UCDAVIS HEALTH SYSTEM

UC Davis Institute for Regenerative Cures

Fee-for-Service Contracting and Cores for IND-Enabling Studies

Stem Cell Program Core Facilities and Resources

The Stem Cell Program provides multiple cores and services, including a retroviral and lentiviral vector core, humanized mouse core, Teratoma and rule-out-tumorigenesis Core, Karyotyping core, Sysmex core for progenitor cell enumeration (for clinical transplantation and cord blood banking units), induced pluripotent stem cell manufacturing core, Quality Control/Quality Assurance unit, and a range of clinical and scale-up services for development of novel therapeutics in the state-of-the art, 6 suite Good Manufacturing Practices (GMP) facility.

Vector Core

The vector core is a centralized service for the development and production of viral vectors necessary for gene transfer in research experiments and pre-clinical studies (lentiviral, retroviral and AAV vectors). Expert technical staff will consult with investigators to plan and develop vectors to fit individual project requirements, design and construct novel vectors and generate purified recombinant vector and vector supernatant. Quality control testing will include vector titering and replication-competent retrovirus (RCR) and Lentivirus (RCL) assays. To use services contact Vector Core Director Karen Pepper at: Karen.pepper@ucdmc.ucdavis.edu

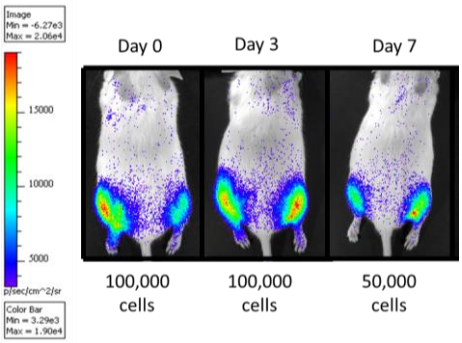
Karyotyping Core

The karyotyping service allows monitoring of the stability of human ES, induced pluripotent stem cell lines and mesenchymal stem cells, as well as porcine, murine and rat cell lines. It is offered as an affordable service for UCD and non-UCD investigators. Contact Catherine Nacey at: Catherine.nacey@ucdmc.ucdavis.edu

Specific Pathogen Free Barrier Facility (SPF) Vivarium

The IRC Barrier Facility Vivarium allows breeding of specialized clean mouse strains and offers a range of services. The facility consists of approximately 10,500 sf^2 of shower-in, disease-free housing for experimental mice comprised of fourteen holding/ procedure rooms. The following resources are situated within the animal facility: animal irradiator for transplantation procedures, stereotactic equipment for brain injections, anesthesia machines, and behavioral testing rooms. A wide range of stem cell imaging modalities are available. Please contact the vivarium's Scientist-in-charge (SIC) Dr. Jan Nolta and vivarium Manager Karyn Tschida for inquiries (Jan.nolta@ucdmc.ucdavis.edu and karyn.tschida@ucdmc.ucdavis.edu).

Immune Deficient Mouse Core for Teratoma Testing and Rule-Out-Tumorigenicity



We have established the Immune Deficient Mouse Core in the IRC. The core performs procedures on NOD/SCID, NOD/SCID/ B2M null, NOG/Rag -/- and NOD/SCID/ IL2Rg (gamma chain)-/- mice for academic and industry investigators. Induced pluripotent stem cell lines generated for investigators are tested there for pluripotentiality (teratoma formation), a hallmark of the induction process. We have developed rule-out-tumorigenicity testing for Mesenchymal Stem/Stromal Cell (MSC) tox batches, before and after transduction at varying multiplicities of infection (MOI). Implanted animals are housed in the clean barrier facility for the number of months required by the FDA (3 or 6) and then sent to the UC Davis Comparative Pathology Laboratory (CPL) for full tissue toxicity workup and report. For rates and availability interested parties should Core Director Jeannine McGee. Jeannine.mcgee@ucdmc.ucdavis.edu

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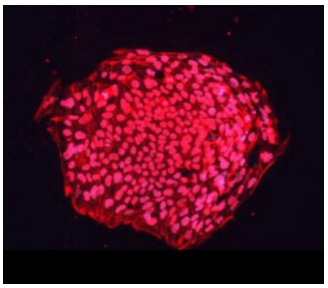
Humanized Mouse Core

We perform 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 for academic and industry partners. Please contact clinical research director Geralyn Annett, CLS. Geralyn.annett@ucdmc.ucdavis.edu



Stem Cell Core

The Stem Cell core generates induced pluripotent stem cell (iPSC) 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, which carries the patient's genes. Successful projects have been done in this core generating patient-specific neurons to allow "disease in a dish" testing of potential therapeutics. Mesenchymal stem cells and umbilical cord blood units are available for adult stem cell research. Please contact Core Director Whitney Cary. Whitney.cary@ucdmc.ucdavis.edu

Regulatory Core

On a case-by-case basis we partner with teams of investigators to assist with the development of preIND and IND applications to the FDA. Our specialty and experience base is with gene-modified adult stem cells. Hourly consultation rates are available. If interested, please contact our Director of Regulatory Affairs William (Bill) Gruenloh. William.gruenloh@ucdmc.ucdavis.edu

Good Manufacturing Practice Facility

The UC Davis Good Manufacturing Practice (GMP) facility is a 6 manufacturing room, Class 10,000, state of the art, multi-use clean room facility and has an associated product scale up and testing lab. It has some very unique features, such as a GMP grade FACS sorter, the ability of switchable room pressurization to achieve negative room pressurization for gene therapy vector manufacturing, and also a hot cell for clinical grade PET reagent manufacturing. The facility is currently manufacturing products for UCD investigators and academic and industry partners. Hourly rates for use of the facility and product manufacturing have been established. We invite all investigators who have an interest in using the facility to develop a gene therapy, cellular therapy, or other product for use in the clinic to contact GMP Director Gerhard Bauer for rates and availability: Gerhard.bauer@ucdmc.ucdavis.edu). 916-703-9305.

Quality Assurance/Quality Control (QA/QC) Laboratory

Standard Operating Procedures (SOPs) are in place for all aspects of the GMP facility. QC is responsible to carry out the QC program of the facility. Quality Assurance (QA) is the final authority and assures that all quality control has been performed to prescribed specifications. The QC group of the testing lab is responsible for the release tests performed on the products. SOPs are in place for all release tests, and all release tests are controlled as specified. Certificates of analysis (COAs) are generated for the final products. QA is responsible for the release of any product. Only if all COAs are in place and the release criteria were met, a product may be released. The QA/QC lab also has a Sysmex instrument for progenitor cell enumeration (for clinical transplantation and cord blood banking units). For rates and availability investigators should contact Core Director Jon Walker. Jon.walker@ucdmc.ucdavis.edu

Stem Cell Program Contact Information:

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