I. SCOPE

This SOP applies to requests from an external institution for research purposes for fresh or archival tissue that was or will be collected at Loyola University Medical Center (LUMC) for clinical purposes.

This SOP does not address requests for tissue for research purposes from a Loyola University of Chicago (LUC) or LUMC investigator.

II. DEFINITIONS

A. **HIPAA authorization** is a detailed document that gives covered entities permission to use protected health information for specified purposes, which are generally other than treatment, payment, or health care operations, or to disclose protected health information to a third party specified by the individual. It contains all of the following elements:
   1. A meaningful description of the information or material to be disclosed
   2. The name of the patient or the name of the person authorized to make the requested disclosure
   3. The name or other identification of the recipient of the information
   4. A description of each purpose of the disclosure (The statement "at the request of the individual" is sufficient when the patient initiates the authorization and does not, or elects not to, provide a statement of the purpose)
   5. An expiration date or an expiration event that relates to the patient
   6. A signature of the patient or their personal representative (someone authorized to make health care decisions on behalf of the patient) and the date.
   7. A separate section for the patient to indicate if he/she permits disclosure of highly confidential information, including: psychiatric/mental health, mental retardation or developmental disabilities information; HIV and AIDS testing, diagnosis or treatment (including the fact that an HIV test was ordered, performed or reported, regardless of whether the results of such tests were positive or negative); communicable disease, including sexually transmitted diseases diagnoses/lab results/treatment; alcohol/drug abuse or addiction diagnosis/treatment; child abuse and neglect; domestic abuse by an adult; sexual assault; and genetic testing.
   8. Statements that:
      a. The patient or personal representative has the right to revoke the authorization at anytime by submitting a written revocation except to the extent the provider has taken action in reliance on the authorization.
      b. The provider generally may not condition its healthcare on the provision of the authorization except (i) for research-related treatment, or (ii) if the purpose of the healthcare is to create information for disclosure (e.g., an employment physical or independent medical exam), in which case the provider may refuse to provide the healthcare if the patient refuses to execute an authorization.
      c. The information disclosed per the authorization may be subject to redisclosure by the recipient and no longer protected by HIPAA.

III. PROCEDURES

A. All tissues to be released to an external institution for research purposes are to be released by Anatomic Pathology (AP).
B. Process
   1. The manager of AP or other designated representative of the AP department is notified as soon as the external researcher contacts an LUMC employee or provider with a tissue request.

a. The LUMC employee or provider informs the external requester that there is a process to be completed before tissue may be released and refers the external researcher to AP at 708-327-2572 (main department phone number) or by emailing the manager of AP directly.
b. The external requester must provide an investigator contact and an administrative contact for the request.
c. Requests received < 2 weeks before the tissue is needed may not be feasible to fulfill.

2. AP confirms the request is feasible to fulfill from a Pathology standpoint.
   a. AP obtains an explanation of the requested tissue and required handling and shipping conditions from the external researcher. Shipping conditions must comply with US Department of Transportation and IATA regulations.
      (1) The external researcher is responsible for the costs of preparing and shipping the tissue. A shipping slip or account number is required with the request.
      (2) Additional fees will be invoiced to the external researcher based on the resources and work effort required for preparing and sending the tissue. AP notifies the external researcher if this applies to the request.
      (3) AP may request the external researcher provide shipping materials if special shipping conditions are required.
   b. For archived tissue requests:
      (1) A pathologist completes a tissue adequacy confirmation.
      (2) Blocks are not typically provided unless other alternatives have been exhausted. AP medical director approval is needed before a block may be provided.
   c. If the request is not feasible or not approved, e.g. due to tissue adequacy, AP informs the external researcher.
   d. If the request is feasible and approved:
      (1) AP forwards the request to LUMC Clinical Research (LUMC CR).
      (2) For fresh tissue, AP notifies the external researcher that the request is feasible but they cannot guarantee the tissue will be provided as requested. Tissue availability cannot be confirmed until it is grossed.
3. LUMC CR confirms the request is permissible to fulfill from a research standpoint.
   a. LUMC CR assesses if LUMC is engaged in the research according to OHRP's guidance 'Institutions Engaged in Research' and validates with the LUCHSC IRB. LUMC CR will retain the IRB's response in its shared drive.
      (1) If LUMC is engaged in the research, LUMC CR informs the external researcher and the LUMC employee/provider. The tissue request follows the internal research processes facilitated by LUC.
      (2) If LUMC is not engaged in the research, the tissue request continues to follow this SOP.
   b. LUMC CR confirms the signed consent form and HIPAA authorization obtained from the patient or the patient's respresentative by the external researcher meets the requirements of a HIPAA Authorization for the request.
      (1) Tissue inherently includes genetic information. Therefore the release of genetic information must be included in the HIPAA authorization.
      (2) If the consent and/or HIPAA authorization are insufficient or were not obtained:
         (a) LUMC CR notifies AP.
         (b) Either AP or LUMC CR contacts the external researcher to explain the deficiency. They provide a copy of LUMC's release of information consent form should the external researcher wish to pursue the patient's or patient representative's consent and authorization for the tissue release.
         (c) If a HIPAA authorization was provided but is missing a required element, such as the genetic information authorization, and the request is time sensitive to the extent that a new HIPAA authorization is infeasible, LUMC

CR contacts the Chief Integrity Officer for guidance on obtaining and documenting verbal consent.

(3) Once all necessary documentation is in place, LUMC CR informs AP the request is approved by LUMC CR.

4. For fresh tissue requests, if at the time of tissue procurement upon grossing AP determines there is inufficient tissue to release for research purposes (all tissue obtained is needed for clinical review), AP notifies the external research and LUMC CR. AP returns materials provided by the external researcher, if applicable and if requested by the external researcher and at the external researcher's expense.
5. AP ships the tissue as required by regulation (see 49 CFR Part 172 and IATA Dangerous Goods Regulations).
6. The documentation for the tissue request, including the consent and HIPAA authorization, are stored in AP.

C. If the external researcher does not have and does not intend to obtain patient consent and HIPAA authorization for the requested tissue, LUMC CR submits the request to the Chief Integrity Officer.

IV. REFERENCES

A. OHRP Institutions Engaged in Research
B. PRO-009 Surgical Specimens for Research
C. PAT-005 LUC requests for LUMC archived tissues
D. 49 CFR Part 172
E. International Air Transport Association (IATA) Dangerous Goods Regulations

V. ASSOCIATED DOCUMENTS AND FORMS

A. Loyola Medicine Authorization for Release of Protected Health Information

VI. APPROVALS

6/28/21

Regional Chief Clinical Officer Date