FAQs for Research Coordinators

Mission
The clinical laboratory supports research endeavors by providing information and services to approved protocols. Interaction with the clinical coordinators, research coordinators and the principal investigators is ongoing.

Many research protocols require that copies of clinical laboratory licensure and accreditation be provided to ensure the quality of laboratory testing performed. Some research protocols request that testing be performed using a specific test kit, test methodology or other parameter. These tests may be performed in the clinician’s office or other area, outside the knowledge of the USC Clinical Laboratory. Please notify the laboratory (contact information below) if you are performing any testing (including dipstick, urine pregnancy, glucose, hemoglobin, INR or other tests) within your area that is a part of a research protocol.

Why? – This test is “just for research”
If any decision is made based on the outcome of the test, it is included in the definition under California State Law as a clinical laboratory test. For example, if the outcome of the test (pregnancy test, glucose level, presence of protein in the urine) is used to establish suitability or exclusion from the study, this is a clinical laboratory test and must have oversight by the appropriate CLIA certificate.

But this is just for research ....
A “research” test would be taking 100 unlabeled specimens, performing a test, and generating a conclusion based on that information. Most of the time, however, a decision is made based on the result of a test performed (for example, a positive pregnancy test excludes someone from participating in a research study). In that scenario, the test that is performed is not “research” but is a clinical laboratory test and is subject to the CLIA requirements.

The sponsor is providing the test kit and all materials; why do I need to be under the oversight of the Point of Care testing program?
There are many test kits available to perform laboratory testing. When different manufacturers or methodology is used to perform any test, procedures need to be generated along with training and competency documentation for all staff performing the test to comply with federal regulations. In order to streamline resource utilization we will only accommodate oversight for the pregnancy testing kit designated for use at Keck Medical Center. This may require that the clinical laboratory perform that test on your behalf, rather than performing the test as a point of care test. This will impact your budget for the research protocol.
I have my own CLIA Certificate

If any area has a CLIA certificate and is reporting to the state and federal agencies information to support compliance with requirements, they would not need a copy of the USC Clinical Laboratories CLIA certificate.

I don’t have a CLIA Certificate, and I need to perform these tests to comply with the Research Protocol

If you are performing laboratory testing as a part of a research protocol and are requesting to be “included” in one of the USC Clinical Laboratories CLIA certificates, the performance of the test, training of staff, and monitoring of equipment would be the responsibility of USC Clinical Laboratories and must be included in the Point of Care program. In order to ensure that all activities that are included in “research” are appropriately monitored under the Point of Care Program, we require notification of tests performed associated with any research protocol.

All testing that is associated with a research protocol is performed by Keck Hospital of USC or USC Norris Cancer Hospital

Please provide that information on the request form.

I have too many protocols and cannot complete your form for each one of them

We understand that there are many protocols under any one department. The request form provides the list of information required. An additional sheet can be attached that lists the protocol number, the name of the protocol, and the clinical laboratory tests that are performed.

Do I have to do this every year?

Once a protocol has been reviewed and approved, we will continue to provide updated copies of the licensing and accrediting documents, per your request.

Where can I get additional information?

Regulatory Information:
Marianne A. Silva MS, MT(ASCP)SBB, CQA(ASQ)
Manager, Quality, Regulatory, Compliance
USC Clinical Laboratories
(323) 442-8583
Marianne.silva@med.usc.edu

Mauricio Cabrera, Data Coordinator
Mauricio.cabrera@med.usc.edu

Point of Care Testing:
Vida Montgomery, EMPH, CLS, MT(ASCP)
Point of Care Testing Supervisor
(323) 442-8578
Vida.montgomery@med.usc.edu
# Study Information

- **Study Title:**
- **IRB #:**
- **Clinical Trial # (if applicable):**
- **Principal Investigator:** Email: Phone #:
- **Sponsoring (Ordering) Physician:** Email: Phone #:
- **Collaborating Pathologist:** Email: Phone #:
- **Study Coordinator:** Email: Phone #:
- **Study Address:** Fax #:
- **Is there a current CTO Research Order Form?** Yes [ ] No [ ]
- **Sponsoring Organization Name:**
- **Address:**
- **Dates of Study:**
- **Total Number of Patients:**
- **Total Monthly Test Volume:**
- **Patient Status:**
  - Inpatients [ ]
  - Outpatients [ ]
  - Both [ ]
  - Samples only [ ]
- **Reporting Communication:**
  - Patient [ ]
  - Excel Spreadsheet [ ]
  - Auto Fax [ ]

# Billing Information

- **Valid USC Account/Grant Number (if applicable):**
  - 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 trial above)*
    - Human tissue and/or histologic slides for purposes other than a clinical trial
    - Leftover (remnant) clinical specimen (blood, urine, body fluid, culture); other: specify:
    - Fresh Human Tissue Biospecimen
    - Formalin Fixed Paraffin Embedded Tissue Biospecimen
  - **Clinical Laboratory (CP) Requests (select all that apply):**
    - Shipping by Clinical Lab
    - Shipping Materials Provided by Study
    - Phlebotomy of Research Specimens
    - **Point of Care Testing: see attached**
    - Overnight Shipping
    - Dry Ice Required
    - Other
  - **Additional Requests (select all that apply):**
    - Storage space within the laboratory for research specimens (include length of time):
    - Individual Patient Reports
    - Computer Searches of Study Results
    - Other

## Requested Laboratory Services

<table>
<thead>
<tr>
<th>Performing Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAC + USC [ ]</td>
</tr>
<tr>
<td>Keck/Norris/CSC [ ]</td>
</tr>
<tr>
<td>Central Lab [ ]</td>
</tr>
</tbody>
</table>

**Additional Comments**

Effective 8/21/2017
LABORATORY AGREEMENT #  
LABORATORY ADDENDUM # (See Comments Section for Details)

For Laboratory Use Only

<table>
<thead>
<tr>
<th>Industry Fee Schedule</th>
<th>Medicare Fee Schedule</th>
<th>Other Fee Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Performed</td>
<td>CPT Code</td>
<td>Cost</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-----------------------</td>
<td>--------------------</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Customized Requisition:</th>
<th>Billing System:</th>
<th>Where Registered:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes □ No □</td>
<td>PBAR □ Cortex □</td>
<td>Keck □ Norris □ CSC □</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phlebotomy Notification:</th>
<th>Patient ID:</th>
<th>Provide Results to EMR:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes □ No □</td>
<td>Name □ Number □</td>
<td>Yes □ No □</td>
</tr>
</tbody>
</table>

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 LAC+USC Facilities, County-responsible physician:
Print
Signature
Date

NOTES:
1. Please submit a copy of the study protocol and lab manual for our review, as well as the IRB Approval Letter, if available.
2. Except under special circumstances, USC/LAC+USC Department of Pathology will not release the only diagnostic tissue block for research unrelated to a clinical trial; however in no event will a tissue block be exhausted 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 financed by the individual study.
3. Specimens obtained at LAC+USC which require shipping to Central Lab will be handled by the PI Study Coordinator.
4. All tests/processing performed at any of the laboratories must be funded and appropriate ordering procedures followed to ensure proper billing.
5. Attached is an explanation of Point of Care Testing (POCT). For studies involving POCT performed at USC facilities, please indicate the POC tests and the specific locations they will be performed.

Effective 8/21/2017
## Research Histology Work Order

<table>
<thead>
<tr>
<th>Ordered By:</th>
<th>Date Submitted:</th>
<th>Date Completed:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator:</td>
<td></td>
<td>Phone:</td>
</tr>
</tbody>
</table>

### # Specimen Submitted:
(List specimen(s) on back)

### Tissue Description – Mouse / Human:

### # H&E per Block:  
Thickness (um): 
# Unstained Sections on Charged Slides:

### Time Fixed in Formalin:  
Fixative Submitted:

(Please label all cassettes with a pencil or solvent resistant marker)

### Fee Schedule:

#### USC Pathology Core Rates

<table>
<thead>
<tr>
<th>Recharge Type</th>
<th>Internal Rates (USC)</th>
<th>External Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histology, Special Stains and IHC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Specimen in fixative or 70% alcohol (not in cassette) – dehydrated, processed, embedded</td>
<td>$12.00</td>
<td>$14.40</td>
</tr>
<tr>
<td>1 Specimen in fixative or 70% alcohol (in cassette) – dehydrated, processed, embedded</td>
<td>$10.00</td>
<td>$12.00</td>
</tr>
<tr>
<td>Embedding only</td>
<td>$2.00</td>
<td>$2.40</td>
</tr>
<tr>
<td>H&amp;E (per slide)</td>
<td>$1.00</td>
<td>$1.20</td>
</tr>
<tr>
<td>Unstained Section, paraffin (first)</td>
<td>$3.40</td>
<td>$4.08</td>
</tr>
<tr>
<td>Unstained Section, paraffin (subsequent)</td>
<td>$1.90</td>
<td>$2.28</td>
</tr>
<tr>
<td>Unstained Section, frozen (first)</td>
<td>$10.00</td>
<td>$12.00</td>
</tr>
<tr>
<td>Unstained Section, frozen (subsequent)</td>
<td>$2.00</td>
<td>$2.40</td>
</tr>
<tr>
<td>Special Histochemistry Stain (per slide)</td>
<td>$20.00 / $15.00</td>
<td>$24.00 / $18.00</td>
</tr>
<tr>
<td>Immunohistochemistry Stain (IHC) (per slide)</td>
<td>$25.00 / $30.00 STAT</td>
<td>$35.00 / $40.00 STAT</td>
</tr>
<tr>
<td>Immunohistochemistry Stain (New antibody/work-up) Pt's Ab.</td>
<td>$350.00</td>
<td>$420.00</td>
</tr>
<tr>
<td>In-situ Hybridization (ISH) (per slide)</td>
<td>$135.00</td>
<td>$162.00</td>
</tr>
</tbody>
</table>

#### Other Services

| Pathologist Consultation (per slide, simple diagnostic) | $12.00 | $14.40 |
| Pathologist Consultation (per hour, complex analysis) | $120.00 | $144.00 |
| Photo Microscopy | $55.00 | $66.00 |
| Whole Slide Imaging | $50.00 | $60.00 |
| Non-Targeted Tissue Microarray (per hour) | $120.00 | $144.00 |
| Targeted Tissue Microarray (per hour) | $220.00 | $330.00 |

#### Slide Storage Container

| Slides box (100 Slides) – $10.00 each | Slides container (10 slides) – $3.00 each | Positive Charged Slides – $0.40 each |