

NEW CHAIRMAN OF SURGERY JOINS YALE



Robert Udelsman, MD, MBA, FACS, has been appointed as Chairman, Department of Surgery at Yale, and Chief of the Surgery Service of Yale New-

Haven Hospital. Dr Udelsman is a graduate of George Washington University School of Medicine. He completed his general surgery training at Johns Hopkins Hospital, Baltimore, MD, and The John Radcliffe Hospital, Oxford, England. Dr. Udelsman has also completed fellowships in surgical oncology at the National Cancer Institute, endocrinology at the National Institute of Child Health and Human Development and gastrointestinal surgery at Johns Hopkins Hospital. Dr. Udelsman spent the last twenty years at Hopkins, most recently as the Professor of Surgery and Oncology and Director, Division of Endocrine and Oncologic Surgery.

Dr. Udelsman has made significant contributions in the basic as well as clinical sciences. He is also the recipient of _____ over, please

YSM TO REQUIRE DATA AND SAFETY MONITORING PLANS FOR CLINICAL RESEARCH

For some time, the National Institutes of Health (NIH) has required the inclusion of data and safety monitoring plans (DSMP) in clinical trial protocols. The YSM Human Investigation Committee (HIC) will now require DSMP for all new clinical research studies in which there are interventions with human subjects or their specimens.

A DSMP is the process by which out- _____ over, please

OPHTHALMOLOGY AND REIMBURSEMENT TEAM UP FOR SUCCESS

Teamwork is an important secret to success. In healthcare today, this is definitely true when physicians and clinical practice specialists (CPS) collaborate to increase reimbursement and decrease rejections. CPS staff, certified by the American Academy of Professional Coders, can help physicians achieve departmental business goals and minimize time spent on billing problems through education and collaboration.

Sally Berardinelli, Director, Reimbursement, Patient Financial Services, states, "our job is to find, fix and prevent problems that work against producing a clean claim. Our goal is to maximize the number of properly paid claims the first time through the system. Working with insurance carriers, clinical departments, and physicians we are able to learn where the process is breaking down and bring the appropriate people together to resolve the problem."

One team achieving tremendous success came out of the broader collaboration between Ophthalmology and YMG and consists of **Dr. George Shafranov** and **Christine Hoyt, CPC**, Patient Financial Services. Christine explains, "I work with three departments: OB, Ophthalmology and Orthopaedics. This enables me to build a working relationship with my counterparts in each section, as well as develop an in-depth knowledge about clinical procedures as they relate to payer billing codes for these specialties." Christine's working methods vary to suit the preferences in each department. In Dr. Shafranov's case it started as weekly in-office meetings.

Dr. Shafranov recalls, "I knew very little about diagnosis and procedure coding, bundling and unbundling, and payer requirements, when I first started collaborating with Christine. I saw the billing system as complicated and realized the physician loses control at the very beginning of the process – at the encounter form. I bought a couple of coding and billing books, and sat down with the books, long rejection reports and Christine." Together Dr. Shafranov and Christine identified problems throughout the process – on the encounter form, entering data, system problems, and payer problems. Dr. Shafranov adds, "I learned to use the IDX system and each week I check the IDX information, look for patterns, and pay attention to specific reimbursement codes. When I need help with a complex problem, I e-mail Christine who promptly responds. I am highly confident that I am now billing at the proper level and being reimbursed as much as possible." Christine independently analyzes the rejection reports, looks for trends, knows the people and the process, understands what is and isn't right for ophthalmology, and identifies when it's a system problem versus a people problem.

Christine also builds working relationships with representatives of the various payers, the contracting department, the PFS teams, the credentialing department and the compliance department. Christine follows through with each and shares resolutions with Dr. Shafranov.

The speed and efficiency with which Christine and Dr. Shafranov resolve billing problems took an investment of time and effort, but the results speak for themselves.



DR. GEORGE SHAFRANOV AND CHRISTINE HOYT

DR. UDELSMAN (CONTINUED)
numerous

honors and awards. His major areas of interest are endocrine physiology and surgical oncology. Dr. Udelsman specializes in endocrine surgery, where he has introduced innovative and minimally invasive techniques for the treatment of thyroid, parathyroid and adrenal disorders.

To contact Dr Udelsman, call 785-2697. Please join us in welcoming Dr. Udelsman to Yale.

CALL FOR ART

AT THE YALE
PHYSICIANS
BUILDING
ART PLACE

The fourth in a series of exhibits is planned for the Yale Physicians Building Art Place in September 2001. Artists from the university and medical center communities, are invited to submit their work for consideration. Artists must complete an application and submit a portfolio of work by **August 9th**. For an application or more information, contact Linda Borer at 785-5144 or linda.borer@yale.edu.

DATA & SAFETY MONITORING (CONTINUED)

come data is reviewed for groups of patients to determine if the intervention(s) should be altered or stopped.

A study PI is responsible for ensuring that a clinical research protocol includes a DSMP and procedures for its implementation. At a minimum a plan should include the definition of adverse events (AE) by both a grading and attribution scale, a plan for reporting anticipated and unanticipated AEs and a plan for whom and at what frequency a safety review will be conducted.

The YSM HIC will review plans relative to level of risk. The approving body for the DSMP may be a funding agency or a YSM committee such as the GCRC Medical Advisory Committee or the Cancer Center Protocol Review Committee. Executive Director of the Office of Grants & Contracts, **Penny Cook**, states, "there is no simple formula for how a plan should be constructed. The elements will vary depending on the potential risks, the complexity, and the nature of the trial."

A minimal risk protocol might only require monitoring by the PI with annual review by the HIC. A Phase II study, where more participants are involved and the disease process may confound the toxicity and outcomes, a more complex plan might be in order drawing on additional individuals with relevant expertise.

Depending upon the nature and potential hazards of the intervention and the procedures, this group might be a formally constituted independent Data Safety Monitoring Board (DSMB). If the participants are from a particularly vulnerable group, such as children, or have a life-threatening condition, a formal DSMB must be strongly considered.

Phase III and multi-center trials require the establishment of an external DSMB. Separate guidance is required for clinical protocols involving gene transfer. A Recombinant DNA Advisory Committee has been established at Yale University to monitor and approve all such protocols and any of the on-campus laboratory facilities that are involved.

For further details outlining criteria for the plans and how they will be assessed, contact staff within the HIC, GCRC, Cancer Center Clinical Trials Office, or Grants and Contracts Administration for assistance.

SAVE THE DATES

July 30th and August 27th are recycle days at the YPB. Pickup will include electronics, usable furniture and other discarded but usable items, e.g. computers.

Call 5-5144 for details.

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THE PHYSICIANS OF YALE UNIVERSITY