

RESEARCH AT THE UNIVERSITY OF PITTSBURGH



Directory of Research Resources

<http://www.oorhs.pitt.edu/Documents/universityResources.pdf>
http://www.clinicalresearch.pitt.edu/docs/Research_Resources.pdf

Compiled and maintained by:
The Office of Research, Health Sciences
The Office of Clinical Research, Health Sciences

RESEARCH AT THE UNIVERSITY OF PITTSBURGH
A DIRECTORY OF RESEARCH RESOURCES FOR INVESTIGATORS

Introduction

A primary mission of the University of Pittsburgh is to nurture a climate that encourages and facilitates research. This Institution is strongly committed to the protection of research subjects, investigators, and the environment during the conduct of research. To that end, the University has compiled this *Directory of Research Resources* for Investigators.

This Directory contains a listing of offices and departments within the University that play a central role in the University's research mission. While these listings are not the only resources at the University, they represent a key source of valuable information about support services, policies, procedures, and regulations related to the conduct of research. Investigators should contact the cited offices to obtain detailed information about requirements and services.

TABLE OF CONTENTS ([an alphabetical listing is located at the end of this document](#))

Budgeting, Grants, Contracts, and Financial Resources

[Office of Research](#)33
[Office of Research/Cost Accounting](#)34
[University of Pittsburgh Medical Center Clinical Trials Office](#)41
[University of Pittsburgh Medical Center Fiscal and Compliance Review](#)43

Core Facilities and Technical Services

[Center for Biologic Imaging](#)7
[Center for Computational Genetics](#)7
[Clinical and Translational Science Institute](#)11
[Division of Laboratory Animal Resources](#)14
[Flow Cytometry Facility at UPCI](#)18
[Functional Imaging Research Program](#)18
[Genomics and Proteomics Core Laboratories](#)20
[John A. Swanson Micro and Nanotechnology \(JASMiN\) Lab](#)26
[Luminex Core Facility](#)27
[Machine Shop](#)28
[McGowan Institute for Regenerative Medicine](#)28
[Microscopy Facility](#)28
[Peptide Synthesis Core](#)36
[Pittsburgh NMR Center for Biomedical Research](#)36
[Positron Emission Tomography \(PET\) Facility](#)37
[Protein Microanalytical Laboratory](#)37
[Transgenic and Chimeric Mouse Facility](#)41
[University of Pittsburgh Cancer Institute \(UPCI\)](#)41

Data, Statistical and Information Technology Services

[Biostatistics Facility at UPCI](#)7
[Business Records Management, Inc.](#)7
[Center for Computational Genetics \(GATTACA\)](#)7
[Center for Research on Health Care Data Center](#)9
[Center for Statistics](#)11
[Epidemiology Data Center](#)17
[Pittsburgh Supercomputing Center](#)37

Funding Resources

[Office of Academic Career Development](#)29
[Office of Research](#)33
[Office of Research, Health Sciences](#)34

General Research Support and Services

[Medical Media Services, UPMC](#)28
[Office of Academic Career Development](#)29

Office of Clinical Research, Health Sciences	29
Office of Clinical Research Education and Support Services	30
Office of General Counsel	30
Office of Research	33
Office of Research/Cost Accounting	34
Office of Research, Health Sciences	34
Office of Technology Management	35
Recruitment/Retention Health Studies Office	39
University of Pittsburgh Medical Center Fiscal and Compliance Review	43
University Policy Office	44
University Research Council	44

Research Compliance and Safety

Conflict of Interest Office	12
Education and Certification Program in Research and Practice Fundamentals	14
Embryonic Stem Cell Research Oversight Office	15
Environmental Health and Safety Department	16
Institutional Animal Care and Use Committee	22
Institutional Biosafety Committee	23
Institutional Review Board	24
Internet Based Studies in Education and Research	25
Investigational Drug Service	26
Office for Investigator-Sponsored IND and IDE Support	30
Radiation Safety Office	37
Recombinant DNA Office	39
Research Conduct and Compliance Office	40
Research Integrity Office	41
Research and Practice Fundamentals	41
University of Pittsburgh Medical Center Fiscal and Compliance Review	43
Western Psychiatric Institute and Clinic Research Committee	45

Research Education, Awareness, and Promotion

Center for Continuing Education in the Health Sciences	8
Center for Minority Health	8
Center for Research on Health Care	9
Clinical and Translational Science Institute	11
Education and Certification Program in Research and Practice Fundamentals	14
Education and Compliance Office-Human Subject Research	14
Education and Compliance Office-Laboratory Animal Research	15
Health Sciences Library System	20
Health Sciences Web Portal	22
Medical Media Services, UPMC	28

Office of Clinical Research Education and Support Services	30
Recruitment/Retention Health Studies Office	39
University Policy Office	44
University Research Council	44
Western Psychiatric Institute and Clinic Research Committee	45
Research Supplies	
Biological Sciences Stockroom	7
Chemistry Department Stockroom	11
Technology Transfer	
Office of Technology Management	35
Index	46

BIOLOGICAL SCIENCES STOCKROOM [top](#)

G-19 Clapp Hall

412-624-4275 (phone)

412-648-3122 (fax)

A wide range of supplies, such as media, chemicals, enzymes, tissue cultures dishes, flasks, pipette tips and tubes are available for purchase by University account number. Special orders from selected vendors! No shipping or dry ice charges on special orders! Next day delivery service is available.

BIostatistics FACILITY at the University of Pittsburgh Cancer Institute [top](#)

<http://www.upci.upmc.edu/facilities/bf/index.html>

See the website for biostatistics resources available for cancer research at the University of Pittsburgh.

BUSINESS RECORDS MANAGEMENT, INC. [top](#)

1018 Western Avenue

Pittsburgh, PA 15233

412-321-0600 (phone)

412-321-5152 (fax)

412-244-7079 (phone for UOP liaison)

<http://www.businessrecords.com/home.htm>

Business Records Management, Inc. (BRM) provides record storage and management services for the University of Pittsburgh. Services include off-site document storage, retrieval, pickup and delivery, destruction, and reporting services. Contact the University of Pittsburgh liaison for further information and training.

CENTER FOR BIOLOGIC IMAGING [top](#)

S233 Biomedical Science Towers

3500 Terrace Street

Pittsburgh, PA 15261

412-648-9796 (phone)

412-648-8330 (fax)

<http://www.cbi.pitt.edu>

The Center for Biologic Imaging provides centralized imaging services including light fluorescent microscopy, confocal laser scanning, electron microscopy, advanced computer aided morphometry, and image analysis.

CENTER FOR COMPUTATIONAL GENETICS (GATTACA cluster) [top](#)

Graduate School of Public Health

Crabtree Hall A308

130 Desoto Street

Pittsburgh PA 15261

412-383-7959 (phone)

412-624-3020 (fax)

barmada@pitt.edu (email)

<http://www.hgen.pitt.edu/resources/cluster.html>

The Center for Computational Genetics (under the direction of Dr. M. Michael Barmada) maintains a computing grid/cluster, which is optimized for parallel processing and large computational projects. This cluster is composed of 250 2Ghz PowerPC G5 processors with between 1-8Gb of physical RAM allocated to each processor (300Gb RAM total). The grid runs MacOS X system software with the Sun GridEngine software for process allocation. The grid has the BioTeam Inquiry™ software installed, allowing users to interface with the system via a secure web-based interface. All of the programs required for genomics, proteomics, bioinformatics and statistical genetics projects are available for the OS X operating systems, and many have XML-based front ends designed such that users can interact with these programs via the Inquiry™ interface. All of these machines are secured behind a multi-headed firewall, which allows for only encrypted communication from the external network (using SSH). All extraneous services on the firewall machines are turned off, including email, file sharing, printing, etc., so that the machines are as secure as possible. The storage space available exceeds 3.5Tb. All data on the cluster are stored redundantly, using a RAID50 storage array network (SAN) as the primary storage container, a second (off-site) RAID5 SAN as an online backup container (with daily backups), and nightly tape backups as a tertiary precaution. One copy of backup tapes is also stored at an off-site location. All user accounts are password-restricted, and all data in individual user's accounts is restricted so that only the individual user has access to the data. Access is available on a per- project-basis, or for more extended usage. All inquiries and/or issues regarding the cluster should be directed to Dr. M. Michael Barmada (email: barmada@pitt.edu).

CENTER FOR CONTINUING EDUCATION IN THE HEALTH SCIENCES [top](#)

Medical Arts Building, Suite 220

Pittsburgh, PA 15213

412-647-8232 (phone)

412-647-8222 (fax)

<http://ccehs.upmc.edu/CCEHS/>

The Center for Continuing Education in the Health Sciences coordinates educational programs of the Schools of the Health Sciences designed to meet the needs of practicing health care professionals, including faculty. Included are internal conferences, formal courses and self-directed learning activities available as monographs, videotapes and computer-based formats. The center provides assistance in instructional design, development of educational objectives, evaluation, and conference management. Continuing education credit is provided through accreditation by national continuing education organizations such as the Accreditation Council for Continuing Medical Education. Programs serve local, regional, national and international audiences. The Center can assist in accessing telecommunications technology available through the University of Pittsburgh Medical Center.

CENTER FOR MINORITY HEALTH [top](#)

125 Parran Hall

130 DeSoto Street

Pittsburgh, PA 15261

412-624-5665 (phone)

412-624-8679 (fax)

<http://www.cmh.pitt.edu>

The Center for Minority Health is in the Graduate School of Public Health and has responsibility for providing leadership to faculty and students within the Schools of the Health Sciences on academic, research and service activities designed to eliminate racial and ethnic health disparities.

CENTER FOR RESEARCH ON HEALTH CARE [top](#)

230 McKee Place, Suite 600

Pittsburgh, PA 15213

412-692-4853 (phone)

<http://www.crhc.pitt.edu>

The Center for Research on Health Care (CRHC) provides a forum for talented multidisciplinary investigators from throughout the university community to collaborate in high-quality health services research and train future investigators in methods and practices critical to the conduct of rigorous and exemplary research. Formal CRHC activities include a weekly Health Services Seminar Series, highlighting projects completed by CRHC investigators and their collaborators, a Research Development Seminar series where junior investigators or those with a new project idea can come for review and feedback, the annual Sonis lecture, a lecture devoted to the latest in patient safety issues and research, and a scientific review system for research grant proposals.

CENTER FOR RESEARCH ON HEALTH CARE, DATA CENTER [top](#)

200 Meyran Avenue, Suite 200

Pittsburgh, PA 15213

412-692-4873 (phone)

412-246-6954 (fax)

CRHCDC@pitt.edu (email)

<http://www.crhc.pitt.edu/DataCenter>

Overview

The Center for Research on Health Care Data Center (DC) provides state of the art data management and analysis services to the University of Pittsburgh's clinical and translational researchers. The DC's mission is to provide researchers with consistent, high quality information technology, data management, and statistical services. The DC operates as a team, providing expertise in all phases of research, thus, ensuring efficient use of resources. The DC is committed to quality assurance and research integrity. With extensive experience, the DC is able to provide research faculty with experts in data management, data entry, programming, and statistical analyses.

DC Structure

The DC consists of 35 faculty and staff. The DC Director (Dr. Doris Rubio) is the primary point of contact for the Principal Investigators (PIs). Dr. Rubio is responsible for:

- ensuring high standards for research quality on every project.
- acting as a liaison between the PIs and the DC team.
- assisting PIs with budget planning to ensure sufficient budget for data needs.
- ensuring that data analysis and data management are completed efficiently and within budget

The DC is comprised of three primary units: Information Technology, Database Laboratory, and

Biostatistics. Each unit is described below.

- The Information Technology unit is responsible for designing internet applications, fulfilling programming needs, evaluating new software, and systems administration.
- The Database Laboratory provides expertise in developing databases, designing tracking programs, and constructing data entry and verification procedures.
- The Biostatistics unit is comprised of Ph.D., Masters' and Bachelors' degree level statisticians. They are responsible for ensuring that each study has the appropriate design, sample size, and statistical analyses. They are involved in all phases of the study, from pre-award (conducting power analyses and consulting on the methodology) to post-award (running statistical applications and consulting with PIs to interpret the findings).

DC Experience

Over the last 5 years, the DC has worked on over 300 research projects. We are the data team for the Pittsburgh Pepper Center (funded through NIA P30 grant), the Multidisciplinary Clinical Research Scholars Program (funded through NIH's Clinical and Translational Science Award, CTSA), the Consortium of Radiologic Imaging Studies of Polycystic Kidney Disease (CRISP) (funded through a cooperative agreement with NIDDK). Dr. Doris Rubio serves as the Core Director for the Design, Biostatistics, and Clinical Research Ethics for the Clinical and Translational Science Institute (funded through NIH's CTSA). We have provided data management and statistical support for numerous grants such as R01, R21, R34, and K awards. Projects on which we have worked range from multisite randomized clinical trials to pilot studies. We specialize in paperless data collection methods with use of the internet and tablet PCs.

DC Resources

The DC has approximately 50 personal computers and 11 servers that are linked via an intranet with every team member having full access to the Internet. One server is a dedicated web server, enabling us to offer 128 bit SSL security for online real time data entry and secured behind a firewall. The second server is committed for web site and database development and is located behind a firewall with only developers on the intranet having access. Two servers are used for data warehousing and for file sharing and is only accessible by individuals on the intranet. We have two high end machines dedicated to statistical analyses. These machines contain up to 8 Xeon processors and up to 32gb of RAM with stripped RAIDed SCSI high end performance hard drives. This provides a framework to manipulate and analyze very large datasets in an efficient and time effective manner. One server is used as the Portal server or running Sharepoint. All servers use hardware fault tolerance methods to assure the continued availability of data and are backed up daily and archived weekly. Weekly archived media is stored at an off site secure location. All of the databases that are developed are relational and either use Access or SQL Server, or a combination thereof. Databases are stored on the intranet, but only select members of each research team have access to the specific databases and folders that contain the de-identified data (principal investigator, project coordinator, systems analyst, database manager, and statistician.) The identified data are stored in a separate table with only the systems analyst, principal investigator, and project coordinator having access. The DC's web page contains resources to enable investigators to monitor and track the progress of their studies as well as to track the level of effort spent by the DC on a particular project (<http://www.crhc.pitt.edu/DataCenter/>).

CENTER FOR STATISTICS [top](#)

2728 Cathedral of Learning

Pittsburgh, PA 15260

412-624-8729 (phone)

<http://www.stat.pitt.edu/consulting/consulting.html>

The Center for Statistics offers statistical consulting services, including design, data summarization, analysis, and interpretation of results. Researchers from various disciplines (within the arts and sciences, as well as clinical research and education) are welcome. Typically, only short-term consulting projects can be undertaken. The consulting is done by graduate students under the supervision of faculty members in the Department of Statistics.

CHEMISTRY DEPARTMENT STOCKROOM [top](#)

326 Chevron Science Center

Pittsburgh, PA 15260

412-624-8550/8551 (phone)

412-624-8552 (fax)

<http://cwt4.chem.pitt.edu/facilities/stockroom/index.asp>

A variety of supplies, such as chemicals, scientific glassware, lab supplies, gases, liquid nitrogen and dry ice, are available for purchase with a University or grant account number.

CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE [top](#)

Suite 401 Scaife Hall

3550 Terrace Street

Pittsburgh, PA 15261

412-648-2332 (phone)

412-648-2741 (fax)

<http://www.ctsi.pitt.edu>

The Clinical and Translational Science Institute (CTSI) serves as the integrative academic home for clinical and translational scientists across the University's six health sciences schools; Carnegie Mellon University; the University of Pittsburgh Medical Center (UPMC). The CTSI's primary focus is to develop, nurture, and support a cadre of clinical and translational scientists by building on the University's existing clinical research training programs (Roadmap K12, K30) to establish a comprehensive research education program. Through "integration and innovation," the CTSI excels in the development of new biomedical knowledge and the translation of that knowledge from the basic and preclinical research settings to individuals, communities, and health practice. Innovative interdisciplinary research initiatives have been developed through the ten CTSI resource cores and translated to health practice via a novel CTSI community partnership program and through centralization of UPMC's extensive clinical networks. The resulting transformations in the institution, scientist, research, health practice, and community will improve health locally, regionally, and nationally.

To initiate a request for services, please visit:

<http://www.ctsi2.pitt.edu/ServiceRequest/index.aspx>

CONFLICT OF INTEREST OFFICE (COI) [top](#)

Suite 206, Hieber Building

3500 Fifth Avenue

Pittsburgh, PA 15213

412-383-2828 (phone)

412-383-1769 (fax)

www.rcco.pitt.edu/coi

The Conflict of Interest Office and Committee

The mission, functions, and activities of the COI Office align with those of the COI Committee (COIC); together, they are responsible for the oversight and management of potential COIs of the University's employees, students, and the institution itself. The COIC's standing subcommittee, the Entrepreneurial Oversight Committee (EOC), reviews potential conflicts involving start-up companies that license or option University technology. These committees and the office also review potential conflicts surrounding research with human or animal subjects, recombinant DNA, the dead, and embryonic stem cell research, as well as conflicts surrounding consulting and purchasing.

COI Disclosure

Using the University's [Superform System](#), investigators must disclose their outside interests and commitments upon appointment, and annually thereafter by April 15, or earlier if new outside interests are accrued. For assistance in completing a disclosure, please consult the [Step by Step Guide to Completing Your COI Disclosure](#).

COI Management Involving Specifically Regulated Research

Investigators also are required to disclose their potential conflicts in research protocols overseen by the University's Institutional Review Board, Institutional Animal Care and Use Committee, Committee for Oversight of Research Involving the Dead, Embryonic Stem Cell Research Oversight Committee, and the Institutional Biosafety/recombinant DNA Committee. Investigators should familiarize themselves with the following COI policies: [Human subject research](#), [Animal research](#), [Research involving the dead](#), and [Embryonic stem cell research](#).

COI Management related to Start-up Companies Optioning or Licensing University Technology

If the University or its employees or students (or members of their immediate family) wish to hold equity in a start-up company with an option or license to University technology, such a proposal must be prospectively approved by the EOC. To facilitate this review, the following forms must be completed (as applicable): [Information Submission Form](#), [Approval of Entrepreneurial Activities Form](#), [Policy Compliance Statement](#), [Notification of Staff and Students](#).

Consulting

Consulting may be undertaken by faculty provided that they receive prior approval from their division chief (as applicable), department chair or dean; University facilities and resources are not used for such outside work; and their total time expenditures on all outside professional activities does not exceed one day per week on the average. [Policy 02-06-01](#) should be

consulted for additional information concerning outside employment.

Outside Consultants

Consultants on research projects must make hard copy disclosures to their project directors at the time of appointment, and annually thereafter, or whenever new outside interests are accrued. The appropriate form can be downloaded through Policy 11-01-04, [Conflict of Interest Policy and Procedure for Consultants](#). Project directors should submit consultants' disclosures to department chairs who will review them, take any necessary action, and convey the forms and descriptions of actions taken to the Office of Research.

Procurement Conflicts of Interest

A procurement COI arises, for example, when researchers request research supplies and equipment from a company in which they have a financial interest, or when they subcontract University work to such a company. COI management strategies involving purchases greater than \$5,000 include competitive bidding, directed/sole source justification, exclusion of the investigator from negotiating costs, and disclosure to and prior approval from the research funding source, as necessary.

Conflict of Interest Training Requirement

The Internet-based Studies in Education and Research ([ISER](#)) Conflict of Interest training module (formerly Research and Practice Fundamentals Module 4) must be completed by University of Pittsburgh faculty, staff, and students who either completed Part II of the University's Faculty/Researcher COI form or are directly involved in industry-sponsored research. Please note, that under certain circumstances, completion of the COI training module may be required before the Office of Research can approve a corporate research agreement, grant proposal, contract, or other agreement.

COI Assistance

The Conflict of Interest Office has created a library of [case studies](#) to assist University of Pittsburgh supervisors in formulating management plans for some of the most common conflict of interest situations. The COI Office and chair of the COI Committee are also available to provide customized presentations to departments and academic units. For help in managing potential conflicts of interest, supervisors and investigators may also contact Dr. Jerome Rosenberg, Chair of the COI Committee (jrosenb@pitt.edu; 412-624-3007) or the Conflict of Interest Office (Mr. David T. Wehrle, Director; wehrledt@upmc.edu; 412-383-1774, or Khrys X. Myrddin, Compliance Coordinator; myrddink@upmc.edu; 412-383-2828).

For technical assistance with the Superform System (e.g., forgotten user names/e-mail addresses, passwords, etc.), please call the iTarget Team (412-648-2222) or request assistance by clicking the "Help" button on the home page of the [Superform Web site](#).

DIVISION OF LABORATORY ANIMAL RESOURCES [top](#)

412-648-8950 (phone)

412-648-8449 (fax)

<http://www.oorhs.pitt.edu/research/dlar.html>

The Division of Laboratory Animal Resources (DLAR) facilitates research using animals through quality services and support. The division educates, trains, and informs the University biomedical community, as well as the public, regarding laboratory animal science. DLAR coordinates efforts to provide a humane, quality animal care program in compliance with legal and regulatory requirements. The programs and facilities are USDA registered and covered under an Assurance with the Office of Laboratory Animal Welfare (OLAW) of the PHS, and are accredited by the Association for the Assessment and Accreditation of Lab Animal Care (AAALAC Int). Husbandry, veterinary, and administrative services are available to assist with meeting the institutions research and teaching needs. DLAR forms and animal care policies may be found on the IACUC website: <http://www.iacuc.pitt.edu/forms.asp>. Forms are also located on the DLAR website: <http://www.dlar.pitt.edu/>.

EDUCATION AND CERTIFICATION PROGRAM IN RESEARCH AND PRACTICE FUNDAMENTALS – See [Internet Based Studies in Education and Research](#)

EDUCATION AND COMPLIANCE OFFICE – for Human Subject Research [top](#)

Hieber Building

3500 Fifth Avenue, Suite 205

Pittsburgh, PA 15213

412-383-1711 (phone)

412-383-1388 (fax)

http://www.rcco.pitt.edu/educ/ed_index.htm

The mission of the Education and Compliance Office for Human Subject Research (ECO-HSR) is to provide education to individuals involved in the conduct of clinical research at the University of Pittsburgh and to strive for research excellence and integrity throughout the University. The goal of the Compliance Program is to routinely audit clinical activities conducted under the approval of the University's Institutional Review Board in order to enhance the quality of clinical research and to ensure proper documentation, record keeping, and adherence to all components that constitute good academic research practice.

In addition to audits performed to evaluate compliance, the ECO also performs RISE Reviews (Research Investigator Startup Education). These reviews are performed following initial IRB approval in support of the research team. The ECO staff reviews assignment of study tasks and procedures as well as planned documentation methods to assure appropriate measures are in place to commence study activity.

Contact the Education and Compliance Office for specific information on the programs and services provided.

EDUCATION AND COMPLIANCE OFFICE – for Laboratory Animal Research [top](#)

Hieber Building

3500 Fifth Avenue, Suite 200

Pittsburgh, PA 15213

412-383-2008 (phone)

412-383-2020 (fax)

http://www.iacuc.pitt.edu/iac_abouttrng.htm

The mission of the Education and Compliance Office for Laboratory Animal Research (ECO-LAR) is to provide education to all individuals involved in the conduct of laboratory animal research at the University of Pittsburgh and to strive for research excellence and integrity throughout the University. The role of the compliance component associated with the Laboratory Animal Research Program is oversight through (a) random protocol reviews, (b) “for cause” protocol audits, and (c) semi-annual site visits to animal housing and use areas. There is a close association with the University Animal Care and Use Committee. Contact the Education and Compliance Office for specific information on the programs and services provided.

EMBRYONIC STEM CELL RESEARCH OVERSIGHT OFFICE

Hieber Building

3500 Fifth Avenue, Suite 205

Pittsburgh, PA 15213

412-383-1711 (phone)

412-383-1388 (fax)

<http://www.rcco.pitt.edu/escro/index.htm>

The primary purpose of the University’s ESCRO Committee is to ensure that all federal and Commonwealth of Pennsylvania regulations governing the conduct of hES cell research are met and that all hES cell research is conducted in accordance with established ESCRO Policies and Procedures.

There are two types of ESCRO review, Registration and Full Committee Review. The type of review depends on the nature of the research. Registration entails merely registering the research protocol with the ESCRO Committee so that there will be a database of all stem cell research at the University of Pittsburgh. Full Committee Review is a lengthier process that requires evaluation of the research protocol by the ESCRO Committee.

All research involving human stem cells—regardless of the type or source of the stem cells—is subject to Full Committee Review, except for the following categories, which are subject to Registration only:

A. **Registration.** <http://www.rcco.pitt.edu/escro/forms/escroform.doc>

The following categories of research are subject to Registration only:

1. **In vitro research involving *non-embryonic* stem cells**, if
 - (a) **IRB review has occurred, i.e.** The cells were obtained by a process approved by an institutional review board to ensure that donor(s) provided

voluntary informed consent in accordance with then current federal and state law, regulations, and guidelines, **and**

- (b) **The cell lines have been de-identified, i.e.** The cell lines and any corresponding information are anonymous or are coded in such a manner that the donor(s) cannot be identified (by the investigators or others) directly or indirectly through identifiers linked to the donor(s), pursuant to a written agreement obtained from the source of the cell lines stating that the identity of the donor(s) will not be released to the investigator under any circumstances.

Non-embryonic stem cells include adult stem cells, fetal stem cells, placental stem cells, and umbilical cord stem cells.

2. **In vivo autologous or allogenic adult stem cell research.** Research involving the transplantation into human subjects of autologous or allogenic adult stem cells derived from human somatic tissue.

In vivo research involving the transplantation of stem cells derived from human gonadal tissue or fetal tissue requires Full Committee Review.

3. **NIH-listed human embryonic stem cells.** In vitro research involving hES cell lines that are listed on the NIH Human Embryonic Stem Cell Registry.
4. **Transplantation of human stem cells into animals.**

Research involving human stem cells (whether adult, embryonic, umbilical, placental, or fetal) transplanted into animals except transplantation into an animal embryo or animal's germline or brain.

B. Full Committee Review. <http://www.rcco.pitt.edu/escro/forms/escroform.doc>

All research not qualifying for Registration requires Full Committee Review, examples of this research include:

1. In vivo research involving the transplantation of stem cells derived from human gonadal tissue, fetal tissue or placental tissue; and
2. The transplantation of any type of human stem cells into an animal embryo or an animal's germline or brain.

ENVIRONMENTAL HEALTH and SAFETY DEPARTMENT [top](#)
Public Safety Building, Floor 4
3412 Forbes Avenue
Pittsburgh, PA 15260
412-624-9505 (phone)

412-624-8524 (fax)

<http://www.ehs.pitt.edu>

The Environmental Health and Safety (EH&S) Department provides direction in matters of health, safety, and the environment for the University of Pittsburgh. The EH&S mission is to serve faculty, staff and students in the achievement of safe and healthful working environments in support of the University's education and research mission.

EH&S provides education through consultation, inspections and formal training. Faculty and staff conducting research utilizing biohazardous agents must complete a blood borne pathogen exposure control training conducted by EH&S within each twelve-month period. Faculty and staff working with chemicals are required by University Policy to complete EH&S Chemical Hygiene Training every three years. These training efforts are offered in person or as on-line modules. All research protocols utilizing animals or rDNA must be registered with EH&S. There is also an annual EH&S inspection of all laboratories, which should be viewed as an educational opportunity to review laboratory safety practices.

All hazardous waste generated during research must be properly disposed of per University Policy and federal regulation. EH&S manages programs for the disposal of biological wastes and the recycling or disposal of all chemicals.

EH&S also offers training and provides guidance in injury prevention, on-the-job injury, fire safety, emergency response, laser safety, environmental compliance, ergonomics, indoor air quality, and occupational safety and health.

EPIDEMIOLOGY DATA CENTER [top](#)

Graduate School of Public Health

Epidemiology Data Coordinating Center

130 DeSoto Street

127 Parran Hall

Pittsburgh, PA 15261

412-624-5447 (phone)

412-624-3775 (fax)

<http://www.edc.gsph.pitt.edu/>

The Epidemiology Data Center (EDC) was established in 1980 as a section of the Department of Epidemiology <http://www.epidemiology.pitt.edu/> in the Graduate School of Public Health <http://www.publichealth.pitt.edu/> (GSPH) at the University of Pittsburgh. Dr. Sheryl F. Kelsey, Ph.D. <http://www.edc.gsph.pitt.edu/faculty/kelsey/> serves as the Director and is assisted by Dr. Stephen Wisniewski as the Executive Deputy Director and Dr. Steven Belle as the Deputy Director, and an executive committee that includes Drs. Kim Sutton-Tyrrell and Maria Brooks, Ms. Kim Beringer, Ms. Sharon Lawlor and Mr. Jeff Martin. The EDC has been involved in more than 85 research studies sponsored by the National Institutes of Health, other government agencies and industry. Presently the EDC coordinates data management and analysis activities for more than 25 research projects sponsored by federal agencies as well as industry. The current studies represent a variety of scientific designs including clinical trials, registries, and case control studies. The EDC hosts groups of researchers from around the world.

The mission of the EDC is to provide a research environment in which complex health questions can be explored and answered using the combined tools of biology and statistics. The EDC established collaborations with clinicians to design, conduct and analyze the data from multi-center, randomized clinical trials and epidemiologic cohort studies. To contribute to the development of new knowledge, the EDC develops and refines data collection, data management, computing and statistical methods, with the ultimate goal of advancing treatment and prevention of disease.

The EDC is headquartered on the first and ground floors of the Graduate School of Public Health. Within the EDC office space, a large central area is used for staff meetings, training sessions, external project meetings, conferences, and special projects. The EDC also has a reception area, conference rooms, a supply room, microcomputer assembly room, and a raised-floor computer room, which houses a Digital Equipment Corporation VAX 6610 computer system as well as Novell NetWare, ORACLE Enterprise, Web and Backup servers.

The EDC employs more than 100 faculty, staff and students. A variety of academic backgrounds and fields of expertise are represented including physicians, biostatisticians, applied mathematical statisticians, epidemiologists, nurses, systems analysts, programmers, data managers, data entry personnel, and administrative personnel.

Most of the faculty and staff are involved in more than one research project. This varied workload promotes a healthy interaction among the projects, and allows for the interchange of the staff ensuring adequate, qualified support for individual projects during periods of peak activity. It also facilitates smooth transitions during periods of staff turnover.

FLOW CYTOMETRY FACILITY at the University of Pittsburgh Cancer Institute [top](http://www.upci.upmc.edu/facilities/fcf/index.html)
<http://www.upci.upmc.edu/facilities/fcf/index.html>

See the website for cytometry resources available for cancer research at the University of Pittsburgh.

FUNCTIONAL IMAGING RESEARCH PROGRAM [top](#)
MR Research Center and PET Facility

The Functional Imaging Research Program (FIRP), a joint facility of the University of Pittsburgh and UPMC, allows researchers to make full use of two powerful imaging modalities, positron emission tomography (PET) and magnetic resonance (MR) imaging. The physical proximity of these facilities encourages collaboration by bringing investigators and imaging specialists together in an atmosphere of open communication. One of the program's main goals is to facilitate combined modality imaging, in which complementary information from PET and MR images is combined in a single functional image. This program is directed by faculty members from the School of Medicine.

Magnetic Resonance Research Center (MRRC) [top](#)
Room B804
UPMC Presbyterian
200 Lothrop Street
Pittsburgh, PA 15213

412-647-9700 (phone)

412-647-9800 (fax)

<http://www.mrctr.upmc.edu/>

The MRRC is dedicated to the development and application of magnetic resonance imaging (MRI) and magnetic resonance spectroscopy (MRS) for medical and biological research and is forging new paths in the use of functional MRI to study cognitive, sensory, and motor function in the brain. The MRRC currently operates state-of-the-art 1.5T and 3.0T MRI scanners. The MRRC is also scheduled to begin operation of a powerful 7.0T whole-body MRI scanner in the spring of 2005. This scanner will be the most powerful whole-body scanner in the state of Pennsylvania and one of a small group of such instruments that are currently being installed at leading research institutions throughout the US, Japan and Europe.

The Positron Emission Tomography (PET) Facility [top](#)

PUH B-938

200 Lothrop Street

Pittsburgh, PA 15213

412-647-0736 (phone)

412-647-0700 (fax)

<http://www.pet.upmc.edu>

The PET Facility supports a variety of research efforts in collaboration with faculty in the Departments of Psychiatry, Neurology, Radiology, Medicine, and Anesthesiology and the University of Pittsburgh Cancer Institute. It is noteworthy that researchers at this facility developed a prototype combined PET/CT scanner, and demonstrated this technology as the most powerful imaging tool available for localizing, evaluating and therapeutically monitoring head and neck cancer. The combined PET/CT scanner, known commercially as the Biograph, was FDA approved in 2001 as a diagnostic and therapeutic tool for cancer treatment.

GENOMICS AND PROTEOMICS CORE LABORATORIES [top](#)

Gold Building

3343 Forbes Avenue, 3rd floor

Pittsburgh, PA 15260

412-648-9440 (phone)

412-648-1891 (fax)

<http://www.genetics.pitt.edu/>

The University of Pittsburgh Genomics and Proteomics Core Laboratories (GPCL) were created in 1999 by Dr. Arthur S. Levine, Senior Vice Chancellor for the Health Sciences. The GPCL is committed to fostering the implementation of modern genomics and proteomics in research, education, and clinical care encompassing the University of Pittsburgh Schools of the Basic and Health Sciences. The GPCL is equipped with state-of-the-art instrumentation and provides a variety of standard as well as customized Genomic and Proteomic analyses and bioinformatics analysis services to university researchers and their collaborators.

Genomics services include DNA sequencing, candidate gene and whole genome SNP genotyping, RNA/DNA extraction, purification and QC services, Affymetrix and Illumina gene expression micro-arrays, miRNA microarrays and TaqMan real-time PCR.

Proteomics services offered include protein identification by Peptide Mass Fingerprinting, de novo sequencing, PTM analysis, DiGE and standard 2D PAGE and LC MALDI. The Proteomic mass spectrometry platforms available include a high performance MALDI TOF-TOF MS/MS, MDLC MSⁿ ion trap, LC or MALDI Quadrupole TOF, LC and MALDI TOF MS and a 12T FTICR.

Bioinformatics Analysis Core (BAC) services include all aspects of gene expression microarray data analysis, advanced proteomics profiling and peptide identification, clinical and demographic data mining, disease prediction modeling, survivorship modeling, analysis of SNP data, and study design consultation.

New technology and capabilities are added frequently. For a complete description of services and pricing, please visit <http://www.genetics.pitt.edu>. The laboratories offer expert knowledge and support with experimental design, new protocol development, technical support, data analysis and interpretation and assistance with manuscript and grant preparation including budgeting.

HEALTH SCIENCES LIBRARY SYSTEM [top](#)

<http://www.hsls.pitt.edu/>

The Health Sciences Library System (HSLs) at the University of Pittsburgh offers a wide array of information services, educational opportunities, and resources in print and electronic format to faculty, medical staff, students and researchers in the Schools of the Health Sciences and the University of Pittsburgh Medical Center. The HSLs web site is the primary access point for library information.

Information Resources:

HSLs offers access to thousands of databases and full-text electronic journals and books at

www.hsls.pitt.edu/. Consult PITTCat for the Health Sciences <http://pittcat.hsls.pitt.edu> for complete information about HSLs print and electronic resources.

Computers connected to the University of Pittsburgh or UPMC networks have direct access to HSLs resources. Remote access is available to users off-site and requires an HSLs account. Check www.hsls.pitt.edu/services/remote/ for more detailed information.

Specialized Services:

Research Consultation: Arrange an individualized consultation with a reference librarian. A consult could include any of the following: assistance in developing and/or refining a complicated search strategy; guidance in locating an appropriate electronic resource; advice on how to approach a difficult topic; or techniques for using the Web to locate specific information. Contact the reference department at medlibq@pitt.edu or 412-648-8796

Ask-A-Librarian: E-mail questions to HSLs reference librarians, and receive a response within 24 hours by using the Ask-A-Librarian link on the front page of the library's Web site.

IACUC (Institutional Animal Care & Use Committee) Compliance: For consultation on searching the literature for alternatives to procedures that may cause more than momentary or slight pain or distress to animals used in research, contact Melissa Ratajeski, MLIS, RLAT at mar@pitt.edu or 412-648-1971

Molecular Biology Information: Visit

http://www.hsls.pitt.edu/about/news/hslsupdate/2007/december/new_molbio to access a specialized portal to tools, resources, and tutorials, or contact Dr. Ansuman Chattopadhyay, Information Specialist in Molecular Biology and Genetics at ansuman@pitt.edu or 412-648-1297.

Document Delivery: Complete an online form to request copies of articles, chapters or other published documents delivered electronically to your desktop. For information, see <http://www.hsls.pitt.edu/services/documentdelivery>

Instruction: HSLs librarians offer an array of instructional opportunities on the use of information resources relevant to health sciences researchers and clinicians. A regular schedule of over 50 walk-in classes is offered each semester in addition to customized presentations. See <http://www.hsls.pitt.edu/services/instruction/> for more information.

Educational Technology: The Computer and Media Center (CMC) in Falk Library houses audiovisual and computer resources, including software, CD-ROMs, videotapes, videodiscs, 35mm slides, and equipment on which to view or use them. The CMC staff can help faculty identify and evaluate instructional software and audiovisual materials for incorporation into the curricula of the schools of the health sciences or residency programs. Call 412-648-9109 for information.

HSLs Libraries (for library hours and directions, see (<http://www.hsls.pitt.edu/about>)
Falk Library of the Health Sciences

200 Scaife Hall
412-648-8866 (Circulation)
412-648-8796 (Reference)

Western Psychiatric Institute and Clinical Library
2nd floor, Thomas Detre Hall
412-624-2378 (Circulation)
412-246-5504 (Reference)

Libraries at UPMC Shadyside
5230 Centre Avenue
412-623-2415
James Frazer Hillman Health Sciences Library
Hopwood Library: A health resource center for patients and their families

Libraries at Children's Hospital of Pittsburgh
Room 7410, DeSoto Wing
412-692-5287
Blaxter Medical Library, Moulis Children's Library, and The Family Resource Center

HEALTH SCIENCES WEB PORTAL [top](#)

<http://www.health.pitt.edu>

The University of Pittsburgh Schools of the Health Sciences sponsors this website. The purposes of the site are:

- to provide a starting point for access to educational and research-related activities in the health sciences community at Pitt and the UPMC,
 - to make available information on health sciences research-related activities, including providing information on funding opportunities,
 - to provide a starting point to additional Internet-based, health sciences related resources,
 - to provide information about events happening across the Schools of the Health Sciences and the UPMC,
 - to serve as a gateway for the health sciences community to University web sites that are of practical interest, and
 - to alert the health sciences community to scientific news of interest and other important announcements.
-

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE [top](#)

Hieber Building

3500 Fifth Avenue, Suite 200

Pittsburgh, PA 15213

412-383-2008 (phone)

412-383-2020 (fax)

<http://www.iacuc.pitt.edu>

The Institutional Animal Care and Use Committee (IACUC) provides oversight of and training related to research involving animal subjects.

All research protocols involving animal subjects must be approved by the IACUC prior to purchasing the animals and/or the initiation of any research procedures on existing animals. Submission forms and instructions are available on the IACUC Website.

Principal investigators, research technicians/assistants, animal care technicians, and other individuals involved with the design and implementation of research studies using laboratory animals must undergo training. Mandatory training includes:

- Research Practice Fundamentals Module 1, Research Integrity
- Research Practice Fundamentals Module 3, Use of Laboratory Animals in Research and Education
- Animal training specific to the animal model listed in the protocol (*e.g.*, small animal, large animal, primate)
- Environmental Health and Safety Training depending on the risk, as determined by the Risk Assessment Officer after the protocol is submitted to the IACUC and EH&S Office for review.

Investigators should contact the IACUC training coordinator for training requirements specific to their research protocols.

Contact information for the IACUC for institutions commonly involved in collaborative research is provided below. The following guidelines should be followed for collaborative protocols:

- If funds are awarded to the University of Pittsburgh and the collaboration is with an institution that is accredited by the US Department of Health (USDA) National Institutes of Health (NIH) and the American Association for the Accreditation of Laboratory Animal Care (AAALAC), a copy of that institution’s approved protocol should be submitted to the University’s IACUC.
- If funds are awarded to the University of Pittsburgh and the collaboration is with an institution that is not accredited by the USDA, NIH and AAALAC, the protocol must be submitted to the University’s IACUC using the standard submission forms and process.

Investigators can determine the accreditation status of collaborative sites by contacting the University IACUC Office.

Children’s Hospital of Pittsburgh IACUC 3460 Fifth Avenue Pittsburgh, PA 15213 412-692-6438 (phone) 412-692-5723 (fax)	Magee-Womens Research Institute IACUC 204 Craft Avenue Pittsburgh, PA 15213 412-641-6070/4053 (phone) 412-641-6156 (fax)	Veterans Affairs Pittsburgh Health Care System IACUC University Drive Pittsburgh, PA 15240 412-688-6104 (phone) 412-648-6945 (fax) http://www.vaphs.research.med.va.gov/
---	---	--

INSTITUTIONAL BIOSAFETY COMMITTEE – See [RECOMBINANT DNA OFFICE](#) top

INSTITUTIONAL REVIEW BOARD [top](#)

Hieber Building

3500 Fifth Avenue, Ground Floor

Pittsburgh, PA 15213

412-383-1480 (phone)

412-383-1508 (fax)

<http://www.irb.pitt.edu>

The Institutional Review Board (IRB) of the University of Pittsburgh is an appropriately constituted administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities. In accordance with the regulations of the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA), the IRB has the authority to approve, require modifications in (in order to approve) or disapprove all research activities involving humans that fall within its jurisdiction.

Research involving human subjects must be reviewed and approved by the University of Pittsburgh IRB prior to the initiation of the research study. This applies to research that:

- is sponsored by the University; or
- is conducted by or under the direction of any employee or agent of the University in connection with his or her institutional responsibilities; or
- is conducted under the direction of any employee or agent of the University using any property or facility of the University; or
- involves the use of the University's non-public information to identify or contact human research subjects or prospective subjects.

Studies to be conducted at or involve the staff or patients of outside facilities must also be approved by the appropriate institutional review board(s).

- The University of Pittsburgh IRB is designated as the institutional review board of record for all medical institutions associated with UPMC, including Children's Hospital and Magee Womens Hospital. The University IRB is the IRB of record for all human subject research conducted by UPP or UPMC employees.
- The University of Pittsburgh has a Cooperative Agreement with the institutional review board of the Veterans Affairs Pittsburgh Health Care System (VAPHCS). Approval should be obtained from the institutional review board as defined by the Cooperative Agreement. Investigators should consult with the University IRB Office to identify the appropriate institutional review board for the specific research study. Contact information for the VAPHCS institutional review board is provided below.
- In the absence of a Cooperative Agreement, investigators must obtain approval of the University IRB as well as the institutional review board for the other institution.

The conduct of federally sponsored research at another institution may be subject to the requirement that the other institution have an assurance agreement with the Office for Human

Research Protections (OHRP). Contact the University IRB Office for clarification of this requirement as it pertains to the specific federally-funded research activities to be performed at other institutions.

IRB submission requirements are addressed, in detail, in the University of Pittsburgh *IRB Reference Manual for the Use of Human Subjects in Research*, which is available on the IRB website. The University IRB Office staff is available to answer questions and to provide assistance to investigators and research staff regarding IRB submission requirements and ethical issues related to conduct of human subject research.

The IRB review committees are composed largely of faculty volunteers. Those faculty who submit research protocols for IRB review are encouraged to serve on an IRB review committee. IRB membership not only provides a valuable and vital service to the University and peer investigators, but will also ensure a solid grounding in the regulations and procedures governing human subject protections.

VA Pittsburgh Health Care System
Institutional Review Board
University Drive
Pittsburgh, PA 15240
412-688-6104 (phone)
412-688-6945 (fax)
<http://www.vaphs.research.med.va.gov/>

INTERNET BASED STUDIES IN EDUCATION AND RESEARCH [top](#)

Website address: <https://cme.hs.pitt.edu/>

Requirements charts:

<http://cme.hs.pitt.edu/servlet/IteachControllerServlet?actiontotake=faq&source=required>

The Internet-Based Studies in Education and Research Program is the result of an observed need for the University of Pittsburgh Health Sciences and affiliated entities to develop an on-line education and certification training program.

The program has been designed to provide training to individuals in the Health Sciences at the University of Pittsburgh, and its affiliated institutions, who wish to participate in research and clinical activities. Currently, the program has developed modules relating to Responsible Conduct of Research, Patient Safety & Risk Management, Safety Training and UPMC Related Training.

Specifically, under the *Responsible Conduct of Research* category modules comprise the topics of Research Integrity, Human Subjects Research, Use of Laboratory Animals in Research & Education, Conflict of Interest, Human Embryonic & Fetal Stem Cell Research, Bloodborne Pathogens Training, Chemical Hygiene Training, Responsible Literature Searching, IRB Member Education, Research with Children, Good Clinical Practice and Small Animal Research and Training as well as six modules related to HIPAA for researchers, staff and University health care providers.

Please review the module requirements chart in the URL link above, that can also be found under the *News and Announcements* heading; or speak with your department chair if you have questions about required training associated with Internet Based Studies in Education and Research.

INVESTIGATIONAL DRUG SERVICE [top](#)

The Investigational Drug Service (IDS), UPMC Department of Pharmacy, evaluates planned procedures for ordering, receipt, storage, preparation, dispensing, and billing of drugs used in research studies. The IDS also evaluates procedures to ensure the accountability of investigational new drugs, compliance with informed consent documentation, and the provision of critical information on investigational new drugs to the Study Coordinators, Investigators and Pharmacy Staff.

The UPMC Presbyterian IDS must be notified of all human subject research involving the administration of an investigational new drug or an approved drug. OSIRIS and the Clinical Trials Office will automatically notify the IDS of a protocol involving the use of a drug. There is no need for the investigator to forward the information to the IDS. After receipt, the IDS will contact the investigator for further information as needed. The IDS will distribute the study information to the location (for example, WPIC, Children’s Hospital of Pittsburgh, UPCI) where the drug will ultimately be stored and dispensed,

UPMC Presbyterian Hospital Investigational Drug Service 326B Scaife Hall 200 Lothrop Street Pittsburgh, PA 15213 412-647-7348 (phone) 412-647-9651 (fax) pharm-IDS@upmc.edu (group email)	UPCI Investigational Drug Service Hillman Cancer Center, 2 nd floor – Pharmacy Room A210.5 5115 Centre Avenue Pittsburgh, PA 15232 412- 623-3464 (phone) 412- 692-2416 (fax)
--	---

JOHN A. SWANSON MICRO AND NANOTECHNOLOGY (JASMiN) LAB [top](#)

**661 Benedum Hall
3700 O’Hara Street
Pittsburgh, PA 15261
412-624-4709 (phone)**

<http://www.engr.pitt.edu/site/scmns/mems/>

The School of Engineering in the University of Pittsburgh has recently established the John A. Swanson Micro and Nanotechnology (JASMiN) Laboratory located in the 6th floor of the Benedum Engineering Hall. A strong research team is on board with expertise in the areas of microfabrication, smart materials (piezoelectric and electrostrictive materials, magnetostrictive materials and shape memory alloys), functional polymers and devices, micro power generation systems, and MEMS device design and applications.

The facilities of the JASMiN Lab are open for the University-wide Microelectromechanical Systems (MEMS) and Nanotechnology research and education activities. The current facilities can be utilized for the fabrication, packaging, and testing of various thin and thick film materials, microsensors and microactuators, and various functional materials based micro- and nano-scale devices and structures. Due to stringent processing requirements, the lab is designed to meet class 1000/10,000 clean room specifications throughout with certain areas and rooms in the lab satisfying class 1000 specifications. Activities that can be performed in the JASMiN Laboratory will include: DC and RF magnetron sputtering, photolithography, chemical vapor deposition (CVD), anisotropic and isotropic etching, reactive ion etching (RIE), bulk and surface micromachining, silicon-silicon bonding, electrostatic bonding, wire bonding, dicing, probe inspection, measurement and testing, etc.

LUMINEX CORE FACILITY [top](#)

Hillman Cancer Center, Lab 1.18

5117 Centre Avenue

Pittsburgh, PA 15213

412-623-7748 (phone)

412-623-1415 (fax)

<http://www.upci.upmc.edu/facilities/Luminex/index.html>

The University of Pittsburgh Cancer Institute (UPCI) Luminex Core Facility was founded in 2003 by Dr. Anna Lokshin and is located in the Hillman Cancer Center. With over 22 years of combined Luminex assay experience, the UPCI Luminex Core Facility staff is familiar with many Luminex protocols and offers researchers accurate, reliable, and reproducible processing and analysis services.

Luminex technology is a flexible platform that permits the simultaneous quantitative analysis of up to 100 different proteins, peptides, DNA molecules and much more from as little as 50µl of sample in a single microtiter well. Luminex is compatible with various sample matrices such as serum, cell culture supernatants, plasma, saliva, spinal fluid, tissue homogenate supernatants, urine, and ascites. Popular applications for Luminex technology include protein, gene and transcription factor expression profiling, isotyping, mRNA expression, microRNA expression, and signal transduction; new applications are added frequently.

The UPCI Luminex Core Facility can process and analyze samples using commercially available manufactured kits or unique Core developed kits. The UPCI Luminex Core Facility can also develop custom analyte Luminex assays using investigator-supplied antibodies and a protein standard.

For additional information on the services provided and pricing, please contact 412-623-7748 or visit our website at <http://www.upci.upmc.edu/facilities/Luminex/index.html>.

MACHINE SHOP [top](#)**A115 Scaife Hall****412-648-9332 (phone)****<http://www.cbp.pitt.edu/shops/machine.html>**

The Cell Biology and Physiology / Pharmacology Machine Shop provides consultation, design and fabrication services to School of Medicine investigators who need specialized devices for experimental use. These services are also available to UPMC faculty physicians who need specialized clinical devices. The Shop personnel can also diagnose and repair mechanical scientific machinery and equipment, and working in conjunction with the CBP/Pharmacology Electronics Shop, can also address the repair of electronically controlled scientific machinery and equipment. Services are fee based and accounts are required at the time of request of service.

MCGOWAN INSTITUTE FOR REGENERATIVE MEDICINE [top](#)**100 Technology Drive, Suite 200****Pittsburgh, PA 15219-3110****412-235-5100 (phone)****412-235-5290 (fax)****<http://www.mirm.pitt.edu/>**

The McGowan Institute for Regenerative Medicine serves as a single base of operations for the University's leading scientists and clinical faculty working to develop tissue engineering, cellular therapies, biosurgery and artificial and biohybrid organ devices.

MEDICAL MEDIA SERVICES [top](#)**University of Pittsburgh Medical Center****230 McKee Place, Suite 102****Pittsburgh, PA 15213****412-647-5050 (phone)****412-647-5556 (fax)****<http://www.upmc.edu/medmedia>**

Medical Media Services offers a variety of photographic, illustration and computer graphic services, dye sublimation prints, large format color poster session printing, color photocopies, typesetting and illustrations. Video production services are available for tape, CD-ROM and DVD duplication, video editing, international standards conversion, videotape conversion to DVD, internet video streaming and video teleconferencing. Audiovisual support for the UPMC Oakland and UPMC Shadyside campuses is also scheduled from this office.

MICROSCOPY FACILITY [top](#)**145 Crawford Hall****Pittsburgh, PA 15260****412-624-4448 (phone)****412-624-4759 (fax)****<http://www.pitt.edu/~biology/>**

The Microscopy Facility of the Biological Sciences Department is a multi-user facility devoted to light and electron microscopy techniques in cell and developmental biology and digital and photographic rendering of biological images. Thomas R. Harper, the facility manager and technician, is available for training and scheduling of equipment use, as well as consultation and

assistance with research projects and imaging. The facility is supported by an hourly fee for the use of equipment and an additional fee for technical assistance.

OFFICE OF ACADEMIC CAREER DEVELOPMENT [top](#)

M252A Scaife Hall

3550 Terrace Street

Pittsburgh, PA 15261

412-648-8486 (phone)

412-648-8121 (fax)

oacd@hs.pitt.edu (e-mail)

<http://www.oacd.health.pitt.edu>

The Office of Academic Career Development, Health Sciences (OACD), established in July 2002, believes that a supportive and collaborative environment, purposeful mentorship, and the encouragement of diversity in leadership roles are integral components of attracting, developing, and retaining the biomedical scientists and clinicians best suited to continuing the tradition of excellence in the health sciences at the University of Pittsburgh. The OACD is dedicated to providing professionals in the Schools of the Health Sciences (Dental Medicine, Health and Rehabilitation Sciences, Medicine, Nursing, Pharmacy, and the Graduate School of Public Health) with the professional tools, resources, and support they need to achieve their full potential as leaders in biomedical research, education, and clinical practice.

As a model for comprehensive academic career development programs nationwide, the OACD seeks to empower the academic health science community, including graduate and medical students, postdoctoral fellows, residents, clinical fellows, and faculty at every level of experience by providing academic career development guidance, training, and support. Programs include a Health Sciences Faculty Professional Development Series, a Postdoctoral Professionalism Series, NIH Career Development Award Workshops, a Women Physician Scientist Seminar Series, among others. The OACD also works in partnership with schools, departments, and units to develop relevant on-site professional development programs best suited to the unique needs of a given group; hosts a Visiting Scholars Program; and represents the Schools of the Health Sciences on a wide range of postdoctoral activities at the national level. Individual services include career counseling and guidance, one-on-one coaching, and mentoring advocacy. Health Sciences professionals are encouraged to visit the OACD website for updated information regarding programs and services.

OFFICE OF CLINICAL RESEARCH, HEALTH SCIENCES [top](#)

Suite 401 Scaife Hall

3550 Terrace Street

Pittsburgh, PA 15261

412-648-2332 (phone)

412-648-2741 (fax)

<http://www.clinicalresearch.pitt.edu>

The Office of Clinical Research, Health Sciences (OCR) promotes the growth of clinical research within and across the six schools of the Health Sciences at the University of Pittsburgh. The OCR's mission is to facilitate promotion of an interdisciplinary collaborative environment that fosters the translation of research to the community. A successful collaborative environment

will increase the institution's competitiveness for clinical and translational research initiatives, promote the development of junior clinical investigators, facilitate participant recruitment into clinical research studies, and improve health in the community by increasing access to university-based and medical system-wide clinical research. In addition, OCR provides research-related resources for participants, investigators and research staff.

The Office offers a number of services including the Study Design and Statistical Consultation Service (including assistance with study design, data collection methods and data analyses), an Institutional Data and Safety Monitoring Board (IDSMB), and assistance in participant recruitment. In addition, OCR provides education and training resources for investigators, coordinators and other key personnel involved in clinical research. The OCR website provides information on these as well as clinical research studies currently being conducted at the University of Pittsburgh.

OFFICE OF CLINICAL RESEARCH EDUCATION AND SUPPORT SERVICES [top](#)

Magee-Womens Hospital
300 Halket Street, Room 2308
Pittsburgh, PA 15213
412-641-6004 (phone)
412-641-5290 (fax)
cress@mwri.magee.edu

The Office of Clinical Research Education and Support Services (CRESS) will serve as the point of contact for all information related to clinical research at Magee-Womens Hospital of University of Pittsburgh Medical Center and Magee-Womens Research Institute. These issues will include, but are not limited to, personnel, recruitment, and training.

OFFICE OF GENERAL COUNSEL [top](#)

1710 Cathedral of Learning
Pittsburgh, PA 15260
412-624-5674 (phone)
412-624-1606 (fax)
<http://www.ogc.pitt.edu/index.html>

The University of Pittsburgh's Office of General Counsel (OGC) provides legal services to the University of Pittsburgh. The OGC attorneys are responsible for preparation and review of University contracts and agreements, representing the University in legal proceedings and providing legal advice to the University, including that related to research compliance issues. The OGC is also responsible for responding to government investigational requests, subpoenas, and requests for information under state or federal open records laws.

OFFICE FOR INVESTIGATOR-SPONSORED IND AND IDE SUPPORT (O3IS) [top](#)

Suite 204, Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
Mr. Dennis Swanson, RPh, MS
Director, O3IS
412-383-1399

swansonp@upmc.edu

www.O3IS.pitt.edu

Introduction to INDs (Investigational New Drug Applications) and IDEs (Investigational Device Exemptions)

The conduct of clinical research studies (i.e., clinical trials) under an FDA-accepted (U.S. Food and Drug Administration) IND or IDE involves a complex set of regulations, requirements, and obligations associated with the submission of initial and supplemental IND or IDE applications; continuing oversight (i.e., monitoring) of the preparation (i.e., “manufacturing”) of the investigational drug or device and the conduct of the clinical trials in accordance with FDA regulations and IND or IDE commitments; and the requisite reporting, at specified times, of clinical trial outcomes. The FDA holds the “sponsor” of the IND or IDE application responsible for ensuring that all of these regulations, requirements and obligations are being met.

Although sponsors of IND and IDE applications are typically pharmaceutical and device companies, the FDA regulations do recognize the concept of an “investigator-sponsored” IND or IDE application.¹ These regulations specify that the requirements to an investigator-sponsor of an IND or IDE application include both the FDA requirements applicable to an “investigator” and the FDA requirements applicable to a “sponsor.”

Institutional Oversight of INDs and IDEs

Proper adherence to the regulations, requirements, and obligations surrounding investigator-sponsored IND and IDE applications is critical to managing related risks. Such risks include, but are not limited to, morbidity and mortality of clinical trial participants; tort liability claims; federal citations and sanctions; and the FDA’s non-acceptance of accrued clinical trial data submitted in support of subsequent University or industry-sponsored IND or IDE applications.

The FDA does not include or copy the University in any of its notifications or comments related to investigator-sponsored IND or IDE applications; i.e., the FDA communicates directly with the investigator-sponsor and holds these communications confidential. However, the University is potentially liable for the actions of its faculty members; thus necessitating that the University be engaged in the communications between the FDA and investigator-sponsors, and also that the University be involved in the initial and continuing oversight of drug and device preparation (i.e., “manufacturing”) and the conduct of clinical trials under investigator-sponsored INDs and IDEs accepted by the FDA.

IND and IDE Policies and Procedures

The full complement of the University’s IND and IDE policies and procedures are available on the O3IS Web site (www.O3IS.pitt.edu).

Please note that these policies and procedures are applicable to all investigator-sponsored IND and IDE applications submitted, or pending submission, by University of Pittsburgh faculty and staff or which involve the use of University laboratories or facilities.

¹ While “investigator-sponsored” IND or IDE is the common terminology used in academic environments, the respective FDA terminology, as defined in the applicable FDA regulations, is “sponsor-investigator” IND or IDE.

All investigator-sponsored IND and IDE applications and all documents relevant to such applications shall be submitted to the FDA by the University's Office for Investigator-Sponsored IND and IDE Support (O3IS). Additionally, investigator-sponsored IND and IDE applications shall be restricted to single site clinical trials conducted by University faculty or staff at a University or UPMC facility; i.e., multi-center clinical trials may not be conducted under an investigator-sponsored IND or IDE application.

The Vice Chancellor for Research Conduct and Compliance, in consultation with the Senior Vice Chancellor for Health Sciences and the Director of the Office for Investigator-Sponsored IND and IDE Support, shall have the right to disapprove the submission, to the FDA, of an investigator-sponsored or University-sponsored IND or IDE application and/or to terminate the approval of an FDA-accepted, investigator-sponsored or University-sponsored IND or IDE.

University of Pittsburgh's Office for Investigator-Sponsored IND and IDE Support

The University of Pittsburgh Office for Investigator-Sponsored IND and IDE Support (O3IS) is a combined service of the Office of Clinical Research, Health Sciences, the Clinical and Translational Science Institute, and the Research Conduct and Compliance Office; established for the purpose of providing assistance to University researchers involved in the development and submission of investigator-sponsored INDs and IDEs for acceptance by the FDA and the conduct of clinical research studies under such FDA-accepted applications and exemptions.

Objectives of the O3IS

The primary objectives of the O3IS are to:

1. Provide a centralized resource of information, expertise, and support related to addressing the complex regulatory requirements, obligations, and responsibilities that govern the conduct of clinical research studies under investigator-sponsored INDs and IDEs;
2. Guide University researchers in their compliance with the regulatory requirements, obligations and responsibilities associated with the conduct of clinical research studies under investigator-sponsored INDs and IDEs; and
3. Ensure appropriate institutional oversight of commitments made under investigator-sponsored INDs and IDEs; the preparation (i.e., "manufacturing") of drugs and devices for evaluation under investigator-sponsored INDs and IDEs; and the conduct of clinical research studies under investigator-sponsored INDs and IDEs.

O3IS Services

Specific services offered by the O3IS include, but are not limited to, the following:

1. Maintain information regarding current FDA regulations and guidance documents pertinent to the preparation and submission of investigator-sponsored INDs and IDEs and the conduct of clinical research studies under such FDA-accepted applications and exemptions;
2. Provide education to University researchers regarding the regulatory requirements, obligations, and responsibilities associated with the conduct of clinical research studies under investigator-sponsored INDs and IDEs;
3. Assist University researchers in determining if there is a requirement for the submission of an investigator-sponsored IND or IDE for their planned clinical research studies;

4. Assist University researchers in identifying appropriate expertise and facilities as necessary for the preparation (i.e., “manufacturing”) of drugs and devices being evaluated under investigator-sponsored INDs and IDEs;
 5. Assist University researchers with the preparation and submission of investigator-sponsored INDs and IDEs;
 6. Assist University researchers with FDA communications concerning planned, submitted, or accepted investigator-sponsored INDs and IDEs;
 7. Guide University researchers in achieving compliance with the regulatory requirements and obligations associated with the conduct of clinical research studies under investigator-sponsored INDs and IDEs;
 8. Ensure institutional awareness of planned clinical research studies requiring the submission of investigator-sponsored INDs and IDEs and/or of planned services to support the submission of investigator-sponsored INDs and IDEs;
 9. Ensure institutional awareness of the submission of investigator-sponsored INDs and IDEs and respective FDA communications;
 10. Coordinate Research Conduct and Compliance Office monitoring of the preparation (i.e., “manufacturing”) of drugs and devices in accordance with FDA-accepted investigator-sponsored INDs and IDEs and/or applicable standards; and
 11. Coordinate Research Conduct and Compliance Office monitoring of the conduct of clinical research studies in accordance with FDA-accepted investigator-sponsored INDs and IDEs and the FDA’s current Good Clinical Practice (GCP) standards.
-

OFFICE OF RESEARCH [top](#)

350 Thackeray Hall

Pittsburgh, PA 15260

412-624-7400 (phone)

412-647-7409 (fax)

<http://www.pitt.edu/~offres/>

The Office of Research is charged with administrative responsibility for all University research and related activities involving extramural sponsorship. The Office serves as both a center for advocacy for research and related activities, and as a facilitator of the research environment. The functional areas supported by the Office of Research staff include information services, project and proposal development assistance, and grants and contracts administration for pre-award and selected post-award tasks. The Office of Research also maintains on-line indices and links about agency regulations and guidelines, funding sources and opportunities, and institutional and national data banks of investigators grouped by research interests. The Director of the Office serves as the authorized University signatory for all related matters and must approve and sign all such documents.

All proposals for external funding submitted by University personnel must be transmitted to and reviewed by the Office of Research to assure adherence to internal and external policies and procedures. All grant and contract awards must be negotiated by or in conjunction with the appropriate Office of Research staff. Material transfer agreements are also processed through this office. The Office of Research also reviews grants and contracts held by investigators who are transferring into or out of the University of Pittsburgh.

OFFICE OF RESEARCH/COST ACCOUNTING [top](#)

3109 Cathedral of Learning

Pittsburgh, PA 15260

412-624-6040 (phone)

412-624-5725 (fax)

<http://www.bc.pitt.edu/rca/index.html>

The Research/Cost Accounting Department is the centralized accounting office for post award accounting and administration of sponsored programs. Responsibilities include sponsored project account activation, account maintenance, invoicing, cash collection and application, financial reporting, account closeout and audit support.

Responsibilities also include preparation of the University's indirect cost and fringe benefit rates, general ledger data integrity, compliance with internal and external policy, procedure and regulation, special studies and audit liaison.

Research/Cost Accounting staff is assigned to specific constituencies to assist department administrators in the research community with financial accounting, administration, and policy and procedure matters related to sponsored projects.

OFFICE OF RESEARCH, HEALTH SCIENCES [top](#)

401 Scaife Hall

3550 Terrace Street

Pittsburgh, PA 15261

412-648-2233 (phone)

412-648-2741 (fax)

<http://www.oorhs.pitt.edu/>

The Office of Research, Health Sciences (OORHS) mission supports the emerging and established research enterprises within and across the six Schools of the Health Sciences at the University of Pittsburgh. The OORHS serves the University of Pittsburgh Health Sciences community by:

- Identifying opportunities to bring investigators together for multidisciplinary research collaborations and programs
- Providing project management and editorial assistance for multi-investigator grant applications
- Providing review and editorial assistance for grant applications prepared by Health Sciences faculty members
- Maintaining the Application Repository To Help University Researchers (ARTHUR), which includes successfully funded grant applications submitted by University of Pittsburgh researchers
- Providing "boilerplate" grant narrative text on core resources, research infrastructure, and institutional background information
- Administering the Competitive Medical Research Fund (CMRF) and the Health Sciences Bridge Funding Program
- Compiling and disseminating funding announcements and federal and University research policy changes

- Providing guidance to new research faculty in the Schools of the Health Sciences
- Maintaining an online handbook for biomedical researchers
- Coordinating the assignment, renovation, and construction of Health Sciences research space and infrastructure
- Fostering the development and use of research resources and core facilities
- Providing administrative oversight to the Division of Laboratory Animal Resources (DLAR)

Essential to the success of our mission is a productive dialogue between the OORHS and Health Sciences investigators. We seek input from both new and established investigators so we can meet the changing needs of the University of Pittsburgh Health Sciences community. Please contact our office <http://www.oorhs.pitt.edu/contacts.cfm> if you require any of the services listed or have suggestions as to how we can better support the basic, clinical, and translational research enterprises.

OFFICE OF TECHNOLOGY MANAGEMENT [top](#)

200 Gardner Steel Conference Center

Thackeray & O'Hara Streets

Pittsburgh, PA 15260

412-648-2206 (phone)

412-648-8525 (fax)

http://www.otm.pitt.edu/about_overview.html

<http://www.pitt.edu/HOME/PP/policies/11/11-02-01.html> (Patent Rights and Technology Transfer)

<http://www.pitt.edu/HOME/PP/policies/11/11-02-02.html> (Copyrights)

<http://www.pitt.edu/HOME/PP/policies/11/11-02-03.html> (Commercialization of Inventions through Independent Companies)

The Office of Technology Management (OTM), with support from resource partners throughout campus, serves as the hub of all innovation commercialization activities at the University of Pittsburgh. Its mission is to facilitate the development of products and processes from University technology for the benefit of the University, its faculty and staff, and the community. At the same time, OTM works to foster long-term relationships with industry in sponsored research, new innovation development, technology out-licensing, and the formation of start-up companies.

To manage the University's fast-growing commercialization activities, OTM employs intellectual property protection experts, specialized licensing managers, business development and technology marketing professionals, education and outreach teams, and reporting and compliance personnel.

OTM services to Pitt innovators include:

- Facilitation of the protection of intellectual property at the University via patents and copyrights
 - Assistance with preparing and submitting Invention Disclosure forms for commercial consideration
 - Strategic planning for the successful transfer of innovations to the marketplace
-

- Negotiation of licenses and options for Pitt innovations to commercial interests
 - Management of post-licensing reporting, revenue collection and royalty distribution
 - Educational opportunities in technology commercialization and “academic entrepreneurship”
 - Unique opportunities for targeted interaction between Pitt innovators and industry, investors and the community
 - Facilitated brainstorming to assist Pitt innovators in developing the right commercial applications
 - Annual recognition for faculty, staff and students who participate in the commercialization process
-

Ultimately, though, OTM’s aim is to bring together Pitt innovators and commercial partners in ways that will allow their collective imagination, ingenuity and innovation to change the world.

Please keep in mind, though, that investigators are responsible for complying with all University policies and procedures related to innovation commercialization and technology transfer. In addition, U.S. federal law mandates that all recipients of federal grants or contracts must report details of inventions and patents that have been made through such awards. NIH awards, in particular, include these requirements. The regulations are stated at 37CFR Section 401. For additional information, please refer to www.otm.pitt.edu/links_government.html or OTM’s Inventor Handbook. Investigators must work with OTM if they want to pursue the commercialization of their inventions at the University.

PEPTIDE SYNTHESIS CORE [top](#)

Center for Biotechnology and Bioengineering

300 Technology Drive

Pittsburgh, PA 15219

412-383-9540 (phone)

<http://www.pitt.edu/~rsup/mgbresupfac17.html>

The Peptide Synthesis Core provides comprehensive services for synthesis, purification, and characterization of synthetic peptides that are verified by mass spectrometry. Facility personnel are available for consultation with investigators regarding the design of synthesis peptides, estimates of yield, and considerations of purity requirements. Peptides can be produced at standard scales of ~0.025 mM (10-20mg), 0.1 mM (50-100mg), 0.2 mM (100-200mg), and 0.5 mM (300-500mg), with actual yields dependent on peptide length and content. Peptides may also be prepared with specialized modification, such as acetylation, biotinylation, phosphorylation, cyclization, or fluorescent dyes. The facility has the capacity to produce certified peptides for use in human clinical trials with appropriate production documentation for submission to the FDA and other regulatory agencies.

PITTSBURGH NMR CENTER FOR BIOMEDICAL RESEARCH [top](#)

Carnegie Mellon University

4400 Fifth Avenue

Pittsburgh, PA 15213

412-268-6336 (phone)

412-268-7083 (fax)

<http://www.cmu.edu/nmr-center/>

The Pittsburgh Nuclear Magnetic Resonance (NMR) Center for Biomedical Research is supported as a Biomedical Research Technology Facility by the National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health. Established in 1986 by Carnegie Mellon University and the University of Pittsburgh, the Center brings together scientists and clinical investigators in a concerted research program focusing on the application of magnetic resonance imaging (MRI) and magnetic resonance spectroscopy (MRS) to the biomedical sciences. Center investigators from Carnegie Mellon University, the University of Pittsburgh and local hospitals use animal and cellular models in their studies and have expertise in such diverse fields as biology, physics, computer science, neuroscience, medicine, and surgery. Other academic, medical, and industrial researchers are welcome to use the Center's facilities.

PITTSBURGH SUPERCOMPUTING CENTER [top](#)

300 South Craig Street

Pittsburgh, PA 15213

412-268-4960 (phone)

412-268-5832 (fax)

<http://www.psc.edu/>

The Pittsburgh Supercomputing Center (PSC) provides university, government, and industrial researchers with access to several of the most powerful systems for high-performance computing, communications and data-handling available to scientists and engineers nationwide for unclassified research. PSC advances the state-of-the-art in high-performance computing, communications and informatics and offers a flexible environment for solving the largest and most challenging problems in computational science. As a leading partner in the TeraGrid, the National Science Foundation's program to provide a coordinated national cyberinfrastructure for education and research, PSC works with other TeraGrid partners to harness the full range of information technologies to enable discovery in U.S. science and engineering.

POSITRON EMISSION TOMOGRAPHY (PET) FACILITY – See [FUNCTIONAL IMAGING RESEARCH PROGRAM](#)

PROTEIN MICROANALYTICAL LABORATORY [top](#)

301 Clapp Hall

412-624-0106 (phone)

412-624-4759 (fax)

<http://www.pitt.edu/~biohome/index.html>

This laboratory is able to provide investigators with as much amino acid sequence data as possible (or desired) from samples they submit. Chemical (Edman) protein/peptide sequencing and amino acid analytical services are provided. An Applied Biosystems 492 Procise cLC sequencer provides state-of-the-art Edman chemistry; in-gel digestion and separation of user-provided samples is also available.

RADIATION SAFETY OFFICE [top](#)

G-07 Parran Hall

130 DeSoto Street

Pittsburgh, PA 15261

412-624-2728 (phone)

412-624-3562 (fax)

<http://www.radsafe.pitt.edu>

The mission of the Radiation Safety Office is to assure the safety of individuals who use sources of ionizing radiation such as x-ray machines, sealed nuclear sources, and radio-labeled chemicals both clinically and in research. The office is also responsible for assuring compliance with all applicable state and federal regulations in the use of sources of ionizing radiation. This office offers training to users, monitors work places and controls the receipt and disposal of radioactive material and radiation producing machines.

The use of all radioactive material must be under the supervision of an authorized user. Individuals who are engaged as a principal investigator and/or have significant responsibility for administrative, medical, academic or experimental functions involving the use of radioactive material may apply to become an authorized user by submitting an application to the Radiation Safety Office. Approval to use radioactive material will be based upon the type and quantity of radioactive materials use requested, and the applicant's training and experience qualifications. For the administration of radioactive materials to humans, an individual must meet the training and experience requirements of the Nuclear Regulatory Commission (10CFR 35) to become an authorized user.

Research involving the exposure of human subjects to sources of ionizing radiation must be approved by the appropriate radiation safety subcommittee. This approval should be obtained by submitting the research study to the Institutional Review Board (IRB). The IRB office will forward the protocol to the appropriate subcommittee of the Radiation Safety Committee. Exposure of human subjects to ionizing radiation in the course of a biomedical research study involves several considerations in addition to those applied to clinical research studies that do not incorporate such an intervention. General guidelines for required review and approval are provided below; however, investigators should refer to the *IRB Reference Manual for the Use of Human Subjects in Research* and to the *Radiation Safety Manual, Regulations Regarding the Safe Use of Sources of Ionizing Radiation*.

- Biomedical research studies involving the use of standard diagnostic procedures (*e.g.*, chest X-ray, angiography, nuclear medicine procedure) for subject screening or follow-up or a standard radiation therapy indicated for routine medical management generally do not require prior approval by the Human Use Subcommittee (HUSC).
- Biomedical research studies directed at evaluating the safety and/or effectiveness of an experimental drug or device that emits ionizing radiation must be approved by the Radioactive Drug Research Committee.
- Research involving the use of a radioactive drug that has FDA approval or for which an IND has been filed must be reviewed and approved by the Human Use Subcommittee.
- Research involving the use of radiographic or fluoroscopic procedures in which radiation use is dictated by the experimental protocol must be reviewed and approved by the X Ray Subcommittee.

The *in vitro* use of radioactive materials and the administration of radioactive materials to

animals must also be prior approved by the Radiation Safety Office. Research involving the exposure of animal subjects to ionizing radiation involves several considerations in addition to those applied to research studies that do not incorporate such an intervention. Investigators should refer to the *IACUC Reference Manual* and the *Radiation Safety Manual, Regulations Regarding the Safe Use of Sources of Ionizing Radiation*.

RECOMBINANT DNA OFFICE [top](#)

Hieber Building

3500 Fifth Avenue, Suite 206

Pittsburgh, PA 15213

412-383-1768 (phone)

412-383-1769 (fax)

<http://www.rcco.pitt.edu/rdna>

The University of Pittsburgh Institutional Biosafety Committee (IBC) for rDNA Research is responsible for monitoring and ensuring compliance with National Institutes of Health (NIH) Guidelines on all activities that involve recombinant DNA, including gene therapy. The rDNA Office coordinates and guides the IBC review process. The focus of the IBC and rDNA Office is to facilitate the compliance efforts of individual researchers and technical staff, assist other University compliance offices regarding rDNA crossover issues, and to ensure the University is in compliance with the NIH *Guidelines for Research Involving Recombinant DNA Molecules*.

The University of Pittsburgh's policy regarding recombinant DNA activities requires that all recombinant DNA work being conducted must be registered with the rDNA Office, including:

- All teaching and research protocols must be reviewed and approved by the IBC if they involve (a) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or (b) molecules that result from the replication from those molecules described in (a);
 - Research protocols that involve human participants in the testing of materials containing rDNA (e.g., human gene therapy or gene transfer protocols) must be approved by the IBC prior to submission to the Institutional Review Board (IRB);
 - Research protocols that involve the use of animal participants in the testing of materials containing rDNA must be approved by both the IBC and the Institutional Animal Care and Use Committee (IACUC) prior to animal purchasing;
 - Any change or modification to a currently approved or registered rDNA protocol must be prior approved by the IBC.
-

RECRUITMENT/RETENTION HEALTH STUDIES OFFICE (RHSO) [top](#)

Keystone Building, Suite 600

3520 Fifth Avenue

Pittsburgh, PA 15213

412-383-1564 (phone)

The Department of Epidemiology maintains a Recruitment Health Studies Office (RHSO). The recruitment office was established in 1989 and has provided recruitment services for more than 40 clinical trials, observational or case control studies sponsored by National Institutes of Health (NIH), Commonwealth of Pennsylvania, or pharmaceutical companies. The RHSO specializes

in recruiting at-risk-participants from local and tri-state populations. To date over 47,342 participants have been recruited to these studies.

The most successful recruitment method utilized by RHSO is mass mailings. With technical assistance from the Epidemiology Data Center, the RHSO manages several large computerized population based lists. Data sources include governmental and public domain lists purchased from various commercial vendors. Mass mailings generated from these lists are used to solicit volunteers. Each mailing contains a cover letter written by the principal investigator, the promotion materials and a postage paid business-reply card or a self mailer brochure.

RHSO contracts with a 24-hour answering service which handles all incoming telephone calls. Telephone recruiters handle the incoming calls; conduct the screening interviews for study eligibility, schedule first clinic visits and provide appointment reminder postcards and phone calls.

Other recruitment methods utilized by the RHSO include placement of advertising and articles in the print and electronic media and public service announcements. The office also coordinates investigator interviews in local media (i.e. newspapers, TV and radio).

RHSO compiles daily and weekly statistics for each study and schedules and tracks outcomes, appointments completed, cancellations, and no-shows for over 800 clinic visits per month. Quality assurance for multi-center national studies is maintained by online statistical reports to coordinating centers, local weekly meetings, and national conference calls.

In addition to recruitment RHSO is currently conducting ongoing retention responsibilities.

RESEARCH CONDUCT AND COMPLIANCE OFFICE (RCCO) [top](#)

Hieber Building

3500 Fifth Avenue, Suite 205

Pittsburgh, PA 15213

412-383-1399 (phone)

412-383-1388 (fax)

<http://www.rcco.pitt.edu>

The Research Conduct and Compliance Office (RCCO) was created in 1999 as an umbrella organization for the purpose of organizing administratively the various offices that support the committees involved in the oversight (non-financial) of the University's research enterprise.

The mission of the Research Conduct and Compliance Office is to oversee and facilitate the conduct of ethical and regulation-compliant human and animal subject research through an integrated system of research review, audit and educational programs established in a manner that maximizes institutional effectiveness.

The RCCO consists of the following offices: the Institutional Review Board Office, the Institutional Animal Care and Use Committee Office, the Conflict of Interest Office, the Education and Compliance Offices for Human Subject Research and Animal Research, the Radiation Safety Office, the Embryonic Stem Cell Research Oversight Committee, the Office of

Investigator-sponsored IND and IDE Support (03IS), and the Recombinant DNA Office. A description of each of the respective offices is included in this guide.

RESEARCH INTEGRITY OFFICE [top](#)

1710 Cathedral of Learning

4200 Fifth Avenue

Pittsburgh, PA 15260

412-624-3007 (phone)

412-624-1606 (fax)

The research integrity officer provides confidential consultation and information on the University's Research Integrity Policy and Procedures and on the organization of departmental and school-wide workshops on topics in research integrity. For additional information, contact the Research Integrity Office or refer to University Policy 11-01-01, Research Integrity, accessible at <http://www.pitt.edu/HOME/PP/policies/11/11-01-01.html>

RESEARCH AND PRACTICE FUNDAMENTALS – See [Internet Based Studies in Education and Research](#)

TRANSGENIC AND CHIMERIC MOUSE FACILITY [top](#)

(412) 383-7986 (phone)

<http://www.genetics.pitt.edu/services/labpage.html?whichlab=tcmf>

The purpose of the Transgenic and Chimeric Mouse Facility is to provide a centralized service to produce transgenic and chimeric mice for investigators throughout the University of Pittsburgh and its affiliated institutions and hospitals. The facility contains injection and tissue culture rooms, and animal rooms for housing and breeding mice involved in the procedures for generating transgenic and chimeric mice. The animal facility is a barrier facility, in which mice are free of specific pathogens known to adversely affect their health and fecundity. This arrangement ensures that pseudopregnant female mice, transgenic mice and knockout mice delivered to the investigator will be healthy and meet the health requirements of their own animal facility. Services include DNA Microinjection, Mouse ES Cell Electroporation, Mouse ES Cell Microinjection, Embryo Derivation, Cryopreservation of embryos and derivation of ES cell lines from blastocysts.

UNIVERSITY OF PITTSBURGH CANCER INSTITUTE [top](#)

<http://www.upci.upmc.edu>

See the website for the many research resources available for cancer research at the University of Pittsburgh.

UNIVERSITY OF PITTSBURGH MEDICAL CENTER [top](#)

UPMC CLINICAL TRIALS OFFICE

Suite 219, Murdoch Building

3434 Forbes Avenue

Pittsburgh, PA 15216

412-647-4461 (phone)

<http://www.irb.pitt.edu/CTO>

The UPMC Clinical Trials Office was established under a formal agreement between the University of Pittsburgh and the UPMC for the purpose of facilitating the implementation of industry-initiated and sponsored clinical trials being conducted by PSD or UPMC investigators within the UPMC environment. The UPMC has delegated, to the UPMC Clinical Trials Office, oversight responsibility for:

- the UPMC research fiscal review and approval of insurance billing procedures associated with the conduct of applicable industry-initiated and sponsored clinical trials;
- the review, negotiation, and final approval of applicable industry sponsor clinical trial contracts/agreements (with exception of negotiation of the clinical trial budget, which is the responsibility of the principal investigator of the clinical trial in cooperation with his/her clinical department);
- ensuring that all other requisite approvals (e.g., institutional review board approval, UPP clinical department or UPMC risk management review and approval) and notifications (e.g., UPMC investigational drug service) are in place so as to permit the implementation of applicable industry-initiated and sponsored clinical trials; and
- providing institutional risk management oversight of the ongoing conduct of applicable industry-initiated and sponsored clinical trials.

The purview of the UPMC Clinical Trials Office is limited to industry-initiated and sponsored clinical trials of drugs and devices conducted within a UPMC or UPP facility or conducted under the direction of a UPMC or PSD staff member in connection with his/her UPMC and/or PSD responsibilities, appointments and clinical privileges, as appropriate.

The UPMC Clinical Trials Office will not be able to process the following types of clinical trials, which require additional oversight by certain University-related committees and/or are subject to certain University-Federal government agreements or additional UPMC-University agreements:

- industry-initiated and sponsored clinical trials conducted exclusively within University facilities;
- industry-initiated and sponsored clinical trials using in any capacity the space or resources of a Federally supported Clinical and Translational Research Center or other Federally supported entity (e.g., the PACT Center or HGTAL);
- industry-initiated and sponsored clinical trials that are directed at evaluating: an experimental intervention that emits ionizing radiation; an experimental gene transfer intervention; or a transgenic xenotransplant; and
- clinical trials, wherein industry support is provided, but either a University faculty or staff member holds the investigational new drug (IND) application or investigational device exemption (IDE) for the drug or device under investigation; or a University faculty or staff member was involved substantially in the development of the respective clinical trial

protocol (i.e., an investigator-initiated clinical trial).

The implementation and oversight of such non-applicable types of clinical trials shall remain subject to standard University of Pittsburgh and UPMC processes, including prospective approval of the conduct of the clinical trial by the University of Pittsburgh IRB and, where applicable (i.e., for University faculty investigators), approval of the industry sponsor clinical trial contract/agreement by the University of Pittsburgh Office of Research.

As of April 1, 2005, all applicable industry-initiated and sponsored clinical trials shall be processed through the UPMC Clinical Trials Office.

Institutional Review Board (IRB) Approval: The UPMC Clinical Trials Office will permit the implementation of applicable industry-initiated and sponsored clinical trials subject to their approval by either an accredited (i.e., by a nationally recognized IRB accrediting body), external (e.g., central) IRB or the University of Pittsburgh IRB. IRB approval (external or University of Pittsburgh) should be obtained concurrently with UPMC Clinical Trials Office processing or other components of the clinical trial application, but submission to the IRB of record should not occur until after the research staff has received subject injury comments from the UPMC Clinical Trials Office and fiscal comments from the UPMC Research Fiscal Review staff.

Principal investigators of applicable industry-initiated and sponsored clinical trials shall be subject to the reporting requirements of the responsible, external IRB or, where applicable, the University of Pittsburgh IRB.

For complete description of the UPMC Clinical Trials Office and corresponding clinical trial submission requirements and procedures, please refer to the UPMC Clinical Trials Office link appearing on the home page of the University IRB web site (<http://www.irb.pitt.edu/CTO>).

UNIVERSITY OF PITTSBURGH MEDICAL CENTER [top](#)

FISCAL AND COMPLIANCE REVIEW

Murdoch Building, Suite 219

3434 Forbes Avenue

Pittsburgh, PA 15213

412-647-0621/412-647-4396 (phone)

412-647-8237 (fax)

<http://www.irb.pitt.edu/upmcforms/fiscal.htm>

It is the policy of the University of Pittsburgh Medical Center (UPMC) that all clinical research studies involving UPMC facilities, staff, and/or patients are fiscally reviewed and approved in writing by a UPMC authorized representative before approval by either the University of Pittsburgh Institutional Review Board (IRB) or by a UPMC Clinical Trials Office (CTO) approved IRB. The Chief Financial Officer, Academic and Community Hospitals (ACHCFO), or designee will review and may impose written limitations upon the conduct of research studies at UPMC based upon reimbursement, fiscal, legal or compliance issues.

The ACHCFO has been granted the authority for this fiscal review for all UPMC institutions located in Allegheny County for which that individual has administrative responsibility. Studies

conducted at Children’s Hospital of Pittsburgh and outlying UPMC facilities beyond Allegheny County will be reviewed and approved by the CFO of that UPMC facility.

For studies involving care at a UPMC facility other than Children’s Hospital of Pittsburgh (Children’s), certain information must be submitted for Research Fiscal Review. This can be accomplished by emailing the information to the “Clinical Trials Fiscal Review” shared mailbox (clinicaltrialsfiscalreview@upmc.edu or ctfreview@upmc.edu). If studies are being submitted to the Clinical Trials Office (CTO) or the Office of Contracts, Grants and Intellectual Property (CGIP) for processing, the fiscal and legal reviews will be initiated by those offices. For studies performed at a UPMC facility other than Children’s, the Clinical Research Agreement (CRA) must be reviewed by Al Ciocca, UPMC Associate Counsel (cioccaaj@upmc.edu, telephone 412-647-8478). The CRA should be emailed to Al Ciocca or faxed to him at 412-647-7852.

If you will be providing services at Presbyterian, Shadyside, WPIC, South Side, Braddock, McKeesport or St. Margaret, a Research Institutional Account will need to be established for the hospital/technical-related services in the research study by completing the “[Institutional Account Request Form](#)”. Contact the facility billing office at non-MediPac facilities for information on how to set up a Research Account. If you will be providing services at a MediPac billing hospital (Presbyterian, Shadyside, WPIC, South Side, Braddock, McKeesport or St. Margaret), obtain the research rates for the hospital/technical related services that will be paid for by the protocol from the Institutional Account/Research Billing Office by calling 412- 432-5465. Research rates for services at Magee can be obtained by calling 412- 641-4383.

Questions regarding Research Rates for Physician Fees or Physician Fee Institutional Accounts can be obtained by calling Karen Krapp at the Physician Services Division Billing Office at 412-432-7579.

UNIVERSITY POLICY OFFICE [top](#)

1817 Cathedral of Learning

Pittsburgh, PA 15260

412-624-6576 (phone)

412-624-1817 (fax)

<http://www.bc.pitt.edu/policies>

The University Policy Office, under Budget and Controller, documents the official policies and procedures of the University that are University-wide in scope. Policies define responsibilities and authority, and formalize operations. Procedures provide the necessary instructions and forms for implementing policy. The University Policy Office coordinates the publication and distribution of University policies and procedures. Policies and procedures are distributed to all administrative officers, deans, directors, campus presidents, department chairs, senior level assistants and associates according to the Administrative Distribution List (3D). Procedures are further distributed to members of the Management Distribution List (Extended 3D). Mailing Services maintains both lists. Policies and procedures are also available on-line.

UNIVERSITY RESEARCH COUNCIL [top](#)

<http://www.pitt.edu/~vpres/URC/index.htm>

The University Research Council (URC) was established in July 1976 as part of a larger effort to stimulate research at the University of Pittsburgh. The Council is charged with helping to nurture

a climate that encourages research as one of the primary missions of the University. The Council advises the Provost and the Vice Provost for Research on policies pertaining to the conduct of research, scholarship, and creative activities within the University.

WESTERN PSYCHIATRIC INSTITUTE AND CLINIC RESEARCH COMMITTEE [top](#)

Room 438 WPIC

Pittsburgh, PA 15213

412-246-5067 (phone)

412-246-5070 (fax)

<http://www.wpic.pitt.edu/research/rescomm/default.htm>

All research protocols conducted by faculty or staff of the Department of Psychiatry and/or involving psychiatric patients or the use of Western Psychiatric Institute and Clinic (WPIC) resources must be reviewed and approved by the WPIC Research Committee. This requirement includes research sponsored by the pharmaceutical industry and research reviewed by an external scientific review committee as a condition of research funding or for inclusion in cooperative group trials.

INDEX [top](#)

Biological Sciences Stockroom	7
Biostatistics Facility at UPCI	7
Business Records Management, Inc.	7
Center for Biologic Imaging	7
Center for Computational Genetics	7
Center for Continuing Education in the Health Sciences	8
Center for Minority Health	8
Center for Research on Health Care	9
Center for Research on Health Care Data Center	9
Center for Statistics	11
Chemistry Department Stockroom	11
Clinical and Translational Science Institute	11
Conflict of Interest Office	12
Division of Laboratory Animal Resources	14
Education and Certification Program in Research and Practice Fundamentals	14
Education and Compliance Office-Human Subject Research	14
Education and Compliance Office-Laboratory Animal Research	15
Embryonic Stem Cell Research Oversight Office	15
Environmental Health and Safety Department	16
Epidemiology Data Center	17
Flow Cytometry Facility at UPCI	18
Functional Imaging Research Program	18
Genomics and Proteomics Core Laboratories	20
Health Sciences Library System	20
Health Sciences Web Portal	22
Institutional Animal Care and Use Committee	22
Institutional Biosafety Committee	23
Institutional Review Board	24
Internet Based Studies in Education and Research	25
Investigational Drug Service	26
John A. Swanson Micro and Nanotechnology (JASMiN) Lab	26
Luminex Core Facility	27
Machine Shop	28
McGowan Institute for Regenerative Medicine	28
Medical Media Services, UPMC	28
Microscopy Facility	28
Office of Academic Career Development	29
Office of Clinical Research, Health Sciences	29
Office of Clinical Research Education and Support Services	30
Office of General Counsel	30
Office for Investigator-Sponsored IND and IDE Support	30
Office of Research	33
Office of Research/Cost Accounting	34

<u>Office of Research, Health Sciences</u>	34
<u>Office of Technology Management</u>	35
<u>Peptide Synthesis Core</u>	36
<u>Pittsburgh NMR Center for Biomedical Research</u>	36
<u>Pittsburgh Supercomputing Center</u>	37
<u>Positron Emission Tomography (PET) Facility</u>	37
<u>Protein Microanalytical Laboratory</u>	37
<u>Radiation Safety Office</u>	37
<u>Recombinant DNA Office</u>	39
<u>Recruitment/Retention Health Studies Office</u>	39
<u>Research Conduct and Compliance Office</u>	40
<u>Research Integrity Office</u>	41
<u>Research and Practice Fundamentals</u>	41
<u>Transgenic and Chimeric Mouse Facility</u>	41
<u>University of Pittsburgh Cancer Institute (UPCI)</u>	41
<u>University of Pittsburgh Medical Center Clinical Trials Office</u>	41
<u>University of Pittsburgh Medical Center Fiscal and Compliance</u> <u>Review</u>	43
<u>University Policy Office</u>	44
<u>University Research Council</u>	44
<u>Western Psychiatric Institute and Clinical Research Committee</u>	45