

# Ancillary Research Services

- Overview
- <u>Anesthesiology/OR Research Services</u>
- <u>Cellular Therapy Research Services</u>
- Investigational Pharmacy
- <u>Center for Pathology Services (CPRS)/Laboratory Services</u>
- <u>Nuclear Medicine</u>
- <u>Ophthalmology Research Services</u>
- <u>Radiology Research Imaging Services (RIS)</u>
- UCLA Clinical and Translational Research Center (CTRC) Services

Below and in the tabs at the left is information on the activities required relating to Ancillary services for you to activate your study. Note that your study activation could be delayed if you do not complete the study start up process required by the applicable Ancillary departments.

# Ancillary departments participating in the ResearchConnect workflow:

- Anesthesiology/OR Research Services
- Cellular Therapy Research Services
- Investigational Pharmacy
- Center for Pathology Services (CPRS)/Laboratory Services
- Nuclear Medicine
- Ophthalmology Research Services
- Radiology Research Imaging Services
- UCLA Clinical and Translational Research Center (CTRC) Services

Last updated: 4 Mar 2025

Studies that require services provided by Anesthesiology and OR Research Services must have a completed webbased application in the Comprehensive Ancillary Forms Engine (CAFÉ).

- Application (in CAFÉ): click here
- Instructions for using CAFÉ: <u>click here</u>

If you have questions or need additional information: Contact: <u>AnesthesiaAncillary@mednet.ucla.edu</u>

Last updated: 26 Aug 2022



Cellular Therapy Research Services is comprised of three departments: Hemapheresis, Bowyer Infusions Center, and Stem Cell Lab. Inpatient infusions take place on Ronald Reagan UCLA Medical Center 6 East Unit and 3F Units.

Studies that require services provided by Cellular Therapy Research Services must have a completed web-based application in the Comprehensive Ancillary Forms Engine (CAFÉ).

- Application (in CAFÉ): click here
- Instructions for using CAFÉ: <u>click here</u>

#### Services Provided

#### Hemapheresis

- Autologous HPC Collection with/without Concurrent Plasma
- Autologous MNC Collection with/without Concurrent Plasma
- Allogeneic HPC Collection with/without Concurrent Plasma
- Allogeneic MNC Collection with/without Concurrent Plasma

We use the Spectra Optia Apheresis System and utilize the CMNC protocol.

#### **Bowyer Infusion Center**

- Provide Study related blood draws and other specimen collections, including baseline, pre, post, timed PK draws
- Obtain vital signs per protocol and other nursing assessment
- EKG at baseline, pre and post treatment
- Administer study related drug infusions and observations All RNs are Chemo/Biotherapy Certified
- Depend on patient's access needs, preform IV insertion or central line access/care
- Provide injection, hydration, transfusion, if indicate
- Provide medical emergency response (e.g. hypersensitivity or anaphylactic event), when indicated

#### Stem Cell Lab

- Receipt of cryopreserved cellular therapy products (CTP)
- Temporary storage of CTP in liquid nitrogen tanks (<-150°C) prior to infusion
- Thawing of CTP in water bath (37°C ± 2°C)
- Basic Processing (Sterility, Nucleated Cell Count, CD34+ or CD3+ enumeration, Trypan Blue Viability)
- Cryopreservation using controlled-rate freezer or dump-freezing method
- CD34+ selection using CliniMACS instrument

If you have questions or need additional information: Contact: <u>CellularTherapyResearch@mednet.ucla.edu</u>

Last updated: 26 Aug 2022

All research studies utilizing investigational drugs will be reviewed by the Investigational Drug Pharmacist to determine scope of services required. In some cases, the IDS pharmacist may request additional study documents (i.e. pharmacy manual) or clarification of procedures before preparing a preliminary budget assessment. For questions, budget modifications or fee waivers, please contact the IDS pharmacist or email RxResearchMgt@mednet.ucla.edu.



For price quotes on commercial drugs used in a study, please complete the Commercial Drug Pricing Application form in CAFÉ.

- Application (in CAFÉ): <u>click here</u>
- Instructions for using CAFÉ: click here

Please view video link here to access pharmacy training for study coordinator personnel.

To view a list of our pharmacy staff, please click here.

Last updated: 12 Sep 2024

#### About Us

This single point-of-service includes assistance with basic inquiries for clinical trials, clinical research and translational research, including service availability, protocol review, pricing inquiries, budget development, IRB support, invoicing, result reporting, and specimen handling, among other operational and logistical needs.

#### Services Provided

- Pathology Research Portal (PRP): Biofluid processing, biofluid storage, biofluid routing for testing, biospecimen shipping.
- Translational Pathology Core Laboratory (TPCL): remnant tissue procurement/processing/storage, histology services including embedding, sectioning, immunohistochemical and immunofluorescent staining, whole slide scanning and image analysis.

**Study Request to Waive Ancillary Services:** If Pathology services are not required, please contact CPRS at <u>CPRS@mednet.ucla.edu</u> to request a Pathology Waiver.

- Application (in CAFÉ): <u>click here</u>
- Instructions for using CAFÉ: click here

If you have questions or need additional information:

- Contact: <u>CPRS@mednet.ucla.edu</u>
- Website: https://www.uclahealth.org/departments/pathology/research-services

Last updated: 2 Dec 2022

Studies that require services provided by Nuclear Medicine Research Services must have a completed web-based application in the Comprehensive Ancillary Forms Engine (CAFÉ).

• Application (in CAFÉ): <u>click here</u>

• Instructions for using CAFÉ: <u>click here</u>

If you have questions or need additional information: Contact: NucMedAncillary@mednet.ucla.edu

Last updated: 26 Aug 2022

# About Us

The Department of Ophthalmology supports clinical research requiring ophthalmic procedures and testing for the UCLA community. While we have six clinical locations, we primarily provide ancillary services through our Stein Eye Institute and Doheny Eye Center locations.

## Services Provided

- Study specific ophthalmic exams (per protocol or for AE assessment as needed), including slitlamp examination, fundoscopy, ophthalmoscopy, etc.
- Studies assigned to appropriate ophthalmologist (ie, Retina specialist, ophthalmic oncology, Cornea, etc) depending on protocol requirements
- Visual acuity assessments, with/or without refraction. (Includes BCVA, LLVA, ETDRS, Color Vision etc).
- Ocular imaging: OCT, OCTA, Fundus Imaging, Fluorescein Angiogram, Slitlamp images, Visual Field etc.
- Application (in CAFÉ): click here
- Instructions for using CAFÉ: click here

#### Other Information

- To avoid delays, please ensure all study specific source documentation and descriptions of procedures are provided in the Café application. Studies are assigned to specific physicians and staff based on the expertise, equipment requirements and availability.
- Please ensure scheduling is completed based on the uploaded LOA. The Department has over 10 divisions that may be involved with the visit. It is important that participants are scheduled correctly to avoid delays or the need to re-schedule. Ophthalmic procedures follow specific workflows that cannot be adjusted once the participant is dilated.
- We strongly encourage the participants be accompanied by a study coordinator. Our staff will not be available to coordinate the visit or accompany the participants to various locations within the Institute.
- Studies that require ophthalmologists to be list as Co-Investigators on the 1572 or complete study-specific training will be charged the complex startup fee (\$1000) vs. the simple startup fee (\$500). In addition, if the study requires the source to be a study-specific document to be completed by the ophthalmologist (rather than CareConnect), this will also require the complex startup fee.

If you have questions or need additional information: Contact: OphCRC@mednet.ucla.edu

Last updated: 26 Aug 2022

#### About Us

Researchers who require research imaging services for their industry-sponsored clinical/translational human studies apply through an electronic portal developed specifically for this purpose by the Radiology Office of Research Affairs (ORA).



We are a group comprised of Technologists, Research Schedulers and Administrators who provide expert coordination in the review and establishment of research imaging services for research studies and clinical trials. We work directly with each study team to determine the needs of the study in the execution of the study protocol. We frequently utilize the expert knowledge of Radiology faculty (across all subspecialties) and the Q3D post-processing lab to assist with questions and provide additional guidance when needed.

**Study Request to Waive Ancillary Services:** If UCLA Radiology research imaging services are not required, please contact RIS at <u>radresearchimaging@mednet.ucla.edu</u> to request a Waiver of services.

## Application: <u>click here</u>

If you have questions or need additional information:

- Contact: <u>radresearchimaging@mednet.ucla.edu</u>
- Website: click here

## Services Provided

Imaging research services fall into various categories: [1] standard of care imaging procedures billed to either insurance/Medicare or to industry sponsors; [2] novel image acquisition protocols not routinely performed in the standard of care; [3] novel image acquisition protocols performed in addition to standard of care sequences; [4] specialized interventional procedures, including percutaneous organ biopsy for either, or both, standard of care diagnosis and research purposes.

This coordination involves scheduling on the correct imaging platform at the appropriate location(s); incorporating dedicated study protocols into the imaging platforms (CT/MR/US/X-ray); ensuring the appropriate time required for examinations; distribution of exams to the correct diagnostic interpretation imagers; use of protocol-mandated interpretation requirements; collection of requested biospecimens for accessioning by Pathology, and correct up-front billing to 3<sup>rd</sup> parties or sponsor.

We provide (but not limited to) the following:

- Initial administrative (initial and secondary) review to ensure that all necessary information and documentation (protocol) is provided at time of application for services. Administrative review includes:
  - Requests for missing information necessary for technical review and study set up.
  - Support questions from study teams in terms of imaging requests, which may involve working with financial and coding teams to support study submission.
- Technical (Radiologist and Technologist) review of the study protocol, imaging manual, and any accompanying study-specific documents to ensure protocol objectives are met, including:
  - Any specialized imaging acquisition requirements beyond standard of care.
  - Suggested revisions to requested imaging examinations to ensure protocol objectives. This may require direct communications and discussion with study Principal Investigator, study coordinators, sponsor, CRO etc. to ensure adherence to protocol objectives.
  - Specialized radiologist patient interpretation and reporting requirements that are above and beyond the standard radiologist interpretation.
  - Procedures to ensure the correct billing of examinations to sponsor or 3<sup>rd</sup> party payer dependent upon protocol requirements
  - Study approval and activation within the Radiological Sciences (research) environment with coordination between the RIS team, study team, and the dedicated Radiology research scheduling team to ensure clarity of all study-related instructions and process to schedule, receive, and image study patients.



- Ongoing maintenance and management of the study that includes, but is not limited to:
  - · Sponsor derived amendments that involve changes in research imaging examinations
  - Study team and patient-specific revisions.
  - Billing reviews.
- Study closure and archiving

## **Services Not Provided**

- Biopsy Bone Marrow
- Contact the Pathology & Laboratory Medicine Department (310) 794-8052
- Biopsy Skin Contact the Department of Dermatology – (310) 825-6911
- Bone Density Exam (DEXA)
  Contact the Department of Orthopedics (424) 259-9807
- Bone Scan Contact the Department of Nuclear Medicine – (310) 983-1419
- Echocardiogram Contact the Kurlan Heart Center – (310) 794-1710
- Electrocardiogram (ECG/EKG) Contact the Lab / MP200 - (310) 794-4238
- Fibroscan (transient elastography) Contact the Pfleger Liver Institute (performed by a Hepatologist) – (310) 794-7788
- MUGA Scan
  Contact the Department of Nuclear Medicine (310) 983-1419
- PET or PET/CT scan Contact the Department of Nuclear Medicine - (310) 983-1419

Last updated: 4 Mar 2025

# About Us

The UCLA Clinical and Translational Research Center (CTRC) is a hospital-licensed clinical space that supports clinical trials in all therapeutic areas and within all age groups, including Phase I and first-in-human clinical trials.

Application (in CAFÉ): <u>click here</u>

Instructions for using CAFÉ: click here

If you have questions about the types of services that the CTRC can provide or need additional information:

- Contact: <u>CTRCServices@mednet.ucla.edu</u> or (310) 825-5225
- Website: <u>https://ctsi.ucla.edu/researcher-resources/ucla-clinical-and-translational-research-center</u>

# Hours of Operations

- M F: 7am 7pm
- Saturday & Sunday: Per Request
- Overnights: Per Request

#### Spaces Available in CTRC



- 8 private rooms
- 3 large procedure rooms
- 4 infusion chairs
- 2 interview rooms
- Phlebotomy area
- Playroom
- Research kitchen

# Staff Available in CTRC

- Research Nurse Practitioners
  - Available to help with consenting, order entry, managing adverse reactions, clearing for investigational product dosing, performing procedures such as skin biopsies, or lumbar punctures.
- Research Nurses
  - CITI Trained
  - ACLS and PALS certified
  - · Chemotherapy/Biotherapy certified
- Research Dietician
  - Nutrition research consultation, meal services, anthropometric measurement, development of specialized diets
- Medical Assistants

# Services Available from CTRC

- Mobile Services
  - Staff may provide services to inpatient, outpatient, or campus locations. Off campus locations by arrangement.
- After Hour Services
  - Available for patients to stay overnight for observation or extended services
- Investigational Product Administration
  - Infusion, injection, inhalation, oral or other
- UCLA Institutional Biosafety Committee core facility for the administration of human gene therapy product, either in the CTRC or at a mobile site
- Research Nursing Care

Pharmacokinetics, ECGs, vital signs, point of care testing for pregnancy or drugs, routine phlebotomy
 Procedures

- Bronchoscopy with sedation
- Fat biopsy
- Flexible sigmoidoscopy
- Food challenges
- Lumbar punctures
- Muscle biopsies
- Skin biopsies
- CTRC Without Walls Service Line



- Staff available for research needs and charged on an hourly basis
- Appropriate for non-traditional clinical research needs.

Last updated: 1 Feb 2024

Last updated: 26 Aug 2022

Source

URL:https://www.researchgo.ucla.edu/ancillary-research-services?qt-view\_vertical\_tab\_section\_block\_28=4

Drupal.jQueryUiFilter.globalOptions('accordion');