

**UC DAVIS INSTITUTE FOR
REGENERATIVE CURES**

Fee-for-service cores for
Investigational New Drug
enabling studies

UC DAVIS
HEALTH SYSTEM



Pipeline pathway at UC Davis Institute for Regenerative Cures

Basic Research

Showing that
an idea for a
therapy has
potential

Proof of Concept

Development Candidate

Showing that
a specific cell
or molecule is
effective in an
animal or test
tube

Filing IND

Gathering
data to show
that the cell
or molecule is
safe to test in
humans

Clinical Trials

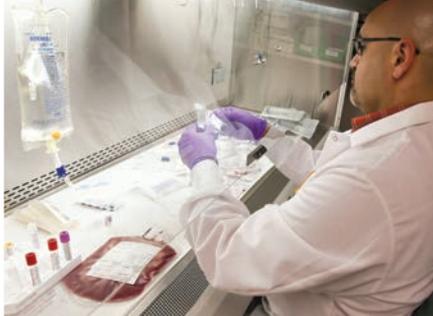
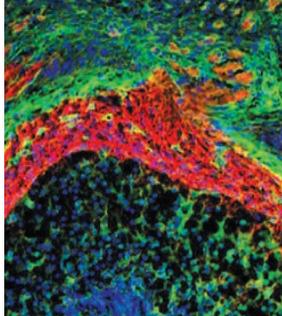
Reasonable rates, flexible scheduling, and a welcoming environment

Stem Cell Program Core Facilities and Resources

UC Davis' Institute for Regenerative Cures offers leading-edge research services for Investigational New Drug (IND) development. Located in Sacramento and anchored by Northern California's largest academic Good Manufacturing Practice facility, the institute's fee-for-service cores and support services include pre-clinical transplantation assays in immune deficient mouse models, as well as an ability to scale-up manufacturing processes for novel cell and gene therapies.

From bench to bedside, UC Davis can meet research needs with affordable services for investigators, including external academic and industry partners.

- Stem cell core
- Vector core
- Karyotyping core
- Vivarium
- Mouse cores
- Regulatory core
- Umbilical cord blood
- Good Manufacturing Practice facility
- Quality control testing laboratory



Stem Cell Core

With interest increasing in induced pluripotent stem cell (iPSC) cultures and embryonic stem cell lines, the Stem Cell Core can generate pluripotent lines from patient fibroblasts or other sources, using state-of-the-art technology. The resulting iPSC lines can be differentiated into the tissue of choice that carries a patient's genes. Successful projects in this core have generated patient-specific neurons that enabled disease-in-a-dish testing of potential therapeutics. Mesenchymal stem cells and umbilical cord blood units are also available for adult stem cell research.

CONTACT: Whitney Cary, wcary@ucdavis.edu

Vector Core

This centralized service features the development and production of viral vectors necessary for gene transfer in research experiments and pre-clinical studies. Expert staff can help investigators plan and develop vectors that fit with individual project requirements. The Vector Core also enables the design and manufacture of novel vectors and purified recombinant retrovirus and lentivirus. Quality control testing includes vector titering and replication-competent retrovirus and lentivirus assays.

CONTACT: Karen Pepper, kpepper@ucdavis.edu

Karyotyping Core

Karyotyping core services enable stability monitoring for human embryonic stem cells, induced pluripotent stem cell lines and mesenchymal stem cells, as well as porcine, murine and rat cell lines.

CONTACT: Catherine Nacey, 916-703-9300

Vivarium

The institute houses a pathogen-free barrier facility that allows for the breeding of specialized transgenic- and immune-deficient mouse strains and a full range of related services. It consists of approximately 10,500 square feet of shower-in, disease-free housing for experimental mice, along with 14 holding/procedure rooms. Resources within the vivarium include an animal irradiator for transplantation procedures, stereotactic equipment for brain injections, anesthesia machines, behavioral testing rooms, and connection to a variety of stem cell imaging modalities through CMGI.

CONTACT: Jan Nolta, janolta@ucdavis.edu or
Karyn Tschida, 916-703-9300

Mouse Core (immune-deficient)

The immune-deficient mouse core performs procedures on NOD/SCID, NOD/SCID/ B2M null, NOG/Rag -/- and NOD/SCID/ IL2Rg (gamma chain)-/- mice. Induced pluripotent stem cell lines generated for investigators can be tested for pluripotentiality (teratoma formation), a hallmark of the induction process. The core offers rule-out-tumorigenicity testing for mesenchymal stem/stromal cell batches, before and after transduction, at varying multiplicities of infection. Implanted animals are housed in a clean barrier facility (3 or 6 months) and then sent to the UC Davis Comparative Pathology Laboratory for a full tissue toxicity workup and report in support of IND submissions.

CONTACT: Jeannine McGee, jlmcgee@ucdavis.edu for rates and availability

Mouse Core (humanized)

The mouse core also offers humanization of newborn immune-deficient mice using a variety of strains and cell sources. Additional models of stem cell and behavioral testing are available. Fee-for-service rates are available.

CONTACT: GERALYN ANNETT, gmannett@ucdavis.edu

Regulatory Core

On a case-by-case basis, the Institute for Regenerative Cures partners with teams of investigators to assist with the development of pre-IND and IND applications to the U.S. Food and Drug Administration. Institute staff has exceptional skill and experience with gene-modified adult stem cells. Hourly consultation rates are available.

CONTACT: William (Bill) Gruenloh, wjgruenloh@ucdavis.edu

Umbilical Cord Blood

Investigators needing umbilical cord blood units for research now have a convenient source. California's Umbilical Cord Blood Collection Program is managed through the Stem Cell Program at UC Davis. Collection teams gather cord blood units from various hospitals throughout California. Research-grade units are released to qualified researchers at cost. These high-quality units are less than 24 hours old and no less than 70 mL total volume. Same-day and next-day pickups, as well as overnight delivery, are available. The collection program is state funded, collecting cord blood from volunteer donors to help build up the nation's public cord blood registry for life-saving transplants. Cord blood units that fail to meet the strict criteria for public banking are available for research purposes.

CONTACT: Christine Posey, ccposey@ucdavis.edu or 844-734-CORD





Good Manufacturing Practice Facility

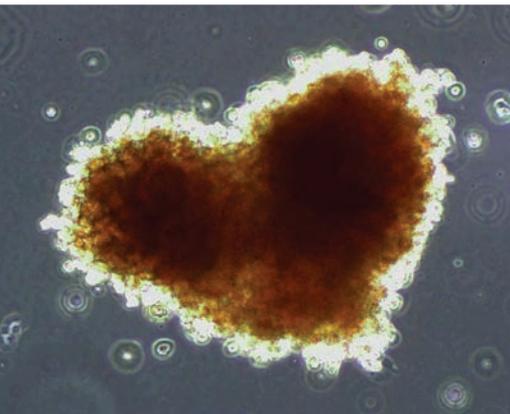
UC Davis' Good Manufacturing Practice facility in Sacramento features six manufacturing rooms with Class 10,000, multi-use cleanroom capabilities. It also offers an associated product scale-up and testing lab. Unique features include a GMP-grade FACS sorter, switchable positive-negative room pressurization for gene therapy vector manufacturing, and a hot cell for clinical grade PET reagent manufacturing. This state-of-the-art facility currently manufactures products for university investigators as well as other academic and industry partners. Reasonable hourly rates make it an ideal resource for both campus and external investigators.

CONTACT: Gerhard Bauer, gbauer@ucdavis.edu or 916-703-9305

Quality Control Testing Laboratory

Quality Control and Quality Assurance form the foundation of UC Davis' Institute for Regenerative Cures. The institute teams are experienced and skilled in every aspect of the QC/QA process. Standard operating procedures form the operational foundation for the Good Manufacturing Practice facility. The lab's Quality Control group is responsible for ensuring quality at every level of manufacturing and overseeing product-release testing. The Quality Assurance team is the final authority for guaranteeing that tests and manufacturing processes are performed to prescribed specifications. Standard operating procedures are in place for all release tests, and all tests are controlled as specified. Certificates of Analysis are generated for final products, and the Quality Assurance group is responsible for the release of that product. Only when all certificates are in place and the release criteria are met can products be released. The lab also offers Sysmex instrumentation for progenitor cell enumeration (for clinical transplantation and cord blood banking units).

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