Dr. Jill Bashutski received a research grant from the Osteology Foundation to support a clinical trial at the Michigan Center for Oral Health Research evaluating the effect of a systemic anabolic agent, teriparatide, on implant therapy. A single center, placebo-controlled, double-blind parallel study of 30 patients undergoing dental implant placement procedures is planned. Thirty subjects will be administered teriparatide (parathyroid hormone 1-34) or placebo in conjunction with a novel quadruple tetracycline labeling protocol and a core bone biopsy taken from an edentulous ‘steady state’ (at least one year edentulous) site at the time of dental implant placement.

The overall hypothesis is that teriparatide will increase bone formation and osseous healing in the oral cavity of humans. The proposed study will not only support the clinical use of teriparatide in patients requiring oral bone regeneration, but provides an opportunity to evaluate parathyroid hormone actions in bone not feasible in other human studies. In addition, information obtained in this pilot study would provide further biologic rationale to launch a multi-center trial evaluating the ability of teriparatide to promote bone regeneration in either periodontitis or implant-based patient populations.

Dr. Susan Taichman received a K23 award from the National Institutes of Health for her research in the area of oral health as it pertains to adjuvant therapy and breast cancer survivorship. Aromatase inhibitors (AIs) are routinely prescribed as adjuvant hormonal therapy for postmenopausal women with hormone receptor positive breast cancer. Aromatase inhibition is associated with an increased risk of low bone mineral density and osteoporosis with increased fracture risk.

This award will support a cross-sectional study to assess the prevalence of oral symptoms among 150 post-menopausal women with a history of early stage breast cancer receiving adjuvant AI therapy and 150 postmenopausal women without cancer recruited from the University of Michigan Health System in Southeastern Michigan. This cross-sectional study will generate pilot data to define the scope and intensity of oral symptoms as well as characterize the oral health-related quality of life in women with breast cancer undergoing adjuvant AI therapy. This information will also serve as a basis for future R01 investigations in adjuvant therapy and oral health.

Dr. Hector Rios was recently awarded a NIH K23 Patient-Oriented Career development grant. This award provides Dr. Rios with the opportunity to validate the clinical periodontal relevance of Periostin, a molecule proposed to be an important regulator of the integrity of the periodontal tissues. Periostin is reported to be essential for collagen fibrillogenesis and involved in cell survival signaling through multiple matricellular interactions. In vivo, this molecule has been deemed essential for normal tissue repair and homeostasis.

These studies will provide novel insights into the regulation of PDL function during periodontal tissue health and disease. The data generated should have significant implications to aid in our understanding of periodontal biology relevant to cell-matrix dynamics and homeostasis. These studies may unravel novel pathways that determine periodontal disease susceptibility that could be targeted in the treatment of inflammatory periodontal diseases.
Upcoming IRBMED Workshops

Full descriptions of each workshop can be found on the IRBMED website at [http://med.umich.edu/irbmed/education.htm](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](https://www-a1.lsa.umich.edu/es_conf/app/ShowSessions.asp?confid=2&sDate=todayafter&shwd=0).

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<tr>
<td>IRB Regulations 103</td>
<td>Regulations and Special Considerations for Vulnerable Populations</td>
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<td>IRB Regulations 104/Applications 103</td>
<td>Guidance and eResearch: Adverse Event, Unanticipated Problem, and Other Reportable Information and Occurrences</td>
<td>04/20/2011</td>
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<td>IRB Regulations 105</td>
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<td>IRB Regulations 106</td>
<td>Compassionate Use, Emergency Use, Humanitarian Use Devices, Orphan Drugs, etc.</td>
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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](http://med.umich.edu/irbmed/Archive/EduArchive.htm).

New IRBMED Consent Template

Effective 2/1/11, changes were made to the Informed Consent Template. These changes include: Addition of language regarding Subject Injury and Instructions regarding International Research. The revised forms are located on the IRBMED web-site at [http://med.umich.edu/irbmed/ict.htm](http://med.umich.edu/irbmed/ict.htm). Current news and updates can be found on the IRBMED homepage: [http://med.umich.edu/irbmed/index.htm](http://med.umich.edu/irbmed/index.htm).

Upcoming HSIP Training Sessions

The Human Subject Incentive Program (HSIP) has developed a web based system for the expedited payment of human subject incentives. Please contact the HSIP staff at subject-incentives@umich.edu for additional information, or see the complete listing of training sessions at [https://finance.umich.edu/treasury/hsip](https://finance.umich.edu/treasury/hsip).

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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 MICHR Clinical Studies website, the University of Michigan Health System patient search engine database of UM research studies found at UMClinicalStudies.org. 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.

MCRU Streamlines Cost Structure for Industry-Sponsored Studies

Effective January 2011 the Michigan Clinical Research Unit (MCRU) now offers a bundled rate for new industry-sponsored studies! A flat, $105 per hour/per participant/per visit bundled rate is now in effect for all outpatient services, as well as an all-inclusive $711 per participant rate for overnight inpatient stays. In addition, the one-time administrative start-up fee per study has been reduced from $750 to $468. Previously, MCRU’s clinical research services, (including the MCRU 2 U mobile nursing service), were charged “ala carte” with separate hourly fees for space, nursing, nutrition, and lab services, which made it challenging for PIs and study coordinators to budget for their studies. The current exceptions to the new flat-rate are for the HAL technician time, which is now $40/hour and the specialized services of NDSR dietary analysis and DEXA bone density analysis, which are now $31/record and $80/scan respectively. All these will continue to be charged as a separate items. To learn more about MCRU’s team of clinical research professionals and their state-of-the-art facilities in the lower level of the Cardiovascular Center, visit www.michr.umich.edu to watch a four-minute YouTube video entitled, Meet the Crew of MCRU.

MICHR Seeks Applicants for $100K Postdoctoral Translational Scholars Program

Michigan Institute for Clinical & Health Research (MICHR) is seeking applicants for its Postdoctoral Translational Scholars Program (PTSP), which provides selected trainees with a $100,000 career development award to be used over 2-3 years. The PTSP is a multidisciplinary career development award designed to prepare individuals with a PhD in biomedical science or social science disciplines for independent careers in translational research. The application process is open to individuals who are interested in additional training in translational sciences. In the past, awardees have come from areas as diverse as engineering and economics in addition to the more traditional health disciplines. Applicants do not need to be affiliated with the University of Michigan; however, applicants from other institutions must establish a fellowship relationship with a U-M faculty member before applying for the PTSP. The application deadline is April 11, 2011. QUESTIONS? Visit the website at https://sites.google.com/site/michrptsp/home for more information and to access the online application. For more information about MICHR, please call 734.998-7474, e-mail um-michr@umich.edu, or visit the MICHR website.

University of Michigan Medical Innovation Center Online Education Video Series

The Medical Innovation Center (MIC) has launched a new online resource, in an effort to reach a wider audience with its educational program. The MIC now offers a series of videos, covering topics on innovation, reimbursement and regulatory approval. These educational units can be viewed “anywhere, anytime.” The format and topics are geared to the busy clinician or scientist. Please see the MIC education website for more details and a suggested reading list at: http://www.med.umich.edu/ummic/resources/education.shtml. Contact the Medical Innovation Center at UM-MIC@med.umich.edu, or (734) 998 - 6994 with further questions.

NIH Eliminating Application Error Correction Window for grant application submissions effective - January 25, 2011

For electronic submissions, correction of errors or addressing warnings after the due date is not considered a valid reason for a late submission. Applicants are encouraged to submit in advance of the due date to allow time to correct errors and/or address warnings identified in the NIH validation process. Inquiries may be addressed to: Division of Receipt and Referral Center for Scientific Review 6701 Rockledge Drive MSC 7720 Bethesda, MD 20892-7720 Voice: (301) 435-0715; Fax: (301) 480-1987

See information regarding the NIH Policy on Late Submission of Grant Applications at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html
University of Michigan Enterics Research Investigational Network Cooperative Research Center Pilot Projects Program Request for Proposals

Solicitation Release Date: February 21, 2011 - Electronic Submission Deadline: April 1, 2011
Approximate Award Date: July 1, 2011

The University of Michigan Cooperative Research Center (CRC) is part of the NIH/NIAID-Funded Enterics Research Investigational Network (ERIN), which is composed of investigators centered at four sites across the US. The focus of the work of the U of M ERIN CRC is the clinical epidemiology and pathogenesis of infection due to C. difficile.

Eligibility
Eligible Principal Investigators (PIs) for this RFP include full-time University of Michigan instructional, research or clinical track faculty and postdoctoral fellows. A minimum of 10% effort is required by the PI, although the equivalent amount of salary support does not necessarily need to be requested if there is cost sharing for the PI’s salary from institutional funds. Proposals may be in any area of basic, clinical, translational or epidemiological research related to enteric diseases and should represent a new research effort that will lead to external funding.

Mechanism of Support
This mechanism will provide support for research that focuses on hospital-acquired enteric disease including C. difficile in an amount up to $75,000 in direct costs for a one-year period.

Application process
Applications will be submitted on-line. Proposals will be for one year of support, with requested funding up to $75,000. Cost sharing is encouraged, and Project Leader must devote at least 10% effort and include a plan for the management of funds associated with the Research Pilot Project must be addressed. Grant proposals will need to include:

- Title of project, project period and amount requested.
- Abstract (250 words).
- Proposal Narrative (in pdf format): 5 pages max, single-spaced with spaces between paragraphs, 11 point Arial font, including text, figures, tables and references. The narrative will be organized as follows:
  - Specific Aims: no more than ½ page.
  - Rationale, motivation, and preliminary findings.
  - Research plan, explicitly tied to Specific Aims.
  - Relationship of the proposed work to current funding.
  - Relationship of the proposed work to the activities of the U of M ERIN CRC
  - Work plan with timeline to credible high-probability funding proposal to NIH or other specific funding agency (includes possibility of promotion to full ERIN project status).
  - References.

Submission of Application
Completed applications are to be submitted electronically in a single pdf document and emailed to Car Nosel at cnosel@med.umich.edu by 12:00 Noon EST on April 1, 2011. If you are unsure whether your proposed research would fit into the aims of this Request for Proposals, please contact Dr. Young at youngvi@umich.edu.

NIH 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. 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.

NIH Blueprint for Neuroscience Research Collaborative Tools to Accelerate Neuroscientific Discovery (U01)

This FOA is 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. 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.
Funding Opportunities, Continued

**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).

**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.

**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.

**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.

**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 http://www.nih.gov/icd).

**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.
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. 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/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.

Pathophysiology and Clinical Studies of Osteonecrosis of the Jaw (R01)
This FOA issued by the National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health, encourages Research Project Grant (R01) applications from institutions/organizations that propose to study the underlying pathophysiology of osteonecrosis of the jaw (ONJ), identify risk factors for this condition, establish the natural history of the disease, and generate evidence for its treatment.

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.
**Funding Opportunities, Continued**

**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.

**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 (NIEHS), 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. 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.

**Neurobiology of Migraine (R01)**
This Funding Opportunity Announcement (FOA) is a program announcement (PA) issued by the National Institute of Neurological Disorders and Stroke (NINDS), National Institute on Deafness and Other Communication Disorders (NIDCD), National Institute of Dental and Craniofacial Research (NIDCR), and National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH). It encourages R01 grant applications from institutions/organizations that intend to perform innovative research that will expand our current knowledge of neurobiological mechanisms underlying migraine headache, examine the role of neuromodulators, genetic and environmental influences in migraine susceptibility, and explore new targets for therapy development. This FOA will utilize the NIH Research Project Grant (R01) award mechanism and runs in parallel with a FOA of identical scientific scope, PA-10-259, that encourages applications under the NIH Exploratory/Developmental (R21) mechanism. Applicants may request support for up to 5 years. It is anticipated that the size and duration of each award will vary.

**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. 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.
Funding Opportunities, Continued

**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. [http://grants.nih.gov/grants/guide/pa-files/PAR-10-041.html](http://grants.nih.gov/grants/guide/pa-files/PAR-10-041.html)

**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. [http://grants.nih.gov/grants/guide/pa-files/PAR-07-418.html](http://grants.nih.gov/grants/guide/pa-files/PAR-07-418.html)

**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. [http://grants.nih.gov/grants/guide/pa-files/PA-10-008.html](http://grants.nih.gov/grants/guide/pa-files/PA-10-008.html)

**Neurobiology of Migraine (R21)**

This Funding Opportunity Announcement (FOA) is a program announcement (PA) issued by the National Institute of Neurological Disorders and Stroke (NINDS), National Institute on Deafness and Other Communication Disorders (NIDCD), National Institute of Dental and Craniofacial Research (NIDCR), National Institute of Environmental Health Sciences (NIEHS), and Office of Research on Women’s Health, National Institutes of Health (NIH). It encourages R21 grant applications from institutions/organizations that intend to perform innovative research that will expand our current knowledge of neurobiological mechanisms underlying migraine headache, examine the role of neuromodulators, genetic and environmental influences in migraine susceptibility, and explore new targets for therapy development. The total project period for an application submitted in response to this funding opportunity may not exceed two years. Direct costs are limited to $275,000 over an R21 two-year period, with no more than $200,000 in direct costs allowed in any single year. [http://grants.nih.gov/grants/guide/pa-files/PA-10-259.html](http://grants.nih.gov/grants/guide/pa-files/PA-10-259.html)

**Advancing Novel Science in Women's Health Research (ANSWHR) (R21)**

The purpose of this Funding Opportunity Announcement (FOA), issued by the Office of Research on Women’s Health (ORWH) and co-sponsoring NIH institutes and centers (ICs), is to promote innovative, interdisciplinary research that will advance new concepts in women’s health research and the study of sex/gender differences. Recent research reports have established the importance of studying issues specific to women, including the scientific and clinical importance of analyzing data separately for females and males. ORWH is particularly interested in encouraging extramural investigators to undertake new interdisciplinary research to advance studies on how sex and gender factors affect women’s health; however, applications in all areas of women’s health and/or sex/gender research are invited. The total project period for an application submitted in response to this funding opportunity may not exceed two years. Direct costs are limited to $275,000 over a two-year period, with no more than $200,000 in direct costs allowed in any single year. [http://grants.nih.gov/grants/guide/pa-files/PAS-10-226.html](http://grants.nih.gov/grants/guide/pa-files/PAS-10-226.html)

**Pathophysiology and Clinical Studies of Osteonecrosis of the Jaw (R21)**

This FOA issued by the National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health, encourages NIH Exploratory/Developmental (R21) applications from institutions/organizations that propose to study the underlying pathophysiology of osteonecrosis of the jaw (ONJ), identify risk factors for this condition, establish the natural history of the disease, and generate evidence for its treatment. [http://grants.nih.gov/grants/guide/pa-files/PAR-11-083.html](http://grants.nih.gov/grants/guide/pa-files/PAR-11-083.html)
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).

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.

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.

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 Anti-retroviral 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.

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.

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, NIEMS, NIMH, NIAAA, 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.
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](http://grants.nih.gov/grants/guide/pa-files/PAR-09-256.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. 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](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-09-186.html](http://grants.nih.gov/grants/guide/pa-files/PAR-09-186.html)

**Manufacturing Processes of Medical, Dental, and Biological Technologies (STTR [R41/R42])**
On February 26, 2004, Executive Order 13329 [http://p257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/pdf/04-4436.pdf](http://p257.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-09-256.html](http://grants.nih.gov/grants/guide/pa-files/PAR-09-256.html)

**NIH Summer Research Experience Programs (R25)**
The purpose of the NIH Summer Research Experience Program (referred to as the “Summer Research Program”) is to provide a high quality research experience for high school and college students and for science teachers during the summer academic break. **Note:** Not all participating Institutes and Centers (ICs) support all aspects of this program. Therefore, prospective applicants must consult the Table of IC-Specific Information, Requirements and Staff Contacts in this announcement to determine if your application will be accepted for review, and should contact staff at the relevant IC (see also Section VII) to discuss the proposed Program.

**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](http://grants.nih.gov/grants/guide/pa-files/PAR-08-117.html)
**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 60 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 MCOHR Studies, continued

Brain as a Therapeutic and Research Target in Trigeminal Neuropathic Pain
PI Alexandre DaSilva

The main purpose of this study is to integrate techniques that produce images of the brain (also called neuroimaging techniques) with non-invasive brain stimulation to investigate structural and molecular mechanisms that may be associated with chronic pain in patients with Trigeminal Neuropathic Pain (TNP). Trigeminal neuropathic pain (TNP) disorders, such as classical trigeminal and postsurgical neuralgia, are debilitating chronic conditions with pain that is either spontaneous or that can be intensely evoked by light touch to the facial skin. We will recruit 15 refractory TNP patients, and 15 age- and gender-matched healthy subjects, including patients with daily chronic TNP for at least 6 months not adequately controlled by pervious medicine therapies, with no history of chronic pain (e.g. back pain), and no recent orofacial surgery or trauma.

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 and without severe periodontal disease and rheumatoid arthritis. 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 or RA; and 2. Characterize the immune regulator activity of periodontitis serum. This proposed 80-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.

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.

Periodontal Disease Prevention Study
PI William Giannobile

The purpose of this study is to evaluate whether dental patients who are classified as “low risk” for periodontal disease progression, based on history of periodontitis, smoking, diabetes, and IL-1 genetic variations, have varying amounts of tooth loss at 10 year and 15 year monitoring periods, periodontal-related dental insurance claims, or risk for dental caries and oral cancer if they had two dental cleanings per year compared to one cleaning per year.
Recently completed MCOHR Studies

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.

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.

For any questions regarding MCOHR’s current or upcoming studies, please contact Anna Galloro (ashafto@umich.edu; 734-998-1435) or Lea Franco (lmfranco@umich.edu; 734-998-1376).
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, or call (734) 998 – 7474. MICHR’s new mailing address is 2800 Plymouth Road, Building 400, Ann Arbor, MI 48109-2800.

MCOHR WEBSITE
Please visit the MCOHR website at 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.