



2015 UPOJ Clinical Research Update

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The themes for Penn Orthopaedics Human Subjects Research (HSR) in FY15 are growth and collaboration. Starting in July 2014, the clinical research program of Penn Orthopaedics joined forces with the Department of Anesthesiology & Critical Care (ACC) to take advantage of the overlap in our patient populations and complementary research goals. Since the last edition of the UPOJ, our team of Orthopaedic Clinical Research

Coordinators (CRCs) has nearly doubled and we have additional shared CRC resources with ACC. It is my pleasure to introduce the research team and summarize their roles for our readers.

Denise Knox, BS has been with Penn Orthopaedics for almost 8 years. She started as a CRC in Adult Reconstruction and has significantly matured in her role. She will be assuming the leadership of all studies for Penn Orthopaedics and ACC that are based out of the Penn Presbyterian Medical Center campus and will supervise all CRCs and assistants based out of Penn Medicine University City (PMUC) and Weightman Hall. As always, Denise has worked tirelessly on the numerous studies in Adult Reconstruction. Currently, there are six extramurally sponsored studies out of PMUC as well as five prospective cohorts and about twenty-five retrospective studies ongoing for the division. The partnership between Denise and Dr. Israelite has led to enthusiastic recognition from Zimmer on enrollment and the quality of data submitted to the sponsor in support of the post marketing follow up study of the Persona Personalized Knee System®. Quality improvement projects are also in place to identify, manage, and prevent risk for our patients. Under the leadership of Dr. Rod Eckenhoff in collaboration with Dr. Gwo-Chin Lee, Denise will be the lead coordinator in an investigator initiated study to study the effects of anesthesia on delirium in the adult reconstruction population. Dr. Hume's efforts on two DePuy studies are supported by Denise as well, and the department is about to launch our affiliation



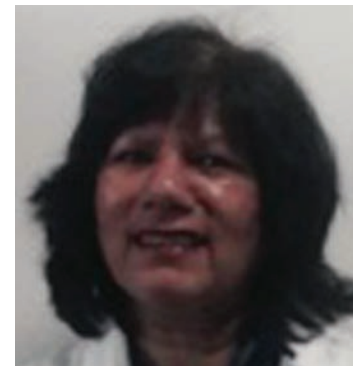
Denise Knox, BS
Supervisor, Clinical Research



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Team FOP, (A–C) from top, Lisa Gardo, BSN, Shannon Chester, BS, and Kamlesh Rai.

with the American Joint Replacement Registry (AJRR). Dr. Hume's effort in coordinating the information technology to make participation in AJRR possible should also be singularly recognized. We look forward to more fully engaging the Pennsylvania Hospital Adult Reconstruction team in research in the upcoming year.

In July of 2014 Lisa Gardo, BSN joined the Fibrodysplasia Ossificans Progressiva (FOP) research team to be the Nurse-Coordinator for the Clementia Pharmaceutical sponsored research program in FOP (Dr. Kaplan, Global PI; Dr. Pignolo, Site PI). She was joined a few months later by Shannon Chester, BS, who serves as the CRC on a series of critical multicenter international studies to test the safety and efficacy of palovarotene as an adjunct treatment for preosseous flare-ups in adults with FOP. The logistic complexity of these trials is astounding and the team has



Dexin Li, BS,
Database Administrator



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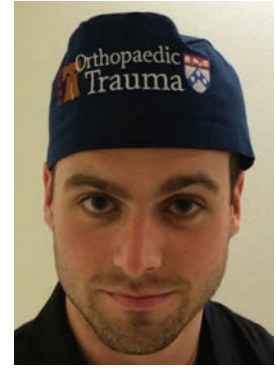
(A) Shannon Marcoon, BS Clinical Research Coordinator, Sports Medicine and (B) Ava Marie Marcoon, CRC in training.



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(A) Patrick Hesketh, BS and (B) Evan Bannister, BS, aka OrthoTraumaTeamSix

to be complimented for their diligence, attention to detail and success. In the past year, Kamlesh “Kay” Rai, who has been a long time administrative assistant to Dr. Frederick Kaplan, has also done an outstanding job of coordinating a Novartis-sponsored biomarker study in FOP patients from beginning to end and we are hopeful that the study will lead to more potential drug targets to treat this terrible disease. Kay’s devotion to the FOP community and research effort is known but deserves special acknowledgement for her work on the Novartis study.

The success of our Sports Medicine research program would not be possible without the contribution of Shannon Marcoon, BS. Shannon has been with our research team for over two years and in that time, Sports Medicine HSR has exploded. Dr. Carey has brought two significant consortia to Penn Orthopaedics. The “ROCK” group (Research in Osteo-Chondritis of the Knee) includes twelve sites in the United States and two international sites. Our site is hosting the ROCK registry which Shannon and Dexin Li, the Departmental Database Administrator, have built for this purpose. The “MOON” group (Multicenter Orthopaedic Outcomes Network) is a national consortia of sites focusing on either knee or shoulder research. Penn has multiple projects open under the MOON Shoulder banner. Dr. Kelly has also been working steadily to engage industry partners to advance the two themes of reducing operative infections and utilizing

T1Rho MRI as a tool to improve understanding of articular cartilage injury and disease. Dr. Sennett continues to be engaged in the Ivy League sponsored study of concussion in university athletes as well as the challenging Histogenics sponsored Neocart® study. Additionally, we now welcome the two newest members of our Sports Medicine research team. Dr. Milt Zgonis, who has already distinguished himself in laboratory based research,



Kara Napolitano, BS serves Upper Extremity, Foot & Ankle, Oncology research

will be joining forces with other faculty to engage in clinical research. New to the team and the world is Ms. Ava Marie Marcoon, who was born 11/15/2014. We anticipate that Ava’s training in clinical research will commence sometime after she finishes preschool. Congratulations to Shannon, and welcome Ava!

Exciting developments have been going on with Upper Extremity HSR as well as Orthopaedic Oncology and Foot & Ankle, all led by Kara Napolitano, BS. Kara joined Penn Orthopaedics in FY15 as the Upper Extremity CRC and in the past year she has become quite the generalist. Kara has been continuously engaged in Hand (NIH funded WRIST study, PI Dr. Bozentka) and Shoulder & Elbow studies, including Dr. Huffman’s work on the molecular assessment of Propionibacterium Acnes (*P. acnes*), the Auxilium-sponsored frozen shoulder study (Dr. Kelly co PI and Shannon Marcoon co-CRC), developing an industry collaboration with Dr. Glaser for the study of frozen shoulder, and managing Dr. Kuntz’s McCabe funded multimodal management of post-operative pain (MP3, Nabil Elkassabany, MD, co-PI). Additionally, Kara has been uniting the east and west sides of campus by working on the STAR study under Dr. Wapner as well as tirelessly engaging Genentech/Roche to enable us to begin an interventional study for pigmented villonodular synovitis (PVNS) under Dr. Kristy Weber. We are hoping to have Kara’s home base at the Cathcart Pavilion to enable her to continue supervising Foot & Ankle as well as solidifying the engagement of the Cathcart practice in HSR.

OrthoTraumaTeamSix@uphs.upenn.edu is no stranger to any resident rotating through Ortho Trauma. Patrick Hesketh, BS and Evan Bannister, BS will overcome almost any obstacle to ensure that enrollment goals, human subject protection, and regulatory compliance are achieved in Orthopaedic Trauma HSR. Patrick joined Ortho Trauma in December of 2013 and Evan joined shortly thereafter in May 2014. Ortho Trauma HSR has never been the same. These two CRCs are ever vigilant in watching new admissions and have demonstrated seemingly inexhaustible devotion to the program. Difficult MRI scheduling and patient follow up does not dissuade TeamSix from their duties. From early morning resident trainings to late night enrollment, Team Six lives up to their



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(A) Kim Lacy, BSN and (B) Rebekah Williams, BS and (C) Marlon Schwarz, MD, Anesthesiology & Critical Care CRCs.

name. And, as if Ortho Trauma was not busy enough, TeamSix has also been working with collaborators in Anesthesiology & Critical Care (Mark Neuman, MD and Benjamin Kohl, MD) to ensure enrollment and data capture for their studies. These

collaborations have strengthened the relationship between the two departments and hopefully will support funded multicenter studies in the near future.

It is now my pleasure to introduce our ACC partners in HSR. Kim Lacy, BSN has been a vital member of ACC research and has worked with Dr. Michael Ashburn for years at Penn Medicine Rittenhouse. In the past year, Kim, Marlon Schwarz, MD with assistance from TeamSix have been engaged in supporting Dr. Ben Kohl's study based out of the Hospital of the University of Pennsylvania (HUP) that investigates the intraoperative use of exenatide in cardiac surgery patients to prevent post-operative complications. Kim and Marlon have been extremely active in HUP-based studies. Dr. Marlon Schwarz, however, will be leaving the research team in May 2015 to join ACC as a resident. Best wishes to Dr. Schwarz and we look forward to continued research collaborations with him. The most recent addition to ACC HSR is Rebekah Williams, BS. Rebekah joined ACC in July of 2014 as a research assistant under Dr. Elkassabany and was working on the Kuntz-Elkassabany MP3 study as well as on a project for Dr. Jack Gutsche. In February 2015 Rebekah assumed a new role in ACC where she will now serve all of ACC HSR projects based out of HUP.

Thank you to all the named staff above as well as the leadership of Penn Orthopaedics and Anesthesiology & Critical Care for developing the shared resources plan for the two departments. Briefly, these include the Chairs, Drs. Levin and Fleisher, the Vice-Chairs for Research, Drs. Soslowsky and Eckenhoff as well as the Chief Operating Officers, Lori Gustave and Dennis Harris. Additional staff will be forthcoming to support this collaborative effort so look forward to ever more exciting and meaningful work in the years to come.