

August 2000

NIH Clinical Center News

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Register now for new clinical research training program

A new course for clinical principal investigators, "Clinical Research Training," will be offered Sept. 12 from noon to 4 p.m. in Lipsett Amphitheater.

This course was designed to address one of the essential standards recently approved by the NIH for performing clinical research.

All clinical principal investigators are required to take the course and successfully complete a final exam.

Former participants of the "Introduction to the Principles and Practice of Clinical Research" and "Ethical and Regulatory Aspects of Human Subjects Research" who have passed both courses, as exhibited by successful completion of the final



exam given in each program, will not be required to take the course.

Course topics:

- Historical and Ethical Perspectives, Dr. Ezekiel J. Emanuel,

chief, Department of Clinical Bioethics, CC.

- Roles and Responsibilities of the Investigator, Dr. Gregory Curt, clinical director, NCI.

- Roles and Responsibilities of the Institution, Dr. Alison Wichman, deputy director, Office of Human Subjects Research, OD.

- Regulatory Issues, Dr. Jay Siegel, director, Therapeutics Research and Review, FDA Center for Biologics Evaluation and Research.

- Clinical Investigators and the Mass Media, Anne Thomas, associate director for communications, OD.

Enrollment in the initial course offering will be limited to those individuals. See **New Training**, back page

Decker, former CC director, dies July 13

Dr. John Laws Decker, Clinical Center director and NIH Associate Director for Clinical Care from 1983 until his retirement in 1990, died of a heart arrhythmia July 13 in Bethesda.

During his retirement, Dr. Decker remained active at the Clinical Center, serving as author, and in later editions contributing editor, of "Protomechanics, A Guide to Preparing and Conducting a Clinical Research Study." He also was a consultant to the FDA.

Dr. Decker steered the Clinical Center through challenging times. He said in a 1990 interview, "The most challenging aspect of my years here has been trying to do all that I could to

accelerate the changes required by Congress in reference to research on AIDS. It was a brand new disease when I took over the directorship."

Major advances at the CC during Dr. Decker's tenure included development of the PET program and clinical use of the MRI.

Dr. Decker came to NIH in 1965 as a chief of the Arthritis and Rheumatism Branch in what is now the National Institute of Arthritis and Musculoskeletal and Skin Diseases, serving as clinical director from 1976-1980 and scientist emeritus following

See **Decker**, back page



Dr. John L. Decker served as CC director from 1983-1990.

Quality of Worklife Committee reports on CC suggestions

The Clinical Center Quality of Worklife Committee recently received the following suggestions:

Suggestion:

Ladies' restrooms are dirty and "unsafe," which is not always the fault of the housekeeping staff. Can NIH place signs asking users to clean up after themselves and wash their hands?

Response: This suggestion was forwarded to the Housekeeping and Fabric Care Department management for input. We were informed that there are signs in the restrooms throughout the building advising people who to call if the restroom is not up to par. The men's rooms in the east half of the building all have "Please Flush" signs over the urinals, but it has not made much difference.

A study is currently under way to see if signage helps. All bathrooms are cleaned daily, and the most used ones are cleaned several times a day.

One major problem is that we have more restroom users than restrooms, but this should be better when the CRC is complete, as more restrooms are slated to be built. Last year, the CC Quality of Worklife Committee distributed a desk-to-desk "Spring Cleaning" factsheet with some helpful hints for staff. Visit <http://www.cc.nih.gov/ccc/qwi/spring.html> for more information.

Suggestion:

The stamp machine does not work. Can NIH get its own post office?

Response: Our CC and ORS

research indicates that plans are currently under way for a full-service post office, which would also provide copying, faxing, and other services for employees and visitors. However, the new post office will be established as part of the Building 10 revitalization and establishment of the CRC in 2002. In the meantime, ORS staff indicate that they are discussing interim plans for improving or upgrading current post office services in Building 10.

Unfortunately, there really isn't space for anything more elaborate than what currently exists in the B1 basement station.

With regard to the specific problem of the stamp machines being broken, we learned that the Bethesda postal station, the service provider, is in transition and has been short-staffed. A new permanent staff person will be assigned to Building 10 within three weeks. That individual will become the Building 10 point-

person for faulty stamp machines and related problems. In case you are not aware, the Recreation and Welfare Association (R&W) also sells stamps. The council will continue exploring other possibilities for improving the postal service.

The CC QWL Council appreciates your suggestions and input. If you have any suggestions and/or proposed solutions, please visit the CC QWL suggestion box near the B1 and 2nd floor cafeteria exits.

Food now available Lickity Split

Work nights? Need a meal when the cafeteria's closed? Eurest has developed a new program that will bring the food to you.

This service, available only in Building 10, is called "Lickity Split." It's offered to provide a meal or snack for those whose schedules keep them busy while the cafeteria is open.

Stop by the 2nd floor cafeteria anytime during the day and pick up an order form. The form lists the items available with options for you

to pick, including wrap sandwiches, salads, cookies, and beverages. Circle the items you would like and take it to the cashier. Make sure to put your name and delivery location in the proper place on the form and pay the cashier.

When the cafeteria closes—9 p.m. during the week and 6 p.m. weekends—Eurest will deliver your order. The package will be sealed and a copy of the order form attached. Call 6-9698 for more information.



Clinical Center
News

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Task force lauded for best practices

The CC Chemotherapy Errors Prevention Task Force received one of six American Society of Health Pharmacists Best Practices in Health-System Pharmacy Management Awards for their submission, "An Interdisciplinary Continuous Improvement Approach to Reducing Chemotherapy-Related Medication Errors."

This award honors innovation and outstanding leadership in health-system pharmacy practice management and pharmaceutical care.

Members of this task force included Charles Daniels, PhD, Robert Dechristoforo, MS, Barry Goldspiel, PharmD, David Kohler, PharmD, (Pharmacy Department); David Henderson, MD, Laura Lee, RN (CC Office of the Director); Laura Chisholm, RN, Priscilla Rivera, RN (Nursing Department); Linda Berry, RN, Greg Hinson, RPh, Lillian Butler, RN (Information Systems Department); Frank Balis, MD, Greg Curt, MD, and Wyndham Wilson, MD, PhD (NCI).

Slogan contest

You have until Sept. 1 to enter the annual contest to find the perfect slogan for NIH Fire Safety Awareness Day.

The winning slogan and the author's name will appear on next year's official NIH Fire Safety Awareness Day posters.

Prizes will be awarded for the best qualifying fire prevention slogans based on originality, inventiveness, and creativity.

For more information, call 6-0487. Details—including submission rules—are on the web, <http://www.nih.gov/od/ors/dps/emb/emb slo.htm>.



DTM hosts annual Sept. symposium

The CC Department of Transfusion Medicine (DTM), in conjunction with the American Red Cross and Nexell Therapeutics, Inc., will sponsor the 19th Annual Immuno-hematology & Blood Transfusion Symposium on September 14 in Masur Auditorium.

This all-day conference will include speakers from the CC, as well as experts in the field from across the nation discussing molecular biology, blood donors, and transplantation and immune therapy. Dr. Harvey Klein, DTM chief, will present "Leukoreduction: Boon or Boondoggle."

Dr. Harvey Alter, infectious diseases chief, will discuss "Can You Fool Mother Nature? A Millennial Perspective on the Natural History of Hepatitis C."

Program and registration details are online: <http://www.cc.nih.gov/dtm>.

Seminar looks at Yan Xin Qigong

The CC's Rehabilitation Medicine Department sponsors a conference on Yan Xin Qigong Aug. 12-13. The event runs 9 a.m. - 5 p.m. in Lipsett Amphitheater. Preregister to ensure a seat, 6-2278 or 6-2291.

Renew parking

NIH general parking permits for campus employees whose last names begin with O, P, Q, or R will expire on the last day of August. To renew yours, visit the NIH Parking Office in Bldg. 31, Room B3B04, weekdays between 7:30 a.m. and 4:30 p.m. Be sure to bring your valid NIH identification card, driver's license, and valid vehicle registration certificate for each vehicle to be registered.

CRC updates

CRC construction status reports and photos of progress are posted online monthly, <http://www.cc.nih.gov/cc/crcnews/updates.html>.

Volunteers needed

The Behavioral Endocrinology Branch, NIMH, needs participants for two studies:

- Volunteers between the ages of 18 and 45 are needed for a five-month study investigating the effects of reproductive hormones on brain and behavior.

Volunteers must be free of medical illnesses and not taking any medication on a regular basis.

For further information, call Linda Simpson-St.Clair at 6-9576.

- Individuals with current or past depression are needed to participate in an evaluation study at the CC. These are not treatment studies for depression.

Those eligible will receive a physical evaluation, metabolic studies, and will participate in studies for possible heart disease and osteoporosis in depression. Participants should be 18-65 years old; otherwise healthy; non-smokers for the last year; and able to spend at least one night at the CC.

For details, call 6-5831 or 6-1892.

Presentations

Dennis Martell, RN, research case manager on the 8th floor AIDS Outpatient Clinic, discussed research he is involved in with a group of visiting faculty from some of the major nursing schools in Puerto Rico. The NIH Offices of Loan Repayment and Scholarship and Equal Opportunity and the CC Nursing Department sponsored two days of presentations with a focus on opportunities in nursing for faculty and students.



Medicine for the Public begins next month

The Medicine for the Public lecture series begins Sept. 19.

The lectures are held at 7 p.m. on Tuesdays in the Clinical Center's Masur Auditorium. The schedule:

Sept. 19, New Directions for Organ and Tissue Transplantation, Dr. Allan Kirk, NIDDK.

Sept. 26, Adolescents and AIDS: Millennium Milestones, Dr. Lauren

Wood, NCI.

Oct. 3, Dangerous Liaisons: Drugs and Herbal Products, Dr. Stephen Piscitelli and Dr. Aaron Burstein, CC.

Oct. 10, Stroke: Rapid Diagnosis, New Treatments, Dr. Alison Baird, NINDS.

Oct. 17, Women's Health Research for the 21st Century, Dr.

Vivian Pinn, Office of Research on Women's Health.

Oct. 24, Prostate Cancer, Dr. Marston Linehan and Dr. William Dahut, NCI.

Visit the web at <http://www.cc.nih.gov/cc/mfp/series.html> for details.

Exhibit spotlighting strength from unity runs through Sept. 4

Strength from Unity: Expressions on Cancer from the Island of Ireland and the United States will be on display in the Lipsett Gallery through Sept. 4. The works were originally displayed in 1999 in Belfast, Northern Ireland, as a part of the NCI All Ireland Cancer Conference.

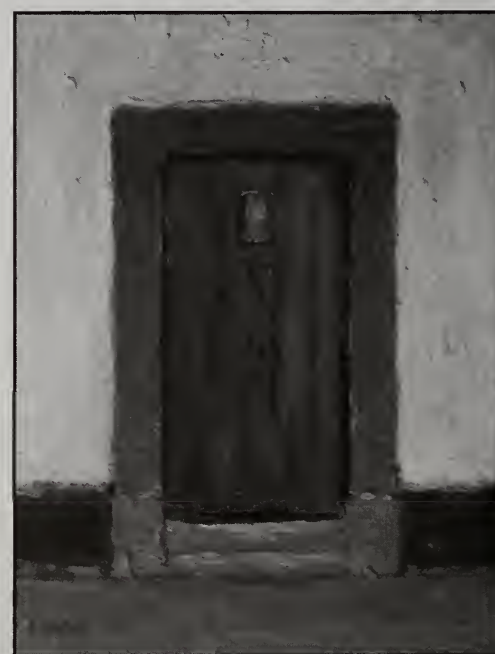
Funded by the Susan G. Komen Breast Cancer Foundation, this is a collection of paintings, photographs, tapestries, and poems of artists from Northern Ireland, the Republic of Ireland, and the United States whose lives have been touched by all types of cancer.

Each of the 18 pieces of art in the CC exhibit is accompanied by the

artist's personal story of how he or she was compelled to work on issues of life, death, strength and above all, hope, through artistic expression. Collectively, the exhibit reflects the idea that cancer knows no political or geographic boundaries and that there is strength in unity.

Bernard Fallon's "Hope" depicts his wife, Trudy's, cancer diagnosis in 1995. For her, the door "exudes comfort, light, and strength." That light, she says, "kept me strong and connected to life through some of the bleakest days of my illness. I'm here. I'm living."

For additional information about the exhibit, visit <http://www.cancer-art.com>.



Hope

Bernard Fallon's "Hope" depicts his wife, Trudy's, cancer diagnosis in 1995.



Suchie, a six-year-old black lab mix, is a member of the Caring Canines team popular with patients and staff alike at the Clinical Center. Under the organizational umbrella of National Capital Therapy Dogs, Inc., the dogs visit here four times a month. Dr. Haines makes sure they are freshly bathed, clipped and cleaned—and healthy—each time. (Photos by Bonnie Flock)

Caring

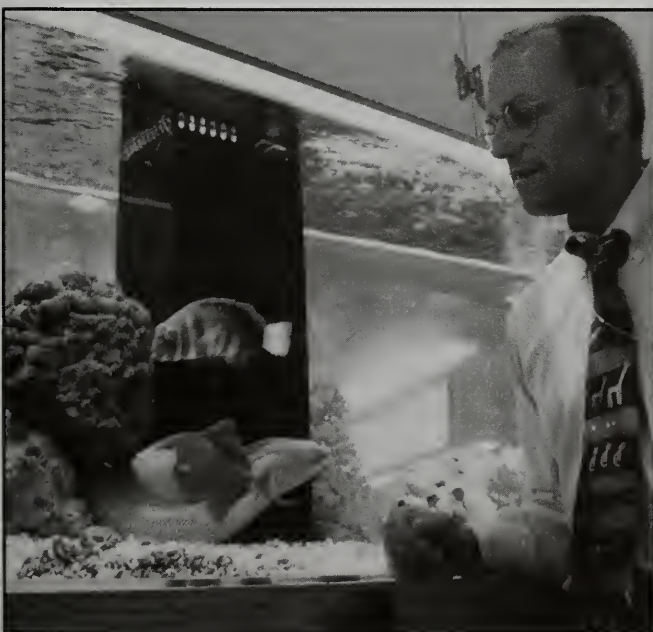
for the animals

They visit and live and support research here—a cadre of animals that play an assortment of roles. Caring Canines are regulars, as are the guinea pigs in the playroom and the fish that circle in lobby aquariums.

Making sure that all the animals at the Clinical Center are healthy and well cared for is part of veterinarian Dr. Mark C. Haines's job. He's the CC's Animal Program Director. These photos offer a glimpse into the sometimes-unseen aspects of animal care here.



Live-in guinea pigs, Cookies and Ice Cream, call the 14th floor playroom home, and Dr. Haines regularly provides routine health checkups to safeguard the children who visit with the duo.



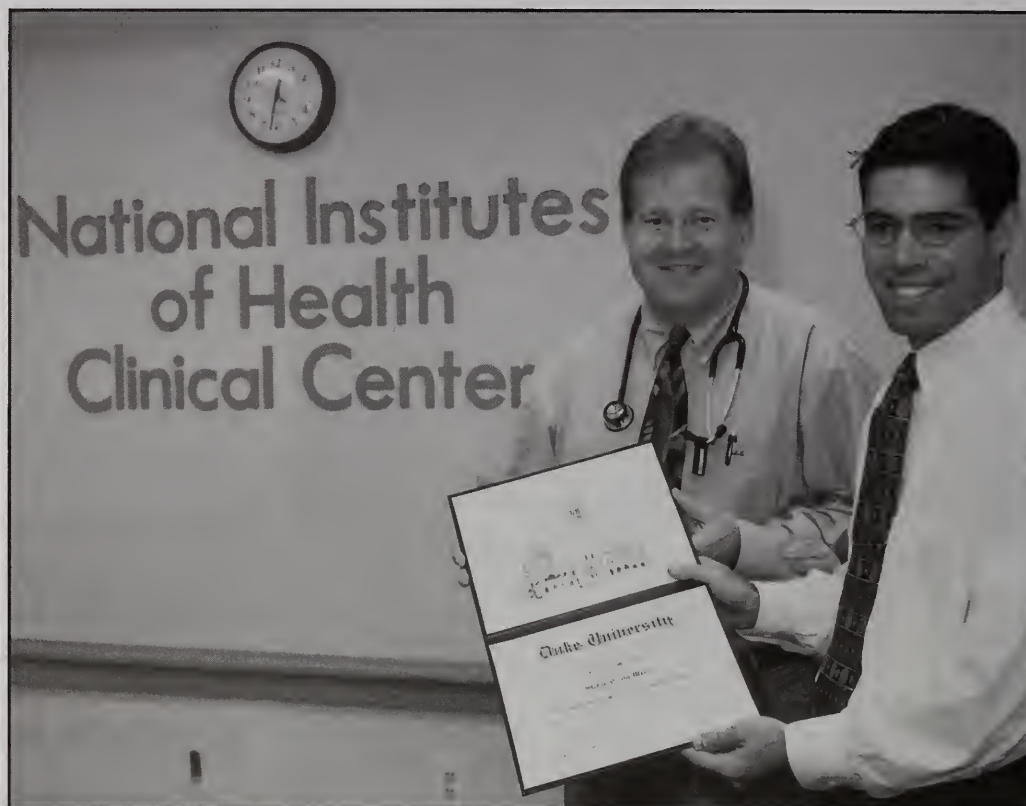
Patients enjoy the calm and color aquariums offered in some Clinical Center waiting areas. Dr. Haines provides oversight to those who care for the fish.



Accessing and advising on the conduct of research involving animals is a major aspect of Dr. Haines' work at the CC. In addition to monitoring the health and safety of research animals, Dr. Haines consults with investigators writing research protocols to make sure all animal issues are appropriately addressed.

New grads

Spring graduates of the NIH-Duke Training Program in Clinical Research included Richard Messman, left, and Stefan Weiss. Not pictured are Michael Brennan, Hiroyu Hatano, and Kara Sovik. The program—which began in 1998—is a collaboration between the Clinical Center and Duke University, in Durham, N.C. It uses distance-learning to strengthen training opportunities in clinical research. The Duke University School of Medicine, which established its program in 1986, awards a Master of Health Sciences in Clinical Research for successful completion of the training program here.



Education programs in clinical research growing

Clinical research—evaluating new and promising treatments in people—provides a blueprint for better health care. To help refine and focus those blueprints, the CC has developed a series of programs aimed at improving how clinical research is conceived, monitored, and carried out.

“This is an extraordinary era of innovation and progress for medicine and science,” notes Dr. John I. Gallin, CC director. “Clinical research can be beneficial and successful only when physician-researchers have the necessary training and expertise to conduct it. Historically, medical students depended on willing and able mentors to teach the intricacies of clinical research. That approach simply doesn’t work today.”

The nation’s clinical research hospital, the NIH Clinical Center offers an excellent environment for exploring new approaches to identifying and providing the tools that researchers need. “Effective clinical research is both an art and a science,” Dr. Gallin adds, “and training in clinical research depends on a thorough grounding in the basic techniques,

rich opportunities for practical application, and the flexibility to meet the changing needs of medical science and health-care consumers.”

How do clinical researchers learn? Bridging the gap.

Cornerstone for Clinical Center training efforts is the course, “Introduction to the Principles and Practice of Clinical Research,” established in 1995. “The program teaches researchers how to design a good clinical trial,” Dr. Gallin, who serves as course director, points out. It covers epidemiological methods and focuses on study design and development, protocol preparation, patient monitoring, quality assurance, and FDA issues. It also includes data management and legal and ethical issues, including protection of human subjects. The course is offered annually. Classes meet twice a week September-February.

Some attend by teleconference sites in Baltimore, Georgetown University and the University of Puerto Rico. The course also has been video-conferenced to NIEHS in North Carolina, NIDDK components

in Arizona, and to the Rocky Mountain Labs in Montana, which are part of NIAID.

Another distance-learning program designed to strengthen training opportunities in clinical research is a collaboration between the NIH Clinical Center and Duke University that began in 1998. It’s designed primarily for clinical fellows and other health professionals training for careers in clinical research. “It meets an existing need at NIH for formalized academic training in the quantitative and methodological principles for clinical research,” Dr. Gallin says.

Offered are courses in research design, statistical analysis, health economics, research ethics, and research management. NIH participants complete coursework primarily through videoconferences with faculty at Duke. NIH staff teach other courses as Duke adjunct faculty. The Duke University School of Medicine, which established its program in 1986, awards a Master of Health Sciences in Clinical Research for

(See **Programs growing**, next page)



Fellows arrive

A reception following orientation for this year's incoming clinical fellows provided an opportunity for new and current trainees to meet one another, as well as chat informally with NIH senior staff and others who will be vital in their training experience. Standing left is Dr. John I. Gallin, CC director.

Programs growing, From page 6

successful completion. The program can be completed in two 16-week semesters. Participants typically spread course work over two years. There's also a non-degree option for qualified individuals who want to acquire specific skills in this discipline.

Clinical Pharmacology: A critical link

Another NIH Clinical Center-based training opportunity is the course, "Principles of Clinical Pharmacology," initiated in 1998 by Dr. Art Atkinson. "Many medical schools don't offer formal courses in clinical pharmacology," Dr. Gallin says. "This program covers what researchers need to know concerning the clinical pharmacologic aspects of drug development and use."

The course, which complements the Introduction to the "Principles and Practice of Clinical Research," includes a review of pharmacokinetics, drug metabolism and transport, assessment of drug effects, drug ther-

apy in special populations, and contemporary drug development. Offered annually, the course is also designed to assist individuals preparing to take the certification exams of the American Board of Clinical Pharmacology.

"A great deal of the clinical research done here at the Clinical Center involves clinical trials of new drugs," explained course director Dr. Atkinson. "Clinical pharmacology is an obviously important component of the design, conduct and interpretation of these trials and it appears that our course fills an unmet need in this regard."

Examining ethical issues

"Medicine and science can't advance unless society trusts that progress never compromises the health and well-being of those who participate in clinical research," explains Dr. Gallin. "Thoughtful and continuing assessments of ethical issues are critical skills that clinical researchers need." To help meet that need, the Clinical Center's Department of Clinical Bioethics has put together a

seven-session overview of ethical and regulatory issues in clinical research for NIH intramural scientists and research staff.

"The goal of the course is to provide clinical investigators and institutional review board members skills with which they can analyze the ethical issues they confront in clinical research," said Dr. Ezekiel J. Emanuel, course director and chief of the CC Department of Clinical Bioethics. "We want to train researchers so they can design their protocols to conform to prevailing ethical standards on ethical research."

The program, which began in 1998, includes sessions on the history of human-subjects research; research principles and guidelines; the ethics of clinical trial design, patient recruitment; and informed consent. A mock IRB (institutional review board) is incorporated, along with extensive panel discussions, including presentations from research patients on their experiences.

Decker, From page 1

his retirement in 1990.

A native of New York and the son of missionary parents, he grew up in China and returned to the U.S. for his education. A World War II Navy veteran, Dr. Decker served in the Pacific and received the Purple Heart.

A graduate of the University of Richmond, he earned his MD from Columbia University College of Physicians and Surgeons in 1951. From 1951-1955, he completed his internship and residency requirements at Presbyterian Hospital in New York. He went on as a research fellow in medicine at Harvard University and at Massachusetts General Hospital, where he received training in rheumatology. Before coming to NIH, Dr. Decker was on the faculty at the University of Washington in Seattle.

His studies in rheumatic diseases earned him international recognition. Among his awards: the Philip Hench Award from the Association of Military Surgeons in 1972, the NIH Director's Award in 1977, the Alessandro Robecchi International Prize for Rheumatology Research on nephritis of systemic lupus erythematosus in 1983, and the PHS Superior Service Award in 1987.

Dr. Decker in 1989 became the second physician to receive the American College of Rheumatology Gold Medal. In 1990, Dr. Decker was the first NIH physician to receive the Master of the American College of Physicians.

Survivors include his wife, Lucille Macbeth Decker of Bethesda; son David L. of Bethesda; and three daughters, Virginia E. Jahnnes of Jefferson, Md., Margaret "Megan" Malario of Chestertown, Md., and Susan Morrow of Bristol, Va.

New Training, From page 1

viduals for whom it is required.

Registration, which is online, ends Aug. 30. Visit the course web-site at <http://www.cc.nih.gov/cc/cr/training.html>.

The course will be repeated Dec. 12.

Science in the Cinema continues

After the screening of each film in this month's *Science in the Cinema*, a guest speaker with expertise in the film's subject area will comment on the science depicted in the film and take questions from the audience.

This Thursday evening program runs from 7 p.m. to about 9:30 p.m. The Aug. 24 film will begin at 6:30 p.m. Come to Bldg. 45 (Natcher) auditorium. Seating is first-come, first-served.

Aug. 10, "Yellow Jack." This film is based on the true story of U.S. Army doctor Walter Reed (Lewis Stone) and his quest to discover the cause of yellow fever (1938). Guest Speaker: Michael Rhode, **Chief Archivist**, National Museum of Health and Medicine, Armed Forces Institute of Pathology, Washington, D.C.

Aug. 17, "Girl, Interrupted." Based on a true story, this film is set in the changing world of the late 1960s. Finding herself at a renowned psychiatric institution for troubled women, Susanna Kaysen must choose between the world of people who belong on the inside or the often difficult world of reality on the outside (1999, Rated R). Guest Speaker: Danny Wedding, PhD, MPH, Professor of Psychiatry and



Director, Missouri Institute of Mental Health, University of Missouri School of Medicine.

Aug. 24, "Not As A Stranger." The story of a nurse who works to put her husband through medical school, this film is a timeless depiction of the relational, financial, and emotional challenges faced by those who embrace the medical profession (1955). Guest Speaker: Peter Dans, MD, Associate Professor of Medicine, Department of Internal Medicine, John Hopkins University School of Medicine.

For details, go to the Office of Science Education web site at <http://science-education.nih.gov/cinema/>.

a u g u s t

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CRIS Educational Series
11 a.m. - 12:30 p.m.
Lipsett Amphitheater

Session II: Status of Sites, Functionality, Implementation Strategies

23

CRIS Educational Series
11 a.m. - 12:30 p.m.
Lipsett Amphitheater

Session IV: Implementing Electronic Patient Record Systems: Success Strategies and Pitfalls to Avoid

16

CRIS Educational Series
11 a.m. - 12:30 p.m.
Lipsett Amphitheater

Session III: Medical Terminology's, Data Dictionaries, and Medical Knowledge Bases

30

CRIS Educational Series
11 a.m. - 12:30 p.m.
Lipsett Amphitheater

Session V: Historical Data Repository for Research and Outcome Analysis (Data Warehousing)

All are welcome to attend. There's no fee or registration requirement. CMEs are available. For details, contact Susan Harris at 5-8721.