IRB Number: 12-002524: Enhanced Neonatal Health and Neonatal Cardiovascular Effects Developmentally

Principle Investigator: Dr. May

The purpose of this research is to help improve the health of mothers and their children. By doing this research, we hope to determine the influence of different types of exercise during pregnancy on the heart and body composition health of the child, before and after birth.

IRB Number: 13-002836 POD (Pregnancy, Offspring, Dentistry)

Principle Investigator: Dr. Kordis

The purpose of this study is to determine the effects, if any, of maternal physical activity during pregnancy on childhood oral health. We hypothesize that we will find mothers with healthy behaviors (i.e. physical activity, balanced nutrition) during pregnancy will have children with enamel, bone density, and dental maturity similar to controls (children from mother’s who were not active, balanced nutrition during pregnancy).
IRB Number: 16-000867: Prevalence of Tobacco Use

Principle Investigator: Dr. Wright

The purpose of this study is to determine the epidemiology of tobacco use among dental patients at East Carolina University SoDM. The results from this study will inform the development of a culturally appropriate tobacco cessation program at East Carolina School of Dental Medicine.

IRB Number: 16-002105: Tobacco Cessation Program

Principle Investigator: Dr. Wright

The aims of this study are to investigate the issues and barriers to tobacco cessation for current dental clinic smokers; determine if the presently available patient education material is appropriate for this target group; and develop a tailored tobacco cessation curriculum that would be suitable for this population. In collaboration with the North Carolina Department of Health and Human Services (NC DHHS) and the Pitt County Health Department, the partners determined that understanding barriers to smoking cessation among dental patient smokers could assist in the development of a tailored tobacco cessation curriculum for dental students. Phase 1 of the project in which 400 dental patients were surveyed about tobacco use.
IRB Number: 16-002153: Child Health After Maternal Physical Activity (CHAMPS)

Principle Investigator: Dr. May

The purpose of the Child Health After Maternal Physical activity Project will have a significant impact by determining if exercise during pregnancy, a time during which certain prevention modalities have not been studied, can decrease cardiovascular and obesity risk factors in children. Secondly, this study will look at the effect of exercise on unique measures of offspring heart health, adiposity and neuromotor development. Lastly, we will be using current technology to assess childhood indicators of heart health in children, with the future goal of longitudinal measures of these offspring.

IRB Number: 17-000464: AG013-ODOM-201 A Phase 2, multi-center, randomized, double blind, placebo, controlled study to assess the safety and efficacy of topically-applied AG013 for the attenuation of oral mucositis in subjects with cancers of the head and neck receiving concomitant chemoradiation therapy

Principle Investigator: Dr. Muzyka

The purpose of this research study is to evaluate the safety, tolerability, and efficacy of topically administered AG013 mouth rinse compared to placebo for reducing oral mucositis in patients undergoing chemoradiation for the treatment of head and neck cancer as measured by the duration, time to development, and overall incidence of oral mucositis during the active treatment phase, beginning from the start of radiation therapy (RT) until 2 weeks following its completion.
IRB Number: 17-000608: VIG001: Clinical Evaluation of the OncAlert Rapid in Subjects Presenting for Evaluation and/or Initial Biopsy; Impact on Decision Making

Principle Investigator: Dr. Muzyka

The OncAlert Oral Cancer RAPID test (OncAlert RAPID) is a qualitative point-of-care lateral flow assay to aid in the decision to biopsy in patients with clinical features associated with oral potentially malignancy disorders and/or oral/oropharyngeal cancer (i.e. head and neck squamous cell carcinoma).

IRB Number: 16-002105: Tobacco Cessation Program: Development of a Culturally Competent Tobacco Cessation Program at East Carolina University School of Dental Medicine

Principle Investigator: Dr. Wright

The aims of this study, with the collaboration of the North Carolina Department of Health and Human Services (NC DHHS) and the Pitt County Health Department, are to investigate the issues and barriers to tobacco cessation for current dental clinic smokers; determine if the presently available patient education material is appropriate for this target group; and develop a tailored tobacco cessation curriculum that would be suitable for this population. This Curriculum will provide dental students with the information they need to provide tobacco cessation counselling services for their patients.
IRB Number: 18-001102 PREVOLAR RRx-001: A Phase 2a Randomized, Parallel Group, Open-Label, Multicenter Study to Assess the Safety and Efficacy of Different Schedules of RRx-001 in the Attenuation of Oral Mucositis in Patients Receiving Concomitant Chemoradiation for the Treatment of Locally Advanced Squamous Cell Carcinomas of the Oral Cavity or Oropharynx

Principal Investigator: Dr. Muzyka

The purpose for this trial is that RRx-001, a four arms IV infusion, as a systemically non-toxic putative dual radiochemoprotector/sensitizer with activity in multiple tumors types including small cell carcinoma of the oral cavity, will protect the normal mucosa but not the tumor and delay the duration of oral toxicity.

IRB Number: 18-001258 GTI-1944-301 A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of the Superoxide Dismutase Mimetic GC4419 to Reduce Severe Oral Mucositis (SOM) Associated with Chemoradiotherapy for Locally Advanced, Non-Metastatic Head and Neck Cancer

Principal Investigator: Dr. Muzyka

The purpose of this research study is to compare the effects of a test drug, GC4419 on the cumulative incidence of severe oral mucositis. GC4419 offers a treatment paradigm for preventing or controlling OM, an IV infusion administered for 35 treatment days of radio-chemotherapy.
IRB Number: 17-001654 Oral Health Status Among Patients with Mental Illness

Principle Investigator: Dr. Wright

In this research proposal, we plan to examine OHS of patients with MI and investigate associated underlying reasons in terms of perceptions, beliefs and practices among persons with MI, psychiatrists and dentists. Establishing the current state of awareness, challenges and practices towards oral health in this vulnerable population may help in designing much needed interventions to improve dental, psychiatric and other systemic morbidity outcomes.

IRB Number: 18-001376 Neutrophil Dysfunction in Individuals Susceptible to Gingivitis

Principle Investigator: Dr. Wallet

The purpose of the study is to identify individuals highly prone to experimental gingivitis by collecting mouth fluids, supragingival plaque, and peripheral blood. Participants will be asked to abstain from brushing and from any means of interproximal cleaning from 1 to 3 weeks, depending on the Aim 1 or 2 they are enrolled in. Participants will undergo additional scaling and tooth polishing until no or only minimal signs of gingival inflammation is re-established.