

	<b>Approval Path A</b>	<b>Approval Path B</b>	<b>Approval Path C</b>
<b>Plan of Research</b>	Non-research use of tissue <ul style="list-style-type: none"> <li>• Tissue for titring probes, controls</li> <li>• Educational use</li> <li>• Validation of clinical test (no intention to publish)</li> <li>• Clinical review</li> <li>• Uses for laboratory QA/QC</li> </ul>	Tissues are all from deceased patients <ul style="list-style-type: none"> <li>• Autopsy tissue</li> <li>• Surgical/cytology tissue from patients with known death dates</li> </ul>	Tissues are irreversibly anonymized (stripped of any link to the original patient) <ul style="list-style-type: none"> <li>• Samples from the archive recoded by the archivist)</li> <li>• Samples anonymized by a tissue repository</li> <li>• Samples anonymized according to an IRB-approved protocol</li> </ul>
<b>Ethical Approval Step</b>	<ul style="list-style-type: none"> <li>• None required</li> </ul>	<ul style="list-style-type: none"> <li>• None required</li> </ul>	<ul style="list-style-type: none"> <li>• Apply to OHSR for exemption from IRB review</li> </ul>
<b>IF YOUR STUDY DOES NOT INVOLVE THE TISSUE ARCHIVE OR LABORATORY OF PATHOLOGY TECHNICAL RESOURCES, STOP HERE, YOU ARE DONE.</b>			
<b>TRC Approval Step</b>	<ul style="list-style-type: none"> <li>• None required, fill out form for archivist to retrieve samples</li> </ul>	<ul style="list-style-type: none"> <li>• Submit information below with TRC form, check “autopsy/ deceased patient” box</li> </ul>	<ul style="list-style-type: none"> <li>• Submit information below with TRC form</li> </ul>
<b>Additional Information Needed</b>	<ul style="list-style-type: none"> <li>• List of materials to be pulled, delivered to archivist</li> </ul>	<ul style="list-style-type: none"> <li>• Autopsy case numbers and/or</li> <li>• Death dates of patients</li> </ul>	<ul style="list-style-type: none"> <li>• If tissues are from NIH archive, search criteria for possible cases</li> <li>• Copy of OHSR exemption approval</li> </ul>
<b>What happens next</b>	<ul style="list-style-type: none"> <li>• Archivist pulls materials</li> </ul>	<ul style="list-style-type: none"> <li>• TRC form is reviewed and approved</li> <li>• Archivist pulls materials</li> </ul>	<ul style="list-style-type: none"> <li>• TRC form is reviewed and approved</li> <li>• Databases queries are performed if necessary</li> <li>• Archivist pulls materials</li> <li>• Recuts, etc. are anonymized by archivist or other third party</li> </ul>

	<b>Approval Path D</b>	<b>Approval Path E</b>	<b>Approval Path F</b>
<b>Research Type</b>	Identifiable tissues obtained for research outlined in an NIH or non-NIH IRB approved protocol with <b>appropriate</b> patient consent <ul style="list-style-type: none"> <li>• Protocol driven case review</li> <li>• Case report or series on NIH patients for protocol-related pathology</li> <li>• Molecular or biochemical analysis on NIH patient material</li> <li>• Evaluation of samples from another institution obtained under protocol</li> </ul>	Identifiable tissues obtained via an NIH or non-NIH IRB approved protocol to be used in research not outlined in original protocol <ul style="list-style-type: none"> <li>• Research to examine tissues using probes/techniques not envisioned at the time of protocol approval</li> <li>• Germline research on tissues obtained under a non-germline protocol</li> </ul>	Identifiable tissues <b>not</b> obtained as part of an IRB-approved protocol <ul style="list-style-type: none"> <li>• Case report or series on non-NIH patients using tissue obtained through routine care</li> <li>• Molecular or biochemical investigation of non-NIH tissues not obtained on a specific research protocol</li> </ul>
<b>Ethical Approval Step</b>	<ul style="list-style-type: none"> <li>• NIH protocol: review proposed research with PI to make sure that the research is covered under original protocol. Work must done as collaboration.</li> <li>• Non NIH protocol: Apply to OHSR for exemption from NIH IRB review, will need copy of IRB approval from outside institutions</li> </ul>	<ul style="list-style-type: none"> <li>• Apply to IRB for waiver of consent</li> <li>-or-</li> <li>• Write amendment to protocol to include new research. (Required for germline example).</li> </ul> <p>IRB may decide not to waive consent. If the waiver is denied, a standard protocol or amendment will have to be written and informed consent (re)obtained.</p>	<ul style="list-style-type: none"> <li>• Apply to IRB for waiver of consent. If the waiver is denied, a standard protocol will have to be written and informed consent obtained.</li> </ul>
<b>IF YOUR STUDY DOES NOT INVOLVE THE TISSUE ARCHIVE OR LABORATORY OF PATHOLOGY TECHNICAL RESOURCES, STOP HERE, YOU ARE DONE.</b>			
<b>TRC Approval Step</b>	<ul style="list-style-type: none"> <li>• Submit information below with TRC form</li> <li>• PI/AI signature required</li> </ul>	<ul style="list-style-type: none"> <li>• Submit information below with TRC form</li> <li>• PI/AI signature required for amended protocols</li> </ul>	<ul style="list-style-type: none"> <li>• Submit information below with TRC form</li> </ul>
<b>Additional Information Needed</b>	<ul style="list-style-type: none"> <li>• Case list</li> <li>• Protocol number</li> <li>• Copy of OHSR exemption (if obtained)</li> </ul>	<ul style="list-style-type: none"> <li>• Case list</li> <li>• Protocol number</li> <li>• Copy of IRB waiver</li> </ul>	<ul style="list-style-type: none"> <li>• Case List</li> <li>• Copy of IRB waiver or new protocol number</li> </ul>
<b>What happens next</b>	<ul style="list-style-type: none"> <li>• TRC form is reviewed and approved</li> <li>• Queries are run against the database if necessary</li> <li>• Archivist pulls materials</li> </ul>	<ul style="list-style-type: none"> <li>• TRC form is reviewed and approved</li> <li>• Queries are run against the database if necessary</li> <li>• Archivist pulls materials</li> </ul>	<ul style="list-style-type: none"> <li>• TRC form is reviewed and approved</li> <li>• Queries are run against the database if necessary</li> <li>• Archivist pulls materials</li> </ul>