

# 2021 TUCOM Research Annual Report and Strategic Plan

*Through achieving research initiatives, we will move forward together by increasing funding to support research that makes a difference in the lives of those we serve and expanding other multiple TUCOM research projects.*

## STRATEGIC PLANNING PROCESS

The 2021 TUCOM Department of Research Annual Report and Strategic Plan was a collaborative effort between the Department of Research, OMM Department, and Dean's Office from June 2021 – September 2021, with leadership from the Senior Associate Dean. In alignment with the mission, this report encompasses the scope of current research within the COM and highlights the unique strategic goals for future growth and improvement in research and scholarly activity. The Dean issued final approval for the plan on October 25, 2021.

## RESEARCH STRATEGIC PLAN 2021-2026

Goals and objectives

### 1. INCREASE RESEARCH FUNDING

#### a. BASIC SCIENCE RESEARCH

- i. Grow major funded projects with critical mass (developed in detail in section 2)
- ii. Increase staff support from Office of Sponsored Programs (OSP)
- iii. Develop new physical infrastructure

#### b. CLINICAL RESEARCH

- i. Expand clinical trial research with additional faculty and staff support
- ii. Expand OMM and/or Ultrasound to assess health outcomes

#### c. EDUCATIONAL RESEARCH

- i. Continue to grow educational grants. Examples include Health Resources and Services Administration Grants
- ii. Expand interprofessional research to include public health initiatives

## 2. INCREASE COLLABORATIONS

- i. Increase our current collaborations with other TUC Colleges
- ii. Increase our current collaborations with other TCUS colleges:  
examples are:
  1. the TCUS Seed and Bridge funds which have been obtained by several of our faculty
  2. The MODI (Metabolism, Obesity and Diabetes Initiative) spearheaded by Provost Salomon Amar at TCUS
- iii. Increase our current collaborations with other local, national, and international universities

## 3. STUDENT RESEARCH

- a. Continue with summer projects for students between first and second year
- b. Continue with budgeted stipends for the above
- c. Continue funding student travel for presentations at OMED and professional conferences
- d. Strengthen and augment the MSMHS research initiatives

## **ANNUAL REPORT WITH STRATEGIC INITIATIVES**

*Objective: To grow major funded projects with a critical mass of researchers. Integration between focused research, curriculum with emphasis in nutrition, and outreach activities produces students with a distinctive profile.*

- 1. Focused research to attack the metabolic root of chronic disease: metabolic syndrome***

TUCOM endeavors to create an environment whereby our college may become a leader in advancing the frontiers of knowledge in nutrition, metabolism and diabetes while translating this excellence into the pedagogical options for our students and clinical practice by fostering an integrated approach of focusing teaching and interaction between basic scientists and clinicians.

For over 15 years our strategic plans have allowed us to create the facilities, environment and infrastructure that *encourages, supports and rewards focused* research in the basic, clinical and health sciences. The process is linked to faculty adequacy, clear goals, and budget.

Targeted faculty hiring has been successful and allowed for development of a critical mass of researchers under an overarching theme. Curbing the morbidity and mortality associated with the epidemics of obesity and type 2 diabetes necessitates attacking the root, metabolic syndrome, which afflicts over 35% of our population.

Together, our campus is leading research in these areas across the translational spectrum, from animals to clinical studies. Exploring new paradigms including the crosstalk between visceral fat and the vascular system, the pathogenesis of fatty liver (NAFLD and NASH), postprandial lipoprotein kinetic studies, fructose restriction intervention, lipoprotein metabolism, HDL function and cardiovascular research are among the key components of our bench research activities. These are paralleled with clinical lipidology and diabetes research.

We strongly believe that all these elements associated with an integrated curriculum with emphasis in nutrition, a committed student body and our global health emphasis will potentiate our results and produce medical students with a thorough understanding of metabolism, capable of translating this knowledge to the patient. On average, 5-10% of TUCOM students participate in research. They present at an Annual Research Appreciation Day that has occurred every year for the past 16 years, as well as at national (OMED, AOA Research Conference, SOMA) and international events.

## *2. Integrated curriculum with emphasis in nutrition*

It is a known fact that biochemistry and physiology as taught in most medical schools is not given its medical context nor its practical importance and that nutrition is not given its necessary weight. Students at TUCOM are taught biochemistry, nutrition, clinical lipidology and endocrinology by the same clinical researchers that are contributing to current knowledge. They visit their laboratories, and participate in Annual Research Day activities, as well as OMED, which helps them understand *prima facie* the intricate workings of metabolism and its direct clinical application.

Nutrition elective courses are offered for students who desire to get a deeper understanding. To change bias towards obese patients we implemented the Fundamental for an Osteopathic Obesity Designed Study (“FOODS”) in which students are given questionnaires to diagnose obesity prejudice over the span of their curriculum as they receive the integrated pedagogical experiences with emphasis in obesity and metabolism. The change in their perception is monitored over their curriculum.

Targeted new faculty hiring to strengthen the delivery of the nutrition curriculum as well as specific teaching experiences to foster understanding of the obesity epidemic contribute to round up a well-informed, curious, and compassionate student with a distinctive profile.

### ***3. Continued growth and development of Osteopathic Research in OMM/OPP***

TUCOM strives to maintain excellence and leadership in current OMM/OPP research as well as continued growth and development of projects which uniquely demonstrate the value of the Osteopathic profession. Ongoing research includes investigation on the impacts of osteopathic manipulative treatment for patients with inflammation, autism spectrum disorder, and accelerated heart rate. Additional data regarding all current TUCOM OMM research, including student projects is included in Appendix B.

#### **a) RIOT- Reducing Inflammation with Osteopathic Treatment - Melissa Pearce, DO**

Melissa G. Pearce, DO is leading a team to implement and complete this study as conceived by Dr. Michael Clearfield looking at whether subclinical inflammation, as in the setting of diabetes, metabolic syndrome, and/obesity, can be reduced by using Osteopathic Manipulative Treatment (OMT). The American Osteopathic Association (AOA) provided grant funding of \$150,000 and milestone goals are imminent. Student involvement has been robust prior to the hiatus due to COVID. Currently, we have Regina Woo, OMS2 as a Work Study Research Assistant.

Implications: OMT has application including and beyond the musculoskeletal system. Inflammation produces significant pathology and with the possibility of affirming the benefit of OMT for inflammation, there are implications for improvement in cardiovascular health and the effects of diabetes and many other conditions.

#### **b) OMM & Autism Spectrum Disorder- Kimberly Wolf, DO**

Kimberly Wolf, DO partners with Robert Hendren, DO (Child and Adolescent Psychiatry UCSF) and the Oak Hill School to investigate the benefits of OMT in patients with ASD. Initially observed 6 patients who were being regularly treated with OMT and witnessed positive improvements in these patients in mood, decreased aggression, increased eye contact, reduced stimming behaviors, etc. A case series based on these initial encounters has been submitted for publication. In fall 2019 UCSF IRB approved a formal prospective study treating new patients at Oak Hill with OMT. Due to Dr. Wolf's maternity leave and COVID the start of this project has been delayed but is scheduled to begin fall 2021. These students will receive regular OMT featuring a protocol + five minutes of individualized treatment and outcomes will be monitored by physicians, school administrators, teachers, therapists, and family.

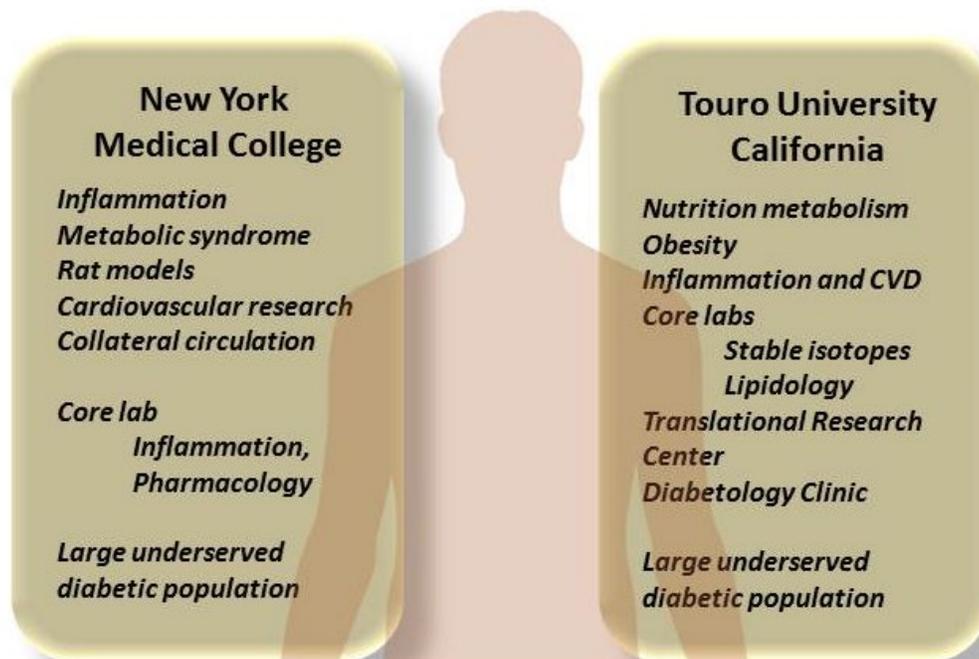
#### **c) Effect of Osteopathic Manipulative Treatment (suboccipital release) on Heart Rate Recovery - Dylan Loquist, OMS1, Ted Wong, PhD, Victor Nuno, DO**

Specific Project Aims:

- Examine how (self-applied) suboccipital release OMT influences autonomic balance via parallel changes in heart rate variability (HRV).
- Determine the effectiveness of (self-applied) suboccipital release OMT to facilitate post-exercise heart rate recovery (HRR).

To examine these aims, HRR and HRV will be assessed in healthy subjects (n = 10-15) after performance of a bout of high-intensity interval training (HIIT) with or without OMT (suboccipital release) administered by a board-certified osteopathic physician. Subjects will be recruited from the Touro University California student body. All subjects must meet inclusion criteria and must be healthy without any underlying conditions. Study will not include subjects from vulnerable populations. HRR and HRV will be measured simultaneously using a mobile heart rate monitoring device (Polar H10®) with data collected and analyzed through pairing with heart rate (Polar Flow® and Polar Beat®) and HRV (Elite HRV®) phone applications linked to online data storage platforms. HRR analysis timeframes will be 1 minute after peak exercise (HRR-1) and 2 minutes after peak exercise (HRR-2). HRV will be monitored for a period of 5-minutes post-exercise. Both HRR and HRV recovery data will be analyzed via a separate data collection bout to isolate recovery data and properly analyze the OMT's effect on HRR/HRV.

#### 4. Consolidation of present collaborative structure and future goals



Our main strategy is to expand on our core critical mass of skills and equipment to tackle key issues in nutrition and public health that have a bearing on the current epidemics of obesity, diabetes, and their correlates on cardiovascular disease. This focus is aligned

with the tenets of the osteopathic profession that focus on prevention of disease by appropriate nutritional and lifestyle advice as well as practice anchored around a public health message.

*This expansion should occur at the local level, with new hires and new labs developed and by integrating our research efforts with NYMC as we have competitive counterparts that carry research that complements ours: inflammation and metabolic syndrome, as shown in the Figure above.*

Two NIH-funded core laboratories on campus function as a tight unit with our Metabolic Research Center that carry out bench research on human intervention studies to unravel the mechanisms of NAFLD, metabolic syndrome dyslipoproteinemia and postprandial lipoprotein metabolism, all key components of atherogenesis.

- **Stable isotopes mass spectrometry laboratory.** Beyond providing state-of-the-art, user-friendly services the laboratory enables education and consultation for the design of translational clinical studies using stable isotopes. We have both experience and special expertise for complex kinetic studies to assess carbohydrate, lipid, and lipoprotein metabolism. The Mass Spectrometry Core is equipped with three GC-MS instruments and one triple quadrupole LC-MS/MS instrument. Kinetic measurements currently performed in the Mass Spectrometry Core Lab include:
  - Endogenous glucose production
  - Gluconeogenesis and glycogenolysis
  - Lipolysis (Ra glycerol and Ra palmitate)
  - *De novo* lipogenesis
  - Lipoprotein kinetics (ApoB48 and ApoB100)
  - Triglyceride production

#### **Personnel:**

Director: Professor Jean-Marc Schwarz, PhD.

Professor Kathleen Mulligan, Principal Investigator Ph.D. Senior Research Associate: Ewan F. Sinclair, Ph.D.; Laboratory Manager: Sergiu P. Palii, Ph.D.

Over the past 10 years our work has shown that high fructose and sugar containing beverage/diets cause hepatic fat accumulation and production, which lead to increased risk of diabetes and cardiovascular disease. Using State-of-the-art stable isotope tracer methodology, we have uncovered that the liver conversion of sugar to fat (*de novo* lipogenesis, DNL) may be a fundamental mechanism linking diet, sugar, and insulin resistance to the metabolic syndrome at the origin of diabetes and CVD. This methodology can be applied in different research directions from fundamental mechanistic clinical studies to public and global health approaches. This methodology

can be further developed to better understand the metabolic stages from pre-diabetes to diabetes. By identifying the tissue/organ at the origin of the glucose metabolic defect and targeting the most effective treatment to prevent the progression from pre-diabetes to diabetes.

- **Lipid and Biomarkers Core Laboratory**

The Glycation, Oxidation and Disease laboratory employs techniques that allow the study of triglyceride rich lipoprotein metabolism and HDL function, with a special focus on HDL subclasses and the antioxidant enzyme paraoxonase 1 (PON1). We collaborate extensively with UCSF, Israel, and Japan.

The lipidology core has developed:

- An immunoaffinity procedure to separate chylomicrons from VLDL for the study of postprandial lipoprotein metabolism
- A method to study PON1 activity in HDL subclasses is being employed to unravel aspects HDL maturation as well as changes in physiological and pathological conditions.
- A preparative method for the isolation of sdLDL for stable isotope kinetic studies

The laboratory carries the following methods:

- All apolipoproteins ELISA, apolipoprotein profiles (Western)
- Sequential flotation density ultracentrifugation
- Small dense LDL by gradient gel electrophoresis (slab and tube- Lipoprint)
- HDL sub-fractions by gradient gel electrophoresis (Lipoprint)
- Paraoxonase 1 (5 substrates, functional genotype)

**Personnel:**

Director: Professor Alejandro Gugliucci, M.D., Ph.D., Associate Dean, Senior Research Associate: Russell Caccavello, M.S.

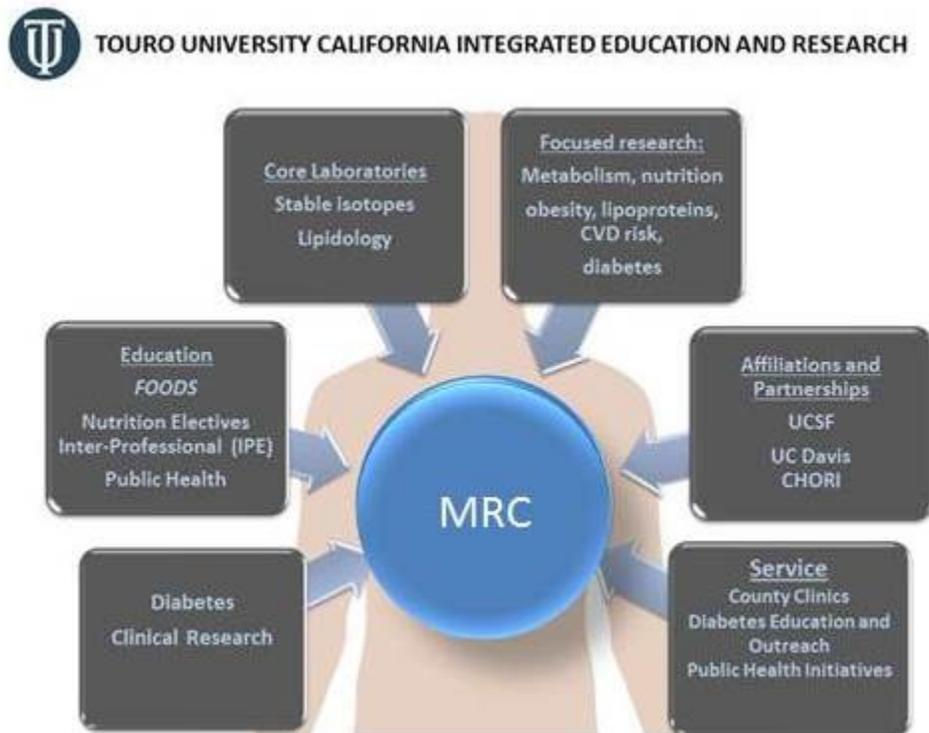
- **Metabolic Research Center**

In an effort to establish a comprehensive research center we developed a Metabolic Research Center which started operations 5 years ago, ensuring that promising findings in the lab are applied to patients and the community in the fastest, safest and most efficient way possible.

This philosophy drives its collaborative, fast-track approach to advancing cutting-edge disciplines that help change paradigms and have a real potential to deliver prevention

and a cure. The broad interplay among basic and clinical research, training as well as clinical and community-based activities under a cohesive, interactive, and unified group facilitates exponential growth of our research footprint.

The MRC not only provides a unique opportunity to consolidate and expand our existing collaborations with Bay Area institutions, it also performs studies for hire, and catalyzes the formation of a metabolic translational research group and further fosters collaborations as well. At present, faculty from UCSF such as Dr. Robert Lustig, and from UC Davis, Dr. Kimber Stanhope have accepted positions as Adjunct Faculty, bringing their expertise and studies to Touro University California. Initially, this new unit will be suited for outpatient clinical research studies, with eventual options to also conduct short inpatient studies. The association of this research clinic with an existing stable isotope mass spectrometry core, a clinical research core, a lipid/lipoprotein core, the Solano County Research Clinic created a new and attractive facility for translational and Public Health investigators across the Bay Area.



### *Outcomes*

The success of this approach can be judged by the impact of our output:

- Together, in the past 10 years the two main core laboratories at TUCOM, the Dean’s Office and the MRC faculty have published over 150 peer reviewed papers in prestigious journals on our focused research (lipidology, metabolism, diabetes).

- Fueled by its currently established core laboratories and their synergy, and already extensively funded by NIH, our paradigm-shifting research has recently attracted widespread national and international press attention (Wall Street Journal, NY Times, CBS, BBC, Canadian TV documentaries, 60 Minutes, CNN, NBC, The Guardian, etc.).
- TUCOM extramural funding 2010-2021 amounted to over \$15,000,000 and over 80% corresponded to the focus area of metabolism.
- We have active productive partnerships with national universities: UCSF, UC Davis, UC Berkeley, and Harvard University.
- We have active productive partnerships with international universities: Hebrew University in Jerusalem, Showa University and Kyoto Medical Center, Japan.
- Results from the FOODS surveys as the student cohort completes their curriculum show efficacy of our intervention.

One of our past successful and current strategies is to recruit and retain high caliber research faculty. The new phase in our research development is also grounded on targeted hiring:

- Jay Shubrook, DO, as Director of Clinical Research and Diabetic services joined us in 2015 and brought his extensive expertise in teaching and clinical studies as well as his diabetes literacy programs and MOBEC (mobile clinic) that created a campus with a high number of qualified staff and students.
- A new position was created in Basic Sciences for a faculty member that complemented our core research on Nutrition: Dr. Grace Jones has been appointed in January 2015. She bridges the teaching of the subject with our current research on human nutrition and is developing her own branched line of research. She has been awarded a TCUS Seed Grant and has just applied for an NIH R01 grant.
- Dr. K. Mulligan, former UCSF Director of Body Mass Composition and Metabolism Core Unit, joined our Research Department in 2015, to help put together program grants and the clinical research facility described above. She recent retired after a very productive period.
- Dr. Robert Lustig, long term collaborator and world-renowned authority in metabolism, joined our Research Department as Adjunct Professor bringing his expertise and know-how.

## 5. *FUTURE GOALS*

*To increase our research footprint, we need to increase the funded faculty critical mass* so as to put together a competitive NIH Program Project Grant. Such a project needs the

core labs (already present) and *at least* 3 heavily funded (R01) laboratories (we currently have 2).

The opening of the H89 Research Clinic has rounded up our well-established, highly successful NIH funding and strengthened our partnerships with UCSF, UC Davis, UC Berkeley, and Harvard University.

To that end (when the pandemic situation returns to normal) the Research Department will be requesting 2 new bench researchers PI. The hiring of whom will have the following objectives:

- Increasing the number of competitive NIH grant submissions and their revenue.
- Facilitating the chances of securing a NIH Program Project Grant (see above), which is our main strategic goal for the next 3 years
- A Program Project will bring millions of dollars in grants and greatly increase our research footprint and prestige.
- Additionally, due to the success of the business model of the stable isotope lab, more bench space is needed to enhance this income flow.
- Increasing the number of NIH R01 funded PIs to 5-6 will allow for the eventual opening of a PhD program funded with MSMHS revenues, rounding up TUC as an academic research institute and fueling the research of the future of TCUS.

We seek to put together a vibrant, extensive, diverse, well-funded and highly productive program that provides the foundation for high-quality, cutting-edge research in diabetes and related studies in obesity, metabolism, and endocrinology that is well positioned for rapid expansion.

### *Milestones and targets*

We will monitor our strategic plan by:

- our productivity in number of papers,
- presentations, national and international recognition,
- student participation and
- extramural funds obtained.

### *Long term goals*

Our integrated research and pedagogic approach has the potential to produce a distinctive osteopathic physician better prepared to address the current obesity and diabetes epidemics.

The program will:

1. Expose both undergraduate and graduate students to obesity, metabolism and diabetes using a specialized focused curriculum
2. Integrate excellence in all phases of clinical training to further improve clinical patient care
3. Advance the field of clinical education by developing and implementing models of inter-professional education and training
4. Create a global, intellectual environment through collaboration with researchers both nationally and internationally
5. Facilitate the translation of new research findings into novel therapies for patients with diabetes and metabolic diseases
6. Train the next generation of scientists and clinicians in diabetes and metabolic diseases
7. Provide continuing educational opportunities for health professionals
8. Become the standard bearer for best practices in diabetes and metabolic diseases and its treatments
9. Provide and deliver innovative health education curriculums customized to meet patients' needs
10. Provide multi-specialty care for the entire spectrum of diabetes and its complications and related metabolic diseases
11. Offer free clinics and screening programs for diabetes and other metabolic diseases to the community
12. Contribute to a healthy community that supports lifestyle changes to prevent or manage obesity, diabetes, its complications, and other metabolic and chronic diseases
13. Develop strategies to overcome the unique socioeconomic and environmental barriers contributing to chronic disease in the region

## Appendix A: Active grants

### Active grants 2020-2021

|  |             |                                  | FY award |         | Total Award |
|--|-------------|----------------------------------|----------|---------|-------------|
| Fructose: Substrate, Stimulus, or Both?  | JM Schwarz  | NIH (R01DK116033)                | 120022   | 714,999 | 2,859,996   |
| The effects of orange juice compared with sugar-sweetened beverage on risk factors and metabolic processes associated with the development of cardiovascular disease and type 2 diabetes | JM Schwarz  | UC Davis Subcontract (NIH R01)   | 120134   | 214,785 | 1,626,797   |
| Efficacy and Safety of LY3298176 Once Weekly versus Insulin Glargine in Patients with Type 2 Diabetes and Increased Cardiovascular Risk (SURPASS-4)                                      | J. Shubrook | Lilly (Clinical Study) SURPASS-4 | 150221   | 19,829  | 83,988      |
| HHS: Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke-Financed in part by 2018 Prevention and Public Health Funds (PPHF)     | J. Shubrook | CDPH (18-10913)                  | 120011   | 89,015  | 192,322     |
| A Randomized, Double-Blind Study with an Open-Label Extension Comparing the Effect of Once-Weekly Dulaglutide with Placebo in Pediatric Patients with Type 2 Diabetes Mellitus           | J. Shubrook | Lilly (Clinical Study)           | 150220   | 0       | 40,680      |
| Mobile Diabetes Education Center (MOBEC)   | J. Shubrook | Solano Sutter Hlth Hospital      | 150320   | 114,014 | 359,513     |
| COLLABORATIVE RESEARCH: FEEDING ONTOGENY AT THE INTERFACE OF BEHAVIOR AND MORPHOLOGY   | A. Taylor   | Duke University (Subcontract)    | 120150   | 6,180   | 12,438      |

### Active grants 2019-2020

|  |                   |                                | FY award |         | Total Award |
|--|-------------------|--------------------------------|----------|---------|-------------|
| The effects of orange juice compared with sugar-sweetened beverage on risk factors and metabolic processes associated with the development of cardiovascular disease and type 2 diabetes | JM Schwarz        | UC Davis Subcontract (NIH R01) | 120130   | 299,721 | 1,616,426   |
| Fructose: Substrate, Stimulus, or Both?  | JM Schwarz        | NIH (R01DK116033)              | 120021   | 714,999 | 1,429,997   |
| The Metabolic Syndrome Project   | A. Gugliucci      | UCSF                           | 130041   | 66,100  | 178,600     |
| Connecting Ethiopian Women to Innovative Patient-Centered Cervical Cancer Care: A Pilot study  | Mahmoud/Hernandez | NYMC Seed Fund                 | 170030   | 12,500  | 25,000      |
| Youth in Action for Health Equity: Increasing Public Health Related Career Readiness with Low-Income Ethnically Diverse High School Students   | A. Aalborg        | Solano County                  | 140040   | 7,450   | 7,450       |
| Covalent capture of small molecule – gp41 complexes  | M. Gochin         | NIH (R21AI140904)              | 120171   | 178,750 | 393,250     |
| Efficacy and Safety of LY3298176 Once Weekly versus Insulin Glargine in Patients with Type 2 Diabetes and Increased Cardiovascular Risk (SURPASS-4)                                      | J. Shubrook       | Lilly (Clinical Study)         | 150221   | 26,742  | 38,361      |
| HHS: Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke-Financed in part by 2018 Prevention and Public Health Funds (PPHF)     | J. Shubrook       | CDPH (18-10913)                | 120010   | 120,680 | 120,680     |
| A Randomized, Double-Blind Study with an Open-Label Extension Comparing the Effect of Once-Weekly Dulaglutide with Placebo in Pediatric Patients with Type 2 Diabetes Mellitus           | J. Shubrook       | Lilly (Clinical Study)         | 150220   | 0       | 40,680      |
| Mobile Diabetes Education Center (MOBEC)   | J. Shubrook       | Solano Sutter Hlth Hospital    | 150320   | 245,499 | 359,513     |

Over 95% of the COM extramural funding stems from the metabolism core, with most of the funding for the whole campus stems from COM and its metabolism research.

## **Appendix B: OMM/OPP Research**

### **2021 OMM Department Research Update**

#### **a) RIOT- Reducing Inflammation with Osteopathic Treatment - Melissa Pearce, DO**

Melissa G. Pearce, DO is leading a team to implement and complete this study as conceived by Dr. Michael Clearfield looking at whether subclinical inflammation, as in the setting of diabetes, metabolic syndrome, and/obesity, can be reduced through the use of Osteopathic Manipulative Treatment (OMT). The American Osteopathic Association (AOA) provided grant funding of \$150,000 and milestone goals are imminent. Student involvement has been robust prior to the hiatus due to COVID. Currently, we have Regina Woo, OMS2 as a Work Study Research Assistant. Immediate need is to recruit 15-20 participants over the next couple of weeks.

**Hypothesis:** OMT utilized in the setting of subclinical inflammation can reduce inflammation as measured by TNF-alpha, C-reactive protein (CRP), and other cytokines and biomarkers.

**Key inclusion criteria:** Diabetes, metabolic syndrome, and/or obesity (BMI 30+), elevated CRP as assessed at the screening visit, willing to forego NSAIDs/steroids for two weeks before and during the study. No physical medicine modalities such as Physical Therapy, OMT, acupuncture for six weeks before and during the study.

**Key exclusion criteria:** Cannot have actual inflammatory disease, such as rheumatoid arthritis, active Hashimoto's thyroiditis, ulcerative colitis, etc. Cannot have significant chronic pain, such as that rated as 7/10 or greater on a pain scale.

**Summary Work Plan:** 5-6 week study duration with four study visits. Screening visit, followed by two visits with an Osteopathic Structural Exam (OSE) for the control group and the inclusion of OMT for the treatment group. Visit 1 and Visit 2 are one week apart. Final visit one month after V2.

**Implications:** OMT has application including and beyond the musculoskeletal system. Inflammation produces significant pathology and with the possibility of affirming the benefit of OMT for inflammation, there are implications for improvement in cardiovascular health and the effects of diabetes and many other conditions.

#### **b) OMM & Autism Spectrum Disorder- Kimberly Wolf, DO**

Kimberly Wolf, DO partnered with Robert Hendren, DO (Child and Adolescent Psychiatry UCSF) and the Oak Hill School to investigate the benefits of OMT in patients with ASD. Initially observed 6 patients who were being regularly treated with OMT and witnessed positive improvements in these patients in mood, decreased aggression, increased eye contact, reduced stimming behaviors, etc. A case series based on these initial encounters has been submitted for publication. In fall 2019 UCSF IRB approved a formal prospective study treating new patients at Oak Hill with OMT. Due to Dr. Wolf's maternity leave and COVID the start of

this project has been delayed but is scheduled to begin fall 2021. These students will receive regular OMT featuring a protocol + five minutes of individualized treatment and outcomes will be monitored by physicians, school administrators, teachers, therapists, and family.

**c) Effect of Osteopathic Manipulative Treatment (suboccipital release) on Heart Rate Recovery - Dylan Loquist, OMS1, Ted Wong, PhD, Victor Nuno, DO**

**The projects specific aims are:**

- Examine how (self-applied) suboccipital release OMT influences autonomic balance via parallel changes in heart rate variability (HRV).
- Determine the effectiveness of (self-applied) suboccipital release OMT to facilitate post-exercise heart rate recovery (HRR).

**Hypothesis:** Self-administered OMT performed after a single bout of high-intensity interval training (HIIT) causes a more rapid HRR that correlates with increased parasympathetic tone during the post-exercise period.

**Summary Work Plan:** To examine these aims, HRR and HRV will be assessed in healthy subjects (n = 10-15) after performance of a bout of high-intensity interval training (HIIT) with or without OMT (suboccipital release) administered by a board-certified osteopathic physician. Subjects will be recruited from the Touro University California student body. All subjects must meet inclusion criteria and must be healthy without any underlying conditions. Study will not include subjects from vulnerable populations. HRR and HRV will be measured simultaneously using a mobile heart rate monitoring device (Polar H10®) with data collected and analyzed through pairing with heart rate (Polar Flow® and Polar Beat®) and HRV (Elite HRV®) phone applications linked to online data storage platforms. HRR analysis timeframes will be 1 minute after peak exercise (HRR-1) and 2 minutes after peak exercise (HRR-2). HRV will be monitored for a period of 5-minutes post-exercise. Both HRR and HRV recovery data will be analyzed via a separate data collection bout to isolate recovery data and properly analyze the OMT's effect on HRR/HRV.

## **Additional research projects:**

### **OMT and Gastroparesis- Jay Shubrook, DO, Nicole Pena, DO, Shalaya Yazdi, OMS1**

Study looking at the impact of OMT on patients with gastroparesis. IRB approved, on hold, interest in reopening study this academic year.

### **OMT and Wound Care- Nicole Pena, DO, Sara Sievers, OMS4**

Assess the impact of OMT on wound healing. IRB written and on hold secondary to pandemic and access to wound care center and their patients,

### **Portable OMM tables for students- Sean Moloney, DO**

Qualtrics survey to assess students' needs, usage and impact with distribution of portable OMM tables. In process.

**COVID-19 Immunization Study- Melissa Pearce, DO, Nicole Pena, DO, Vanessa Newman, DO**

Study developed in collaboration with Western University of Health Sciences OMM Department and AOF. Western going ahead with study on their campus and we will be a part of the publication process.

**3rd year Callbacks Data- OMM Communication- Nicole Pena, DO**

Data needs to be evaluated and paper written.

**3rd year Osteopathic Modules Survey Data- Nicole Pena, DO**

Data needs to be manually entered to be evaluated. Awaiting student engagement to proceed.

**4th year rotation survey data- Victor Nuno, DO**

Data needs to be manually entered to be evaluated. Awaiting student engagement to proceed.

**TUCOM Student OMM/OPP Research Projects:**

*Dylan Loquist 2021 MSMHS, now OMS1 – Heart Rate Recovery Following Suboccipital Tension Release.*

IRB ( ). Heart rate recovery was monitored after volunteers physically exerted themselves comparing application of self-administered suboccipital l tension release versus control. Lower HRR recovery times are associated with better cardiovascular health. Self-OMT administration revealed lower HRR times. For the 2021-2022 academic year, Victor Nuno, DO is elevating this IRB approved project to better apply OMT and monitor outcomes.

*Purpose of the following community outreach messages and relevance to osteopathic medicine and osteopathic manipulative treatment (OMT):*

Patient testimony of OMT outcomes has been considered anecdotal. As of 2021, documentation of the History in an outpatient/office encounter in the health record is no longer part of the physician payment formula. Instead, patients themselves are encouraged to answer the standardized History questions to providers so the information can be used as the subjective History in the health record. This process reduces provider clerical burden and also empowers patients to report their experiences with disease and previous treatment efforts. This policy change changes the patient's words from anecdotal to an official entry into the health record. This opens the door for patients of osteopathic physicians to capture OMT outcomes data. This discoverable data can be used to justify medical necessity for OMT administration and also serve as a resource for OMT research.

*Shalaya Yazdi, MPH, 2021 MSMHS, now OMS1– Community outreach message encouraging patients to read their health records.*

IRB M2120 - A YouTube video was created delivering a message with over a dozen Master of Science and Osteopathic medical students and a faculty member to raise awareness and importance of reading your health record after a medical encounter. Reading one's record helps check for accuracy as well as engaging patients to take an active role in patient-provider communication. An associated Qualtrics survey assesses viewer concerns, beliefs, and inclinations to read their health records.

*'Jori' Charles Enfield 2021 MSMHS, now OMS1 – Community outreach message reviewing new verbiage in the 2021 CPT manual.*

IRB M0821 - A YouTube video was created delivering a message with over a dozen Master of Science and Osteopathic medical students to analyze a new paragraph in the 2021 CPT manual regarding health record documentation for outpatient/office medical encounters. This paragraph replaces nearly 2 pages of text from 1995-2020 and changes the rules as to what the provider must document in regard to the History and Examination. The paragraph updates policy removing documentation of the History and Exam from the physician payment formula. The paragraph promotes a patient authored History questionnaire. An associated Qualtrics survey assesses viewer concerns, beliefs, and inclinations toward this new policy.

*Jaspreet Dhanoya, 2021 MSMHS - Community outreach message encouraging patients to answer all history questions in preparation for every medical encounter.*

IRB M0621 - A YouTube video was created delivering a message with over a dozen Master of Science and Osteopathic medical students to promote and discuss active engagement of patients to prepare for a medical encounter by answering a series of standardized questions. An associated Qualtrics survey assesses viewer concerns, beliefs, and inclinations toward this type of active engagement.

*Charndee Sahota, 2021 MSMHS - Community outreach message encouraging medical students to view health record documentation through the lens of all 7 osteopathic core competencies.*

IRB M0721 - A YouTube video was created delivering a message with over a dozen Master of Science and Osteopathic medical students and a faculty member to frame health record documentation through each of the core competencies. An associated Qualtrics survey assesses viewer concerns, beliefs, and inclinations toward this consideration of health record documentation through the lens of core competencies.

*Kyle Chung, 2021 MSMHS - Community outreach message addressing how a patient can represent their experience with a chronic condition in their health record.*

IRB M1421 - A YouTube video was created delivering a message with over a dozen Master of Science and Osteopathic medical students, a faculty member, and a chronic disease advocate to consider how a person can represent their experience with a chronic disease in their health record. An associated Qualtrics survey assesses viewer concerns, beliefs, and inclinations toward this consideration of health record documentation through the lens of core competencies.