

July 2000

# Clinical Center News

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## Isolating a diabetes cure

### *Clinical Center's Cell Processing Section leads in islet cell isolation*

The Clinical Center's Department of Transfusion Medicine is once again at the forefront of exciting new clinical research as its Cell Processing Section (CPS) prepares islet cells for transplantation in an effort to cure diabetes.

Canadian researchers made headlines last month when they reported successfully transplanting insulin-producing islet cells into eight patients with diabetes, freeing them from daily insulin shots. The CPS is working hand in hand with NIDDK researcher Dr. David Harlan to replicate and improve upon the Canadians' work here at the Clinical Center.

However, according to Dr. Harlan, "Islet isolation is not simple. There are a lot of variables to consider."

It all starts with a donor pancreas. Islet cells are clustered in ducts deep within the organ and make up only about 2 to 3 percent of its cellular mass. Extracting the islets requires a 6-hour procedure and three CPS technologists working simultaneously in a sterile environment.

In brief, fat is trimmed off the pancreas, and an enzyme called collagenase is pumped into the ducts. The enzyme digests away the connective tissue that comprises most of the pan-



From left to right, Larry Moses, Sue Ellen Frodigh, and Ken Hines, of the Cell Processing Section.

creas. To aid the breakdown process, the tissue is also placed in a stainless steel chamber full of marbles and agitated back and forth.

As the islet cells are released, they are further separated and washed. The result is a volume of pure islet cells ready for transplanta-

tion into the patient's liver via the portal vein. This will be done in the Diagnostic Radiology Department's Special Procedures Lab. Once imbedded in the liver, the islet cells appear to produce insulin in response to blood sugar levels, according to the Canadian team's report.

Already skilled in cell-processing techniques, CPS lead technologists Janet Lee and Ken Hines visited experts at the University of Miami in early 1999 to learn the basics of islet isolation. They carried their new knowledge back to the Clinical Center, and set to work modifying their lab to do islet isolations for Dr. Harlan's original protocol, which planned to test an antirejection drug called anti-CD154. That study was shelved when the drug was found to cause blood clots.

Dr. Harlan retooled his approach to replicate the Canadian team's work, and Lee and Hines recently visited the Canadians to see exactly how they do their isolations. The CPS team has processed more than 20 pancreata so far, and they are ready to move forward with a clinical application.

See **cell processing**, page seven



## New "Clinical Research Training" course

A new course for clinical principal investigators, "Clinical Research Training," will be offered Sept. 12 from 12 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 include:

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

M.D., Ph.D., Chief, Department of Clinical Bioethics, CC.

- "Roles and Responsibilities of the Investigator," Gregory Curt, M.D., Clinical Director, NCI.
- "Roles and Responsibilities of the Institution," Alison Wichman, M.D., Deputy Director, Office of Human Subjects Research, OD.
- "Regulatory Issues," Jay Siegel, M.D., Director, Therapeutics Research and Review, CBER.
- "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 for whom it is required. Registration begins on Aug. 1 and ends on Aug. 30. To register, please visit the course website at <http://www.cc.nih.gov/cc/cr/training.html>. The course will be repeated Dec. 12.

## New Board members

Five new members join the Clinical Center Board of Governors this month. Joining new board chair Dr. Stephen Schimpff, who was profiled in last month's issue, are:

Ralph D. Feigin, M.D., President and CEO, Department of Pediatrics, Baylor College of Medicine, Houston, Texas; R. Edward Howell, Director and CEO, University of Iowa Hospitals and Clinics, Iowa City, Iowa; Elizabeth G. Nabel, M.D., Director, Clinical Research Programs, NHLBI; Joan Y. Reede, M.D., MPH, MS, Associate Dean of Faculty Development and Diversity, Harvard Medical School, Boston, Mass.; and Vivian E. Reifberg, Practice Principal, McKinsey & Company, Washington, D.C.

## "Principles of Pharmacology" course to begin soon

The "Principles of Clinical Pharmacology Course," sponsored by the Clinical Center, will begin Sept. 7. The course will be held Thursdays from 6:30 p.m. to 8 p.m. in Lipsett Amphitheater, and runs through April 26, 2001.

Topics include: pharmacokinetics; drug metabolism and transport; assessment of drug effects; drug therapy in special populations; and drug discovery and development.

An outstanding faculty has been assembled to present the lectures,

including Dr. Carl Peck of Georgetown University's Center for Drug Development Science, Dr. Jerry Collins of the Food and Drug Administration, and the Clinical Center's Dr. Arthur J. Atkinson, Jr., course director. Before coming to NIH, Dr. Atkinson was at Northwestern University, where he directed the Clinical Pharmacology Center, and at the Upjohn Company, where he was in charge of clinical drug development programs.

This is the third year that the

course is being offered. Last year 305 students registered, and there was considerable sustained enthusiasm for the course.

Registration is free and open to all interested persons. Syllabus materials will be provided for each lecture. Certificates will be awarded at the end of the course to students who attend 75 percent of the lectures. For more information, including the registration form, consult the course website at <http://www.cc.nih.gov/cc/principles/>.

Clinical Center  
**News**

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## Parking renewals

NIH general parking permits for campus employees whose last names begin with M or N will expire on the last day of July. 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. Call 6-6851 if you have any questions.

## Jaw pain study

NIDCR researchers seek patients for studies of pain-relief medications. Patients with early-stage temporomandibular disorders (TMD) will receive either a study drug (celecoxib), a standard treatment drug (naproxen), or a placebo. Patients with later-stage TMD will receive either a study drug (etanercept) or a placebo. If you are between the ages of 18 and 65 and have TMD jaw pain, call 1-800-411-1222 to find out if you might be eligible. There is no charge to take part.

## Brain study

NIMH researchers seek children ages 6–13 years for a study of how the brain controls finger movements. Children may be healthy volunteers or those with a diagnosis of Attention Deficit and Hyperactivity Disorder (ADHD). The study takes 3 hours and involves a neurological examination, ADHD assessment, and noninvasive tests. Compensation provided. Call Dr. Marjorie Garvey at 6-5323 for details.

## Normal volunteers

The Clinical Brain Disorders Branch of NIMH is looking for normal volunteer college-educated men between the ages of 30 and 50 for a 2-day outpatient study of variables that might be related to the cause of schizophrenia. No overnight stay is required. The study includes MRI, neurocognitive testing, and a neurological examination. A stipend is available. Call Kayleen Hadd at 1-888-674-6464 for more information.

## New look

In case you haven't noticed or visited lately, the Clinical Center's website has a new look. It's also been reorganized to make information easier to find. New features include "Research Today," which focuses on interesting aspects of CC research, and "Staff Shortcuts" to frequently needed sites. Feedback is welcome. Check it out at <http://www.cc.nih.gov>.

## Poster deadline

The 14th annual NIH Research Festival will be held Oct. 10–13. Poster abstracts are now being accepted. Posters in any area of research conducted on campus will be considered for presentation, but the organizing committee requests only one poster submission per first author. The deadline for online poster registration is 5 p.m., Aug. 7. For details, consult the website at <http://festival2000.nih.gov>, or call Paula Cohen at 6-1776, or e-mail, [pc68v@nih.gov](mailto:pc68v@nih.gov).

## Sjögren's study

Doctors at NIH seek adults with Sjögren's syndrome for research studies to improve understanding and treatment of the disease. Participants receive study-related diagnosis, evaluation, and medication at no charge. Please call for more information about taking part: 1-800-411-1222.

## Uveitis study

NEI researchers seek adults and children diagnosed with uveitis for research studies to help find ways to improve diagnosis and treatment of this eye disease. Please call 1-800-411-1222 for details.

## Goldspiel's award

Barry R. Goldspiel, Pharm.D., was one of six in the nation to receive the second annual American Society of Health Pharmacists Best Practices in Health-System Pharmacy Management Award. This award honors innovation and outstanding leadership in health-system pharmacy practice management and pharmaceutical care. At the organization's annual meeting in June, Dr. Goldspiel presented a summary of the award-winning program, "Interdisciplinary Continuous Improvement Approach to Reducing Chemotherapy-related Medication Errors," which improved the quality of patient care at the CC by use of the continuous quality improvement process.



# Reduce! Reuse! Recycle!

Were you among the folks who thought “Clean Your Files Week” (April 17-21) was a good idea but did not quite get around to it then? Perhaps you were confused because your office did not have bins for recycling either white office or mixed paper. You are not alone.

Although recycling has grown at NIH since the mid-1980’s, and paper recycling was high during the recent “Clean Your Files Week,” there is room for improvement, said David Crook, recycling coordinator in the Environmental Protection Branch, Division of Safety, ORS.

According to Crook and William (Kenny) Floyd, chief, EPB Waste Management Section, the amount of waste generated in Bldg. 10 alone is about one quarter of the campus total (3,203 of 11,500 tons last year). The CC currently recycles 28 percent of its wastes, and NIH, about 30 percent.

Could we do better? The official recycling goal is 50 percent in Montgomery County, Md., where NIH is located, and the county itself recycled 36 percent last year.

The Montgomery County recycling regulation says that businesses, including government facilities, **must** recycle office paper, corrugated cardboard, newsprint, aluminum and bi-metal food and beverage cans, glass and plastic food and beverage containers, and yard trimmings.

Businesses can **voluntarily** recycle scrap metal, plastic film, food waste, wood waste, batteries, motor oil and antifreeze, construction and demolition debris, toner cartridges, and phone books.

But how? Crook works with each



Newspapers and soda cans are but two of the many items that can be recycled at NIH. Kenny Floyd, left, chief of the Waste Management Section, and Dave Crook, right, NIH recycling coordinator, encourage you to get involved and help set up a recycling effort in your work area, if none currently exists.

NIH building or cluster to devise a recycling plan. Volunteer area coordinators help by determining which categories each office, corridor, or complex is willing to recycle and by calling Crook to arrange for containers or for troubleshooting.

In a typical week in early spring 2000, the CC generated 2.8 tons of recyclables in a campuswide total of 12.1 tons. Crook emphasizes that the main goal of recycling is to reduce the amount of waste going to landfills. The fact that recycling also

reduces the cost of waste disposal (about \$44 per ton) is a bonus. The 1999 bonus was \$125,000 for 2,842 tons that NIH recycled in a year.

Aluminum is the clear winner when it comes to the value of recycling—both for cash payback and environmental value. Scrap metal dealers this spring were paying nearly \$640 per ton. Every ton recycled is one less ton to be imported: the United States no longer mines any aluminum and must import all of it.

The per-ton payback recently for

## Making a difference

The NIH recycling website (<http://www.nih.gov/od/ors/ds/recycle/>) provides threefold advice: (1) reduce the amount of materials we consume, (2) reuse materials, and (3) recycle if possible.

Specific individual actions can flesh out this advice. The Natural Resources Defense Council (<http://www.nrdc.org>) lists the following ways that individuals can help reduce garbage:

- Buy products made with recycled content and packaged in recyclable materials.
  - Buy goods in returnable and recyclable containers.
  - Learn where you can take items to be recycled and make the effort to go there.
  - Find out your community's waste management strategy,
- and encourage local officials to consider more ambitious recycling initiatives.
  - Learn about and avoid products that contain potentially hazardous contents.
  - Bring your own (cloth) bags to local stores, and encourage others to do the same.
  - Tell store managers and manufacturers who are making good environmental choices that you recognize and appreciate their efforts.
  - Encourage the introduction of and participate in bulk buying programs whereby you can purchase larger quantities with less packaging.
  - Use the consumer hotlines provided by many companies to explain to them the need for less packaging.

—L.S.

some other wastes was \$120 for office paper; \$30 for cardboard; and \$10 for scrap metal. The NIH waste contractor looks for the best price when hauling the recyclables to local dealers.

How could the CC do more to reduce waste? Crook says, "If you could get all that mixed paper out of the trash, it would make a huge difference." Many papers listed as "don'ts" on the white office paper recycling containers are eligible for recycling in the mixed paper containers.

Rental buildings in Montgomery County, such as on Executive Boulevard where many CC off-campus employees work, are required to make collection and storage of recyclables available, if requested, to tenants. But a county brochure notes,

"The responsibility for participating and reporting, however, falls to the individual business (already defined as including government facilities) generating the waste materials." (Details about business recycling can be found on the Montgomery County website – <http://www.co.mo.md.us/> – under the Department of Public Works and Transportation, Solid Waste Division.)

To learn more about NIH recycling or to request supplies, visit the recycling website <http://www.nih.gov/od/ors/ds/recycle/>. If you cannot find a volunteer area coordinator listed for your area, Crook points out, "A sign-up form is always available on the website!" Or you can call him at 2-6036.

—by Linda Silversmith

## CRIS questions?

July 17 marks the debut of the "CRIS Educational Series."

Developed by the CC Information Systems Department, the series will provide opportunities for CC and NIH personnel to learn about the selection process for a replacement for the aged Medical Information System, or MIS. The new system will be called the Clinical Research Information System, or CRIS.

Topics will include: the electronic patient record; what's currently being marketed commercially for health care information technology; how information technology can be used in a research medical center; and other topics relevant to the selection of a replacement system.

The first session is July 17 from 2 p.m. to 4 p.m., in Lipsett Amphitheater. The topic is "Overview of the Computer-Based Patient Record (CPR)," presented by Dr. Marshall Ruffin.

The remaining sessions will take place from 12 noon to 2 p.m. in Lipsett Amphitheater:

- Aug. 9 – "Session II: Status of Sites, Technology and Trends, and Vendors and Product Offerings."
- Aug. 16 – "Session III: Medical Terminologies, Data Dictionaries, and Medical Knowledge Bases."
- Aug. 23 – "Session IV: Implementing a CPR: Success Strategies and Pitfalls to Avoid."
- Aug. 30 – "Session V: Historical Data Repository for Research and Outcome Analysis (Data Warehousing)."

All are welcome to attend. There is no fee or registration requirement. Contact Rubi Defensor at 5-8516 for more information.



# New head for pain and symptom management

Dr. Ann Berger joins the staff of the Clinical Center on Aug. 1. She will set up and head a new Pain and Symptom Management Service, which will help manage pain as well as other symptoms that make patients physically uncomfortable, such as difficulty breathing, nausea and vomiting, and weight loss.

"I am quite excited about coming to the Clinical Center," said Dr. Berger. "Clearly NIH is ready for pain and palliative care. I am anxious to start the service as well as educational programs in pain and palliative care, and also to have national input into this issue."

Dr. Berger earned a B.S. degree in nursing from New York University and an M.S.N. degree in oncology nursing from the University of Pennsylvania. After working as an oncology clinical

nurse specialist for several years, Dr. Berger completed her medical training at the Medical College of Ohio, in Toledo. She completed an internship and residency at Hartford Hospital in Connecticut, and went on to Yale University for a fellowship in medical oncology and pain and palliative care. She stayed on the faculty at Yale, where she started a palliative care service. She achieved the rank of assistant professor in medicine and anesthesiology.

Dr. Berger comes to the CC from Cooper Hospital/University Medical Center, in Camden, N.J., where she is director of supportive care services. She is actively involved in the care of patients as well as in education and research. She teaches a palliative care course to medical students, residents, and

fellows, and chairs the ethics committee.

Nationally, Dr. Berger is the leader for supportive care research in the Cancer Control Committee in Cancer and Leukemia Group Board, chair of the CME committee for the Academy of Hospice and Palliative Care, and is involved in many professional societies. She has lectured extensively on pain and palliative care and has published many articles in the field. She is senior editor of a major textbook in palliative care, "Principles and Practice of Supportive Oncology."

"We are delighted to have Dr. Berger join our staff," said CC Director Dr. John Gallin. "Her expertise in pain and palliative care will provide the leadership that is crucial to the success of this new program."

## NIH Labor Partnership Council

Union and management relations just aren't what they used to be...at least at NIH they aren't. Thanks to the NIH Partnership Council, union leaders and NIH management can proactively look at issues or concerns that the organization at large faces, before they become serious problems. And by employing techniques that "loosen" some of the traditional bargaining rules to form a common understanding as to how things can be done to benefit workers and managers alike, collaboration has truly taken on a new meaning.

Established in 1993, the NIH Partnership Council promotes the objectives set forth in the President's Executive Order 12871, which called for a change in the nature of relationships between labor unions and management. Specifically, the NIH Partnership Council is charged with identifying issues with agency-wide impact and developing recommendations and/or solutions.

"The Council is dedicated to supporting and facilitating the NIH's mission of the pursuit and promotion of beneficial research through the practice of

constructive, interest-based bargaining between labor unions and NIH management," says Maria Gorrasi, the NIH labor relations specialist. "Council members are encouraged to engage in a free flow of all information that is relevant to the labor issues under consideration. This has helped to foster mutual respect and understanding of all opinions and ideas."

Areas of interest to the group are diverse, from transportation and parking on campus to daycare and quality of worklife concerns. The group tackles these concerns as they relate to the entire NIH community. The Clinical Center, in particular, has representation that can bring to the table issues that will potentially affect the entire NIH community.

Union representation at the CC is limited to the Nutrition and Housekeeping and Fabric Care departments, who look to this group as an excellent way to bring unions and managers together. "The more that people learn about this organization and the value that it can bring to employees and managers, the more exciting it is," said Alberta Bourn, chief of the Nutrition

Department, and alternate CC representative for the Council. "The group stands poised to address a broad base of concerns."

The Council meets on the first Tuesday of every month. Members and their alternates comprise an equal number of union and management representatives. The four unions represented to date on this Council are: American Federation of Government Employees (AFGE) Local 2429; Washington Area Metal Trade Council (WAMTC); Local F-271 International Association of Firefighters (IAAF); and the Fraternal Order of Police (FOP) Lodge #1. One member from each of the four union locals is appointed; four members from management are determined by the NIH collective bargaining official; and one member is chosen by the Federal Managers Association.

Meetings are open to visitors, and a website will be launched soon. For more information, contact Maria Gorrasi at 4-1461.

—by LaTonya Kittles

## ...Cell Processing Section joins fight against diabetes

continued from page one

The cell processing facility opened in 1997 with the goals of developing and improving procedures for collecting, modifying, growing, and preserving human cellular components. The facility was designed to meet the Food and Drug Administration's regulatory requirements for a biologics production facility. A *biologic* is a treatment derived from a living organism, for example, a vaccine. Islet cells fall into this category.

"The isolation process is very labor intensive, and one of our goals is to streamline and automate parts of it," said CPS chief Dr. Elizabeth Read. She also pointed out that each pancreas yields different amounts of islets. Additional research goals include standardizing the "dose" of islets and developing ways to predict the amount of insulin they might produce once in the body.

Other CPS staff involved in this



Janet Lee, left, and Angela Pickett, right, of the Cell Processing Section.

work include section supervisor Charley Carter, Sue Ellen Frodigh, Larry Moses, Chauha Pham, Angela Pickett, and Hoi May Wong. Three technologists are on call 24 hours a day, because a pancreas can arrive at any time.

"Their expertise, attention, and effort put together the islet isolation unit. They bring a squared-away, regulatory mindset to the process that a clinician might not have," said Dr. Harlan.

"Only eight patients in the world have had this therapy work, and none of them have been in the United States. It is still very experimental. NIH will be one of the first institutions to try this therapy in humans," said Dr. Harlan. His new protocol is in review. He hopes to study up to 20 patients. And CPS will be with him every step of the way.

—by Sue Kendall

## "Enterprise Directory" brings order to information

NIH employees who move or transfer need to update information in at least one printed and two online directories. Didn't know that? Most people don't. That's why the information is often wrong.

Meet NED, NIH Enterprise Directory. It's a new system that automatically and simultaneously updates information for you.

NED is like a well-organized butler or mother. NED actually is a secure, centralized electronic directory—which a technical committee recommended 4 years ago—to coordinate directories for e-mail, personnel,

parking, and more.

A specialized data base, NED will store locator information for NIH staff, fellows, guests, contractors, volunteers, and tenants (such as CBER employees) and link with other NIH data bases and applications to share information and reduce redundancy.

NED will assign each individual a unique identifier, different from social security numbers, that will then be used by all the linked systems. One result is no more writer's cramp for new workers, who will no longer have to fill out multiple forms

with the same information. NED also will make checkout easier for folks leaving NIH by identifying all associated resources, such as ID badges, computer accounts, and keys. Other uses include access to TRANSHARE for transportation assistance, card key access, library cards, and training.

The first step in getting information into NED is to import it from existing data bases, such as human resources, fellowship payment, telecommunications, Fogarty International Center, parking and

continued on next page





## FOCC donation

The Friends of the Clinical Center (FOCC) received a generous donation recently. Craig Widmaier, left, of Becton Dickinson and Co., a medical supply company, presents FOCC President Maria Stagnitto with a check for \$5000 to benefit the NIH charity that financially assists Clinical Center patients.

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ID's, the e-mail directory, and ITAS (the integrated time and attendance system). Next, administrative officers (AO's) will become the registrars or gatekeepers, adding new workers, entering updates, and de-registering departing workers.

Your AO is the person to see if you have questions about whether your information is accurate and current. CIT is offering 3-hour NED training courses to AO's and technicians. (See their website at <http://training.cit.nih.gov/>.)

Each institute and center has a coordinator and a cut-over date. The CC coordinator is Elaine Ayres, deputy chief operating officer, assisted by Ann Ellis, facility management AO. The CC cut-over date was June 30.

Ellis emphasizes, "NED will operate under strict privacy and disclosure rules, with listed individuals having the right to access and amend their listings." The access of AO's is limited to only the records of the staff for which they are responsible.

More details on NED are at <http://www.alw.nih.gov/dsc/overview.htm>.

-by Linda Silversmith

## j u l y

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**Grand Rounds**  
noon - 1 p.m.  
Lipsett Amphitheater

*Novel Therapies in Psoriatic Arthritis: Rationale and Early Clinical Experience*, Gabor Illei, M.D., NIAMS

*Gamma-Delta-T-Cell Lymphomas: From the Laboratory to the Clinic*, Elaine Jaffe, M.D., NCI, and Jorge Toro, M.D., NCI

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**Grand Rounds**  
noon - 1 p.m.  
Lipsett Amphitheater

*Clinical Trials of Breast and Prostate Cancer Prevention*, Peter Greenwald, M.D., Dr.P.H., NCI

*In Vivo Imaging Studies of Transcription*, James G. McNally, M.D., NCI

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**CRIS Educational Series**  
noon - 2 p.m.  
Lipsett Amphitheater

*Overview of the Computer-Based Patient Record (CPR)*, Marshall Ruffin, M.D., President, Informatics Institute & Ruffin Informatics

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**Grand Rounds**  
noon - 1 p.m.  
Lipsett Amphitheater

*Translational Approaches to Aerodigestive Cancer*, James L. Mulshine, M.D., NCI

*Does Stress Make You Sick and Believing Make You Well?* Esther M. Sternberg, M.D., NIMH

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**Grand Rounds**  
noon - 1 p.m.  
Lipsett Amphitheater

*The TNF Receptor-associated Periodic Syndrome (TRAPS): Clinical and Molecular Analysis of a New Autoinflammatory Disease*, Daniel Kastner, M.D., Ph.D., NIAMS

*Cancer Genetic Clinical Studies*, Jean Jenkins, Ph.D., R.N., NCI