**Obtaining tissue for Research Purposes**

1. If a principal investigator (PI) wishes to use archived tissue for research, he or she should proceed as follows:

On a case by case basis, Pathology and Laboratory Medicine Service (P&LMS) will release archived tissue for research purposes if the following measures are met:

* a diagnosis has been established
* the request will not consume all of the remaining specimen
* the amount of tissue released will be at the discretion of the signing pathologist (the pathologist that signed out the case). For a thick specimen, it may be appropriate to give away a few re-cuts or a short paraffin "ribbon." For specimens with an abundance of homogeneous diagnostic material, it may be appropriate to give away thick sections of a specific block.
* the submission to the Institutional Review Board (IRB) contains an email from the Chief of P&LMS supporting the study. **This email must be present prior to review by the IRB.**
* the project is approved by the IRB

To obtain tissue in larger amounts (such as an entire tissue block) working with fresh tissue will be required. A study protocol must be developed with P&LMS and the IRB where excess fresh tissue removed at surgical resection can be used for research (see below).

1. If a PI wishes to use fresh tissue for research, he or she should proceed as follows:

All fresh tissue removed from a Veteran by a biopsy or surgical procedure must be reviewed by the Path and Lab Service and may not be released directly to a PI except in the following cases:

Tissue collected during a procedure performed solely for research purposes

This tissue will be exempt from examination by P&LMS and will be released directly to the research team. To qualify for this exemption the tissue must be collected under a protocol approved by the IRB, with an IRB-approved consent and authorization signed by the patient. The written consent should state that the release of the tissue without P&LMS examination may potentially impair the ability to obtain a definitive diagnosis, and obtain prognostic data, or guide therapy. The IRB will only approve consents that meet their standards for full and understandable disclosure of all risks to subjects. If the IRB feels the wording is too technical, they will request that consent forms be written with simpler wording. For example, “…a diagnosis of cancer or other serious health issue may be missed.”

Tissue collected during a clinically indicated diagnostic procedure

This tissue may be exempt from examination by P&LMS and may be released directly to the research team. To qualify for this possible exemption, the PI must prepare an appendix to the protocol and attach it to their initial submission to the IRB. The appendix should describe how the tissue will be divided (or sampled) and collected. It must describe how this can be done without increasing the risk of P&LMS not having enough or the correct tissue to make a diagnosis. The appendix must contain the signature of the Chief of P&LMS (or designee) under this sentence; “I have met with the PI, reviewed the procedures involving P&LMS, and commit to P&LMS supporting this protocol as written.” The Deputy ACOS/R&D (or designee) will review and initial the same sentence when the signed appendix is submitted to the Research Service office as part of the initial submission to the IRB. **This signed appendix must be present prior to review by the IRB.** The IRB will only approve consents that meet their standards for full and understandable disclosure of all risks to subjects.

Excess or unnecessary tissue collected during a clinically indicated diagnostic procedure

PIs wishing to use what they consider to be excess or unnecessary tissue (whether fresh, frozen, or fixed) for research purposes after the amount of tissue necessary for clinical and diagnostic purposes has been processed by P&LMS, should likewise describe this in an appendix to their initial submission to the IRB and proceed with obtaining the signatures described in the section on ‘tissue collected during a clinically indicated diagnostic procedure’ (above). **This signed appendix must be present prior to review by the IRB.**