



Center for Clinical and Translational Science e-NEWSLETTER

Center News

\$15 million Gift from Helmsley Trust to Fund Research on Digestive Diseases

By Zach Veilleux

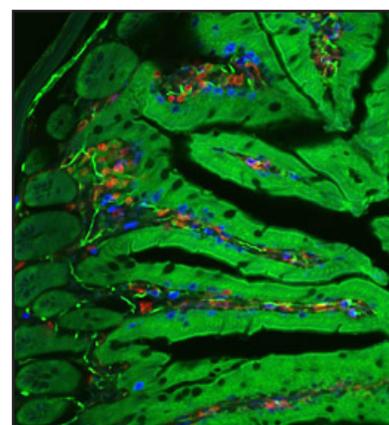
The Rockefeller University has received a \$15 million gift from the Leona M. and Harry B. Helmsley Charitable Trust to fund research into digestive disorders including metabolic diseases, cancers and infections, university officials announced today. The funds will establish a new center, to be known as the Center for Basic and Translational Research on Disorders of the Digestive System, which will support interdisciplinary basic research and foster collaborations among some 20 Rockefeller labs that study biological processes related to the digestive system. The center will also encourage clinically oriented studies centered in The Rockefeller University Hospital.

Conditions under study in the new center will include inflammatory bowel disorders such as Crohn's disease and colitis; obesity and metabolic disease; celiac disease; and many types of cancer, notably GISTs (gastrointestinal stromal tumors) and colorectal, liver, and pancreatic cancer.

"Diseases that affect the digestive system are among the most prevalent health problems in the world today, but little is known about the fundamental causes and basic biology of these conditions," says Marc Tessier-Lavigne, the university's president. "The grant from the Helmsley Trust will allow us to bring together faculty for intensive interdisciplinary collaboration that will pave the way for new treatments for a broad range of disorders."

"Major progress in the medical management of digestive disorders depends on large-scale efforts that integrate basic biological investigations and clinical studies," says Barry S. Collier, the university's vice president for medical affairs and the physician-in-chief of The Rockefeller University Hospital, who has been named founding director of the Center. "Rockefeller's new center will be an enormous help in this regard. It will advance the work of

scientists doing basic research related to the digestive system as well as those faculty members who want to accelerate the translation of their discoveries from the laboratory bench to the patient's



A segment of small intestines from a mouse is infected with bacteria used as a model for human colitis. Colitis is one several digestive diseases under study at Rockefeller that will receive new funding from the Helmsley Trust. (Image from the Mucida Lab.)

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AAHRPP Invites Center to "Showcase" its Navigation Program at its Annual Meeting

By Michelle Romanick

In March, 2011, The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) announced that The Rockefeller University had been awarded Full Accreditation by the Council on Accreditation. AAHRPP's accreditation program is the field's primary vehicle for setting uniform, high standards across the research enterprise -in both the private and non-profit sectors. Accreditation indicates that the institution's human subject protection plan demonstrated its commitment to protect research participants and its ability to deliver on that promise. According to the AAHRPP, "When an organization earns accreditation, the global benchmark for human research protection is raised."

In January, 2012, AAHRPP informed us that Rockefeller University was one of the few organizations accredited in the last year to earn the honor of meeting Element I.1.F. with "distinction" from the AAHRPP Council on Accreditation. This element is, "The Organization has and follows written policies and procedures for reviewing the scientific or scholarly validity of a proposed research study. Such procedures are coordinated with the ethics review process."

In citing Rockefeller University for this distinction, AAHRPP indicated that the University's Center for Clinical and Translational Science Research Navigation Process was a crucial element as was the University's

Announcements

National Center for Research Resources (NCRR) is now the National Center for Advancing Translational Sciences (NCATS).

How do we cite NCATS?

This winter The National Institutes of Health (NIH) established a new center called the National Center for Advancing Translational Sciences (NCATS). The development of this new center has realigned existing NIH programs and CTSA awards are now supported by NCATS. Since the CTSA was originally awarded by the National Center for Research Resources (NCRR) when acknowledging CTSA support in publications, manuscripts, projects and abstracts please use the following language: "Supported in part by grant UL1 TR000043 from the National Center for Research Resources (NCRR) and the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health."

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Four Clinical Scholars Scheduled to Receive Masters' Degrees

Pending approval by the University's Board of Trustees, four Clinical Scholars are scheduled to receive Masters' of Clinical and Translational Science degrees in June 2012. A dinner celebrating the Scholars and their mentors is scheduled for June 7, 2012. A list of the Scholars, and their mentors, research titles, and future plans follows:



[Dr. Niroshana Anandasabapathy](#)

Mentor: Dr. Ralph Steinman

Potentiating Cutaneous and Subcutaneous Immunity with Flt3L

Dr. Anandasabapathy is considering several Assistant Professor offers by major academic medical centers.



[Dr. Jennifer Belasco](#)

Mentor: Dr. James Krueger

Characterizing Skin and Joint Tissue in Psoriatic Arthritis

Dr. Belasco received an Arthritis Foundation grant and will continue her studies in Dr. Krueger's laboratory as an Instructor in Clinical Investigation.



[Dr. Iddo Ben-Dov](#)

Mentor: Dr. Thomas Tuschl

microRNA as Biomarkers in Autosomal Dominant Polycystic Kidney Disease

Dr. Ben-Dov has accepted a faculty position as an Attending Nephrologist and Associate Professor of Medicine at the Hadassah-Hebrew University Medical Center in Jerusalem.



[Dr. Dana Orange](#)

Mentor: Dr. Robert Darnell

Basic and Clinical Insights Into the Regulation of Cellular Autoimmunity

Dr. Orange received an Arthritis Foundation grant and will continue her studies in Dr. Robert Darnell's laboratory as an Instructor in Clinical Investigation.

\$15 million Gift from Helmsley Trust to Fund Research on Digestive Diseases

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bedside through disease-focused studies in our hospital. We believe that the Center will be a springboard for the development of new diagnostic tools, therapeutics, and preventive measures for digestive disease."

In addition to supporting laboratories working in the fields of immunology, microbiology, cancer biology, and metabolic disease, the new center will help fund the training of Ph.D. students, postdoctoral researchers, and physician-scientists, and provide seed funding for early phase projects involving promising new paths to discovery. The center will also sponsor seminars, symposia and retreats, and provide support for the purchase of essential shared equipment.

"We are thrilled about this grant," says John Codey, one of four trustees of the Helmsley Charitable Trust. "Some of the most interesting problems in science are found at the intersections of disciplines, and the best way to solve them is through collaboration. Rockefeller University is known for its interdisciplinary and cooperative approach to science, its bold and innovative research, and the extraordinarily high caliber of its faculty. Rockefeller is the ideal environment for a concerted effort to understand the digestive system and find answers to some of the most critical health-related problems of the 21st century."

The Leona M. and Harry B. Helmsley Charitable Trust aspires to improve

lives by supporting effective nonprofits in health and medical research, social services, education and conservation. Established in 1999, it is administered by four trustees selected by Leona Helmsley and supports a diverse range of organizations. It has committed more than \$540 million in grants to charitable organizations since 2008.

Faculty slated to participate in the new center include one recipient of the Albert Lasker Basic Medical Research Award, seven members of the U.S. National Academy of Sciences, and five members of the Academy's Institute of Medicine.

AAHRPP Invites Center to "Showcase" its Navigation Program at its Annual Meeting

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"robust mechanism for scientific review of all human participant research." The Research Navigation Process is a comprehensive process that assists researchers in designing a clinical research protocol. The Research Facilitation Office, led by Ms. Brassil, developed the process. Although, initially focused on Clinical Scholars, the program expanded to include basic scientists beginning to develop clinical research projects and experienced clinical investigators who would benefit from expert multidisciplinary input into the development of their protocols.

The goal of Navigation is to facilitate the rapid development of an outstanding scientific protocol that:

- 1) addresses an important aspect of human biology and/or health
- 2) incorporates the highest standard of human subject protection
- 3) meets all of the bioethical, regulatory, and biostatistical requirements of Good Clinical Practice
- 4) meets the standards for participant safety of the Rockefeller University Hospital medical and nursing leadership; and
- 5) is highly likely to be approved by both the Advisory Committee and on Clinical and Translational Science (ACCTS) and the Rockefeller University IRB at the time of its first submission.

To accomplish this goal, the Navigator works closely with the investigator to refine the protocol by enlisting expert consultants, as needed, in the fields of scientific validity, study design, study plan formulation, research nursing, research pharmacy, regulatory guidance, biostatistics, bionutrition, bioinformatics, clinical medicine, contract negotiation, technology transfer, and protection of human subjects. This expertise is called on by the Navigator in the most efficient manner, varying from one-on-one meetings to small group meetings, to full multidisciplinary Navigation meetings tailored to the needs of the individual protocol.

Throughout the process, the investigator is

informally educated about GCP standards and other regulations involving human subject protection. After establishing the initial feasibility of a study, the ongoing needs assessment process continues throughout the process to insure the development of an optimal protocol.

In recognizing Rockefeller's achievement and to showcase the Rockefeller Navigation process and acknowledge its contribution to achieving the highest standards for human research protection, AAHRPP formally invited Rockefeller to present the Navigation process at the upcoming AHRPP Annual Conference in Denver, CO on April 19, 2012.



Arlene Hurley, Veronica Whalen, Jorge Ortiz,
Kathleen Dowd, and Donna Brassil
The Clinical and Translational Research Facilitation Office

Meet the Scholar: Niroshana Anandasabapathy, MD, PhD

By Michelle Romanick



Niroshana Anandasabapathy, MD, PhD

Dr. Niroshana (Niro) Anandasabapathy is the recipient of The Skin Cancer Foundation 2012 Research Award. The Foundation funds basic research and clinical studies to improve methods of prevention, detection, and treatment of skin cancer. Dr. Anandasabapathy also received the 2012 American Academy of Dermatology (AAD) Young Investigators Award. The AAD Awards recognize outstanding research by dermatologists-in-training in the United States and Canada, and the educational institutions that support their efforts. The purpose of the award is to acknowledge and support research that improves diagnosis and therapy in the practice and science of dermatology. Dr. Anandasabapathy has also been selected to serve as Associate Scientific Advisor for Science Translation Medicine, Science's sister journal.

Her first commentary was published on February 29th 2012.

Dr. Anandasabapathy began as a Clinical Scholar in 2009 in Dr. Ralph M. Steinman's Laboratory with the goal of studying the immune basis for cutaneous autoimmune diseases, skin cancers, and vaccine priming through the skin. She received her MD and PhD from Stanford University School of Medicine. Dr. Anandasabapathy completed her dermatology residency at New York University, focusing on cutaneous immunity and the intersection between autoimmune disease, cancer, and infectious disease.

Dr. Anandasabapathy has successfully competed for CCTS Pilot Project awards for the past three years and received project support from the Dermatology Foundation for the past two years. Her Pilot Project for 2012 is the Use Of Flt3L to Help Phenotype and Characterize Human Cross-Presenting Dendritic Cells In Vivo. This project will help to develop effective approaches to vaccine design based on fundamental principles of immune memory, which include targeting vaccine antigens to specialized dendritic cell subsets.

When asked to describe her experience in

the Clinical Scholars Program, she stated, "I am hugely grateful for the opportunity to have interacted with leaders in clinical investigation and translation, such as Drs. Collier and Steinman and to gain mentors such as Dr. Krueger and Nussenzweig. Their expertise spanning a range of topics on ethics, the regulatory process, health policy, basic and translational immunology, and clinical investigation has allowed me to move my work from the pre-clinical arena in animal models into Phase I drug development for people. This is hugely gratifying. The other major benefit of the program are seasoned faculty such as Dr. Schlesinger and additional senior scholars transitioning from K awards to R awards, such as Drs. Caskey, Renwick, and Lowes. Through their guidance it was possible to garner peer-review and hands-on practical advice. This allowed better navigation of the IRB application process, NIH review process, and daily life as a researcher outside of standard clinical routes."

Dr. Anandasabapathy is scheduled to receive a Master's degree in Clinical and Translational Research in June 2012. Her next career step after completing a Phase I clinical trial will be to initiate her own research program and laboratory group while treating patients in the clinic.

Streamlining the Medical Staff Reappointment Process

By Kevin Johnson

Renewing one's medical staff appointment is not a task most people look forward to, but Kevin Johnson, Medical Staff Services Coordinator, has worked hard to take some of the pain out of the process. The seven page reappointment packet is no longer mailed to the home or office; instead, it is emailed to each member of the medical staff who is up for reappointment. This saves time, postage, and paper. Kevin used Crystal Reports software to customize the reappointment application.

Information stored in the CACTUS credentialing database can now be imported into the reappointment application. Individuals can easily update and edit the pre-populated information and complete and submit it electronically.

Many of the changes came from recommendations from the members

of the medical staff involved in the reappointment process and, so far, feedback on the upgrade has been positive.

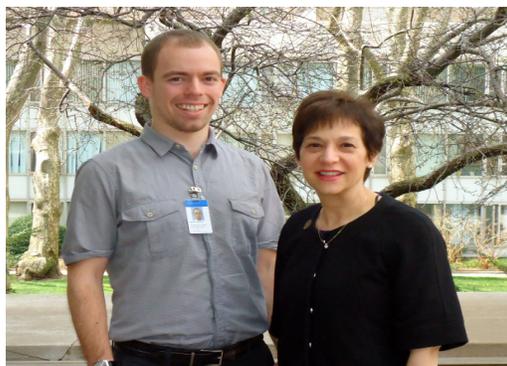
Comments from satisfied customers include:

"I do like this format, it is much easier to complete than in prior years"

"Nice work in organizing this"

"The prepopulated form was fantastic; it was very easy and efficient"

The Medical Staff Services is constantly looking for ways to improve the initial appointment process and welcomes your suggestions. Please forward comments and suggestions to Kevin Johnson at kjohnson@rockefeller.edu.



Kevin Johnson and Cynthia Seidman
Medical Staff Services

Clinical Scholar Dr. Daniel Gareau Merges Physics and Medicine for CUNY Undergraduates

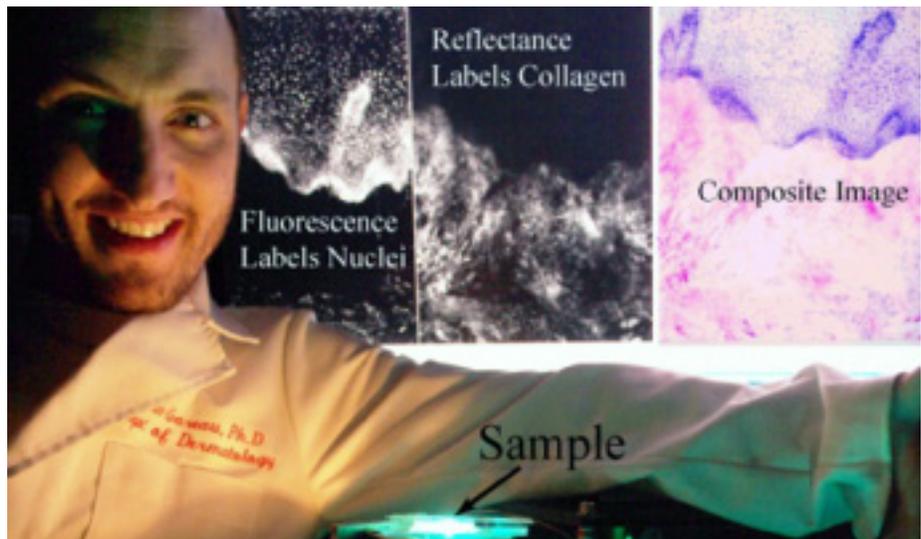
By Michelle Romanick

Dr. Daniel Gareau, Clinical Scholars in Dr. James Krueger's Laboratory gave a seminar on "Novel Confocal Microscopes Fuel Digital Pathology" at the City College of New York for the Department of Physics on March 8, 2012. The audience consisted of college students majoring in physics and biology, and faculty from each discipline.

Quantitative endpoint metrics for cancer diagnosis make biomedical optoelectronic imaging technology with automated image processing/analysis an attractive diagnostic asset for clinicians, pathologists, and surgeons. Confocal microscopy is a rapid, inexpensive, and non-invasive procedure to image skin cells as compared to histology. Unique engineering adjustments are made to achieve the sensitivity and specificity needed for clinical translation. Rapid polygon LASER beam scanning to eliminate motion artifact during in vivo imaging and multimodal imaging for contrast and counter-contrast are used in this procedure, as well as software solutions utilizing automated pathological pattern recognition in 3D images and pseudo-coloring to present the multimodal images in a way that the medical community can use to diagnose a disease and develop a treatment plan.

Dr. Gareau's stated, "I love talking to college students because they have enough background to begin to understand the science and complexity of the biology involved but they have the novice wonderment that is just perfect for infection by a well packaged story. The story I tell is one of engineering tools to help fight cancer. Audiences generally understand the concept of surveillance so it's easy to explain the fancy LASER scanner that detects the cancer cell through the "where's Waldo" analogy. Our adventures in biophotonics for dermatology have yielded some successful projects that

span from the very basic science (where we are considering the light/tissue interaction) through engineering (where we are designing the scanning LASER microscopes) to clinical translation where we are addressing a health care need (rapidly guide surgery for skin cancer removal). When you put the whole story together, highlighting the translational research, the activation energy can be achieved when people are really excited about science. I love it when I see a student leave one of my talks saying: "he did it, now it's my turn."



Dr. Daniel Gareau

Translational Research Opens the Door for a New Area of Pharmaceutical Support

By Johanne Andersen

The pharmaceutical process is divided into five categories: procurement, prescribing, dispensing, administering, and monitoring. These categories apply to all FDA approved drugs and assist to ensure the safe outcome of drug therapy. Most investigational drugs dispensed in hospital pharmacies are sponsored by pharmaceutical companies. The companies have formal policies about following the pharmaceutical process and pharmacists are usually responsible for adhering to them. After the establishment of The Center for Clinical and Translational Science (CCTS), more investigator-initiated clinical studies are conducted and pharmacists therefore take a more active role in study development. This increase in clinical studies led to a number of enhancements in the services provided by the Rockefeller University Pharmacy.

The Clinical and Translational Research

Facilitation Office in the CCTS (the Navigation office) provides researchers assistance with protocol development, continuing education, and study conduct through its Navigation program. Any use of a drug product in a protocol receiving Navigation also receives consultation from the pharmacist focused on the five categories of the pharmaceutical process.

The pharmacy may be contacted in the very early stage of protocol development to provide input about the feasibility of transferring a "bench" chemical into a compound suitable for clinical use, to evaluate whether a subcutaneous formulation would be better than an intravenous, or oral formulation, or to help determine the proper dose. At this level, the pharmacist strives to gather information through literature searches to provide the best possible information at the navigation meeting. Information may be limited, so the pharmacist often



Awilda Mejias, and Johanne Andersen
Hospital PHarmacy

provides direction for the investigator on where to obtain further information. If the investigator knows the name of the chemical, the pharmacist can determine if the chemical exists as a drug or if a clinical grade of the chemical is available. The next step is to evaluate whether the chemical

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Dr. Claire Hastings, Keynote Speaker for 2012 Beatrice Renfield Lecture in Research Nursing

By Diane Maydick



Clare Hastings, RN, PhD, FAAN
Chief for Nursing and Patient Care Services
NIH Clinical Center

The 2012 Beatrice Renfield Lecture in Research Nursing was held at The Rockefeller University on Tuesday, March 20, 2012. The program was devoted to recognizing the critical role of clinical research nursing science in the increasingly complex world of research. The audience consisted of nurses from Rockefeller and other New York institutions. Clare Hastings, R.N., Ph.D., FAAN, discussed the past, present, and future of Clinical Research Nursing.

Clare Hastings is Chief for Nursing and Patient Care Services at the NIH Clinical Center in Bethesda, Maryland. As the Clinical Center Chief Nursing Officer, she directs patient care services that support intramural research activities conducted by the National Institutes of Health at its 240-bed research hospital and ambulatory care facility in Bethesda, Maryland. Dr. Hastings represents the Clinical Center in defining the roles of clinical nurses within the national clinical research infrastructure and in setting standards for integrating patient care and management of the clinical research process. She provides executive leadership for the nursing research program at the Clinical Center with portfolio strengths in quality of life, symptom management, health disparities reduction and research career development.

The evening was hosted by Barry S. Collier, M.D., vice president for medical affairs at The Rockefeller University and physician-in-chief of The Rockefeller University Hospital. Rockefeller's Hospital, which celebrated its centennial last year, is the nation's only private hospital devoted exclusively to clinical investigation. Research nurses at the Hospital are experienced R.N.s, rigorously trained on site in the specialized practices of clinical research nursing. Since the Hospital's founding in 1910, research nurses have played an essential role in studies aimed at improving the understanding and treatment of cancer, heart disease, diabetes, infectious diseases, addictive disorders, HIV/AIDS, and a wide range of other conditions.

Dr. Hastings's presentation, entitled The Past Present and Future of Clinical Research Nursing was timely and thought provoking. The audience included individuals from varied fields of nursing and medicine, from universities and medical centers, as well as students, faculty, and university friends. Dr. Hastings provided a compelling description of the origin of the movement to establish clinical research nursing as a specialty practice, the progress that has been made, and the remaining challenges to full recognition.

The Beatrice Renfield lecture is made possible by a generous contribution from the Beatrice Renfield Foundation, which created this lecture series in 2007 to advance clinical research nursing education and clinical

medicine at The Rockefeller University Hospital. A longtime supporter of research in the Hospital, Mrs. Beatrice Renfield was one of New York City's leading philanthropists in the area of nursing. Since their inception, the lectures have attracted a wide audience of nurses from the New York area and beyond.

The Renfield Lectureship is an initiative of The Rockefeller University Hospital's Heilbrunn Family Center for Research Nursing. The Center provides support for the nurses who, through their participation in clinical studies at The Rockefeller University Hospital, make essential contributions to the advancement of scientific knowledge for the benefit of humanity. The Center serves as a resource for the development of programs and collaborations to promote research nursing as a profession on a local, national, and international level. Through these efforts, the Center raises public awareness of research nursing as an integral component of clinical and translational science.

Dr. Hastings visit to Rockefeller also included meeting with the nursing staff during a luncheon held in her honor. The nurses are excited about their nursing practice and look forward to continuing to work together with clinical research nursing colleagues at the NIH and other research organizations.



Dr. Clare Hastings and The Rockefeller University Hospital
Nursing Staff

The Invention of the Formula Diet: A Vital Tool for Metabolic Research and a Therapy for Patients With Digestive Disorders

By Elizabeth (Betsy) Hanson



Ahrens, Jr., Edward
Courtesy of the Rockefeller Archive

In the early 1950s, Edward H. Ahrens, Jr. (1915-2000) wanted to study the relationship between fat in the diet and atherosclerosis, the fatty deposits of cholesterol inside arteries that lead to heart attacks and strokes. He started clinical studies in which patients in the Rockefeller Hospital were fed standardized diets. But eating the same food every day became boring for patients who participated in weeks-long studies, and it was difficult to precisely control the balance of nutrients in the food. Then a pediatrician colleague advised Dr. Ahrens, "Feed them like babies. Feed them formula." Taking that

lead, with colleague Vincent P. Dole, Dr. Ahrens created the first formula diets, an approach that soon became standard for studying not only heart disease, but also obesity, and many other aspects of metabolism.

With a formula diet, Dr. Ahrens could test the effects of changing different components in the diet with chemical precision. For example, keeping calorie levels constant, he could change the proportions of protein, carbohydrate, and fat. Critical to Dr. Ahrens interest in atherosclerosis, chemically defined diets also permitted him to vary the constituent fatty acids of the diet in ways not possible with ordinary foods, for example, by altering the unsaturation or chain length of the fatty acids. Eventually some 40 fats were tested in several hundred patients, leading Dr. Ahrens to the important finding that the degree of saturation of fat affects plasma cholesterol.

Dr. Ahrens proved the safety and utility of chemically defined formula diets in nutritional studies. In other early research, formula feeding was used to limit sodium in patients with hypertension, and to investigate dietary copper in Wilson's disease. Since then, formula diets have been used in many studies of human nutrition and as therapy for people who cannot eat or absorb a normal diet.

Edward H. Ahrens, Jr., received the BS (1937) and the MD (1941) from Harvard



Equipment used for homogenization of formula in 40-kg batches

University. He joined the Rockefeller Institute in 1946 and was appointed professor in 1960. In 1982 he became the University's first Frederick Henry Leonhardt Professor. Dr. Ahrens was elected to the U.S. National Academy of Sciences, and he founded the Journal of Lipid Research. Throughout his career Dr. Ahrens advocated for patient-oriented research, and was known for his 1992 book, *The Crisis in Clinical Research*, which examined how medical science had moved toward laboratory research.

Translational Research Opens the Door for a New Area of Pharmaceutical Support

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can be obtained from a wholesaler, if it needs to be imported from another country, and if we should compound it in our pharmacy or outsource compounding to another pharmacy. After the chemical is obtained, the pharmacist determines if it needs to be sent for chemical and biological analysis to ensure it is suitable for clinical use. Whereas compounding with a non-clinical grade chemical for a therapeutic use may be appropriate in the treatment or cure of a specific illness, the same compound would not be acceptable to administer to a healthy research volunteer or to a sick volunteer with options for alternative treatments. In those situations the pharmacist will require that the investigator apply for an Investigational New Drug (IND) exemption or ask the U.S. Food and Drug

Administration (FDA) whether an IND is needed. Once the chemical is obtained and has undergone testing, the next challenge is deciding how to formulate it into a suitable drug. The pharmacist will search the literature for articles describing the method for making a similar formulation. Information from professional organizations and informal contacts with other research pharmacists also may provide very valuable information. The specific formulation is developed once the preparation and dosing are determined. After the compound is formulated, it is sent to a certified lab for potency analysis to validate the compounding method. If it is a sterile product, it will also require testing for sterility and pyrogens.

At Navigation meetings, the pharmacist

can further assist in determining the subject inclusion and exclusion criteria by deciding if there are contraindications or drug-drug or drug-disease interactions that need to be considered in the specific study population.

By being part of the Navigation process the pharmacist can insure the incorporation of the proper pharmaceutical methods at the very beginning of the study, which leads to a better protocol design. It also saves the investigator time by avoiding having to amend to the protocol at a later stage. Thus, the pharmacist plays a vital role in efficiently and rapidly developing a scientific sound and safe protocol!