



## Clinical Research Section

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In 2020, the Penn Orthopaedics Clinical Research Program marks its 10<sup>th</sup> Anniversary. Clinical Research activity at Penn Orthopaedics encompasses retrospective and prospective cohort studies as well interventional studies and clinical trials. This writing intends to celebrate and highlight the accomplishments of the program and of each Division.

**Table 1. Summary of Clinical Faculty Research Activity 2010-Present**

	Funded Projects (Total)	Pubs (Total)	Protocols (Current)	# Faculty (Current)
Adult Reconstruction	24	183	56	6
Foot & Ankle	4	17	14	4
FOP	8	81	8	2
Hand	6	178	22	4
Oncology	1	38	3	2
Shoulder & Elbow	5	68	15	3
Spine	2	52	12	5
Sports Medicine	9	133	32	4
Trauma	25	282	59	3
	84	1032	221	33

Table 1 shows the extent of activity that has occurred in the past decade in Penn Orthopaedics. For the period 2001 - 2010, there were only 4 funded Clinical Research awards from any source. Since 2010, each Division has significantly increased Clinical Research activity in the form of funded projects, the number of all types of protocols approved by the University of Pennsylvania Institutional Review Board (IRB), and the number of publications. Increased funding from grants and industry sponsored projects has allowed the program to hire Clinical Research Coordinators (CRCs) to support the faculty in the conduct of funded studies and other projects, and enables Clinical Research to take on new and exciting projects. We currently have 10 full time staff members supporting the 221 protocols active in the Department.

**Adult Reconstruction** has had 24 funded projects initiate at either Penn Presbyterian (PPMC) or Pennsylvania (PAH) Hospitals since 2010, 11 of which are still active. The 11 studies are distributed among all 6 faculty in this Division, each whom serve as the Principal Investigator (PI) on one or more ongoing funded clinical research projects. Our CRCs connect with patients at PPMC, PAH, Radnor, Cherry Hill, and Valley Forge locations as needed for each study. The primary CRC for Adult Reconstruction is Helena Moses. Helena has been with the team for 6 years and works out of PPMC. She also is actively working

toward a Nursing Degree. In addition, Adult Reconstruction is served by both Christine Wojciechowicz at PPMC and Warren Harding at PAH. Christine has worked with the team for 10 months. She will be attending Geisinger Commonwealth School of Medicine in the Fall of 2020. Warren Harding has been with the team for 8 months and plans to begin a PhD program in Fall 2022. The largest ongoing study in Adult Reconstruction is myMobility (NCT03737149) (PI, Dr. Israelite). The myMobility study is a post-market prospective, multi-center longitudinal study to determine if mobile application-guided education and exercise paired with accurate and sensitive activity monitoring, captured from consumer wearables, can provide a viable, and potentially improved, alternative to current standard of care physical therapy for hip and knee arthroplasty. This winter saw the completion of enrollment for the first phase of the study: a randomized controlled trial. We successfully enrolled 92 of our target 100 subjects and are now working towards enrolling a further 500 subjects in the second phase of the study.

**Foot & Ankle** has had 4 funded projects initiate since 2010. There are 3 active funded projects in this Division. The primary site for Clinical Research is on the PAH campus at the Farm Journal Building (FJB). The CRCs in service to the Foot & Ankle Division are a shared resource with other Divisions (Warren Harding and Dr. Mary Dooley). In the past fiscal year, Foot & Ankle initiated a funded study sponsored by Treace Medical Concepts Inc. entitled “Early Weight-Bearing After the Lapiplasty Procedure (ALIGN3D)” (NCT03740282). This study evaluates the outcomes of the Lapiplasty® Procedure for patients in need of hallux valgus surgery. Foot & Ankle has also seen a surge in the past year of unfunded studies comprised of prospective Division initiatives and retrospective chart reviews. The CRCs support the conduct of these studies that give residents, fellows, and medical students the opportunity to participate in a strong research program.

**FOP** continues its track record of success in the search for therapies to ameliorate symptoms of FOP and perhaps, someday, to even cure the disease. Currently under the leadership of Drs. Kaplan and Al Mukaddam, there are 3 active studies in FOP supported by 2 different sponsors. There are 2 staff who exclusively support FOP Clinical Research, Project Manager Katherine Toder and CRC Renee Jurek. Both Katherine and Renee have been on staff for about 4.5 years, are in the Penn Masters of Regulatory Affairs Program, and we are lucky they will be with our team for the foreseeable future. In addition, Mrs. Kamlesh Rai is an essential part of the team as well. Kay has been with the Department for over 30 years. The FOP team has been working for several years on the Clementia program and is more recently also engaging in a study with a different sponsor, Regeneron (“LUMINA-1”,

NCT03188666). Additional sponsors are taking interest in the FOP disease state and we anticipate increased research activity in this population in the near future.

**Hand Surgery** has initiated six funded clinical research projects in the past 10 years and they are all currently active. The Division is supported by 2 CRCs, Dr. Mary Dooley and Ashley Iwu. Mary is coming up on 2 years of service and Ashley is approaching 10 months. We are happy to report that both of them plan to stay with us for some time. All 4 faculty in this Division have at least one funded clinical research project. Dr. Bozentka serves as PI for a randomized prospective trial that all Division faculty members participate in through patient enrollment. Entitled “Comparison of Processed Nerve Allograft and Collagen Nerve Cuffs for Peripheral Nerve Repair” (NCT01809002), this study compares the performance of a specially processed human allograft vs. a collagen nerve cuff in nerve injuries. As this trial draws to a close and is anticipated to finish enrollment during FY21, we are celebrating the accomplishment of being the #4 site nationwide in terms of enrollment and completion. This is a double success for our team because while Dr. Bozentka is the local PI, Dr. Levin serves as the Global PI. We are looking forward to seeing the results.

**Shoulder & Elbow** has developed a strong Clinical Research presence over the past 10 years with 5 funded studies currently ongoing. The Division is supported by Evan Bannister in the CRC role. Evan has been with the Department for 6 years and is expected to graduate with a Masters in Regulatory Affairs in May 2020 (Penn). Evan plans to stay with our team for the near term. Currently, all studies in Shoulder & Elbow are led by Dr. Kuntz as PI, though there are pending projects for Dr. Huffman anticipated for FY21. The featured study for this year is the OrthoFix RCstim Study (NCT03339492). This study investigates the safety and efficacy of treating full thickness rotator cuff repairs with pulsed electromagnetic fields (PEMF). We are excited to participate in a clinical study that parallels the research completed by our McKay Lab colleagues on PEMF technology for tendon repair.

**Spine** currently has 2 active funded studies: “An ACDF Multi-center Study Using ViviGen Cellular Bone Matrix” (NCT02814825) and “An Assessment of P-15L Bone Graft in Transforaminal Lumbar Interbody Fusion with Instrumentation” (NCT03438747), with additional studies at the preparatory phase. The Spine Division also has a large unfunded research

arm involving both prospective and retrospective study designs. At the moment, we do not have a dedicated Spine CRC, but Dr. Mary Dooley and Warren Harding both assist to cover Spine at PPMC, PAH, and Valley Forge. The 2 current funded studies are led by Dr. Smith as PI with the pending studies split between Drs. Smith and Saifi. It will be very exciting to revisit this Division and their progress next year.

**Sports Medicine** has 6 active funded projects shared amongst 3 faculty as PIs. Dr. Carey is the Local and Global PI on the Vericel sponsored PEAK study (NCT03588975) entitled “A Study of MACI in Patients Aged 10 to 17 Years With Symptomatic Chondral or Osteochondral Defects of the Knee”. This study compares the efficacy and safety of MACI® vs arthroscopic microfracture in the treatment of patients aged 10 to 17 years with symptomatic articular chondral or osteochondral defects of the knee. Dr. Carey has long been interested in knee cartilage defects and their repair and regrowth possibilities, and it is great to see that he has been recognized with this leadership role. Dr. Carey has been supported by Shawn Simmons as CRC. Shawn joined our team about 2 years ago and will be leaving us to attend Medical School at Columbia in the Fall.

**Ortho Trauma** has been a very strong Division these past 10 years. There have been an astounding 25 funded projects in Ortho Trauma over the 10 years with 3 currently funded studies active and more on the horizon. This team has also had the most comprehensive funding mix of federal, foundation, philanthropy, and industry sponsorship. Currently, Dr. Mehta is the PI on 2 multicenter trials and 1 single site trial investigating the diagnosis, prevention, and management of surgical site infections in the Ortho Trauma population. At the moment, we do not have a dedicated Trauma CRC, but Dr. Mary Dooley and Ashley Iwu both assist to cover this Division.

We also want to recognize the outstanding collaboration that occurs within Divisions and across the Clinical Research Programs in the Departments of Orthopaedic Surgery and Anesthesia and Critical Care. Highlights include a study led by Dr. Farber and sponsored by DJO, “CMF Bone Stimulation as Adjunct to Surgical Treatment of Ankle Fractures” (NCT02688855), which both the Foot & Ankle and Ortho Trauma faculty support recruitment for; the PCORI sponsored REGAIN Trial (NCT02507505) (PI, Dr. Neuman) that incorporates a well-integrated team of Orthopaedic Surgery and Anesthesiology & Critical Care faculty; and an investigator



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initiated trial (PI, Elkassabany in collaboration with Dr. Glaser) studying the effects of liposomal bupivacaine injected prior to surgery in the Shoulder Elbow patient population. These and other anesthesia studies are supported by a team including Project Manager Aliaksei Basatski and CRCs Annie DiLisio, Nnamdi Ilonzo, Anmol Madaan, and Cassandra Dinh.

Thank you to all the named and unnamed staff and faculty on our team, the residents, fellows, and other clinical

support staff, and the leadership of Penn Orthopaedics and Anesthesiology & Critical Care for their ongoing support of our team. Specifically, we thank the Chairs, Drs. Levin and Fleisher, the Vice-Chairs for Research, Drs. Soslowky and Eckenhoff, as well as the Chief Operating Officers, Neil Ravitz and Dennis Harris for your ongoing guidance and support in every way throughout the year.

## FY 20 Clinical Research Team



**Figure 1** Top row: Evan Bannister, Aliaksei Basatski, Mary Dooley, Annie DiLisio, Cassandra Dinh. Middle row: Warren Harding, Nnamdi Ilonzo, Ashley Iwu, Renee Jurek, Anmol Madaan. Bottom Row: Helena Moses, Kamlesh Rai, Shawn Simmons, Katherine Toder, Christine Wojciechowicz.