

PATHOLOGY REVIEW FAQs

1. What is Pathology Review and why is it necessary?

Pathology Review is performed

- to ensure that protocols involving tissue procurement do not have an adverse impact on patient care,
- to ensure that the study is technically feasible in regard to tissue
- to ensure compliance with federal, state, local and hospital regulations

2. When is Pathology review needed?

Any research study which uses human tissue from patients at this institution requires Pathology Review. Exceptions are:

- Protocols in which the standard of care requires biopsies be performed and only the results are used in the study for data collection.
- Protocols which utilize tissue from outside sources such as outside hospitals or laboratories. .

These explanations must be clearly stated in the non technical research plan.

3. What tissue may be used for research purposes?

After tissue, fresh or archival, has been reserved for all necessary clinical testing and pathologic examination, any tissue left over may be used for research purposes. This is always at the discretion of the Department of Pathology and Laboratory Medicine and is evaluated on a case by case basis.

4. What if I have a protocol in which the sponsor or other outside agency requires that tissue blocks be sent to a central lab?

As per policy, diagnostic tissue blocks **cannot** be released from the Department of Pathology and Laboratory Medicine. There are several possible solutions:

- Blank slides and tissue sections may be obtained so long as sufficient tissue is present in the tissue block. Please check.
- In some cases, left over fresh tissue may be obtained and processed into blocks by investigator or outside lab.
- If the patient can be identified before surgery, an additional prospective tissue block may be prepared (in collaboration with the Pathology Department and in coordination with a specific Pathologist) which will be separate from the blocks submitted for diagnostic purposes.

5. What if I need tissue from small biopsies that are normally entirely submitted for diagnostic purposes?

Small biopsies such as endoscopic biopsies,, tranbronchial biopsies, needle core biopsies and other small biopsies are submitted entirely for pathologic examination as per standard or care as this is necessary for diagnosis. If your study requires these types of biopsies then additional biopsies, beyond what would be taken for diagnostic purposes, must be obtained and the risks of doing so much be included in the protocol and consent form (see section on exceptions). An exception to the tissue submission policy must be requested.

6. How do I actually obtain the tissue after I have received Pathology Approval and IRB approval for my protocol?

Once the protocol has been approved by Pathology and the IRB, the investigator must send a copy of the IRB approval letter and the Tissue Section to Pathology. Once logged in, tissue may either be obtained from the Pathology Gross Room in the case of fresh tissue or via written request in the case of slides prepared from paraffin-embedded tissue blocks (see next question).

7. What do I do if I need Pathology technical services such as cutting slides from tissue blocks, immunohistochemistry, etc?

These requests are included in Section C3. Billing information must be provided to the Department of Pathology and Laboratory Medicine if technical work is requested. A clinical research protocol form must be completed and submitted to pathology. Forms are available at www.cornellpathology.org/research.

8. Who do I go to for questions?

Additional questions on how to fill out the necessary paperwork or concerning utilization of tissue for research should be directed to Dr. Rebecca Baergen at rbaergen@med.cornell.edu.

9. Under what circumstances do I need an exception to the tissue submission policy?

Permission for an exception to the tissue submission policy is required in the following circumstances.

- Tissue is taken solely for research purposes and not for clinical care or for diagnostic purposes. In this case the subject must give consent for procedure to obtain tissue.
- Additional tissue (above and beyond what would normally be taken for diagnostic purposes) will be taken solely for research purposes. Again, the subject must consent to the surgical procedure to obtain additional tissue.
- Tissue is being used that is normally not sent to pathology for examination. There are only two specimens that fall into this category and they are:
 - Bone marrow aspirates (but **not** bone marrow biopsies)
 - Umbilical cord or umbilical cord blood
 - Tissue that might be considered to be “surgical waste” but does **not** meet specific definition above. This will be reviewed on a case by case basis.

10. Do I still need Pathology Review if tissue never goes to Pathology and/or I am requesting an exception?

Yes. Any protocol that uses tissue that does not meet the specific definition for surgical waste (see Pathology Review Instructions), but is human tissue, must go through Pathology Review.