DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

Keck Medicine Laboratories: Keck, Norris and CSC LAC+USC Medical Center Request for Laboratory Agreement

Study Information					
Study Title:					
IRB#:	Clinical Trial # (if applicable):				
Principal Investigator:	Email:	Phone #:			
Sponsoring (Ordering) Physician:	Email:	Phone #:			
Collaborating Pathologist:	Email:	Phone #:			
(Required for protocols requesting fresh, frozen, fixed or FFPE tissue)					
Study Contact:	Email:	Phone #:			
Study Address:		Fax #:			
Is there a current CTO Research Order Form? □ Yes □ No □ Pending					
Sponsoring Organization Name:					
Address:					
Dates of Study:	Total Number of Patients:	Total Monthly Test Volume:			
	Billing Information				
Valid USC Cost Center and Worktag (if a	pplicable):				
Name:	Phone #:	Fax #:			
Address:					
Anatomic Pathology (AP) Requests (select all that apply)					
☐ Human tissue and/or histologic slides	to qualify a patient for a clinical trial				
(Include name/number of clinical tria	l above)				
☐ Human tissue and/or histologic slides	for purposes other than a clinical tri	al			
☐ Fresh human tissue biospecimen					
□ Formalin fixed paraffin embedded tissue biospecimen					
Clinical Laboratory (CP) Requests (select all that apply)					
□ Remnant clinical biospecimens (blood, urine, body fluid, culture; other); specify:					
□ Phlebotomy of research specimens to be performed by (select all that apply):					
☐ LAC+USC (provide name of authorized Research Phlebotomist):					
□ Research Study Coordinator					
□ Keck/Norris drawstations					
□ Point of Care Testing (Norris and Keck only)					
□ Processing of specimens by Clinical Laboratories Research Support Section (ZNI)					
□ Shipping by Clinical Laboratories Research Support Section to Central Lab					
□ Dry Ice required					
□ Shipping materials provided by study					

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LABORATORY AGREEMENT #	
LABORATORY ADDENDUM #	

Additional Requests (select all that apply)							
☐ Storage space within the laboratory for research specimens (Keck Medicine only); include length of time:							
☐ Provide laboratory data or prepare	☐ Investigators who need	□ Other					
laboratory database reports for	research data collected						
research purposes including computer	specifically for an IRB approved						
searches of study results and/or	protocol at LAC+USC must also						
individual patient reports.	submit a request to the DHS						
	Research Oversight Board. The						
	request can be found by clicking						
	on the link shown below and						
	following the instructions						
	provided:						
	https://sc-ctsi-						
	<u>cri.atlassian.net/wiki/spaces/FA</u>						
	QS/pages/696877062/How+to+S	-					
	ubmit+a+County+Data+Request-	-					
	to+the+DHS+Informatics+Analytic	<u>i</u>					
	<u>cs+Core</u>						
Performing Laboratory							
,	□ LAC+USC □ Keck/Nor	-					
List below any	requested laboratory services not	already indicated					

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Additional Comments								
For Laboratory Use Only								
Test Performed	CPT Code		Cost					
Principal Investigator or Designee:		Print:						
		Signature:						
		Date:						
CAO, Pathology or Designee:		Print:						
		Signature:						
		Date:						
For Keck Medicine Labs:								
Anatomic Pathology Laboratory Resear	ch Manager	Print:						
		Signature:						
		Date:						
Clinical Pathology Laboratory Research	Director	Print:						
		Signature:						
		Date:						
For LAC+USC Facilities:								
County-responsible physician		Print:						
		Signature:						
		Date:						

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NOTES:

- 1. Please submit a copy of the study protocol and lab manual for our review, as well as a copy of the IRB Approval Letter, if available.
- 2. Except under special circumstances, neither the Keck Medicine facilities nor the LAC+USC Department of Pathology will release the only diagnostic tissue block for research unrelated to a clinic trial; however, under no circumstances should a tissue block be exhausted exclusively for research purposes. The USC Translational Pathology Core Facility at USC Norris Cancer Center is available to prepare such slides for a fee, to be funded by the individual study budget.
- 3. At LAC+USC, it is the responsibility of the study P.I. and/or research coordinator to arrange shipping and testing of research specimens that require testing at a Research Lab, Reference Lab or Central Lab.
- 4. At LAC+USC, for studies that require bone marrow aspirations exclusively for research purposes, the LAC+USC laboratory staff cannot participate in the collection, processing or reporting of these research specimens.
- 5. All tests/processing performed at any of the laboratories must be funded and appropriate ordering procedures followed to ensure proper billing.
- 6. For studies that propose the evaluation of POCT, please indicate which device and tests are to be evaluated and the specific locations where the testing will be performed. Written authorization must be obtained from each facility's CLIA designated director (or designee) for POCT based research to commence.