I. SCOPE

The SOP applies to fresh irretrievable specimens originating in the Loyola University Medical Center (LUMC) operating room, surgery center, or other procedural area that are to be removed from LUMC for research purposes.

Irretrievable specimens include tissues, bone marrow, and neonatal specimens.

II. PROCEDURES

1. The Principal Investigator and/or his/her designee ("Study Team") obtains consent from a patient according to Institutional Review Board (IRB) approved practices or obtains IRB approval for Waiver of Consent.

2. Before the study begins, the Study Team notifies Pathology of the future specimen requests by emailing Pathology at Kristina.Snyder@luhs.org and nicole.powell001@lumc.edu. The email follows the template:
   a. Subject: Notification of new research [LU#]
   b. Body of the email:
      (1) Study LU
      (2) Name of procedure(s) and surgeon(s) targeted by the study if known
      (3) Specimen requested
      (4) Attach a copy of the IRB approval letter.
      (5) State if the study obtains consent for the specimen or if it received a waiver of consent.
      (6) Explain how far in advance the Study Team will be able to notify Pathology of research specimen needs.
3. Pathology will inform the Study Team if the specimen is exempt from Pathology review and/or if the specimen should be obtained from an area other than Frozen Section.

4. When a patient specimen is identified, the Study Team emails Pathology at Kristina.Snyder@luhs.org and nicole.powell001@lumc.edu 24 hours in advance of the procedure or as soon as they are aware the specimen will be requested for their study. The email follows the template:

   a. Subject: Notification of research specimen for [LU#] on [date of service]
   b. Body of the email:
      (1) Study LU
      (2) Patient MRN and date of birth
      (3) Name of procedure and surgeon if known
      (4) Specimen requested (i.e. excess lung tumor, lung tumor collected for research purposes)
      (5) Consent documentation may follow one of three options:
         (a) Note the consent is available in Epic
         (b) Attach the signed consent to the email if it is not available in Epic
         (c) Attach the IRB approval letter specifying a Waiver of Consent if patient-specific consent is not required

5. After the specimen is collected, the Study Team member presents to the Pathology Frozen Section room to collect the specimen unless Pathology previously instructed him/her to present to a different location.
   a. The Study Team wears the appropriate personal protective equipment for obtaining the specimen (scrubs or a bunny suit, surgical cap or bonnet, and booties) and brings the supplies and labels necessary for transport. Refer to SOP Specimen Transport.

b. All specimens must undergo a gross exam by Pathology before release to the Study Team unless previously approved by Pathology as exempt.

III. REFERENCES

A. Illinois Administrative Code Section 250.510 Laboratory Services
B. Loyola Medical/Dental Staff Rules and Regulations

IV. ASSOCIATED DOCUMENTS AND FORMS

None

V. APPROVALS

LUMC EVP, Clinical Affairs (or designee) — Date: 8/29/18

LUC Senior Director, Clinical Research Office (or designee) — Date: 8/24/18