

Promoting the Rights and Safety of Research Participants

An Interview with Research Subject Advocate Cathleen Acres



Cathleen A. Acres, R.N., M.A., recently met with Focus to discuss her role as a Research Subject Advocate (RSA) at the Medical Center's General Clinical Research Center (GCRC). A member of the Division of Medical Ethics since 2001, Ms. Acres,

along with RSA Juan J. Cordero, M.D., works with investigators and GCRC staff to promote the safety and rights of research participants at the GCRC and oversees approximately 150 active protocols in this capacity. The following is an edited version of Ms. Acres's conversation with Focus.

What is the General Clinical Research Center (GCRC)?

The NIH-supported Weill Cornell General Clinical Research Center was founded in 1961. Like the other 80-odd Centers in the country, it provides resources, infrastructure and staff for investigators who are engaged in patient-oriented clinical research. The Center currently provides support for quite a wide range of human subject studies including those related to hematology-oncology, infectious diseases, endocrinology, transplant surgery, neurobiology, behavior and gene transfer. In order to receive GCRC support, investigators must submit the study's protocol for review and approval of both the GCRC Scientific Advisory Committee (SAC) and the Institutional Review Board (IRB).

Discuss your role as a Research Subject Advocate (RSA).

In response to the series of well-publicized deaths of research subjects at major academic medical centers, the NIH in 2001 mandated that every Clinical Research Center must have an RSA who would report directly to the Dean of the College. The overall objective was to regain the public's trust in the human subjects research enterprise by providing another layer of oversight by someone who would advocate for the rights and safety of participants. I share the RSA position with Dr. Juan Cordero, an experienced clinical researcher. We have, in a sense, joined forces to integrate his experience with clinical research and my expertise in medical ethics and advocacy.

RSAs have defined their roles in different ways, depending on the needs and culture of their respective institutions and their own areas of expertise. Dr. Cordero and I review all protocols submitted to SAC, paying particular attention to the safety monitoring plans and the content of consent forms. We report our findings to SAC members, and to the IRB when necessary. We also provide ongoing education and advice to investigators and GCRC staff regarding regulatory compliance and research ethics.

The RSA serves the research subject in several ways. 1) We provide information about research in general and about the particular study in which the subject may be participating 2) serve as an objective witness in the informed consent process should the patient request it, and 3) discuss and address the patient's questions, concerns or complaints regarding their

rights and safety as a research participant. We are in the process of initiating a program to observe consent discussions between investigators and potential subjects as an educational resource for the investigators, and as a way to make sure subjects get all the right information and have opportunities to ask questions.

What is the toughest aspect of your job?

Although everyone recognizes and supports the concept of safe and ethical research, RSAs – like IRBs – may be perceived by some as impediments to progress. And there is an element of "change agent" implicit in this role, which although part of the appeal, is at times difficult and frustrating. Across the country, the medical, research and ethics communities are grappling with many dilemmas, including the limits of truth-telling and disclosure, the ethics of conducting high-risk studies on subjects who cannot consent for themselves, and investigator and institutional conflicts of interest.

What is the most rewarding part of your job?

Like so many people, particularly in health care, I need to feel that my work in some way contributes to making life better for others. The interests of research participants need to be represented by people on the "inside." Although they take all the risks, the balance of power and knowledge and the promise of fame and fortune are not on their side. I am enjoying the challenges of advocacy and the opportunity to work as part of a team in this endeavor. ❖

Recent Department Site Visits

Site visits offer external checks and balances that ensure our educational programs and outreach clinics maintain the highest standards set out by accrediting agencies and that our research is competitive and innovative enough to obtain and maintain funding. The following is a recap of our recent site visits.

- **Dec. 2003:** Adult and Adolescent Methadone Clinics undergo JCAHO survey. Both clinics pass with scores of 98.
- **Feb. 2004:** Division of Prevention and Health Behavior undergoes extensive NIDA site visit to renew funding for its NIDA-funded center grant.
- **May 2004:** ACGME conducts site visit of the Residency in Addiction Psychiatry to review its accreditation — a standard procedure for all ACGME-accredited programs.

Issue 3, Summer 2004

feature story

Our EAPs Provide Essential Service to NYC's Workers

A Word from the Chairman...

I would like to take a moment to highlight some of our recent activities, many of which enhance the collegial and collaborative environment of our Institution and the Department of Public Health.

On Jan. 28, the Department held its first-ever Faculty Retreat. Full-time faculty gathered at the Cornell Club in Manhattan to discuss and revise the Department's strategic plan and to share ideas for the future. The Retreat was a success due to our faculty's teamwork and forthright discussions.

Over the past six months, the Department was awarded more than \$4 million in grants. Twenty percent of these projects are being conducted on a collaborative basis within the Department or with our colleagues at Ithaca and other institutions. The future looks bright as we continue to pursue innovative areas of research.

This spring we hosted several exciting visits from the Ithaca campus to explore collaborative opportunities. These included Dr. Daniel Harris, Director of the Institute for Social Sciences, Dr. Susanne Bruyere, Director, Employment and Disability Institute at the School of Labor and Industrial Relations, and Dr. Will White, Director of the Sloan Program in Hospital Administration.

On a final note, our 2001-2003 Bi-Annual Report was published in April. You may access the report on the Public Health website or contact my office to receive a copy.

Much has happened since we published the last issue of Focus and I hope you will enjoy reading about our talented faculty and staff and their activities.

Alvin I. Mushlin, M.D., Sc.M.

Employee Assistance Programs (EAP) have been in existence since the 1940s when employers became concerned with absenteeism and a lack of productivity assumed to be due to alcohol abuse following WWII. EAPs hit their stride in the 1970s when EAP services became more broad brush as it was recognized that there were other problems affecting employees aside from substance abuse, such as mental, legal and family issues. The number of companies implementing these programs increased significantly due to the business community understanding that many everyday life stressors can negatively impact an employee's ability to perform well on the job. In addition, unions began offering Member-



"The prevention aspect of the job is extremely rewarding. We are able to help people before they lose their jobs." - Dr. Austrian

ship Assistance Programs (MAP) to their members, which provided services similar to EAPs. Today, the Department of Public Health runs two EAPs: the Employee Assistance Program Consortium (EAPC), directed by Sonia G. Austrian, D.S.W., and the Employee Development Center (EDC), led by Jeffrey Emil Diaz. The EAPC was founded in 1980 by Community and Public Health Programs Division Chief Robert B. Millman, M.D., who saw the need for an EAP at the Medical Center. Because EAPs are considered an employee benefit, the EAPC was formed as a consortium with other area institutions in order to relieve some of the financial burden of providing this free, confidential service to employees and

their dependants. "As early as the 1980s, the EAPC offered wellness and preventative programs such as planning for the care of an elderly parent," said Mr. Diaz. "People who attended our programs were surprised to see physicians participating. Whether you work in the mailroom or the laboratory, the problems we as working people face are universal. Even back then, we were way ahead of the curve with regard to the types of programs offered."

The current EAPC comprises Weill Medical College of Cornell University, NewYork-Presbyterian Hospital, the Hospital for Special Surgery, Memorial Sloan-Kettering Cancer Center and Rockefeller University. All services are free and confidential and include assistance with emotional problems such as depression, anxiety and loss; relationship or interpersonal issues; family problems such as single parenting, domestic violence, and marital conflicts; substance abuse;

and job or school performance, to name a few. From time to time, the EAPC offers group workshops on such topics as being a new parent, stress management, and communication skills. "The prevention aspect of the job is extremely rewarding," said Dr. Austrian. "We are able to help people before they lose their jobs – whether problems at home are affecting their job performance or they are struggling with substance abuse."

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Qatar Medical Ethics Program Off to Promising Start

The ethical aspect of medicine is an ever-present consideration no matter what country physicians are practicing in. With the opening of its Qatar campus, the Medical College faced the unique challenge of adapting the American version of its Medical Ethics curriculum to suit a predominantly Middle Eastern student body. Preparing students in this increasingly critical area of study, while addressing how religion and culture may affect the manner in which bioethical issues are addressed in that region, was a top priority.

Pablo Rodriguez del Pozo, M.D., J.D., Ph.D., was recruited to lead this effort last year. A native of Argentina who has studied and taught in Europe, Latin America and the U.S., Dr. del Pozo was chosen to triangulate between the sometimes clashing cultures of America and the Middle East. In October, following three months of intensive training, he moved to Qatar to begin the first stage of the curriculum development. "We wanted to prepare students for the medical school curriculum, which includes medical ethics," Dr. del Pozo explained. "However, in many ways modern medicine is a Western product, as are the ethics that have been developed in conjunction with it. It was necessary for us to bridge the cultural gap in order to help our students understand and put into context the kind of medicine and implicit values that inform that medicine. Most importantly, we sought to foster among students the development of their own set of values according

to their individual cultures and traditions to deal with the human side of medicine. This will allow them to render a real service to future patients in the region."

With the guidance of Division Chief Joseph Fins, M.D., F.A.C.P., and the help of other members of the Division of Medical Ethics, Dr. del Pozo created a second-year, pre-med course. *Medical Ethics: An Introduction to Medical Humanities* was designed to introduce students to the theory of medicine and clinical ethics, and to put them on the same



Dr. Pablo Rodriguez del Pozo

educational footing as their fellow pre-med students entering the New York campus of Weill Medical College. Through discussions and readings that included such classics as Kafka's *The Metamorphosis*, Hippocrates's *Oath*, *Physician*, *Decorum*, *Epidemics* and *Aphorisms*, and Sophocles's *Antigone*, the seven-week course exposed students to the humanistic issues they will face as doctors. A different thematic area was covered each week: Biology and Nature, the Patient, the

Family, the Doctor, the Hospital and other Healthcare Systems, Resource Allocation in Healthcare, and the Law and Medicine.

"At the end of the course, students had a very integrative vision of the nuclei of moral conflict found in medicine," said Dr. del Pozo. "For me, this was a refreshing experience because I had the opportunity to go back to the basics of medical ethics issues. However, the most fulfilling part was watching the students' growth and maturation. It was fascinating to see how most students changed over the two months I taught this course. Their discussions and reactions to the readings became more and more accurate and insightful. This transformation is epitomized by a student who commented on Kafka's masterpiece *The Metamorphosis*: 'When I first read the book, I thought it was a piece of poorly written fiction. But after the discussion, I understood that it deals with how families are affected by one member's illness.'"

Dr. del Pozo will be in Qatar for at least three years. During that time he will implement the complete second- and third-year Medical Ethics curriculum, as well as gain a greater understanding of the local laws and traditions that will affect students once they become practicing physicians. Dr. del Pozo will also help implement institutional requirements to comply with the ethical standards of research carried out by Weill Medical College in Qatar. ❖

Research Data Specialists Play Key Role in Successful Outcomes Research

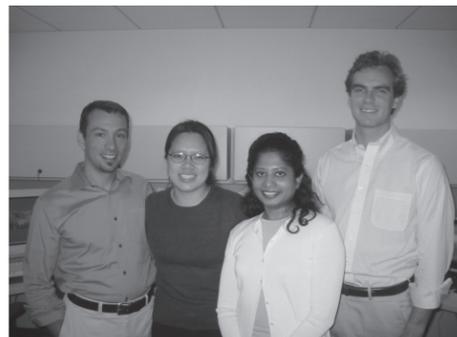
The Outcomes Division's research centers on determining ways to increase the efficiency and effectiveness of healthcare delivery. Many of our successful faculty researchers work closely with skilled research data specialists who provide an important service to the research team: outcomes data collection, analysis and modeling. Computer programs such as Excel, Access, SAS and DataPro are some of the most commonly used tools for data modeling and analysis.

Kristof Neukermans, who joined the Department in December, works with Drs. Nathaniel Hupert and Bruce Schackman. Mr. Neuker-

mans earned his degree in molecular biology and also studied economics – it was the modeling work and theoretical aspect of those two disciplines he particularly enjoyed. His current projects include examining how to best model hospital capacity in the event of a bioterrorist attack and creating a model for the treatment of syphilis in Haiti. For Dr. Schackman's syphilis study, Mr. Neukermans uses U.S. historical data and data collected from trials currently being conducted in Haiti. "One challenge with building models is pulling everything together," he said. "Mod-

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staff focus



(l-r) Paul Teixeira, Huong Do, Mary Koshy and Kristof Neukermans

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Dr. Austrian joined the EAPC as director in 1991. She developed an internship program, which is now the top choice for social work students from Columbia for their second-year placement. "Having six to eight students placed here each year makes an incredible difference because we're able to treat clients on a longer-term basis than we could on our own." The EAPC has two full-time counselors and treats approximately 600 individuals per year. "We are an important resource for employees, but many don't even know what we offer," said Dr. Austrian. "This is something I'd like to see change. I want to get the word out about the EAPC and see even more employees utilizing our services."

The Employee Development Center was created after members of the EAPC were approached by various outside organizations who heard about the Consortium and were interested in having the EAPC provide those same services to their employees. Mr. Diaz, who was one of the original EAPC counselors, was named director of the EDC and has held that position for 20 years. Among its many programs, the EDC offers marital and substance abuse counseling, childcare/elder-care planning through its Life Points program, organizational development, management training, help with legal and financial issues, and alternative wellness programs.

Research Data Specialists, continued

els are so theoretical that it can be difficult to make them work with the information that you have, which can be limited."

A member of the Department since July 2003, Mary Koshy, M.P.A., works with Dr. Hupert on his Bioterrorism Task Orders and U.S. Health Systems Epidemic Response capacity grant. She is also involved in a project with Dr. Hupert and Maryelena Vargas, R.N., that examines the role of treatment variations in diabetic foot ulcer outcomes. "This study is very interesting because I am using TSI, the Hospital's clinical and cost accounting information system, for outcomes research," said Ms. Koshy. Originally a senior financial analyst at the Hospital, Ms. Koshy became interested in outcomes and increasing quality through process improvement – and the Outcomes Division seemed the perfect place to gain that experience.

Paul Teixeira, M.P.H., has been working with Dr. Schackman for two years on a project

"It's important for working people to have access to these resources because so much of our life is spent in the workplace," said Mr. Diaz. In addition to improving the well-being of their employees, companies that offer EAPs are seen as more desirable to potential hires. The EDC's 60-plus pool of clients ranges from leading New York City corporations to



Nawan Bailey

non-profit organizations like the Wildlife Conservation Society, which runs the Bronx Zoo. "I love my job because we work with such a diverse group of clients and I never know what sort of issues I'll be handling when I walk in the door each day," said Mr. Diaz.

EDC Senior Counselor Nawan Bailey, M.S., one of four counselors on staff, has been on board for seven years. Born in Trinidad, Mr. Bailey is fluent in French and Japanese. He has lived in Japan, where he was employed as a translator and teacher. Mr. Bailey's multi-cultural background and his experience studying international social welfare policy as an intern at the United

Nations, give him a unique insight into the problems of the EDC's many international clients. A proponent of alternative wellness programs, Mr. Bailey has led programs in office yoga, healthy eating and alternative healing. Day-to-day, he focuses on counseling clients, while also supervising the interns and directing the in-services for staff and interns. "One of the toughest aspects of my job is working with clients who have been through significant trauma and abuse," said Mr. Bailey. "But working with these same clients is also very rewarding because I am helping them through their problems."

Both the EAPC and EDC offer internships, which enable the EAPs to keep costs down while employing highly motivated, energetic individuals who bring fresh ideas and enthusiasm to the programs. These internships are among the most sought after in New York City for students studying social work.

For more information about the EAPC or EDC, visit their respective websites:

www.eapc.us / www.edcworks.com. ❖

studying patients' attitudes and preferences toward hepatitis C treatment. Mr. Teixeira helped create a patient survey instrument to measure patient attitudes and preferences. Over the past year, he has interviewed over 100 patients at nine clinics throughout the NewYork-Presbyterian Healthcare system. "I enjoy the interaction with patients," said Mr. Teixeira, who previously worked as a patient interviewer at an HIV clinic. "People really connect when you ask them questions about themselves and many are proud of their contribution to our study." Mr. Teixeira is a Dr.P.H. candidate at Columbia whose dissertation will focus on HIV prevention. "The skills I'm learning here will be directly applicable to my doctoral study."

Huong Do, who recently earned a master's in statistics from Columbia, has always had a fondness for challenging data analysis. She spends half her time performing data management for Dr. Heather Gold's projects, in-

cluding a study that examines the disparities in radiotherapy for patients with ductal carcinoma in situ, an early form of breast cancer. A member of the Department since September, Ms. Do also works with Drs. Mark Callahan and Debra Quinn on their beta-blocker study, managing data and conducting statistical analysis. In addition, she is building the database for Dr. Callahan's electronic ICU decision support project. "It's rewarding and educational to work on a project from the early stages to the very end – to know what's going on at every stage," said Ms. Do. "This will be especially important for me as I look to becoming a P.I. [principal investigator] one day."

"It's exciting to know that the work you're doing has a direct impact on healthcare delivery," said Mr. Neukermans – which is the prevailing sentiment of this talented group. ❖