE

- To ensure that procurement and use of human biological materials for research occurs only after review and approval by an NIH Institutional Review Board (IRB), or a determination of exemption issued by the NIH Office of Human Subjects Research (OHSR).
- To protect investigators' access to human biologic materials collected under protocols, while providing access of others to the archival CC specimen collection (THE ARCHIVE) maintained in CLIA certified laboratories (e.g., Laboratory of Pathology, CCR, NCI; Department of Laboratory Medicine, CC; Department of Transfusion Medicine, CC; etc.) within the NIH.
- To provide mechanisms for documenting and tracking the acquisition of human biologic materials by investigators (rather than the pathology department).

DEFINITIONS

- Human biologic materials, for the purpose of this policy, include all tissues and fluids obtained from living individuals, with the exception of blood. (The collection of blood is addressed under M95-9, "Guidelines for Blood Drawn for Research Purposes in the Clinical Center.")
- CLIA certified laboratories, (e.g., NCI/CCR/LP, CC/DLM, DD/DTM, etc.) within the NIH are accountable for diagnostic human biological materials in the CC. They must safeguard proof of diagnoses based on these materials and must retain and protect

sufficient archived materials (e.g., slides, blocks, transplantable material, etc.) for diagnostic and/or clinical purposes.

- A CLIA certified laboratory is a clinical laboratory that is certified by the Department of Health and Human Services, Centers for Medicare & Medicaid Services (or HHS/CMS, previously known as the Health Care Financing Administration).

EXEMPTIONS

- a) Human biological material(s) collected only for the intent of testing for clinical purposes (e.g., no research will be performed on any part of the human biological material) by a CLIA certified laboratory (e.g., NCI/CCR/LP, CC/DLM, CC/DTM, non-NIH reference laboratory, etc.) with report/results recorded into the medical record.

Note: Human biological materials archived in a CLIA certified laboratory might be used for research if done in accordance with IRB, OHSR, and CLIA certified laboratory policies.

- b) The Department of Transfusion Medicine (CC/DTM) has internal procedures in place to document collection, processing, and release of human cells, tissues, and cellular and tissue-based products (HCT/P), in accordance with FDA policy; therefore, human biological materials released for research through this mechanism are exempt.
- c) Human biological materials that are collected for storage for potential clinical transplant are exempt.

Note: Human biological materials archived in a transplant laboratory might be used for research if done in accordance with IRB, OHSR, and transplant laboratory policies.

POLICY

- 1) Human biologic materials may be used for research only after obtaining IRB approval, or an exemption from OHSR. IRB approval includes review of the protocol, written informed consent (or waiver of consent), and need for pathologic review of the specimens.

- a) All protocols and informed consents will address the issue of human biologic materials acquisition and research use as a mandatory inclusion item, including discussion of whether the human biologic materials will be reviewed by a pathologist. In accord with the Federal Regulations for the Protection of Human Subjects, the IRB has the authority to waive the requirement for research subject consent for the research use of human biological materials in certain circumstances. Investigators are advised to consult the IRB for advice on this matter.
 - b) All human biologic materials must have clinical pathologic review unless the IRB approves a waiver of this pathologic review for specimens obtained for research. For example, biopsies of skin blisters that were produced for purposes of research may not require pathology review for clinical purposes. However, while not required for clinical care in this setting, pathologic review may provide useful research endpoints. When human biologic material is collected for research, the consent form must indicate whether human biologic materials will undergo formal pathology review.
 - c) Investigators may elect to use IRB-endorsed generic language in their protocols and informed consents. Such language will still undergo IRB approval in the context of the specific protocols.
- 2) Investigators and those who acquire human biologic materials will document the protocol intent to obtain human biologic materials and the eventual acquisition of the human biologic material(s).
- a) The 1195 form shall document the intent to collect human biologic material for research by indicating whether or not blood or tissue (including fluids, aspirates, cell scrapes, hair, etc.) will be collected for research purposes. This information will be entered into the protocol services database and will be available to the LP to track protocols that involve collection of non-blood biologic material.
 - b) The “Request & Certification for Research Procurement of Human Biological Materials” form, (NIH-2803-1), (Appendix A) with instructions (appendix B) will be used to provide a record

of transfer of human biologic materials from the point of acquisition to a site other than a CLIA certified laboratory. This record will reduce the chance that human biologic material is procured for an investigator without IRB approval, or that human biologic material will be acquired only for research when a diagnostic specimen also is necessary.

- c) Individuals performing procedures to remove human biologic materials other than blood must document this procedure in the medical record.
 - d) Transfer of identifiable tissue to non-NIH investigators will be documented in the medical record and also will require patient signature for materials release.
- 3) The NCI Laboratory of Pathology (LP) will maintain in the ARCHIVE sufficient specimen for diagnostic purposes and will prospectively protect specimens originally obtained for research purposes.
- a) Guidelines in the LP will protect patient diagnostic material and protocol-specific archived material through a standardized application process through which an investigator requests human biological materials (see below).
 - b) Archival Clinical Center specimen collection materials cannot be released unless sufficient diagnostic material is maintained. Specimens prospectively collected for particular protocols will be protected from non-protocol specific research.
- 4) The NCI Laboratory of Pathology (LP) will facilitate acquisition of human biologic materials from THE ARCHIVE.
- a) To obtain specimens, intramural and extramural investigators will submit the appropriate form that identifies the Principal Investigator, resource needs (service, tissue, slide preparation, and anticipated methodology), and protocol approval, waiver or consent, or OHSR exemption. For intramural requests, see Appendices C & D; for extramural requests refer to Appendices E & F.
 - b) LP will monitor turn-around-time for these requests to assess the quality of its service.

PROCEDURES

1) Responsibilities of the Intramural Principal Investigator and Research Team

- a) When samples are collected, protocols must address human biologic materials acquisition in the body of the protocol; those that acquire human biologic materials must address this in the consent. All current protocols must be amended no later than the time of continuing review, to address items above. Investigators may use an IRB-endorsed generic language that will require approval in context by the IRB as per review requirements. The Principal Investigator is responsible for indicating on the protocol 1195 form whether human biologic materials will be obtained.
- b) The research team will complete the “Request & Certification for Research Procurement of Human Biological Materials” form, (NIH-2803-1, Appendix A) (see Appendix B for instructions).
- c) To obtain archival specimens, investigators will submit the form “Intramural Request for Human Biologic Materials for Research Purposes” (Appendix C) to the Laboratory of Pathology. The instructions for completing the form are outlined in an accompanying memo (Appendix D). The form includes information about the research and the resource that is requested. This description is intended to allow a cross-check of whether the requested resource will work in the intended experiments—for example a plan to use PCR to amplify mRNA might not work well with paraffin sections.
- d) For archival materials of other CLIA certified laboratories, contact the laboratory responsible for storing the material.

2) Responsibilities of the IRB

The IRB will consider this policy when reviewing all new and continuing protocols.

3) Responsibilities of the Office of Protocol Services

The Office of Protocol Services will enter information about collection of human biologic materials into the protocol database

and will provide this to the Laboratory of Pathology upon request.

4) Responsibilities of the Medical Record Department

- a) The Medical Record Department will file the original top copy of the “Request & Certification for Research Procurement of Human Biological Materials” form under the “authorization” section in the medical record.
- b) Contact the CC Tissue Procurement Nurse to order new forms.
- c) Incomplete forms will be returned to the CC Tissue Procurement Nurse for quality improvement purposes.

5) Responsibilities of the Laboratory of Pathology (LP)

- a) The LP will follow standard operating procedures (SOP, full document available upon request) including guidelines for the protection of clinical material and archived material obtained for research. The SOP maintains accountability and protection of patient diagnostic material through a standardized application process through which an investigator requests human biological materials as noted elsewhere in this policy. The Protocol Services database will be available to the LP to track protocols that involve collection of non-blood biologic material for research. In turn, that information will be used to permit the access of non-protocol investigators to THE ARCHIVE.
- b) The LP will process requests for acquisition of human biologic materials from THE ARCHIVE as a service, according to the standard operating procedure discussed above (SOP, full document available upon request). The SOP assures that the LP operates within compliance of the regulatory and proper ethical authority to release archival biological materials or to divide fresh human biologic materials to satisfy research and clinical diagnostic needs. The LP will provide consultation about collaborative and non-collaborative proposals, but apart from this, will not review the proposed science or prioritize the requests by their perceived scientific merit.
- c) Materials cannot be released from the archival Clinical Center specimen collection unless sufficient diagnostic material is

maintained. If the requested material is in danger of being exhausted, the Pathologist and original Principal Investigator (PI), when applicable, must be consulted to determine if the request can be fulfilled.

- d) LP will use a database of the requests to monitor turn-around-time and obtain internal quality control information. The attending staff of the Laboratory of Pathology will review applications. Incomplete applications are returned to the investigator. If there is a perceived problem with the proposed research, the LP reviewer will discuss the issues and provide a consultation to the research team about the proposed use. The LP will process the original request if the investigator does not decide to amend it. After approval, the appropriate service will fulfill the request. The Laboratory of Pathology is responsible for anonymizing the material if requested, and for protecting limited material (see above). Any interim documentation created in organizing the request for anonymized resources is destroyed at the time of releasing the material. Recuts will be billed to the CAN of the requesting Investigator.
- e) Non-NIH investigators who request archival NIH human biologic materials will receive a letter (Appendix E) from the Laboratory of Pathology that explains the acquisition and billing process and asks the investigator to complete a “Extramural Request for Human Biologic Materials for Research Purposes” form (Appendix F).
- f) The Laboratory of Pathology will document transfer of identifiable human biologic materials to non-NIH investigators in the medical record by a copy of the “Extramural Request for Human Biologic Materials for Research Purposes” form (Appendix F) and also will require patient signature for materials release.
- g) Requests for tissue for research from extramural investigators require approval by the PI of the protocol under which the tissue was collected, if the sample was collected for research. The institute Clinical Director should review the request if the PI is unavailable.

MEDICAL RECORD

Request & Certification for Research Procurement of Human Biological Materials

Research materials will not be released unless form is complete and signed (MAS M01-2 policy).

INSTRUCTIONS:

- Please complete one form for each procurement procedure. Attach form to chart/medical record prior to sending patient to procedure (e.g., surgery, radiology, consult). A separate form must be used for each IRB protocol number.
- This form is required to document ALL SPECIMENS collected for research, EXCEPT when collected:
 - In a manner that yields documentation of tests results by a CLIA certified laboratory (e.g., CC/DLM, CC/DTM, NC/CCR/LP) in the medical record.
 - By the Department of Transfusion Medicine (CC/DTM).
 - As blood or urine ordered via the MIS Research Screen.
 - For storage for potential clinical transplant, mandated by patient's protocol.

IRB Protocol Number:	Principal Investigator (print legibly):	Phone:	Pager:	Date of Request:
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Specimens Removed By This Procedure Will Be Acquired For (check one):

- Research Use Only
 - Place original white (top) copy in Medical Record or send to 10/1N208.
- Research and Diagnostic/Transplant Purposes
 - Place original white (top) copy in Medical Record or send to 10/1N208.
 - Send yellow (2nd) copy with the specimen to the diagnostic lab or to the transplant bank.

Research Sample(s):	Name of Recipient / Phone / Pager / Location:
1. _____	1. _____
2. _____	2. _____
3. _____	3. _____
4. _____	4. _____
5. _____	5. _____

I certify that the specified IRB approval covers both the protocol and patient-executed consent, and that the research proposed is specified within the approved protocol and consent documents:

_____	_____	_____
Print name of PI/AI of the specified protocol	Signature of PI/AI of the specified protocol	Date

Indicate how materials are released/transported (for tracking/retrieval purposes)

- Delivery to Principal Investigator or Lab
- Delivery to Research Recipient or lab
- By CC Patient Escort Services
- By Other Courier
- Other (specify): _____

_____	_____	_____
Print name of person releasing material	Signature of person releasing material	Date

Patient Identification

APPENDIX A-1

Request & Certification for Research Procurement of Human Biological Materials
NIH-2803-1 (11-02)
P.A. 09-25-0099
File in Section 4: Authorization
Medical Records 10/1N208

MEDICAL RECORD

Request & Certification for Research Procurement of Human Biological Materials

Research materials will not be released unless form is complete and signed (MAS M01-2 policy).

INSTRUCTIONS:

- Please complete one form for each procurement procedure. Attach form to chart/medical record prior to sending patient to procedure (e.g., surgery, radiology, consult). A separate form must be used for each IRB protocol number.
- This form is required to document ALL SPECIMENS collected for research, EXCEPT when collected:
 - In a manner that yields documentation of tests results by a CLIA certified laboratory (e.g., CC/DLM, CC/DTM, NC/CCR/LP) in the medical record.
 - By the Department of Transfusion Medicine (CC/DTM).
 - As blood or urine ordered via the MIS Research Screen.
 - For storage for potential clinical transplant, mandated by patient's protocol.

IRB Protocol Number:	Principal Investigator (print legibly):	Phone:	Pager:	Date of Request:
----------------------	---	--------	--------	------------------

Specimens Removed By This Procedure Will Be Acquired For (check one):

- Research Use Only
 - Place original white (top) copy in Medical Record or send to 10/1N208.
- Research and Diagnostic/Transplant Purposes
 - Place original white (top) copy in Medical Record or send to 10/1N208.
 - Send yellow (2nd) copy with the specimen to the diagnostic lab or to the transplant bank.

Research Sample(s):	Name of Recipient / Phone / Pager / Location:
1. _____	1. _____
2. _____	2. _____
3. _____	3. _____
4. _____	4. _____
5. _____	5. _____

I certify that the specified IRB approval covers both the protocol and patient-executed consent, and that the research proposed is specified within the approved protocol and consent documents:

_____	_____	_____
Print name of PI/AI of the specified protocol	Signature of PI/AI of the specified protocol	Date

Indicate how materials are released/transported (for tracking/retrieval purposes)

- Delivery to Principal Investigator or Lab
- Delivery to Research Recipient or lab
- By CC Patient Escort Services
- By Other Courier
- Other (specify): _____

_____	_____	_____
Print name of person releasing material	Signature of person releasing material	Date

Patient Identification

Request & Certification for Research Procurement of Human Biological Materials
NIH-2803-1 (11-02)
P.A. 09-25-0099

APPENDIX A-2

Yellow copy: Diagnostic/Transplant Labora

MEDICAL RECORD

Request & Certification for Research Procurement of Human Biological Materials

Research materials will not be released unless form is complete and signed (MAS M01-2 policy).

INSTRUCTIONS:

- Please complete one form for each procurement procedure. Attach form to chart/medical record prior to sending patient to procedure (e.g., surgery, radiology, consult). A separate form must be used for each IRB protocol number.
- This form is required to document ALL SPECIMENS collected for research, EXCEPT when collected:
 - In a manner that yields documentation of tests results by a CLIA certified laboratory (e.g., CC/DLM, CC/DTM, NC/CCR/LP) in the medical record.
 - By the Department of Transfusion Medicine (CC/DTM).
 - As blood or urine ordered via the MIS Research Screen.
 - For storage for potential clinical transplant, mandated by patient's protocol.

IRB Protocol Number:	Principal Investigator (print legibly):	Phone:	Pager:	Date of Request:
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Specimens Removed By This Procedure Will Be Acquired For (check one):

- Research Use Only
 - Place original white (top) copy in Medical Record or send to 10/1N208.
- Research and Diagnostic/Transplant Purposes
 - Place original white (top) copy in Medical Record or send to 10/1N208.
 - Send yellow (2nd) copy with the specimen to the diagnostic lab or to the transplant bank.

Research Sample(s):	Name of Recipient / Phone / Pager / Location:
1. _____	1. _____
2. _____	2. _____
3. _____	3. _____
4. _____	4. _____
5. _____	5. _____

I certify that the specified IRB approval covers both the protocol and patient-executed consent, and that the research proposed is specified within the approved protocol and consent documents:

_____	_____	_____
Print name of PI/AI of the specified protocol	Signature of PI/AI of the specified protocol	Date

Indicate how materials are released/transported (for tracking/retrieval purposes)

- Delivery to Principal Investigator or Lab
- Delivery to Research Recipient or lab
- By CC Patient Escort Services
- By Other Courier
- Other (specify): _____

_____	_____	_____
Print name of person releasing material	Signature of person releasing material	Date

Patient Identification

Request & Certification for Research Procurement of Human Biological Materials
NIH-2803-1 (11-02)
P.A. 09-25-0099

APPENDIX A-3

Blue copy: Research Team (optional)

**REQUEST & CERTIFICATION FOR RESEARCH PROCUREMENT
OF HUMAN BIOLOGICAL MATERIALS [NIH 2803-1 (11-02)]**
(FORM INSTRUCTIONS Revised April 2003)

1. Complete one form for each procurement procedure.
2. Provide patient identification information (last name, first name, middle initial, NIH medical record number) in the lower left hand corner of the form.
3. Print the IRB Protocol Number and its designated PI (first and last name).
4. Add the designated PI's telephone number and pager so he/she may be contacted if needed.
5. Indicate the date of the request.
6. Check only one box to specify if the specimen(s) collected during a procedure are:
 - a. Procured (collected) for "Research Use Only", or
 - b. Procured (collected) for both "Research and Diagnostic/Transplant Purposes (e.g., split sample between research and clinical). Be sure to check this box when a research sample is collected and any part collected during the same procedure goes to a diagnostic lab (or transplant bank).
7. Indicate the description of the anticipated research sample(s) and the corresponding name of recipient, phone, pager, and location.
8. The principal investigator (PI), or an associate investigator (AI), specified in writing on the IRB protocol must sign the request. This certifies that the specified IRB approval covers both the protocol and patient-executed consent, and that the research proposed is specified with the approved protocol and consent documents. Be sure to print name to the left of the signature and record date.
9. The form must be completed prior to receipt of specimens for research. Please insert the signed form in the jacket of the medical record before the patient arrives for his/her procedure.
10. Check the appropriate box or boxes to indicate how or where the materials are released (for tracking/retrieval purposes):
 - a. Delivery to Principal Investigator or lab; check this box if the material is given to a researcher designated in the protocol.
 - b. Delivery to Research Recipient or lab; check this box if the material is given to a researcher, other than the PI.
 - c. By CC Patient Escort Services; check this box when the CC Patient Escort Services transport material. Patient Escort Services maintains a log of all deliveries.
 - d. By Other Courier; check this box if research team uses a standard contracted courier. Research team should be able to track specimens if necessary through the courier.
 - e. Other (specify); check this box, if appropriate, and specify enough information so that specimen may be tracked if necessary.
11. The person releasing the materials (e.g., PI, AI, MD, researcher, nurse, technologist, technician, etc.) must indicate method of release and sign the form. Do not ask a courier or escort to sign this section. Be sure to print name to the left of the signature, and record date.
12. Separate the three part form and send to appropriate destination:
 - a. If specimen was acquired for "Research Use Only":
 - i. Place original white (top) copy in Medical Record or send to 10/1N208.
 - ii. Retain blue copy (3rd copy) for Research team (optional).
 - b. If specimen was acquired for both "Research and Diagnostic/Transplant Purposes":
 - i. Place original white (top) copy in Medical Record or send to 10/1N208.
 - ii. Send yellow (2nd copy) with the specimen to the diagnostic lab or to the transplant bank so they are notified that research samples have been procured and sent to other areas.
 - iii. Retain blue copy (3rd copy) for Research team (optional).

Note: An approved electronic version of the form and instructions are posted at <http://home.ncicrf.gov/ccr/lop/Clinical/labres/hbm.asp>



**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) Anonymous Autopsy Deceased
 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 (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: _____
 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.

OHSR EXEMPTION FORM or IRB APPROVAL NUMBER MUST BE PROVIDED

Attach OHSR Exemption Form or provide IRB Protocol #: _____
 Note: An OHSR 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, Clinical Lab Manager
 (301) 594-9532 e-mail: chinqueej@mail.nih.gov _____
 Return form and attachments to: Laboratory of Pathology, Tissue Resource Committee
 10 Center Drive, Room 10/2A33, MSC 1500
 Attn: Susan Gantz (susangant@mail.nih.gov)



MEMORANDUM

To: Principal Investigator

From: NCI/CCR/Laboratory of Pathology
Tissue Resource Committee

Subject: Request for Human Biological Materials for Research

Thank you for your inquiry into Laboratory of Pathology for Human Biological Materials. 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 (OHSR) for the exemption form or refer to web site: <http://ohsr.od.nih.gov/>

Biological material from autopsy cases or deceased patients does not require OHSR exemption or IRB approval. Release of biological material from deceased patients without an OHSR exemption requires certification or proof that the patient has expired.

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 2A33, MSC 1500. Requests will be reviewed by the LP Tissue Resource Committee and forwarded to the Laboratory of Pathology Service Chief as quickly as possible.

Materials cannot be released unless sufficient diagnostic material is available for NIH archives. For approved requests with adequate material is remaining will be prepared by the NCI Laboratory of Pathology, Histology section. 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 outside laboratory 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.



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

9000 Rockville Pike
Bethesda, Maryland 20892
Bldg 10 Rm 2N212, MSC 1516
Attn: Kevin Nellis
(301) 594-9532

<Insert Date>

<Type Investigator Name Here>

<Type Investigator Address Here>

<Type Investigator Address Here>

<Type Investigator Address Here>

<Type Investigator Address Here>

Subject: Extramural Request For Human Biological Materials For Research Purposes

Dear Dr. <Type Investigator Name Here>:

To obtain material from specimens stored in the NCI Laboratory of Pathology please complete one NIH-2803-2form (attached) for each patient. The requestor must obtain the appropriate approval before requesting resources through the NIH. Be sure to provide your IRB approved protocol and obtain the consent from the patient for release of the sample. 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. The Tissue Resource Committee (TRC) will evaluate requests as quickly as possible. All requests for paraffin block recuts without pathologic review will receive expedited review. The TRC may question the technical approach of any request and may contact the requestor for additional information to justify or modify the request.

The Laboratory of Pathology is responsible and accountable for the use and protection of patient materials that are in the archive and insuring 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. Materials will not be released unless sufficient diagnostic material is available for the NIH archives.

If adequate material is remaining, it will be sent to a reference laboratory, chosen by NIH, for processing 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,

Kevin L. Nellis, MS, MT(ASCP)
Clinical Laboratory Manager

Enclosure: NIH-2803-2 form

MEDICAL RECORD

Extramural Request for Human Biological Materials For Research Purposes

PRINCIPAL INVESTIGATOR INFORMATION

Extramural Principal Investigator (print legibly)

Institution

Address

Phone:

E-mail:

Billing Information for Recuts/Restains:

COPY

(Reference Lab will bill requestor for work requiring recuts or restains)

Material will be shipped to above address unless otherwise specified. Indicate preferred shipping company and billing account number:

DESCRIPTION OF RESOURCE NEEDS

Tissue Source Requested:

- Normal Tissue
- Abnormal Tissue (indicate key diagnostic terminology for database search):

Recuts:

- Recuts Number of Slides:
- Pathology Review
- RNase Precautions
- Other (specify):

Tissue Type (check all that apply):

- Paraffin Cytology Autopsy
- Other (specify):

Recut Slide Type (check):

- Regular/Untreated Poly-L-Lysine
- Gelatin Silanated
- Other (specify):

NOTE: Materials cannot be released unless sufficient material is retained for clinical diagnostic purposes.

Patient Name

NIH Medical Record Number

Patient Date of Birth

NIH Attending Physician (if known)

Date of Surgery/Specimen Collection

NIH Block Number(s) (if known)

Title of Your Protocol:

Date of Current Approval by Your IRB

Permission is hereby granted to the National Institutes of Health to release the materials requested herein and to obtain copies of pathology reports pertaining to the material to the individual/organization as identified above. (Note: submission of this form authorizes the release of materials and information specified within one year from date of signature.)

Patient (or Guardian) Signature _____ Date _____

CERTIFICATION BY EXTRAMURAL PRINCIPAL INVESTIGATOR

I certify that the research use of the requested human biological material will be in accordance with the IRB approved protocol and consent referenced above.

Signature of Extramural Principal Investigator _____ Date _____

APPROVAL BY INTRAMURAL PRINCIPAL INVESTIGATOR/CLINICAL DIRECTOR

Approve Disapprove Date: _____

Signature: _____ Title: _____

FOR INTERNAL USE ONLY BY NCI, LABORATORY OF PATHOLOGY:

Date Received: _____ Outcome: _____ Signature: _____

Patient Identification

APPENDIX F

Extramural Request for Human Biological Materials For Research Purposes
NIH-2803-2 (9-01)
P.A. 09-25-0099
File in Section 4: Authorization