

July/August 2002

NIH Clinical Center News

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Town hall meeting addresses clinical research challenges

Conducting clinical research in the current regulatory environment and what the NIH Clinical Center is doing to address related challenges was the focus of an early June Clinical Town Hall meeting in Lipsett Amphitheater. Clinical Center Director Dr. John Gallin's opening remarks emphasized that in a time when everyone is being asked to do "more with less" it is important to evaluate, assess, and design tools that will improve the facilitation of clinical research and streamline the bureaucracy.

"This is something we have to do

together. We're here today to share information with you and get your feedback about the directions we're taking. Your input will enable us to approach these directions in support of an efficient, forward thinking, comprehensive clinical research vision," he said.

Three integral research enhancement efforts were highlighted at the Town Hall meeting: the Clinical Research Information System (CRIS); the Picture Archiving and Communication System through the Web (PACSweb); and ProtoType: a

web-based clinical protocol-writing application. A construction progress update for the Mark O. Hatfield Clinical Research Center was also provided.

Clinical Research Information System (CRIS)

Dr. Stephen Rosenfeld, chief, Division of Clinical Research, Research Informatics, pointed out that when the Medical Information System (MIS) was installed a quarter century ago, it did what it was supposed to do in streamlining

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Team NIH National Race for the Cure

Team NIH members, 400 strong, braved the heat and humidity on June 1 to run and walk 3.1 miles in the National Race for the Cure in Washington, D.C. A crowd of 70,000 race participants took to the streets in support of research for breast cancer and related women's health initiatives.

Full story on page four

PACSweb now available across NIH

Web access to the Picture Archiving and Communication System (PACS), which stores and displays new and prior digital radiology images is available on workstations and desktop computers across NIH.

Developed as part of the new CRIS system, PACSweb is a collaboration by the Diagnostic Radiology Department, Department of Clinical Research Informatics and Department of Networks and Applications. The application makes images and reports available to authorized users (currently physicians, physician assistants, nurse practitioners and anesthesia nurses) on their desktops on the day the study is performed.

"This significantly increases efficiency of patient care," said Dr. King Li, associate director for Radiologic and Imaging Sciences. "For many studies, physicians no longer need to send for films or run to the film library to see their patients' images. They can access them from their office computers within minutes of test completion."

Authorized users can search for images by patient name or medical record number. On the day a patient exam is scheduled, users can view the four most recent prior studies taken in the scheduled modality (MRI, CT or X-ray) of the requested body region (head and neck, torso, or extremities), as well as the two oldest prior studies in the system.

Imaging modalities stored and available on the system include all

briefs

Primary care updates

Join the Clinical Center Nursing Department for its fifth primary care update seminar on August 21, 3-4 p.m. in Lipsett Amphitheater. Mary Schroeder, M.S., C.R.N.P., and Jennifer McKeon, M.S.N., C.R.N.P., will present the topic, "Management of Common Dyslipidemias."

Lipsett renovations

Lipsett Amphitheater will be closed for renovations beginning November 4 through January 31, 2003. The ORS Management staff will contact all clients with events scheduled in Lipsett during this closure period to arrange for an alternate location. Contact Marianne Bachman at 301-435-1677 for more information.

ClinPrat training program

The NIH Clinical Pharmacology Research Associate Training Program is a three-year postdoctoral research fellowship sponsored by the Clinical Center and the National Institute of General Medical Sciences. Postdoctoral training positions are

MRI and CT scans taken since 1995, and X-rays taken in the past two years. The images displayed can be enlarged, magnified, panned, displayed as a series, and displayed in different orientations.

For a tutorial and further information on the PACSweb system, go to

www.nihtraining.com/pacsweb.

—by Colleen Henrichsen

available starting July 1, 2003 and in subsequent years. Candidates must have an M.D., have completed three years of residency training and be board eligible in a primary medical specialty. Candidates must be U.S. citizens or permanent residents of the United States. For more information visit www.cc.nih.gov/OD/clinprat/ or call Donna Shields at 301-435-6618.

Science in the Cinema

The Office of Science Education announces the return of its popular film and discussion series "Science in the Cinema." Every Thursday evening beginning July 11 at 7 p.m. in Natcher Auditorium, a film with a medical, science-related theme will be shown. The event is open to the public. For more information, visit <http://science.education.nih.gov/cinema>.

CRIS educational session

A video rerun of a popular CRIS education session is set for August 14 at 1:30 p.m. in the CC Medical Board Room (2C116).

"Implementing Electronic Patient Record Systems," was first presented in August 2000. The speaker is Stephanie Reel, chief information officer and vice provost for information technology, Johns Hopkins University, and vice president for information services, Johns Hopkins Medicine.

CME credit is offered. For more information visit,

<http://cris.cc.nih.gov/summer>.



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Clinical research enhancements discussed at Town Hall meeting

patient care. Today with MIS the Clinical Center has an information system that will support the Center during the extensive transition to CRIS. MIS will remain "live" and serve as a fallback system while CRIS is being implemented.

There are two main components to CRIS. One is the Clinical Data Repository, which is basically where all data (i.e., lab reports, etc.) are collected. This replaces the MIS core piece on the patient care units. The other system component is the Clinical Data Warehouse, the research arm that feeds the Institute research system. The new core piece, the Clinical Data Repository, should be selected by September and is expected to be 'live' ten months later, according to Dr. Rosenfeld.

"The Clinical Center comprises individuals with competing priorities and very different ways of using data. We're moving away from a culture of restraint to one where the system will adapt to us, not us to the system," said Dr. Rosenfeld.

Picture Archival and Communication System through the Web (PACSweb)
"The PACSweb will replace images and reports in your hands with access to the same items through any personal computer interface in the Clinical Center," said Dr. King Li, associate director for Radiologic and Imaging Sciences.

He described three advantages to a digital approach: it allows images to be viewed in many places at the same time; it produces a large volume of imaging data quickly (as high as 1,000 images in two minutes); and it allows the use of features such as color-coded maps, 3-D renderings and quantitative data.

With PACSweb, authorized users can easily access relevant exam reports and images. The tool has features that allow for magnifying and moving images, saving them to a disk or CD, utilizing different layout formats, printing films, and using

any monitor size.

Other benefits of the PACSweb are that it uses JPEG images with compressed files that are easily delivered over the web and that the FDA has certified use of these web-based images for clinical review purposes. Physicians can use an online request form and all patient information is encrypted and resides on a secure internal server. Email notices are sent to the user when the request is received, filled and available. Both same-day (up to 10 requests per user per day) and next-day (no limit) service is available.

"Our next plans are for the PACSweb Enhanced. This will provide better images but the downloading time will be slower," said Dr. Li.

ProtoType: a web-based clinical protocol-writing application

"ProtoType will change the way we do our clinical research business," said Dr. Robert Nussenblatt, Director, Office of Protocol Services. He noted that this application is the first step in the protocol services migration toward better use of information technology and paperless systems, standardization of systems with built-in flexibility and enhanced patient care and safety.

ProtoType will simplify the protocol writing process by providing recommended language cassettes for protocol and consent form use. The application will assure that regulatory requirements are met by providing help on relevant parts of the protocol and linking to NIH/Clinical Center policies. Ultimately, it will provide links to other clinical and research databases

Dr. Nussenblatt demonstrated that the application contains all the

essential protocol elements. Thus, an investigator can have multiple protocols under construction; view pages that show the major subdivisions of a protocol; search on keywords that will be linked to the clinicaltrials.gov website; buildout protocols in any order; make use of updated standard language for consent forms; and quickly and electronically submit information to agencies, institutional review boards and other relevant organizations.

Investigators are encouraged to test ProtoType at <http://www2.cc.nih.gov/protocoltest>.

Mark O. Hatfield Clinical Research Center (CRC)

"Construction has progressed well since we first began in January 1999," said CRC Project Director Yong-Duk Chyun. "The entire concrete structure is in place, and I am very pleased with how

things are moving along," he said.

Chyun highlighted several unique features of the structure including: use of the NIH Clinical Research Model providing a bridge from basic research to inpatient and outpatient care; flexibility and adaptability, including modular planning,

allowing patient care units and the research labs to interchange if necessary, and interstitial (between floors) space to accommodate a changing utility infrastructure; and indoor air quality, assuring a clean air supply and thermal comfort levels.

"I am confident we will be ready for the target readiness timeframe of March 2004," said Chyun.

Bringing the Town Hall meeting to a close Dr. Gallin said, "These four individuals have presented what will be an exciting transition for clinical research at NIH. I view the CRC as a new laboratory as we move forward in this century."

Research enhancement efforts highlighted at the Town Hall meeting:

- Clinical Research Informatics System (CRIS)
- Picture Archiving and Communication System through the Web (PACSweb)
- ProtoType: a web-based clinical protocol-writing application



Team NIH races for a cure

Team NIH members, 400 strong, braved the heat and humidity on June 1 to run and walk 3.1 miles in the National Race for the Cure in Washington, D.C. A crowd of 70,000 race participants took to the streets in support of research for breast cancer and related women's health initiatives.

Several hundred teams took part this year. The Clinical Center spearheaded organization of Team NIH. Family members, patients and friends joined with employees to represent NIH. For many the reason to participate was personal—a wife, a mother, a sister, a brother, had experienced breast cancer. For others the reason was simple—expressing the importance of breast cancer research and breast health.

The National Race for the Cure is the largest 5K event in the world. It has grown steadily from 7,000 runners and walkers in 1990 to 26,000 in 1995, to more than 70,000 in the past several years. The race is part of a series of 5K runs and fitness walks in support of breast cancer research and breast health initiatives, with more 1 million participants in at least 100 American

cities and three foreign countries.

Onsite Clinical Center registration, publicity and word-of-mouth communication throughout NIH helped to get people involved. Many NIH volunteers assisted in making the first Team NIH a success. Pat Piringer, Special Assistant, Office of the Director; Georgie Cusack, Clinical Nurse Specialist, Nursing Department; and

Dianne Needham, Deputy Chief, Office Of Communications served as Team NIH co-captains.

There will be a Team NIH in 2003. Preparation and planning will begin in the Fall. Anyone interested in volunteering should contact one of the 2002 co-captains. And don't forget to keep using those running or walking shoes—to be ready for the next National Race for the Cure!



New FDA guidelines increases need for Blood Bank donations

The Clinical Center's Blood Bank is calling for increased blood donations to compensate for deferments caused by new Food and Drug Administration guidelines that took effect June 1.

Previously, those who spent six months in the U.K. from 1980 to 1996 were deferred from donating blood or blood products for patient care. Now, new guidelines reduce the acceptable travel period from six to three months. In addition there are new travel restrictions on those who have been in Europe for a total of five years since 1980, as well as a requirement to defer those who lived on a military base for six months or more in certain European countries.

The measure is aimed specifically at reducing the risk of Bovine Spongiform Encephalopathy (BSE, or "Mad Cow Disease") entering the U.S. blood supply. It was spurred by recent research showing that a new human neurologic disease, vCJD, is caused by the same infectious agent (prion)

that causes BSE. Although there is no evidence that prion infection is transmissible from person to person via transfusion, the FDA is taking every precaution.

"The word 'guidance' gives the impression that compliance is voluntary, but this is not actually the case," said Janet Browning, chief nurse of Blood Services in the Department of Transfusion Medicine. "As usual, some experts are in total agreement with the deferral criteria while others believe there is insufficient scientific evidence that vCJD is transmitted through blood."

The impact of the new regulation is being monitored by Jaime Oblitas, managing director of the NIH Plateletpheresis Center. The NIH Marrow Donor Program is concerned that the deferral rate at NIH could well exceed the estimated national donor deferral rate of six to eight percent, based on the fact that about 70 percent of donors are NIH employees and many have lived

abroad or traveled extensively. Blood products given by deferred donors can be used for research but the FDA requires special labeling that will inform investigators that the product was obtained from a donor with a vCJD risk.

Oblitas and Browning urge those who can give blood to do so to help make up the shortfall. Questions about the eligibility to donate should be directed to the Blood Bank at (301) 496-1048.

Intern awarded Goldwater Scholarship

Victoria Rose Sharon, who worked as a summer intern in the Department of Transfusion Medicine last year, is the recipient of the 2002 Barry M. Goldwater Scholarship.

The scholarship is awarded to 300 undergraduate students in the United States and Puerto Rico who have outstanding potential and intend to pursue a career in mathematics, the natural sciences, or engineering.

Sharon is a junior at Columbia University in New York, majoring in biology and neuroscience and behavior. She will receive a \$7,500 award to cover tuition, fees, books, and room and board for one year.

"She is an outstanding student and has done an outstanding job," said Dr. David Stroncek. "That's why we are here—to bring students into the lab and teach them. We want them to have a good experience and hope it will lead to a career in the clinical sciences."

Sharon worked with Dr. Stoncek for two months last summer. She researched the filterability of red blood cells from people who carry the sickle cell anemia trait.

"I think my experience at NIH is what helped me to get the award," said Sharon. "It was just a wonderful experience and it will definitely help me in the future."

Smith honored for melanoma research

Kina Smith, a pre-intramural research training awardee working in the immuno-genetics section of the Department of Transfusion Medicine, is the recent recipient of a Minority Training Research Forum (MTRF) travel award.

Smith, who won the award for a scientific abstract on melanoma research, was one of 12 recipients from her educational level nationwide. The travel fellowship consisted of airfare, hotel accommodations, and daily admission to a trainee breakfast, luncheon, and awards dinner in San Diego this spring. There, she conversed with peers and met with representatives from academia, the pharmaceutical industry, and other areas of NIH.

As a winner, Smith was required to give a 15-minute oral presentation with slides and a one-hour poster



session on her paper.

"I was very happy," Smith said. "It was a great honor to present the research I've been working on." Smith has a B.S. in biology from Syracuse University, Syracuse, N.Y., and will remain with the Clinical Center until July. She then plans to complete a year of research at NIH or at a local company, and go on to complete her post-graduate work.

Not your typical rabbi

Teacher of Orthodox and 'Polydox' brings new evening quorum outreach program

It's been said that Rabbi Reeve Brenner, of the Clinical Center's Department of Spiritual Ministry, isn't your typical rabbi. And it's true. In his off time he raises endangered turtles and releases them back into their natural habitats, and invents competitive sports. But his work on the NIH campus is far more demanding, even hectic.

"I stay very busy," he laughs. "A chaplain at NIH has to be prepared to be supportive of the needs of the entire diversity of the Jewish community," he explains. "That means everything from an orthodox minyan, which is a quorum of men who pray during the week and conducts a service, to Reform, conservative or secular members of the community and their religious and service needs."

Because of this diversity, Brenner says, he serves as a rabbi of not only the orthodox community, but of what he calls the "polydox" community. "That's everyone who isn't orthodox," he tacks on. "When we have a service for the High Holy Days, it's much more of a progressive, liberal service because we know the orthodox community has it's own service."

As part of its continuing outreach to the orthodox Jewish community, the Department of Spiritual Ministries recently announced a completely new program of Monday and Wednesday worship quorums on the 14th floor of Building 10.

When patients check in to the Clinical Center and indicate that they're Jewish, the rabbi soon comes calling, combining genuine concern with well-honed humor. "Hello, I'm Rabbi Brenner," he says, greeting both patients and family members. "How can I waste your time this morning?"

Most are very receptive.

"You see, a rabbi is a teacher.

Nothing is off-limits because every Jew looks upon a rabbi as his or her rabbi, regardless of where they come from. It's almost like the extension of a family—an interchangeable uncle you can turn to in confidence."

Often, Brenner's duties are routine, obtaining candles or Torah texts for ceremonies, or arranging for the dietary requirements of patients. But there are also the spiritual needs that he meets for both Jewish and non-Jewish patients.

"Sometimes I'll call on a patient and end up talking to other patients and visitors who drop by, and we have discussions," he says. The topics range from mundane to the philosophic. One of the philosophical views Brenner expresses concerns atheism.

"It's difficult to be a Jewish atheist," he proclaims, "because you have to ask what idea of God you have problems with and why. It's a philosophic position and it's more complex than merely saying God is some consciousness in the sky, a super being—that's a very narrow understanding of God. You have to earn being an atheist; you have to explain what problems you have with Borowitz's conception or Kaplan's conception and all the disciplines that deal with it. You have to define the God you deny, and for that you need a good education."

Patients who are very sick and

near death many times inquire of the rabbi about what lies beyond this life. "They're concerned," Brenner says, "not only that there is a God, but if there's anything waiting for them. The answer, of course, is that we don't know. I say it's a 'country of no report.'"

In such circumstances, Brenner gives what he calls the "dragonfly analogy."

When dragonfly larvae are deposited on the bottom of a fresh water body, they exist in a



community, he explains. When the time comes, they "pop up" and ascend to the surface. There, they find a reed or blade of grass and climb it, finally breaking free of a protective shell and emerging as a dragonfly.

"Each one of the larvae community may think, when another pops up, that it dies," he says. "One of the others may say to it, 'When you pop up, please communicate with us and let us know what it's like.' But after its metamorphosis, the dragonfly can only hover near the surface of the water. It can't convey that there's a different world, a different consciousness. It's in a land of no report."

Brenner has been with the Clinical Center for three years and loves his work. About half his time, he says, is spent at NIH. The rest of

See Brenner, next page

NIH'ers rally to beat the beltway blues

The Beat the Beltway Blues commuter bus route from Annapolis to downtown Bethesda via Glenarden and Silver Spring is back in action with the help of nearly 100 NIH employees.

The route, which was slated to end April 30 due to low ridership, received overwhelming support when 70 NIH employees met with Senator Ulysses Curry (District 25, Prince George's County), at the Maryland Senate Office Building in May to request continuance of the bus service.

"We made a big difference," said Betty Wise, Clinical Imaging Processing Service, Diagnostic Radiology Department. "If we had not gone to the Senate Building with the large number of people that we had, we would not have been taken seriously."

Wise took on the role of coordinator along with several other NIH employees; the group got 300 riders to sign petitions for the bus route to continue and sent letters to Senator Curry who granted them a meeting sponsored by the Maryland Transportation Authority. The group presented a slide

presentation about the benefits of commuting and offered to accept an increase in fare in order for the bus route to continue.

"This is a great benefit for NIH commuters," said Wise. "It's an easier way to get to work, and a stress reliever. You can relax in a comfortable coach bus, read, and not have to worry about the traffic. It makes for a more productive day."

"We made a big difference"

—Betty Wise

Tom Haden agrees. "Using mass transit or other forms of public transportation benefits the employee," said Haden, a traffic management specialist with the Office of Facilities Planning, Office of Research Services. "It saves employees money in gas and auto insurance and also decreases roadway congestion."

According to Haden, 4,000 NIH employees currently commute by

public transportation and receive Transshare, an incentive to encourage employees to commute by public transportation or vanpool. Employees can receive up to \$100 a month in Transshare subsidies, but must be willing to surrender any NIH parking permits and off-campus parking access cards.

In an effort to encourage carpooling, NIH has made 536 carpool parking spaces available on campus. Currently, there are only 316 carpools and 10 vanpools registered with the NIH Parking Office.

"When employees commute together or use other forms of transportation, it cuts back on the greenhouse emissions and also reduces the number of cars on the campus parking lots," said Haden. "However, with varying work schedules, some employees find it difficult to carpool or even be locked into timed schedules that are used by buses or vanpools."

Instead, most employees rely on the 848 off-campus parking spaces and take one of four off-campus shuttles to the main campus. According to the 2000 Census, nearly seven out of 10 Washington area residents are choosing to drive alone to work. The average one-way commute has increased to 32 minutes, up three minutes from a decade ago.

But those statistics don't matter to Wise, who will continue to commute via the Beat the Beltway Blues bus. "Before I started riding this bus, if I woke up with a headache, I would just call in sick, because I knew it wasn't going to get any better by the time I fought traffic and got to work," she said. "Now I just take some aspirin, get on the bus and when I get to work, I feel much better."

For more information about the Beat the Beltway Blues bus or to find a route in your area, visit www.mtmaryland.com.

Brenner: a rabbi of diversity

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the time he spends writing books and enjoying his grandchildren. His books include *The Faith and Doubt of Holocaust Survivors* and *Yiddle's Riddles*. He is currently completing *Jewish, Christian, Chewish, and Eschewish: Interfaith Pathways for the 21st Century*. His books have won the National Jewish Book Award and the Yivo Prize.

An avid basketball player and fan, Brenner is enthusiastic about the sports he invents.

"There are plenty of running-, jumping-, speed-, stamina-, strength-oriented sports," he says. "I love 'em all. Baseball, football, soccer, rugby,

basketball—I've played 'em all. But how many non-aggressive ball-playing sports can you name? How many games do you know where you're not playing against someone, you're playing with or alongside someone?" Brenner, in fact, is the president of The Bankshot Organization and has dedicated an entire website to such sports (www.bankshot.com).

Rabbi Brenner is one of the Clinical Center's staff of five chaplains. For further information on the Monday and Wednesday quorums, or to contact him, call (301) 496-3407.

—by John Iler

Here's the scoop on Pharmacy's ice cream social

This is a tale about appreciation, remembrance, and ice cream—a tale that occurred in May but seems a more fitting summer story.

When the Pharmacy staff held an ice cream social on May 13 they probably weren't thinking about President Ronald Reagan's 1984 designation of July as National Ice Cream Month, or how 90 percent of Americans enjoy ice cream. But they may have been wondering why the Pharmacy Department was hosting it at all.

It all began with the Pharmacy Residency Class of 2001. The class wanted to give something back to the Pharmacy team for the training, mentoring, and support they had given the residents. To show their gratitude, residents sponsored the department's inaugural Pharmacy Ice Cream Social last year.

Pharmacy staff decided to keep up the tradition in 2002. "We wanted to continue it in the spirit of the 2001 Class and in memory of Kelli Jordan," said Chuck Daniels, chief, Pharmacy Department. Jordan, a resident in that Class, passed away in the fall of 2001.

Whether the focus of a social gathering or just eating pleasure, ice cream has been historically popular, as evidenced by the amount

Americans consume each year—about 23 quarts per person.

In terms of the Pharmacy staff's ice cream social though, just how much of the sweet stuff, aside from the cones, sprinkles and sundae fixings, was there?

"Last year it was like a Baskin-Robbins ice cream shop in here," said Patricia Smith, program support specialist. This past May, according to Smith, management made sure to "gear up with at least eight and a half gallons."

Vanilla, chocolate, Neapolitan, and butter pecan were America's top five favorite individual flavors in 2001. Pharmacy's leading flavor this year (by definition, the "one that ran



out first"), was Edy's 'Almond Joy' said Smith.

The Pharmacy Residency is a one-year postgraduate program with four different areas of concentration—Pharmacy Practice; Drug Information and Pharmacotherapy; Oncology; and Primary Care. Visit www.cc.nih.gov/phar/resident/index.html for further information on the residency opportunities.

Please don't call Ben & Jerry's.

—by Dianne Needham



a u g u s t

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**Grand Rounds for Fellows
noon-1 p.m.**
Lipsett Amphitheater
*Introduction to Pain and
Palliative Care Management*
Ann Berger, R.N., M.S.N.,
M.D., CC

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**Grand Rounds for Fellows
noon-1 p.m.**
Lipsett Amphitheater
*The Role of Cultural Factors
in Clinical Medicine and
Medical Research*
James W. Thompson, M.D.,
M.P.H., University of
Maryland

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**Grand Rounds for Fellows
noon-1 p.m.**
Lipsett Amphitheater
*What Is Happening in
Academic Medicine: A
National Overview*
Robert Dickler, M.H.A.,
Association of American
Medical Colleges

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**Grand Rounds for Fellows
noon-1 p.m.**
Lipsett Amphitheater
*Informed Consent for
Research in Vulnerable
Populations*
David Wendler, Ph.D., CC