

DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE
Keck Medicine Laboratories: Keck, Norris and CSC
LA General Medical Center
Request for Laboratory Agreement

Study Information		
Study Title:		
IRB #:	Clinical Trial # (if applicable):	
Study involves cell or gene therapy <input type="checkbox"/> Yes <input type="checkbox"/> No		
Principal Investigator:	Email:	Phone #:
Sponsoring (Ordering) Physician:	Email:	Phone #:
Collaborating Pathologist: (Required for protocols requesting fresh, frozen, fixed or FFPE tissue)	Email:	Phone #:
Study Contact:	Email:	Phone #:
Study Address:		Fax #:
Is there a current CTO Research Order Form? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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 applicable):		
Name:	Phone #:	Fax #:
Address:		
Anatomic Pathology (AP) Requests (select all that apply)		
<input type="checkbox"/> Human tissue and/or histologic slides to qualify a patient for a clinical trial (Include name/number of clinical trial above)		
<input type="checkbox"/> Human tissue and/or histologic slides for purposes other than a clinical trial		
<input type="checkbox"/> Fresh human tissue biospecimen		
<input type="checkbox"/> Formalin fixed paraffin embedded tissue biospecimen		
Clinical Laboratory (CP) Requests (select all that apply)		
<input type="checkbox"/> Remnant clinical biospecimens (blood, urine, body fluid, culture; other); specify:		
<input type="checkbox"/> Phlebotomy of research specimens to be performed by (select all that apply):		
<input type="checkbox"/> LA General (provide name of Research Phlebotomist): Phlebotomy Location:		
<input type="checkbox"/> Research Study Coordinator		
<input type="checkbox"/> Keck/Norris drawstations		
<input type="checkbox"/> Point of Care Testing (Norris and Keck only)		
<input type="checkbox"/> Processing of specimens by Clinical Laboratories Research Support Section (ZNI)		
<input type="checkbox"/> Shipping by Clinical Laboratories Research Support Section to Central Lab		
<input type="checkbox"/> Dry Ice required		
<input type="checkbox"/> Shipping materials provided by study		

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LABORATORY AGREEMENT # _____

LABORATORY ADDENDUM# _____

Additional Requests (select all that apply)

<input type="checkbox"/> Storage space within the laboratory for research specimens (Keck Medicine only); include length of time:		
<input type="checkbox"/> Provide laboratory data or prepare laboratory database reports for research purposes including computer searches of study results and/or individual patient reports.	<input type="checkbox"/> Investigators who need research data collected specifically for an IRB approved protocol at LA General must also 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-cri.atlassian.net/wiki/spaces/FAQS/pages/696877062/How+to+Submit+a+County+Data+Request+to+the+DHS+Informatics+Analytics+Core	<input type="checkbox"/> Other

Performing Laboratory

<input type="checkbox"/> COVID-19 Biorepository	<input type="checkbox"/> LA General	<input type="checkbox"/> Keck/Norris/CSC	<input type="checkbox"/> Central Lab
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List below any requested laboratory services not already indicated

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Additional Comments

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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 Research Manager	Print:
	Signature:
	Date:

Clinical Pathology Laboratory Research Director	Print:
	Signature:
	Date:

For LA General 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 LA General 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 LA General, 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 CentralLab.
4. At LA General, for studies that require bone marrow aspirations exclusively for research purposes, the LA General 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.