

DRAFT VERSION Appendix 3**Research Histology Facility Fee Schedule and Policy Statement****The Yale Research Histology Facility (YRHF)
(a division of Yale Pathology Tissue Services)**

Director: Alexander Vortmeyer, M.D.

Mission Statement:

The mission of the research histology unit is to provide

1. Timely high quality histology services to the Yale community
2. Access to tissue services from Yale Pathology archives

Animal tissues

For routine animal tissue processing, the investigator provides fixed tissue within standard tissue cassettes. Tissue dissection is the responsibility of the investigator. The tissue will normally be placed in the research histology processor that same day and embedded the next morning. Special embedding instructions will be honored insofar as they are technically possible.

Frozen sectioning of animal tissues can be done either by research histology staff or by investigators who have been adequately trained by the research histology staff.

Turnaround time for cutting and staining routinely processed animal tissues must be less than one week. When this turn around time cannot be met in greater than 90% of cases, tissue blocks will be sent to an outside laboratory designated by the director until the goal is met.

Human tissues

Investigators who perform biopsies on human subjects as part of an HIC approved clinical research project (protocol-defined tissue) may have tissues processed in research histology. The Yale HIC approved consent form for such biopsies must clearly state that no Yale pathology diagnosis will be available on such tissues.

De-identified human tissue samples are available from research histology with no additional HIC approval. These will be provided from the research paraffin cassettes or from frozen tissue as available. A listing of cases for which research material is available is maintained in research histology. If no suitable tissue is available from the research tissue archives, the Yale pathology paraffin archives may be used. The tissue coordinator will provide the case numbers. The research histology staff will pull and refile these blocks as needed. These tissues provided to investigators will have no identifier on them other than tissue type. Additional tissue from the same block will not be available.

For cases which are labeled with the Yale pathology number, a Yale HIC approval is required. The Yale HIC number will be included in the order database.

In no cases will blocks from Yale pathology archives be cut through without approval from the director of research histology. In no case will Yale pathology archive blocks be released to investigators. For long term research projects involving the creation of a unique patient cohort, segregation of tissue blocks into a physically segregated tissue archive may be possible.

Frozen tissues

Investigators are encouraged to have tissue sections prepared from frozen tissue from the tissue bank (either as frozen sections or as portions thawed and conventionally processed) prior to use in order to ensure the nature of the tissue provided. Investigators must have pathology collaborators to help them with this process. Otherwise, the director of research histology will assist them in finding a collaborator that will examine those sections.

Immunohistochemistry

Immunohistochemical projects are performed on both human and animal tissues. In some cases of clinically available immunostains, the clinical immunohistochemistry lab will do the work at their discretion. For human studies, tissue controls can be provided within the guidelines as described above for accessing human tissue. Protocols for staining (automated vs manual staining) and control selection should be worked out in advance or can be done by the facility. When protocol development is required, users will be required to cover the cost of test slides, test reagents, and staining costs. For example, titrating a new antibody may require 5 slides with different antibody concentrations. The user would be billed for 5 immunostains (see below).

Billing

The research histology billing database provides billing information for routine histology, immunohistochemistry (regardless of lab which performs the work), human tissue fees, and fresh tissue access fees. The database provides sufficient information for the business office to direct the funds to the appropriate account.

Embargo and Patient Safety:

To prevent tissues from being used in a manner that jeopardizes patient care, an embargo policy is in place. This means tissue must be held in storage prior to research use for a time period dependent on tissue type, as outlined below:

YPTS Embargo Time Table:

Tissue Type	Time
Frozen Tissue	one month after sign out
Fresh Tissue (for cell culture)	none
Formalin Fixed Paraffin Embedded Tissue	one year from accession date

*note, this timing is in compliance with CAP guidelines since only excess tissue is used for research. Thus it is critical that SOPs carefully define minimum sizes of lesions from which fresh tissue can be taken.

**Price list for research histology and tissue products:
Effective March 1, 2010**

Embedding/sectioning

SERVICE	Academic Investigator Costs	For-Profit Clients
Embedding tissue in paraffin	\$7/block	\$14/block
Sectioning paraffin blocks	\$2 section/block,	\$4 section/block,
Sectioning frozen tissues	\$4 per section	10\$ per section
Pathologist-based Laser Capture Microdissection	Hourly rate of \$100 with minimum charge of \$50	Hourly rate of \$200 with minimum charge of \$100

(Procurement and freezing blocks is 25\$ according to TPD price list)

Stains

SERVICE	Academic Investigator Costs	For-Profit Clients
H&E	\$2/slide	\$4/slide
Special stain II (PAS, Trichrome, etc.)	\$10/slide	\$20/slide
Special slides for laser capture micro-dissection (including cutting and special staining)	\$15/slide	\$30/slide
Immunostains	\$20/slide plus reagent costs (see below)	\$40/slide plus reagent costs (see below)

Imaging (using the Bioimagine Platform)*

SERVICE	Academic Investigator Costs	For-Profit Clients
Whole slide imaging	\$25/slide	\$50/slide
TMA imaging	\$25/slide	\$50/slide

* images will be provide on a CD or via the network with the Bioimagine Image

Viewer

TOTAL FEE EQUALS EMBEDDING FEE PLUS SECTIONING FEE PLUS STAINING FEE.

If Yale clinical blocks or tissue bank products are used an additional surcharge is added (see below). Yale Cancer Center members get a discount proportionate to facility support (historically about 20%).

Many immunostains (especially for human tissue) are routinely available along with control tissues. The director and technical director will maintain stocks of commonly

used reagents. This stock will include commonly requested primary antibodies and commonly used secondary reagents. A list of these reagents will be available from the facility. Reagents that are not on the list and unusually expensive reagents must be provided by the client investigator. For routine anti-mouse or anti-rabbit secondary antibodies, cost is currently \$1/slide. Yale cancer center discount does not apply to reagent cost.

For fees for processing/ sectioning/ staining for laser capture microdissection, “PCR safe sections”, plastic sections, TUNEL staining and other specialized projects, contact director of research histology. Special assays will be billed on the basis of the costs plus the hourly charge.

Tissue Access Fee: surcharge for Yale Pathology human tissues

The standard tissue access fees for excess tissue obtained by Yale Pathology are as follows:

Pricing is based on the concept of a "tissue unit". One tissue unit is defined as follows:

- A) Up to twenty 4-6µm tissue sections cut from a single paraffin block, or
- B) A single tissue core (ranging from 0.6 to 4mm in diameter) taken from a paraffin tissue block, or
- C) A 5 to 60 µm thick frozen section (must be excess tissue; may not include diagnostic tissue) or
- D) 50mg – 1gm of fresh frozen or custom-fixed tissue (must be excess tissue; may not include diagnostic tissue), or
- E) Protocol-defined tissue that requires the review or oversight by the Dept of Pathology (independent of amount), or
- F) A whole organ from autopsy (1 organ or large slice is equivalent to 10 tissue units)

Each *tissue unit* has at a minimum annotation that includes the patient's age, sex, pathologic diagnosis, and tissue of origin. Significantly more information may be available.

The price/tissue unit is as follows:

User	Price/tissue unit	Second unit and subsequent units of same sample
Academic	\$25	\$15
Commercial (other)	\$150	\$100

Quotes are available on request and are required for orders larger than \$1000.

Additional charges are required for all materials sent outside of Yale:

- A) Any tissue sent to a commercial party is charge 15% Yale Indirect costs (overhead) and 6% sales tax
- B) Any tissue sent outside Yale to other non-profit institutions is subject to the 15% Yale indirect charge.

Secondary Transfer of tissue:

Clients, whether academic or commercial, who obtain tissue from YPTS are not authorized to secondarily transfer the tissue to third parties for sale or otherwise. Agreement with this policy will be conveyed and certified by client signatures on quotes or invoices.