The mission of the Center for Oral Health Research is to serve the University of Michigan School of Dentistry, the profession, and the public in the translation of basic knowledge into new clinical therapies and the evaluation of existing therapies in contexts in which there are important evidence gaps to improve oral, dental and craniofacial health.

**New Steering Committee Members for MCOHR**

The School of Dentistry’s Michigan Center for Oral Health Research (MCOHR) has ushered in a new steering committee for 2010! The new faces of our committee include:

- **Nisha D’Silva**, DDS, MSD, PhD - Donald A Kerr Endowed Collegiate Professor of Oral Pathology, Assoc Professor of Dentistry, Dept of Oral Medicine/Pathology and Oncology, & Associate Professor of Pathology, Medical School. Her research interests include oral carcinogenesis, and the identification of serum-based biomarkers for early detection of oral cancer.

- **Alex DaSilva**, DDS, DMSc - Assistant Professor of Prosthodontics, Dept of Biologic and Materials Science. Dr. DaSilva is investigating the brain as a target for chronic trigeminal pain disorders, including primary headaches (e.g. migraine), TMJD and trigeminal neuropathic pain.

- **Maria Regina (Nina) Estrella**, DDM, MS - Clinical Assistant Professor, Dept of Orthodontics/Pediatric Dentistry. Her interests include dentistry for children with special health care needs, with a focus on clinical studies among children with autism, craniofacial anomalies, and the medically compromised population.

- **Carlos Gonzalez**, DDS, MSD, PhD - Associate Professor of Dentistry, Dept of Cariology, Restorative Sciences and Endodotics. Dr. Gonzalez is researching our understanding of dental caries, erosion, with a particular interest in secondary caries, dental erosion-abrasion, remineralization, fluorides, and oral health products.

- **Blake Roessler**, MD - Associate Professor of Internal Medicine, Medical School, and MICHRC’s Associate Director for Research Innovation. Dr. Roessler has a broad-based research program exploring many facets of chondrocyte biology, has a long-standing interest in development of model systems and clinical applications of gene therapy, and is currently studying mechanisms of vector-host cell interactions.

- **Brent Ward**, DDS, MD - Assistant Professor of Dentistry, Dept of Oral and Maxillofacial Surgery. His clinical practice focuses on cancer and pre-cancer treatment, as well as reconstruction of face and jaw structures, and his research interests include targeted chemotherapy for head and neck cancer and pain management.

We want to sincerely thank our previous committee members, for their commitment of service to MCOHR and clinical research at the University of Michigan. Drs.:

- Dan Clauw
- Geoffrey Gerstner
- Carol Murdoch-Kinch
- James McNamara
- Mathilde Peters
- George Taylor
- Hom-Lay Wang
Attention Researchers: Advertise Your Study with MCOHR

MCOHR offers many ways to aid recruitment for your research study. Your study information can be posted on both the MCOHR and the MICHRI Clinical Studies website, the University of Michigan Health System patient search engine database of UM research studies. Investigators are encouraged to contact Lea Franco (lmfranco@umich.edu) at MCOHR to post studies on these websites. This service is offered at no cost to all School of Dentistry researchers.

Engage Registry is now UMClinicalStudies.org!

Engage has recently become UMClinicalStudies.org, and has added a Dental stem of questions to help recruit patients for clinical research studies. The stem includes 20 questions to acquire potential patients for your research.

U-M researchers and their teams are invited to contact the registry team to learn how to utilize the website to post studies and enhance research recruitment for their studies. Contact the registry team for more information at umclinicalstudies@umich.edu or 1- 877 - 5 - ENGAGE. For instructions on how to use the registry please see the information at https://www.umms.med.umich.edu/registry/tempUMStaffResearch.htm.

Media advertising regarding Engage for research studies can now also be heard on local radio stations!

Upcoming IRBMED Workshops

Full descriptions of each workshop can be found on the IRBMED website at http://med.umich.edu/irbmed/education.htm. All workshops are also available for presentation at department or unit meetings etc. Upcoming workshops are in the Taubman Medical Library, or in 2710 of the Furstenberg Student Study Center at Catherine Street and Zina Pitcher. To register, click on the workshop at https://www-a1.lsa.umich.edu/es_conf/app/ShowSessions.asp?confid=2&sDate=todayafter&shwd=0.

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Investigator 101 is available as a CD-based training module, created by the organization, Public Responsibility in Medicine and Research. The module includes, "The History and Ethics of Human Subject Research," with Dr. Jeffrey Cooper and "The Top 10 Responsibilities of Investigators" with Ms. Ada Sue Selwitz. To sign out a copy of the computer CD "Investigator 101" please email Monica Stiddom at mhealy@umich.edu.

The IRBMED does provide additional educational information on their education archive site for investigator and study staff use. http://med.umich.edu/irbmed/Archive/EduArchive.htm.
MICHR Has Moved to NCRC

MICHR has become one of the North Campus Research Complex “pioneers”, and are continuing to serve researchers and their teams. MICHR is located in Building 400 of NCRC (North Campus Research Complex), located at the southeast corner of Plymouth Road and Huron Parkway. You may enter the parking lot at 1600 Huron Parkway, just south of Plymouth Road. Enter through the gate and turn left towards the parking area in front of Building 100 (you must enter through Building 100). The front parking lot has metered visitor spaces as well as Blue and Gold permit spaces. Just past Building 100 is a Yellow permit lot. Please identify yourself to the receptionist when you enter Building 100. If the receptionist is not present, please press the Security call button for entry. After entering the reception area, continue to the left, then straight ahead to the windows, and then turn right. Continue down the hallway to the MICHR reception area.

Main phone number: (734) 998 - 7474
Mailing Address:
Michigan Institute for Clinical & Health Research (MICHR)
2800 Plymouth Road
Building 400
Ann Arbor, MI 48109-2800

Considering All the Costs: Budgeting Proposals Workshop

This workshop, sponsored by the Medical School Office of Research, was held on May 4, 2010. The purpose of this workshop was to review the conceptualization of the full costs required to perform research work plans, consider the sources of funds to complete the work, and discuss how peer reviewers perceive budget requests. Concepts presented and discussed applied to all types of externally sponsored activities and sponsors. Heather Offhaus, Director of the Grant Review & Analysis Office, hosted the workshop and was joined by experienced peer reviewers from the Medical School faculty. See the powerpoint presentation or watch the video at http://www.med.umich.edu/u/medschool/research/events/100504_budgeting_workshop/.

Contact Kathryn Ridner at kridner@umich.edu, or (734) 763 - 4086 with any questions about the workshop.

Burroughs Wellcome Fund Investigators in the Pathogenesis of Infectious Disease Research Awards Internal Deadline: September 10, 2010

The Investigators in the Pathogenesis of Infectious Disease award program provides $500,000 over a period of five years ($100,000 per year). The goal of the program is to provide opportunities for accomplished investigators still early in their careers to study the pathogenesis of infectious disease at its most fundamental level – the points where human and microbial systems connect. The program supports research that sheds light on the fundamentals that affect the outcomes of this encounter: how colonization, infection, commensalism and other relationships play out at levels ranging from molecular interactions to systemic ones. Before submitting an application for this internal competition, visit the foundation website to verify that both the applicant and their project meet ALL eligibility criteria. For consideration as an institutional nominee, submit the following electronically in a single PDF document - in the order listed - by September 10, 2010 to limitedsubmissions@umich.edu:

- Cover sheet (downloaded from this webpage)
- Nominating letter from the department chair
- 3-page research plan
- NIH formatted biosketch

Contact Kathryn Ridner at (734) 763 – 4086, or kridner@umich.edu with any questions.

Please see additional Biomedical News presented by the Office of Research at http://www.med.umich.edu/medschool/research/biomednews/ #
**Funding Opportunities**

For a list of due dates for these NIH applications, please visit:
http://grants1.nih.gov/grants/funding/submissionschedule.htm

**NIH Blueprint for Neuroscience Research Competitive Revisions for Studies Focused on Neuropathic Pain or Neural Plasticity to Promote Collaborative Pain Research (R01)**

This Funding Opportunity Announcement (FOA) is issued as an initiative of the NIH Blueprint for Neuroscience Research. The Neuroscience Blueprint is a collaborative framework through which 16 NIH Institutes, Centers and Offices jointly support neuroscience-related research, with the aim of accelerating discoveries and reducing the burden of nervous system disorders (for further information, see http://neuroscienceblueprint.nih.gov/). The goal of this FOA is to facilitate the partnering of pain scientists and non-pain neuroscientists from the field of neural plasticity to capture insights and expertise from disciplines where transitions from health to disease have been extensively examined. An expected outcome of this FOA will be the formation of partnerships between pain researchers and non-pain neuroscientists to develop new collaborations focused on understanding the maladaptive neuroplastic changes that occur during the transition from acute to chronic pain. It is anticipated that these initial collaborations will lead to new applications for highly innovative projects centered on similar studies of the transition from acute to chronic pain. The purpose of this FOA is to encourage the submission of competitive revision applications that propose a collaborative, one-year pilot study or a new specific aim associated with an active NIH grant. The parent grant may be focused on pain or on neural plasticity outside the area of pain. http://grants.nih.gov/grants/guide/pa-files/PAR-10-204.html

**NIH Blueprint for Neuroscience Research Grand Challenge on the Transition from Acute to Chronic Neuropathic Pain (R01)**

This Funding Opportunity Announcement (FOA) is issued as an initiative of the NIH Blueprint for Neuroscience Research. The Neuroscience Blueprint is a collaborative framework through which 16 NIH Institutes, Centers and Offices jointly support neuroscience-related research, with the aim of accelerating discoveries and reducing the burden of nervous system disorders (for further information, see http://neuroscienceblueprint.nih.gov/). The goal of this FOA is to facilitate research collaborations between pain scientists and non-pain neuroscientists with expertise in neuroplasticity in order to study biological mechanisms underlying the transition from acute to chronic pain. These collaborations will capture insights and expertise from disciplines where transitions from health to disease have been extensively examined. The purpose of this FOA is to encourage submission of multi-PI grant applications that propose highly collaborative, multidisciplinary research projects addressing neuropathic pain conditions. An expected outcome of this FOA will be the formation of partnerships between pain researchers and non-pain neuroscientists to develop new collaborations focused on understanding the maladaptive neuroplastic changes that occur during the transition from acute to chronic neuropathic pain. http://grants.nih.gov/grants/guide/rfa-files/RFA-DE-11-002.html

**Novel Approaches to Study Polymicrobial Diseases (R01)**

This FOA issued by the National Institute of Dental and Craniofacial Research (NIDCR), the National Heart, Lung, and Blood Institute (NHLBI), and the National Institute on Deafness and Other Communication Disorders (NIDCD), National Institutes of Health (NIH), solicits research grant applications to conduct studies designed to develop innovative approaches that would contribute to our understanding of the mechanisms that impact on the virulence of infections involving two or more microorganisms or strains of microorganisms (with the exception of HIV). http://grants.nih.gov/grants/guide/rfa-files/RFA-DE-11-002.html

**Metagenomic Analyses of the Oral Microbiome (R01)**

This Funding Opportunity Announcement (FOA) issued by the National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health (NIH), solicits proposals to develop new insight into the role of microbes in human oral health and disease through research on the total oral microbial community (microbiota) using metagenomic approaches built upon recent developments in DNA sequencing, gene assembly, and bioinformatics. The ultimate goal is to completely characterize all microbes and their genes (microbiome) in the oral environment. To this end, we are soliciting projects that will analyze the genomes of both cultivatable and uncultivable bacteria, archaea, viruses, fungi, and parasites. Applicants will be expected to work with state-of-the-science genomic sequencing centers and bioinformatics groups to sequence and annotate all microbes in the oral cavity under conditions of health and disease. http://grants.nih.gov/grants/guide/pa-files/PA-08-091.html http://grants.nih.gov/grants/guide/pa-files/PA-07-185.html
Funding Opportunities, Continued

Nanoscience and Nanotechnology in Biology and Medicine (R01)
This funding opportunity (FOA) is aimed at enhancing nanoscience and nanotechnology research focused on problems in biology and medicine. Nanoscience and nanotechnology refer to research and development on the understanding and control of matter at a length scale of approximately 1 - 100 nanometers, where novel properties and functions occur because of the size. A major challenge facing medicine is to develop novel and more sophisticated approaches for the diagnosis, treatment and management of an array of diseases and traumatic injuries. Nanotechnology and nanoscience have the capacity to drive a new wave of medical innovation through the engineering of bioactive nanoscale structures, processes and systems based on the advancement of our understanding of biology at the nanoscale. [Link]

Behavioral and Social Science Research on Understanding and Reducing Health Disparities (R01)
The purpose of this opportunity is to encourage behavioral and social science research on the causes and solutions to health and disabilities disparities in the U.S. population. Health disparities between, on the one hand, racial/ethnic populations, lower socioeconomic classes, and rural residents and, on the other hand, the overall U.S. population are major public health concerns. Emphasis is placed on research in and among three broad areas of action: 1) public policy, 2) health care, and 3) disease/disability prevention. Particular attention is given to reducing “health gaps” among groups. Proposals that utilize an interdisciplinary approach, investigate multiple levels of analysis, incorporate a life-course perspective, and/or employ innovative methods such as system science or community-based participatory research are particularly encouraged. [Link]

Understanding and Promoting Health Literacy (R01)
The ultimate goal of this program announcement is to encourage empirical research on health literacy concepts, theory and interventions as these relate to the U.S. Department of Health and Human Services’ public health priorities that are outlined in its Healthy People initiative. Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. [Link]

Collaborative Research on the Transition From Acute to Chronic Pain: New Models and Measures in Clinical and Preclinical Pain Research (R01)
The overall goal of this FOA is to stimulate preclinical and clinical research that will accelerate our understanding of the biological and behavioral determinants driving the transition from acute pain to chronic pain disorders. An understanding of the mechanisms and risk factors that determine who will transition to a chronic pain state is necessary in order to intervene in this transition and to design new, effective treatments to resolve acute pain before it becomes chronic. The objectives of this FOA are to: 1) assemble research teams with expertise in basic and clinical pain research and related expertise outside the pain field that will provide novel, collaborative, multidisciplinary approaches to answer crucial questions about the transition from acute to chronic pain; 2) discover biological and behavioral mechanisms that drive the transition from an acute pain state to a chronic dysfunctional pain condition; 3) develop new clinical and preclinical models and measures of pain that will be essential to identify and characterize these mechanisms. Studies that involve considerable risk but with the potential for breakthroughs in the field are strongly encouraged. [Link]

Research Project Grant (Parent R01)
The Research Project Grant (R01) is an award made to an institution/organization to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in areas representing the specific interests and competencies of the investigator(s). The R01 research plan proposed by the applicant institution/organization must be related to the stated program interests of one or more of the NIH Institutes and Centers (ICs) based on descriptions of their programs. All research project grant applications described in this announcement will be assigned to NIH ICs according to standard Public Health Service (PHS) referral guidelines and specific program interests. Investigators are encouraged to consult the participating NIH ICs and their Web sites (see [Link]).

Bioengineering Research Grants (BRG) (R01)
Participating Institutes and Centers of the NIH invite applications for R01 awards to support Bioengineering Research Grants (BRGs) for basic and applied multi-disciplinary research that addresses important biological, bioengineering or medical research problems. The BRGs support multi-disciplinary research performed in a single laboratory or by a small number of investigators that applies an integrative, systems approach to develop knowledge and/or methods to prevent, detect, diagnose, or treat disease or to understand health and behavior. A BRG application may propose hypothesis-driven, discovery-driven, developmental, or design-directed research. [Link]
Funding Opportunities, Continued

Mechanisms, Models, Measurement, and Management in Pain Research (R01)
The purpose of this Funding Opportunity Announcement (FOA), Mechanisms, Models, Measurement, & Management in Pain Research issued by the National Institute of Nursing Research (NIINR), in conjunction with members of the NIH Pain Consortium as listed above, is to inform the scientific community of the pain research interests of the various Institutes and Centers (ICs) at the National Institutes of Health (NIH) and to stimulate and foster a wide range of basic, clinical, and translational studies on pain as they relate to the missions of these ICs. New advances are needed in every area of pain research, from the micro perspective of molecular sciences to the macro perspective of behavioral and social sciences. Although great strides have been made in some areas, such as the identification of neural pathways of pain, the experience of pain and the challenge of treatment have remained uniquely individual and unsolved. Furthermore, our understanding of how and why individuals transition to a chronic pain state after an acute insult is limited. Research to address these issues conducted by interdisciplinary and multidisciplinary research teams is strongly encouraged, as is research from underrepresented, minority, disabled, or women investigators.


Innovations in Biomedical Computational Science and Technology (R01)
The NIH is interested in promoting research and developments in biomedical informatics and computational biology that will support rapid progress in areas of scientific opportunity in biomedical research. As defined here, biomedical informatics and computational biology includes database design, graphical interfaces, querying approaches, data retrieval, data visualization and manipulation, data integration through the development of integrated analytical tools, and tools for electronic collaboration, as well as computational and mathematical research including the development of structural, functional, integrative, and analytical computational models and simulations.


Chronic Fatigue Syndrome: Pathophysiology and Treatment (R01)
This Funding Opportunity Announcement (FOA) issued by the Office of Research on Women’s Health (ORWH) and co-sponsoring Institutes and Centers (ICs) of the National Institutes of Health (NIH) encourages investigator(s)-initiated applications that propose to examine the etiology, diagnosis, pathophysiology, and treatment of chronic fatigue syndrome (CFS), also known as myalgic encephalomyelitis (ME/CFS) in diverse groups and across the lifespan. Innovative applications that address gaps in the understanding of the environmental and biological risk factors, the determinants of heterogeneity among patient populations, and the common mechanisms influencing the multiple body systems that are affected in CFS are encouraged. The NIH is particularly interested in funding interdisciplinary research that will enhance our knowledge of the disease process and provide evidence based solutions to improve the diagnosis, treatment, and quality of life of all persons with CFS.


Biomarkers of Infection-Associated Cancers (R01)
This funding opportunity announcement (FOA), issued by the National Cancer Institute (NCI) and the National Institute of Dental and Craniofacial Research (NIDCR), of the National Institutes of Health (NIH), encourages the submission of Research Project Grant (R01) applications from institutions and organizations that propose to identify biomarkers for cancers where the etiology of the disease is attributed to infectious agents.

http://grants.nih.gov/grants/guide/pa-files/PA-08-156.html

Roadmap Transformative Research Projects Program (R01)
As part of the NIH Roadmap for Biomedical Research, the National Institutes of Health invites transformative Research Project Grant (R01) applications from institutions/organizations proposing groundbreaking, exceptionally innovative, high risk, original and/or unconventional research with the potential to create new scientific paradigms or challenge existing ones. Projects must clearly demonstrate potential to produce a major impact in a broad area of biomedical or behavioral research. The NIH common fund intends to commit $25 million dollars in FY 2010. The number of awards will depend on the size and scope of the most meritorious applications.


Community Participation in Research (R01)
This Funding Opportunity Announcement (FOA) issued by the Office of Behavioral and Social Sciences Research (OBSSR), National Institutes of Health (NIH) solicits R01 grant applications that propose intervention research on health promotion, disease prevention, and health disparities that communities and researchers jointly conduct.

Funding Opportunities, Continued

Human Pluripotent Stem Cell (hPSC) Research Using Non-Embryonic Sources (R01)
This Agency-wide Funding Opportunity Announcement (FOA) is a Program Announcement (PA) to encourage new research applications proposing research on hPSCs from non-embryonic sources. This FOA addresses Executive Order 13435 issued by President George W. Bush on June 20, 2007. The Executive Order requires that The Secretary of Health and Human Services shall conduct and support research on the isolation, derivation, production, and testing of stem cells that are capable of producing all or almost all of the cell types of the developing body and may result in improved understanding of or treatments for diseases and other adverse health conditions, but are derived without creating a human embryo for research purposes or destroying, discarding, or subjecting to harm a human embryo.
http://grants.nih.gov/grants/guide/pa-files/PA-08-043.html

NIDCR Small Research Grants for Data Analysis and Statistical Methodology (R03)
The goal of this funding opportunity announcement (FOA) is to support meritorious research projects that involve secondary data analyses or statistical methodology using existing dental or craniofacial database resources. The R03 grant mechanism supports different types of projects including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology. The R03 is intended to support small research projects that can be carried out in a short period of time with limited resources.

Genetic Susceptibility & Variability of Human Structural Birth Defects (R01)
This Funding Opportunity Announcement (FOA) issued by the National Institute of Child Health and Human Development (NICHD), National Institute on Dental and Craniofacial Research (NIDCR), and the National Institute of Environmental Health Sciences (NIEMS), National Institutes of Health (NIH), encourages innovative investigator-initiated applications designed to study fundamental developmental processes using animal models in conjunction with translational/clinical approaches with the goal of advancing our understanding of the etiology of structural birth defects. In 2000, the Developmental Biology, Genetics and Teratology Branch at NICHD began its Birth Defects Initiative with the funding of a number of research grants and program projects focused on the use of molecular genetic approaches for the study of genetic susceptibility, epidemiology, and developmental biology of human congenital structural malformations. These grants established the basis for a working group of investigators, who meet annually to present research updates, share ideas and technical advances, establish new collaborations, and provide input and advice to NICHD staff.

NIDCR Small Research Grants for Data Analysis and Statistical Methodology applied to Genome-wide Data (R03)
This funding opportunity announcement (FOA) will support meritorious research projects that involve secondary data analyses or development of statistical methodology using existing genome-wide data, relevant to human dental or craniofacial conditions or traits.

NIDCR Small Grant Program for New Investigators (R03)
This funding opportunity announcement (FOA) issued by the NIDCR solicits Small Research Grant (R03) applications from scientists who are in the early stages of establishing an independent research career in dental and craniofacial research. This mechanism will support pilot and developmental research with the intention of facilitating subsequent submission of an Individual Research Project Grant (R01) application. Preliminary data are not required.

Mechanisms, Models, Measurement, and Management in Pain Research (R03)
The purpose of this Funding Opportunity Announcement (FOA), Mechanisms, Models, Measurement, & Management in Pain Research, issued by the National Institute of Nursing Research (NINR), in conjunction with members of the NIH Pain Consortium as listed above, is to inform the scientific community of the pain research interests of the various Institutes and Centers (ICs) at the National Institutes of Health (NIH) and to stimulate and foster a wide range of basic, clinical, and translational studies on pain as they relate to the missions of these ICs. New advances are needed in pain research, from the micro perspective of molecular sciences to the macro perspective of behavioral and social sciences. Research to address these issues conducted by interdisciplinary and multidisciplinary research teams is strongly encouraged, as is research from underrepresented, minority, disabled, or women investigators. The R03 grant mechanism supports different types of projects including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology. The R03 is intended to support small research projects that can be carried out in a short period of time with limited resources.
Funding Opportunities, Continued

Novel Approaches To Study Polymicrobial Diseases (R21)
The NIH Institutes listed above invite research grant applications to conduct studies designed to develop innovative approaches that would contribute to our understanding of the mechanisms that impact on the virulence of infections involving two or more microorganisms or strains of microorganisms (with the exception of HIV). http://grants.nih.gov/grants/guide/pa-files/PA-08-092.html

Chronic Fatigue Syndrome: Pathophysiology and Treatment (R21)
This Funding Opportunity Announcement (FOA) issued by the Office of Research on Women's Health (ORWH) and co-sponsoring Institutes and Centers (ICs) of the National Institutes of Health (NIH) encourages investigator(s)-initiated applications that propose to examine the etiology, diagnosis, pathophysiology, and treatment of chronic fatigue syndrome (CFS), also known as myalgic encephalomyelitis (ME/CFS) in diverse groups and across the lifespan. Innovative applications that address gaps in the understanding of the environmental and biological risk factors, the determinants of heterogeneity among patient populations, and the common mechanisms influencing the multiple body systems that are affected in CFS are encouraged. The NIH is particularly interested in funding interdisciplinary research that will enhance our knowledge of the disease process and provide evidence based solutions to improve the diagnosis, treatment, and quality of life of all persons with CFS. http://grants.nih.gov/grants/guide/pa-files/PA-08-247.html

Human Pluripotent Stem Cell (hPSC) Research Using Non-Embryonic Sources (R21)
This Agency-wide Funding Opportunity Announcement (FOA) is a Program Announcement (PA) to encourage new research applications proposing research on hPSCs from non-embryonic sources. This FOA addresses Executive Order 13435 issued by President George W. Bush on June 20, 2007. The Executive Order requires that The Secretary of Health and Human Services shall conduct and support research on the isolation, derivation, production, and testing of stem cells that are capable of producing all or almost all of the cell types of the developing body and may result in improved understanding of or treatments for diseases and other adverse health conditions, but are derived without creating a human embryo for research purposes or destroying, discarding, or subjecting to harm a human embryo. http://grants.nih.gov/grants/guide/pa-files/PA-08-044.html

Research on Malignancies in the Context of HIV/AIDS (R21)
The purpose of this funding opportunity announcement (FOA) is to advance our understanding of the risks, development, progression, diagnosis, and treatment of malignancies observed in individuals with an underlying Human Immunodeficiency (HIV) infection or Acquired Immune Deficiency Syndrome (AIDS). Through this FOA, the NCI and NIDCR seek to encourage research in areas such as the study of the etiologic factors, cofactors, pathogenesis, and consequences of HIV-associated malignancies in [the members of] diverse populations. The incidence of non-AIDS-defining malignancies (e.g., anal, skin, and lung cancers as well as Hodgkin's disease) appear to be increasing in the era of Highly Active Antiretroviral Treatment (HAART). This FOA extends to research efforts that will (i) provide information on the clinical outcomes of such cancers in the HIV-infected population and (ii) identify specific contributions resulting from HIV infection for the development and pathogenesis of these cancers. Ultimately, such efforts could inform screening approaches and therapies targeted to the HIV-infected population. http://grants.nih.gov/grants/guide/pa-files/PA-07-454.html

Biomarkers of Infection-Associated Cancers (R21)
This funding opportunity announcement (FOA), issued by the National Cancer Institute (NCI) and the National Institute of Dental and Craniofacial Research (NIDCR), of the National Institutes of Health (NIH), encourages the submission of Research Project Grant (R01) applications from institutions and organizations that propose to identify biomarkers for cancers where the etiology of the disease is attributed to infectious agents. http://grants.nih.gov/grants/guide/pa-files/PA-08-157.html

Using Systems Science Methodologies to Protect and Improve Population Health (R21)
This funding opportunity announcement (FOA) is being issued by the Office of Behavioral and Social Sciences Research (OBSSR) of the National Institutes of Health (NIH) with participation from the following NIH components: FIC, NCI, NIA, NICHD, NCCAM, NHLBI, NIAMS, NIMH, NIDDK, NIDCR, NIDA, ODP, and ODS. This FOA solicits Exploratory/Developmental (R21) applications from institutions/organizations that propose to apply one or more specific system science methodologies to public health and health care systems problems and contribute knowledge that will enhance effective decision making around the development of and prioritization of policies, interventions, and programs to improve population health, especially where resources are limited. Applicants are encouraged to submit projects that tackle policy resistant health problems (i.e., ones in which the effects of planned interventions, programs or policies tend to be delayed, diluted or defeated by responses of the system to the intervention itself) using a systems science methodology. http://grants.nih.gov/grants/guide/pa-files/PAR-08-224.html
Funding Opportunities, Continued

NIDCR Dentist Scientist Pathway to Independence Award (K99/R00)
The overall goal of NIH-supported career development programs is to help ensure that a diverse pool of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation's biomedical, behavioral, and clinical research needs. The primary purpose of the Pathway to Independence Award (K99/R00) program is to increase and maintain a strong cohort of new and talented NIH-supported independent investigators. The program is designed to facilitate a timely transition from a mentored postdoctoral research position to a stable independent research position with independent NIH or other independent research support at an earlier stage than is currently the norm. http://grants.nih.gov/grants/guide/pa-files/PAR-09-256.html

Interdisciplinary Research on Oral Manifestations of HIV/AIDS in Vulnerable Populations (P01)
The primary goal of this funding opportunity announcement (FOA) is to drive interdisciplinary research to study the oral manifestations and complications associated with HIV/AIDS-related immunosuppression in vulnerable populations, including children and adolescents. The applicants are expected to develop highly integrated projects that comprehensively address the existing gaps in knowledge of the epidemiology, prevention and pathogenesis of the oral complications of HIV disease and that promote interventions that could reduce the burden of disease among disproportionately affected racial and ethnic minority communities. Regardless of the theme, projects in each multidisciplinary program will be expected to be synergistic and to utilize cutting-edge approaches such as genomics, proteomics, molecular imaging and other emerging technologies to achieve their goals. In addition, it is expected that these projects will provide interdisciplinary career development opportunities for investigators new to the field of oral AIDS. Applicants are encouraged to include pediatric/adolescent populations in their research. http://grants.nih.gov/grants/guide/pa-files/PAR-08-117.html

NIDCR Clinical Trial Planning Grant (R34)
This FOA, issued by the National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health, will support clinical trial planning (R34) grants for the comprehensive planning, design and documentation of investigator-initiated Phase I, II, III, or IV interventional clinical trials. Intervventional behavioral studies, sometimes referred to as Stage I, II, III or IV studies, are included. The R34 planning grant is designed to: (1) permit early peer review of the rationale for the proposed clinical trial; (2) permit early assessment of the design and implementation plans of the proposed trial; and (3) provide support for the development of a comprehensive clinical trial protocol and associated documents including a Manual of Procedures. The complete protocol and associated documents are required components of any subsequent clinical trial implementation (U01) application. The product of the R34 will be either an application for a clinical trial implementation cooperative agreement (U01) or a report summarizing the work completed and the reasons for not proceeding to a clinical trial implementation application. Pre-approval from the NIDCR is required for the submission of the R34 application. http://grants.nih.gov/grants/guide/pa-files/PAR-08-195.html

NIH Clinical Trial Planning Grant Program (R34)
This Funding Opportunity Announcement (FOA) invites applications under the NIH Clinical Trial Planning Grant Program, the purpose of which is to provide support for the development of a Phase III clinical trial. This includes the establishment of the research team, the development of tools for data management and oversight of the research, the definition of recruitment strategies, and the finalization of the protocol and other essential elements of the study included in a manual of operations/procedures. The Clinical Trial Planning Grant is not designed for the collection of preliminary data or the conduct of pilot studies to support the rationale for a clinical trial. http://grants.nih.gov/grants/guide/pa-files/PAR-08-195.html

Manufacturing Processes of Medical, Dental, and Biological Technologies (STTR [R41/R42])
On February 26, 2004, Executive Order 13329 [http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/pdf/04-4436.pdf] was signed by President George W. Bush requiring SBIR/STTR agencies, to the extent permitted by law and in a manner consistent with the mission of the Department, to give high priority within the SBIR and STTR programs to manufacturing-related research and development (R&D). In response to this Executive Order, NIH is expanding its focus by encouraging eligible United States small business concerns to submit STTR Phase I, Phase II, and Fast-Track grant applications whose biomedical research is related to advanced processing, manufacturing processes, equipment and systems, and manufacturing workforce skills and protection. http://grants.nih.gov/grants/guide/pa-files/PAR-09-114.html
**NIH Loan Repayment Program: Deadline December 1, 2010**

**Participants Receive Up to $35,000 Annually**
The National Institutes of Health (NIH) repays outstanding student loans through its extramural Loan Repayment Programs (LRPs). The LRPs target researchers who are or will be conducting nonprofit biomedical or behavioral research, and the application cycle opens September 1. The five extramural LRPs are Clinical Research, Pediatric Research, Health Disparities Research, Contraception and Infertility Research, and Clinical Research for Individuals from Disadvantaged Backgrounds. Applications will be accepted online from September 1, 2010, until 8:00 p.m. Eastern time on December 1, 2010, at [http://www.lrp.nih.gov](http://www.lrp.nih.gov).

**Benefits:** New LRP contracts are awarded for a two-year period and repay up to $35,000 of qualified educational debt annually. Tax offsets also are provided as an additional benefit. Participants may apply for competitive renewals, which are issued for one or two years. Undergraduate, graduate, medical school, and other health professional school loans qualify for repayment. An NIH grant or other NIH funding is not required to apply for or participate in the LRPs.

**Eligibility:** Applicants must possess a doctoral-level degree (with the exception of the Contraception and Infertility Research LRP); be a U.S. citizen, national, or permanent resident; devote 20 hours or more per week to conducting qualified research funded by a university, nonprofit organization, or federal, state, or local government entity; and have qualified educational loan debt equal to or exceeding 20 percent of their institutional base salary.

**Awards:** Each year, some 1,600 research scientists benefit from the more than $70 million NIH invests in their careers through the extramural LRPs. Twenty-six percent of awards are made to individuals within one to five years of receiving their doctoral degree. More than 75 percent of awards go to individuals within 10 years of receiving their doctoral degree. Approximately 40 percent of new applications and 70 percent of renewal applications are funded.

**Questions?** Visit the LRP website at [http://www.lrp.nih.gov](http://www.lrp.nih.gov), and see specific information about this LRP at [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-107.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-107.html) for more information, and to access the online application. For additional assistance, call or e-mail the LRP Information Center at (866) 849-4047 or lrp@nih.gov.

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**Office of Research Launches NIH Proposal Repository**

The Medical School Office of Research has launched a new online resource, the NIH Fellowship Proposal Sampler. This is a collection of sample proposal and proposal sections that have been donated by UM graduate students, postdoctoral fellows and faculty members, with the purpose to offer insight into proposal development, including: proposal writing (e.g., organization, detail); responding to reviewers’ comments; ways to respond to required sections; etc.

The gallery is password-protected and can be accessed by all UM graduate students and postdoctoral fellows as well as Medical School faculty and staff. Users are required to login using their uniqname and Level 1 (Kerberos) password.

Currently, the site contains examples of F31 and K99/R00 proposals. They are currently soliciting more examples of successfully resubmitted proposal samples, i.e., the original proposal, the reviewers’ comments (NIH summary sheets), and the successfully revised resubmissions. We are especially interested in F32 proposals as well as F31, F32 or K99/R00 proposals that follow the new NIH guidelines (shorter page limits and scored with the 1 - 9 scale). Please consider donating your successful fellowship proposal with the reviewers’ comments.

Contact Chris Black at ckblack@umich.edu, or (734) 615 - 1630 with samples that you are willing to share, or suggestions, or comments about the sample proposal site.
**Current MCOHR Studies**

Oral health and oral health-related quality of life in early stage breast cancer survivors: The role of aromatase inhibitors  
PI Susan Taichman

Aromatase inhibitors (AIs) are routinely prescribed as adjuvant hormonal therapy for postmenopausal women with hormone receptor positive breast cancer (BCa), and is associated with increased risk of osteoporosis and fracture as a result of lower bone mineral density (BMD). Oral BMD is one aspect of systemic BMD and correlates positively with the risk for osteoporosis and hip fracture in older women. Periodontal diseases and tooth loss are associated with estrogen withdrawal and osteoporosis. The Specific Aims are (1) To determine the prevalence, incidence and severity of oral conditions in postmenopausal early stage BCa survivors within the first 18 months of adjuvant AI therapy, (2) To determine the OHRQoL among postmenopausal early stage BCa survivors who are receiving AI therapy, (3) To determine the utilization of dental care among postmenopausal women receiving AIs with a history of early stage BCa over time.

**Cell Therapy Using Autologous Bone Marrow Cells Expanded Ex Vivo and Delivered Using Tricalcium Phosphate**  
PI William Giannobile

The purpose of this study is to determine if Bone Repair Cell (BRC) Therapy autologous bone marrow tissue grafts are safe when used as a bone graft in a routine sinus grafting procedure, and to determine if BRC can induce bone regeneration in the maxillary sinus. 30 subjects who are edentulous in the upper posterior jaw and who have atrophic bone in this region (below the maxillary sinus), will be selected to participate in this Phase I/II pilot data feasibility trial. Half (15) of the sites will receive the BRC therapy (BRC + β-TCP carrier) and the other half will receive the control treatment (β-TCP carrier), with each subject only receiving one of the two possible treatments. The primary outcome variables are bone density (mg/cc) and bone volume (BV/TV) and these will be measured by histological and μCT analyses at 4 months post-treatment. Secondary outcome variables include soft tissue wound healing and the bone density on re-entry.

**The Importance of Periostin in Periodontal Health and Disease**  
PI Hector Rios

The goal of this study is to determine the clinical importance of Periostin in oral health and disease. It is hypothesized that Periostin levels are decreased during periodontal diseases, thereby, elevating the hosts’ susceptibility to periodontal breakdown. The long-term goal will be to develop practical applications for the diagnosis, treatment, prevention and cure of human periodontal diseases. The specific aims are the following: To determine if Periostin is a biomarker of periodontal disease, and To evaluate Periostin in periodontal tissue healing and homeostasis by harvesting healthy or diseased tissue from 22 patients requiring periodontal surgery.

**Structural and Molecular Neuroplasticity in Migraine**  
PI Alexandre DaSilva

The main purpose of this study is to integrate novel MRI techniques with positron emission tomography (PET) for the study of structural and molecular neuroplasticity in the brains of migraineurs, and its clinical association with changes in pain perception and modulation (e.g. allodynia). It is hypothesized that migraine is sustained by mal-adaptive changes that occur at both the molecular and cellular levels in brain circuitry. Specifically, at the molecular level, the brains of migraine patients have alterations in certain subtypes of opiate and dopamine receptors; and at the cellular level, patients have cortical thickness and white matter alterations. Such information would help us to shed some light on the pathophysiologic mechanisms associated with migraine, which may result in the development of novel and more evidence-based therapeutic approaches.
Current MC OHR Studies, continued

Treatment of Alveolar Bone Defects Using Autologous Tissue Repair Cell Therapy
PI Darnell Kaigler

The purpose of this study is to determine if a patient’s own bone marrow can be used to regenerate bone at the site of extraction. Totaling 24 subjects, 12 have received the Tissue Repair Cell (TRC) therapy and 12 have received a control treatment. Subjects randomly assigned to the TRC therapy group underwent cells harvesting from the posterior iliac crest. These cells were cultured, processed, and after 12 days were harvested for placement in the extraction socket with a Gelfoam carrier. The primary objective of this study is to determine whether the placement of TRCs at the time of tooth extraction can safely and effectively promote bone regeneration in alveolar bone defects created by tooth extraction. The secondary objective is to determine if TRC therapy regenerates bone enabling the installation and stability of dental implant fixtures.

Circulatory Microbial Components and Immune Regulators of Patients with Periodontal Disease (CirCo Study)
PI William Giannobile

The aim of this project is to investigate the immune regulatory activity of microorganism components present in the blood of patients with severe periodontal disease. This analysis will aid in clarifying the mechanism by which periodontal disease might affect systemic diseases, such as rheumatoid arthritis. This project will have two specific goals: 1. Identify microorganism components in the plasma of patients with severe periodontitis; and 2. Characterize the immune regulator activity of periodontitis serum. This proposed 40-patient feasibility study will then aid in providing the impetus for sample size and other design requirements for larger, more expanded human clinical trial testing.

Clinical and Histological Evaluation of Healos for Alveolar Ridge Augmentation
PI William Giannobile

Ten subjects in need of ridge augmentation procedures prior to dental implant placement will be recruited to clinically, histologically, and radiographically evaluate alveolar ridge augmentation using Healos® during ridge splitting procedures in patients exhibiting deficient alveolar ridges as candidates for dental implant reconstruction. The ultimate goal of this study is to evaluate how this graft material can help bone healing, specifically the primary outcome measure for this study will be increase in ridge width from baseline measured at re-entry. Secondary outcome measures will include bone width changes as measured by CBCT and bone density by histology.

Risk Factors for Implant Bone Loss in Patients with Diabetes Mellitus: A Feasibility Cohort Study
PI T-J Oh

The purpose of this pilot study is to determine if patients with significant metabolic disease represent a cohort at increased risk for implant bone loss and failure. Patients with Diabetes are evaluated to determine risk factors for alveolar bone loss at dental implants and teeth, and evaluated for bone-resorptive biomarkers present in saliva and blood serum. A total of thirty-two patients with and without diabetes have been enrolled in the study, and it is expected to conclude in May, 2011.
**Recently completed MCOHR Studies**

**Development of Oral Inflammatory Disease Model Relating Protein, Genetic, and Microbial Biomarkers**

PI Janet Kinney

The purpose of this pilot study was to use an experimental gingivitis model to analyze pro-inflammatory biomarkers in whole saliva and the presence of specific bacteria, while evaluating their relationships with the IL-1 polymorphism. 30 subjects with healthy gingival indices were enrolled; 15 subjects that were genotype positive, and 15 subjects that were genotype negative following Periodontal Susceptibility Test, or PST analysis. Saliva and plaque samples were collected from 4 teeth at Days 0, 3, 7, 10, 14, 21, and 35. These samples will be analyzed and compared with clinical measurements for statistically significant associations.

**Apoptotic Biomarkers for Periodontal Disease**

PI Yvonne Kapila

The purpose of this study was to determine whether specific apoptosis-associated proteins, specifically fibronectin fragments, caspase-3, soluble Fas, and soluble Fas ligand, sampled from gingival crevicular fluid (GCF) could be used to predict periodontal disease progression. 50 subjects with moderate to severe periodontal disease activity, and 10 with little to no periodontal disease activity were enrolled. GCF, saliva, and blood samples were collected at screening, and months 3 and 6. These samples will be analyzed and compared with clinical measurements for statistically significant associations.

**Impact of Parathyroid Hormone (I-34 PTH) on Osseous Regeneration in the Oral Cavity**

PI Laurie McCauley

The purpose of this study was to determine if the drug I-34 PTH, approved by the FDA to increase bone build-up in osteoporosis patients, is effective on bone build-up in patients with periodontitis. 40 patients, 20 who received Forteo and 20 who received a placebo, were recruited. Subjects were seen for screening, and baseline/surgery, at 1, 3, and 6 weeks and 3, 6, 9, and 12 months post surgery. Subjects administered self-injections (either placebo or I-34 PTH) once a day for six weeks. Dr. Jill Bashutski won the Orban award from the Balint Orban Memorial Program (Orban Competition) at the 2009 Annual Meeting of the American Academy of Periodontology in Boston, MA, September 2009 for her abstract submission of this research.

**Expression of Angiogenic Biomarkers During Healing of Intra-Oral Soft Tissue Engineered Grafts**

PI Rodrigo Neiva

The purpose of this pilot study was to compare the expression of angiogenic biomarkers involved in the wound healing process of two different periodontal surgical approaches: 1) Living bilayered cell therapy product, and 2) Free gingival grafts. Wound fluid was collected from the donor palate site, and the treated sites before and after the placement of the cell therapy product or conventional treatment to measure which proteins and how much of each are present during the first 4 weeks of wound healing. This study was carried out in conjunction with the Clinical Trial Evaluating CelTix™ as an Alternative to Tissue from the Palate to Enhance Oral Soft Tissue Regeneration and Wound Healing study.
**Resources**

**MICHIGAN INSTITUTE FOR CLINICAL AND HEALTH RESEARCH (MICHR)**

MICHR has a vast number and variety of services to assist researchers in developing, receiving IRB approval, conducting, and concluding clinical trials. For more information, please visit [http://www.michr.umich.edu](http://www.michr.umich.edu).

**MCOHR WEBSITE**

Please visit the MCOHR website at [http://www.dent.umich.edu/mcohr](http://www.dent.umich.edu/mcohr). The goals of the website are to provide faculty and staff with information and resources regarding the conduct of clinical research, as well as providing education of the mission of MCOHR, and our clinical research for current and potential patients. Please contact us if you would like to place an announcement, or to advertise your clinical study.