

Guidance regarding requirements to attach the Pathology Approval form to your IRB submission:

You are required to obtain approval from the Division of Anatomic Pathology, when:

- A research protocol involves a procedure that will produce, in part or in whole, tissue that will be sent for diagnostic purposes to the Division of Anatomic Pathology of the Department of Pathology and Cell biology ("Anatomic Pathology"). Tissue will be maintained by Anatomic Pathology and access to use a portion of it for research purposes requires Pathology approval.
- A research protocol requires the use of any material maintained by Anatomic Pathology (example: diagnostic or research formalin-fixed paraffin-embedded (FFPE) tissue slides/blocks), fresh tissue, frozen tissue from its Tissue Bank...).
- Note: most research biopsies should have at least a component (1-3 cores) sent to Anatomic Pathology to confirm the diagnosis (standard of care) and require Pathology approval. In the rare exception when a procedure is performed for research only and specimen(s) will not transit through Anatomic Pathology, pathology approval is not required (e.g. material normally discarded during a procedure in which no diagnostic tissue is taken). All such instances should be verified by Anatomic Pathology and require email communication and confirmation from the persons listed below.

A request for Pathology approval for a specific research study is documented via the completed Anatomic Pathology Approval form (i.e. Request from Principal Investigator) available at:

<https://research.columbia.edu/sites/default/files/content/HRPO/19%20Blank%20Pathology%20Approval%20Form%20for%20IRB%20version%2002%2024%202020.doc>.

The completed form should be submitted via an email to Carlibi Rojas BAS/MHA/MBA (Dept. of Pathology) cr2698@cumc.columbia.edu, with a cc to Hanina Hibshoosh, MD, hhh1@columbia.edu and Hua Guo, MD, hg2489@cumc.columbia.edu.

Once the form has been signed, it should be attached in Rascal prior to final approval of the protocol by the IRB.

Please consider the following items when completing the study-specific request form and contact members of the Department of Pathology listed above if you have any questions:

1. Release of tissue blocks is generally prohibited by Anatomic Pathology so please request tissue sections only, unless specific research blocks were or will be collected as a part of the protocol and consented to by the subject.
2. A new signed Anatomic Pathology Approval form is required if there is a change in Principal Investigator on the protocol.
3. This form is not required if material requested are maintained or will be sent to Dermatopathology.
4. Approval for access to material through this process is not a guarantee of receipt of requested material as it is subject to availability and other constraints.