

New Outpatient Research Center Opens

by KELLY McCLARY, R.N. Director of Nursing and Patient Care Services

Patients, investigators, and staff of The Rockefeller University Hospital are all delighted with the new Outpatient Research Center, which opened this past January 22. The attractive, warm, and spacious facility conveys a friendly, yet professional first impression of the hospital and its research mission. The environment is truly commensurate with the quality of research that is carried out in the hospital.

The Center contains two private consultation rooms to obtain informed consent from our patients. The phlebotomy room accommodates significant traffic without difficulty. The fully stocked specimen-processing laboratory is well designed to insure the proper preparation of samples. Several well-equipped and well-lit examination rooms are optimally designed to meet the requirements of investigators from all of the different labs.

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The Rockefeller University Hospital's newly renovated Outpatient Research Center features a friendly, warm waiting area.

RUH Strategic Information Technology Plan Designed to Support Investigators

by RHONDA G. KOST, M.D., AND BARRY S. COLLER, M.D.

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BARRY S. COLLER and RHONDA G. KOST

enhancing the protection of human subjects, and facilitating and improving scientific discovery from clinical investigation. But converting that promise into tangible reality is not simple. Recognizing this challenge, the senior administrative leadership of the hospital has been meeting weekly for the past ten months with Jerry Latter, The Rockefeller University's Chief Information Officer, to develop an Information Technology (IT) Strategic Plan. The plan was presented to the Hospital Committee of the Board of Trustees on March 19, and has been submitted to the administration for review.

The overall goal of the plan is to integrate multiple systems that either currently exist as stand-alone systems – or do not exist at all – into a mutually reinforcing network (see diagram on page 2). What will this mean for the investigator? Among the enhancements that will be available when the system is complete are:

1. The ability to write and submit protocols online (with no requirement for 24 copies!) using a protocol development program that has direct links to all sources of information required to complete the application (such as the NIH, FDA, OHRP, HIPAA, biostatistician, and Clinical Research Office). The program also incorporates prompts to avoid common mistakes or omissions.

2. The ability to receive notice of IRB actions, approvals and stipulations online as soon as the protocol is reviewed, and to submit revisions online to reduce turnaround time.

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The dictation room and nursing station area are separated from the patient waiting area, providing privacy for patients as well as staff. There is a room with abundant storage to safely keep the materials needed to conduct all active protocols.

The new Patient Education room has multiple purposes. It has been used as a classroom to teach patients how to care for themselves, as a conference room to educate staff about research protocols, and as an eating area for patients participating in dietary protocols. It will also be used as a meeting room for patient support groups, small conferences, and other functions.

Future efforts to improve the clinic include the following:

- All of our examination rooms, consultation rooms, and specimen-processing areas are scheduled to have new computers.
- The scaffolding around the perimeter of the hospital building is scheduled to be removed shortly, thus opening the moat area at the A-level. The Planning and Construction Office is designing landscaping with plants and benches, which will make this area an inviting place for patients and staff.
- RxArt, an innovative nonprofit organization that has placed original works of art in the inpatient areas of the hospital, is in the initial stages of placing original artwork in the Outpatient Research Center.

Since the Outpatient Research Center is still in its early stages of development, we invite suggestions for improvement.



Ana Cecilia Trilla-Hernandez, Hospital Clerk, greets patients entering the Outpatient Research Center (above). The nursing station (below) is separated from the waiting area, providing privacy for patients and staff. Shown here: Kenneth Tenebro, Nursing Assistant, and Lanie Fleischer, Social Worker.



STRATEGIC INFORMATION TECHNOLOGY PLAN continued from page 1

Hospital IT: Major Components



- **3.** Online access to the latest IRB-approved versions of protocols and informed consent forms.
- **4.** Protocol management tools to insure proper scheduling and data collection.
- **5.** The ability to create case report forms for data collection and protocol monitoring from sample templates or de novo.
- **6.** Programs to prevent drug ordering errors and to identify drug interactions.
- **7.** A revised web page that facilitates the recruitment of study participants.
- **8.** A "physician desktop" for outpatient and inpatient workstations, populated with shortcuts linking to key hospital systems, pharmacy, and online medical information resources.
- **9.** Tools to report adverse events electronically to

all appropriate regulatory oversight agencies, along with documentation of delivery.

- **10.** Tools to capture and track all adverse events (AE),among both inpatients and outpatients, into a central AE log, thus eliminating redundant recording.
- **11.** Online access to all Rockefeller University Hospital documents, such as the Disaster Plan, Bylaws, and the IT Strategic Plan itself.
- **12.** Opportunities for data analysis using an advanced statistical and presentation tool, as well as a data warehouse containing de-identified information that can be used for meta-analysis.

The plan has already benefited from extensive input from faculty and staff, but the next phase will require even greater input from individual investigators as the plan is refined and tailored to meet the needs of the projects conducted by the laboratories. The plan will require several years for full implementation, since we are preparing extensive training prior to implementing its individual components and careful review and modification of systems as they are brought online. We welcome your feedback on the plan and specific suggestions for additional IT resources to support individual programs and the mission of the hospital.



A New Paradigm and New Therapies for Psoriasis

by EDMUND LEE, M.D., PH.D., *Laboratory for Investigative Dermatology*, Dr. James G. Krueger, Head

y interest in skin biology goes back to the beginning of my research career at Rutgers University, when I did my Ph.D. thesis on the mechanism of action of psoralens and ultraviolet light – a very effective therapy for several skin disorders, including psoriasis. I continued my postdoctoral research at the National Cancer Institute in Bethesda, Maryland, studying alterations in the inositol phosphate-diacylglycerol signal transduction pathway in a mouse model of multistage carcinogenesis. In this work, I observed that the v-*ras* gene caused constitutive activation of the inositol phosphate signalling pathway, a pathway known to stimulate cell proliferation. After finishing my medical education at Harvard Medical School, I trained in dermatology at New York Hospital, and it was there that I had my first taste of clinical research.

After residency training, I joined the Krueger Lab, which has focused on the pathologic mechanisms operative in the common skin disease psoriasis vulgaris.Dr. Krueger had made several key discoveries that convinced me to join the lab. Most notable was his evidence that psoriasis was primarily an immune disorder driven by an unknown autoantigen. The evidence came from a seminal clinical trial of a T-cell specific toxin, DAB-IL2 – a chimeric protein composed of diphtheria toxin linked to interleukin-2 to target the toxin to activated T cells that express high affinity IL-2 receptors.

Patients given this chimeric peptide responded with clearing of the rash and resolution of symptoms. This discovery set in motion a series of events that caused the most recent paradigm shift in the study of this ancient, enigmatic disorder, which previously had been classified as a proliferative disorder of keratinocytes. The new paradigm, developed by Dr. Krueger, placed psoriasis squarely in the category of a Tcell driven autoimmune disease. I was given the task of bringing a new molecular technique, genetic arrays, to the laboratory, and to coordinate the lab's initial efforts in real-time gene expression to characterize the genomic changes occurring in psoriasis after therapy. Over the past several years, the lab has been systematically examining tissue taken from psoriasis patients who are undergoing therapy for changes in gene expression of Th1 inflammationrelated genes, including IL-12, interferon-, and genes dependent on interferon-. Dr. Krueger and I tested his hypothesis that psoriasis is a Th1-dr iven immune disease by using a drug that is targeted to T cells, called alefacept (Amevive®). We found that therapy resulted in significant decreases in Th1 cytokines and effector-memory CD8+ T cells.

In addition to genetic arrays providing a global view of gene expression changes during therapy, we used realtime, quantitative RT-PCR for more



detailed genetic analysis. Use of gene arrays often produces more questions than answers; we are now using these arrays to generate additional hypotheses to evaluate, some of which may shed light on other autoimmune disorders..

In collaboration with Dr. Anne Bowcock of Washington University, we have recently identified a set of 1,338 genes that are expressed at abnormal levels in psoriasis. Of these, some are transcription factors that are consistent with the hypothesis that psoriasis is a Th1-driven disease, with T cells playing the central role. The mRNAs for proinflammatory molecules – including interferon- , IL-8, Mig, iNOS (inducible nitric oxide synthase), and a newly described cytokine, IL-20 – are also expressed at higher levels in psoriatic skin.

These discoveries have influenced the biotechnology and pharmaceutical industries. Most dramatically, the recent FDA approval of Amevive® for psoriasis was based, in part, on work done in the Krueger Lab. This approval not only supports the immune basis of psoriasis, but also places psoriasis in the forefront of translational research.

I recently received a five-year career development award from the National Institutes of Health (K23) to study the genomic changes resulting from treatment of psoriasis with ultraviolet light, a known immunosuppressant. I was gratified to receive this grant, which shows that the peer review system believes that my work as a Clinical Scholar is meritorious.

Studies of Obesity and Weight Loss at RUH

by SAGIT ZOLOTOV, M.D., The Laboratory of Molecular Genetics, Dr. Jeffrey Friedman, Head

The worldwide prevalence of obesity is rising. Obesity is a major public health problem, principally because of its association with diabetes, heart disease, stroke, and hypertension. The severity of these disorders is markedly reduced after even relatively modest weight loss. Despite this, weight loss is extremely difficult for most obese individuals, and maintenance is even more difficult: 90-95% of those who lose weight by dieting regain it.

The scientific community has been interested in obesity for many years. Fundamental clinical studies, some performed here, elucidated the physiologic mechanisms underlying the failure of dieting to maintain long-term weight loss. These studies showed that the body meticulously maintains energy balance, and that a state of negative balance, such as that which occurs after dieting, leads to a series of compensatory changes. These include a reduction in energy expenditure and a persistent sense of increased hunger, both of which act to resist weight loss.

In 1994, Dr. Jeffrey Friedman and colleagues here at The Rockefeller University

weight loss is regulated by leptin, could leptin administration diminish this response, leading to less unwanted effects of a low-calorie diet and accelerated weight loss?

We designed a double-blind, placebo-controlled study to investigate the effects of leptin on the biologic response to weight loss in healthy obese woman aged 20-45 with a body mass index of 29-40 kg/height². After a period of weight stabilization and a 12-day baseline testing period, subjects begin a very low-calorie formula diet, together with treatment with either leptin or placebo until they lose 20% of their initial weight.

Subjects are managed as inpatients in a controlled environment until they lose 10% of their initial weight, and continue to lose weight under medical supervision as outpatients, attending weekly clinic visits until a 20% weight loss is achieved. During the last month, the reduced weight is stabilized with a solid food weight-maintenance diet and education about weight maintenance.



discovered the weight-regulating hormone leptin. This discovery led to the identification of a molecular framework of the system that controls body weight, and ushered in an era in which molecular tools could be applied to study obesity. Since then, numerous neuronal pathways through which leptin works in the brain have been identified, as well as other hormones involved in weight control, often working through the same pathways.



Leptin plays a key role in regulating the response to weight change. As fat mass is lost, leptin levels fall, stimulating increased appetite and reducing metabolic activity. A decreased leptin level also has potent effects on other physiologic systems, including those that control reproduction, immune function, and growth.

In mice, the biologic response to weight loss is blunted by leptin replacement. Leptin treatment of patients deficient in this hormone successfully led to weight loss and corrected many of the abnormalities associated with leptin deficiency. If the biologic response of the body to

SAGIT ZOLOTOV

During weight loss, participants undergo comprehensive testing to determine the clinical, physiological, behavioral, and molecular responses to weight loss, and the effects of leptin on these responses. We plan to study 40 subjects.

We are also initiating studies of patients undergoing gastric bypass surgery, a growing patient population that has not been well studied. Our goal is to understand why morbidly obese subjects differ from lean and overweight subjects, and if the mechanism of weight loss after surgery is significantly different than that achieved by dieting.

New molecular tools have greatly advanced our understanding of the mechanisms of obesity. Our clinical studies complement these basic science advances, and offer the hope of translating them into improved therapies for obesity.

Dr. Zolotov completed medical school at the Technion in Israel. She trained in Internal Medicine at Asaf-Harofeh Medical Center of Tel Aviv University, and then pursued a research fellowship at the Arthritis Center of Boston University Medical Center. During her fellowship, her interest in complex genetic diseases resulted in her meeting Dr. Friedman. She came to The Rockefeller University as a Clinical Scholar in Dr. Friedman's lab to pursue one of the first studies of the effects of leptin on weight loss. The study described above is one of several projects she has pursued at The Rockefeller University Hospital.



Original Art Brightens Hospital Units

Reposure to original fine art in patient, procedure, and examination rooms of healthcare facilities, has been instrumental in placing original artwork throughout The Rockefeller University Hospital. The artwork Rx Art recently placed in the hospital's inpatient unit is being well-received by patients. The group is extending their work to the Outpatient Research Center as well. Several works of art, including a wall mural, are under construction.

"One of the things that Rx Art feels strongly about is that the works that are chosen are of the highest quality," explained Diane Brown, Rx Art's founder. "We have a selection committee that chooses the art, which includes top people in the field. Our goal is to place art that is not only uplifting, but also stimulating and challenging. We want to make the atmosphere lively, to take your mind to another place."

In addition to Rx Art's selection committee, all artwork is reviewed by the physicians and staff of The Rockefeller University Hospital to ensure their appropriateness for the hospital.



The Great Wall (1970), a relief sculpture by the late Louise Nevelson, graces a hallway of a patient floor at The Rockefeller University Hospital.



JBOSH STEPANE



If the Color Changes (Wittgenstein) (2001), by American artist Mel Bochner, is an embossed engraving of a quote by the late Austrian philosopher Ludwig Wittgenstein. It hangs in a patient waiting area of the hospital.



Shards Illa (1982), by American abstract artist Frank Stella, is an offset lithograph and screenprint that hangs in a hallway of a patient floor at the hospital.







GCRC Grant Up for Renewal

by JAMES G. KRUEGER, M.D., PH.D. Rockefeller University GCRC Program Director

The National Institutes of Health grant that largely supports the operations of the hospital is due for competitive renewal. The current five-year grant period expires on November 30, 2004. The grant in the current year of funding provides \$4.15 million of direct funds and \$612,515 of indirect funds to the GCRC, for a total of \$4.77 million.

As a bit of past history, this grant was first obtained in 1963, and funding at that time was based on a six-page application. The current renewal process requires submitting a complete grant application by January 31, 2004. The number of pages is obviously not yet known, but is expected to be in excess of 1,200 – at least 200 times longer than the grant submission 40 years ago.

Looking forward to our site visit. In early May 2004, there will be a one-day site visit by a review team that will include members of the study section reviewing all GCRCs, ad hoc reviewers chosen for scientific competence in the protocols to be presented, and NIH staff to deal with administrative details. At that time, we will have a full day to present our program.

Post-review timeline. Later that July, we will receive a postcard informing us of our score. The study section report will become available a few weeks afterward. In September 2004, the Council that oversees the programs of the National Center for Research Resources (NCRR) will obtain the report from the study section, approve or disapprove funding, and make budget recommendations to the Program. Then the NCRR Program Office, using these budget recommendations, will arrive at the budget that they will devote to this program, noting the funding approved for the five-year period between December 1, 2004 and November 30, 2009.

Gentlepeople, *"start your engines."* The site visit agenda has a major impact on the written grant submission due next January. Seven presenters will have drafted substantial protocols that allow up to 25 pages to describe their scientific plans. In addition, the grant will contain approximately 30 to 35 additional scientific protocol descriptions, each limited to a length of five pages. The remainder of the application will be devoted to a full description of our past accomplishments; the vision of the center; the administrative structure; the justification for personnel in Nursing, Bionutrition, Biostatistics, and Informatics; human subjects protection; and our training programs. A proposed budget and the justification to support the request will also be included. Many of these topics will be presented during the morning session of the site visit.

We expect to have the write-ups for the non-presented protocols submitted in October, and those for the seven presented protocols in November, leaving December and January for final assembly of the document.

Starting in late February and continuing through April, we will be polishing and rehearsing the site visit presentations to ensure that they will be strong, and most important, within the time limits set by the site visit team.

From Brain to Mind: Children with the 22q11 Deletion Syndrome

by CHRISTINA SOBIN, PH.D., The Laboratory of Human Neurogenetics, Dr. Maria Karayiorgou, Head

extinct, The Rockefeller University Hospital offers a rare and precious resource for the investigation of childhood disease. Our study of children with the 22q11 deletion syndrome (22q11 DS) benefits enormously from the hospital's intimate setting and welcoming staff.

22q11 DS is the most common deletion syndrome known, occurring in 1 of 4,000 live births. It can cause a wide range of congenital anomalies – some barely detectable,



others fatal – including heart defects,

immunologic deficits, craniofacial dysmorphologies, velopharyngeal defects, or inflammation-related pain syndromes. However, virtually all children with the deletion share a remarkably consistent pattern of early neurodevelopmental anomalies and specific learning disabilities that may reflect a pattern of anomalous brain development. Moreover, while most children with 22q11 DS do not have psychiatric symptoms in childhood, 25% are predicted to develop schizophrenia in late adolescence or early adulthood (versus a 1% prevalence of schizophrenia in the normal population). genetics of schizophrenia at this chromosomal region. It is under way in the Laboratory of Human Neurogenetics, headed by Dr. Maria Karayiorgou. In studying these children, we are considering the possibility that a combination of early neurodevelopmental and neurocognitive problems, not currently included in the psychiatric nomenclature, may be meaningful precursors of later mental illness.

First, we are trying to better characterize the neurocognitive profiles of children with 22q11 DS. Earlier studies that used older IQ batteries and limited neuropsychological tests to characterize deficits may have missed important aspects of neurocognitive development. Our initial cross-sectional data have helped to characterize 22q11 DS neurocognitive deficits more fully, and narrow our focus on key areas of neurodevelopment.

Second, the study is longitudinal. Once a year we see each of our 50 children with 22q11 DS and their unaffected siblings to conduct extensive neurocognitive and neuropsychological evaluations. The in-depth written reports of these evaluations provided to our families serve several purposes. First, testing of this kind can be expensive for many families. We've provided families and schools with evaluations that can guide targeted programs of remediation. Second, from a research perspective, our evaluations provide rich, qualitative descriptions of

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CHRISTINA SOBIN

Hospital Investigators Evaluate Novel Drug that Blocks HIV Entry into Cells

by CHRISTINE HOGAN, M.D.

Aaron Diamond AIDS Research Center, Drs. David Ho and Martin Markowitz

The development of different classes of anti-HIV medications – antiretroviral agents that include nucleoside and non-nucleoside reverse transcriptase inhibitors, nucleotide reverse transcriptase inhibitors, protease inhibitors, and fusion inhibitors – has led to substantial improvements in morbidity and mortality for HIV-infected persons in the developed world. These medications are not without problems, however. Patients are asked to adhere to complicated medication regimens with substantial short-term and long-term toxicity. In addition, resistance to one agent may lead to resistance to other agents in that class, and may even compromise the efficacy of all other agents in that class. Many patients have therefore exhausted all available medication options. As a result, new classes of antiretroviral medications are needed.

One of the projects in the Aaron Diamond AIDS Research Center, which has relied heavily on the services of The Rockefeller University Hospital, has been a study to investigate the safety and virologic efficacy of SCH-C – an experimental medication in a new class of anti-HIV medications called "entry inhibitors." HIV enters the cells of its human host by binding to the CD4 receptor on host cells, as well as to one of two chemokine co-receptors – CCR5 or CXCR4. The normal function of these chemokine co-receptors is induction of chemotaxis and activation during inflammation.

The CCR5 receptor is the co-receptor used by most HIV strains during early infection. People who are homozygous for a deletion mutation in the gene that encodes the CCR5 receptor make essentially no functional CCR5 receptors. These individuals are partially protected from acquiring HIV infection,



HIV-1 entry into the host cell is preceded by binding to CD4 and the CCR5 or CXCR4 co-receptor

and progress more slowly if they do acquire it. Furthermore, these patients appear to be healthy otherwise. Inhibition of the CCR5 co-receptor would therefore be a rational therapeutic goal.

SCH-C is a small molecule that inhibits the CCR5 co-receptor with *in vitro* HIV-suppressive activity. We and three other clinical sites have collaborated to perform the first study of a CCR5 inhibitor in HIV-infected patients by evaluating SCH-C.

In the study, 44 volunteers with untreated chronic HIV infection were hospitalized and received 10 days of treatment with SCH-C at one of three doses, or a placebo. Safety, pharmacokinetic, and virologic data were collected. In addition, the volunteers were monitored with telemetry throughout the 15-day hospital stay and underwent several daily electrocardiograms, because previ-



CHRISTINE HOGAN

ous studies have shown that SCH-C may prolong the QT interval.

Dosing has been completed, and the data are now being analyzed. We did observe a reduction in viral load in the cohort of patients receiving the lowest dose of SCH-C, proving the principle that CCR5 inhibitors have anti-HIV effects *in vivo*. Whether or not SCH-C progresses in its clinical development will depend in part on close analysis of the electrocardiographic data.

Dr. Hogan completed her undergraduate studies at Harvard University, where she majored in English literature, and then attended medical school at the University of California, San Francisco. She completed a residency in internal medicine at Massachusetts General Hospital in Boston, and then came to New York to pursue an infectious disease fellowship at the Columbia University College of Physicians & Surgeons. During her fellowship, her interest in acute HIV infection resulted in her meeting Dr. Martin Markowitz at the Aaron Diamond AIDS Research Center. She decided to come to The Rockefeller University as a Clinical Scholar in the lab of Dr. Markowitz and Dr. David Ho to pursue research into novel treatments and strategies for HIV infection. The study described above has been one of several projects she has pursued at The Rockefeller University Hospital.

FROMBRAIN TO MIND continued from page 6

years later. To realize the full potential of this study, it will be necessary to follow these children into adulthood. Our families are eager to see us do so, and the high quality of our professional team could make this goal a reality.

I would like to acknowledge the dedicated and talented staff who have worked on this study: neuropsychological testers Karen Kiley Brabeck, Sarah Daniels, Jananne Khuri, Meredyth Kravitz, Ben Michaelis, and Lisa Taylor; Maude Blundell, who recruited families; research assistant Rosemary Collier; and the nurses and dietary professionals who welcome our families to The Rockefeller University Hospital.

Before coming to The Rockefeller University, Dr. Sobin completed her degree in Clinical Psychology at New York University. She was awarded a post-doctoral fellowship at Columbia University College of Physicians & Surgeons, where she pursued training in neuroscience research and, as an NARSAD Young Investigator, studied motor impairment and mood disorders in Parkinson's disease and depressed elderly patients. Dr. Sobin was a Clinical Scholar at The Rockefeller University from January 1998 – June 2002, when she was appointed Assistant Research Professor in Dr. Karayiorgou's Laboratory. In June 2001, Dr. Sobin received a Career Development award from the NIH to study children with 22q11 DS.

FISH (florescence in situ hybridization) analysis of chromosome 22, q 1 1.2 deletion







GOOD NEWS



Ho honored for HIV research

Dr. David Ho, Scientific Director of the Aaron Diamond AIDS Research Center, received the Edward H. Ahrens, Jr. Award from the Association of Patient-Oriented Research at the Clinical Research 2003 meeting in Baltimore, Maryland on March 14.Dr. Ho was honored for his numerous landmark contributions to understanding and treating HIV. Dr. Ho delivered a plenary lecture entitled *Insight into HIV Pathogenesis from Clinical Investigation*, in which he detailed the human studies that led to an appreciation of the kinetics of HIV replication. Those data, in turn, resulted in the development of multidrug strategies that have dramatically improved the treatment of HIV infection.

Osman receives ASCO award

Keren Osman, a Clinical Scholar in Dr. Madhav Dhodapkar's laboratory, was awarded an American Society of Clinical Oncology Young Investigator Award for the upcoming year for her studies on CD4 cells in the peripheral blood and tumor bed of patients with the plasma cell disorder multiple myeloma. Dr. Osman's project is entitled *Anti-Tumor Immunity in Multiple Myeloma*.



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Lee featured in Vows

Dr. Ed Lee, a Clinical Scholar in Dr. James Krueger's laboratory, and his wife, Mary DeMarco Lee, were the subjects of a recent *Vows* article featured in the *New York Times*, highlighting their courtship and marriage. The article generated much interest among his former Stuyvesant High School classmates, as well as his colleagues at The Rockefeller University.

The Rockefeller University Hospital UPDATE

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Celebrating a long tradition of

On May 5, 2003, The

research nursing at The Rockefeller University Hospital



Rockefeller University Hospital celebrated National Nurses Day with a variety of activities recognizing the outstanding contributions of the nursing staff.

Nursing Staff circa 1938

(left to right) Stella Hoffman Miss Ellicott's Assistant Kathrine Christhill Housekeeping & Laundry Alice N. Lockie Second Nursing Superintendent Nancy P. Ellicott First Nursing Superintendent Georgina M. Drew Miss Lockie's Assistant Mary B. Thompson Miss Ellicott's Assistant