Editorial

Clinical Research Update

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The Human Subjects Research (HSR) program in the Department of Orthopaedic Surgery is a subset of the overall musculoskeletal research enterprise in the department. HSR differs in important ways from basic and cadaveric research. Costs and revenues in HSR can vary considerably from study budgets due to many contributing factors that include the high cost of regulatory maintenance and the clinical trial reimbursement process. Historic patient profiles do not guarantee an eligible patient population and stringent study criteria further limits enrollment. It is common for research staff at the University of Pennsylvania Health System to pre-screen hundreds to even thousands of patients before encountering a patient who not only qualifies for a particular study but who is also interested in participation. We thank our dedicated Clinical Research Coordinators and Project Managers for their dedication to improving patient care through research. We are also especially grateful to those of our patients who volunteer their participation in our numerous studies.

In the past four years, the Department of Orthopaedic Surgery has made a considerable investment in the HSR program, and the early returns suggest that our faculty will continue to grow and diversify the departmental portfolio of clinical research (Figure 1). The success of the department's HSR growing program is strengthened by the diversity of the divisions engaged in extramurally sponsored studies. A selection of these studies is shown in Table 1. Of note, there are over 120 active clinical protocols in the department, many of which involve collaborators within the department, within the institution, and at one or more institutions across the country and around the world.

Two of our clinical faculty have been selected to serve as overall study Principal Investigators for upcoming randomized clinical trials. Dr. L. Scott Levin has been selected as the national co-PI with collaborator Dr. Jason Isaacs in an upcoming study to evaluate the superiority of a peripheral nerve graft product. Dr. David Bozentka will serve as the Penn PI for this study. Dr. Frederick Kaplan has been invited by a new pharmaceutical company to be the global PI of the first ever drug trial in the treatment of Fibrodysplasia Ossificans Progressiva (FOP). Dr. Robert J. Pignolo will serve as the Penn PI on this trial. The honor of these leadership roles in clinical research can only be attributed to the renown of these two outstanding faculty. We look forward to being able to report the success of these two pending trials as well as similar recognition for our other faculty in years to come!

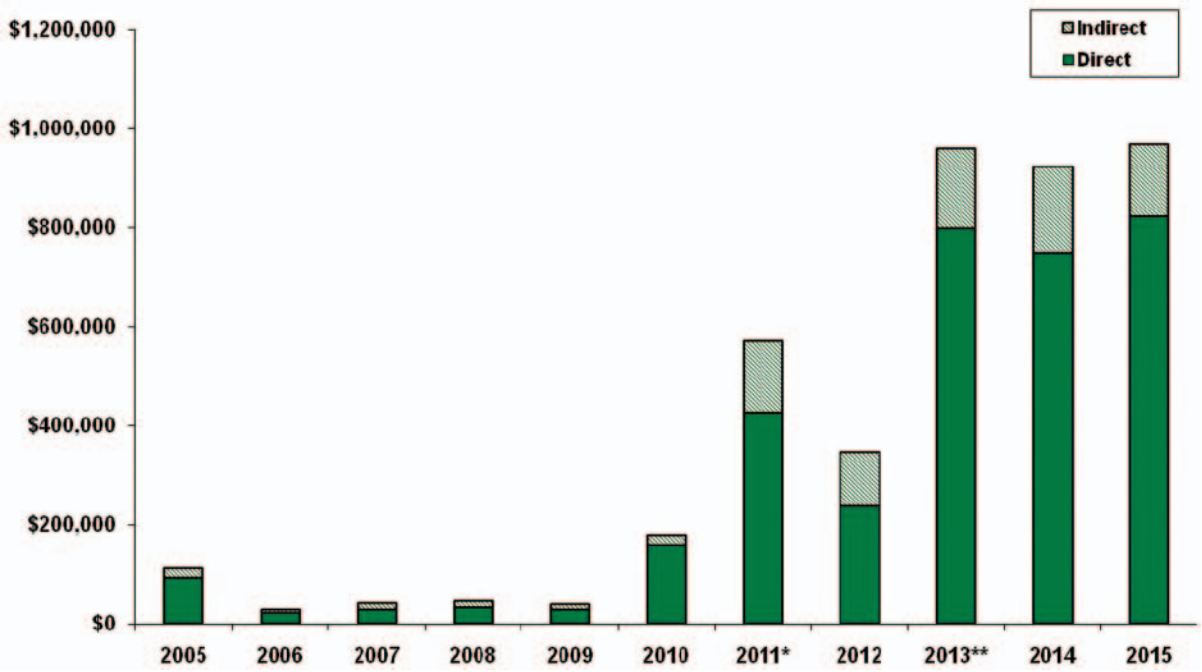

Figure 1. Clinical research revenues in the Department of Orthopaedic Surgery. (FY08-FY15). *FY11 reflects an accumulated back-payment from an industry sponsor as well as a double posting of funds from an NIH grant which ends in FY15.**FY13 information includes two DOD grants in trauma, one of which ended in FY14. Indirects for almost all activity in clinical research is lower than for basic research awards per institutional policy. In the case of federally sponsored clinical research, reduced indirect revenues are realized due to the proportion of funds required to pay other sites and contractors. Funds depicted for FY14 and FY15 are projections and may vary.

Table 1. Representative extramurally sponsored studies

Division & PI	Sponsor	Study Title
Adult Reconstruction		
Gwo-Chin Lee, MD	CD Diagnostics	Acquisition of Synovial Fluid Samples: Creating a Repository for Biomarker Research
	CEM-102 Pharmaceuticals, Inc.	An Open-Label, Multi-Center, Randomized Study to Evaluate the Safety and Efficacy of Oral Fusidic Acid (CEM-102) in Combination with Oral Rifampin for Prosthetic Joint Infection, in Comparison with Standard of Care Intravenous Antibiotic Treatment Regimens, during Two-Stage Prosthesis Exchange.
Eric Hume, MD	DePuy Orthopaedics, Inc.	PMA Post-Approval Study for Ceramax™ Ceramic Hip System
	DePuy Orthopaedics, Inc.	36mm Ceramax™ Ceramic Hip System PMA POST-APPROVAL STUDY: Short to Mid-Term Follow-up of New Study Subjects
Hand		
David Bozentka, MD	University of Michigan	A Clinical Trial for the Surgical Treatment of Distal Radius Fracture in the Elderly: Wrist and Radius Injury Surgical Trial (WRIST)
Shoulder		
G. Russell Huffman, MD and John D. Kelly IV, MD (Co-PIs)	Auxilium Pharmaceuticals, Inc.	A Randomized, Double-Blind, Placebo-Controlled Study Of The Safety And Efficacy Of Aa4500 For The Treatment Of Adhesive Capsulitis Of The Shoulder
Sports Medicine		
Brian J. Sennett, MD	Histogenics Corporation	A Randomized Comparison of NeoCart® to Microfracture for the Repair of Articular Cartilage Injuries in the Knee
Trauma		
Samir Mehta, MD	Hansjoerg Wyss Fund for Orthopaedic Genomics and Immunology*	Biomarker Identification in Fracture healing
Foot & Ankle		
Keith Wapner, MD	Small Bone Innovations	2-Year Post-Approval Study To Investigate The Star Ankle Under Actual Conditions Of Use

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