Grants for Molecular Imaging and Therapy

At the close of a year that saw large and diverse increases in federal funding for imaging research, the National Institutes of Health (NIH) announced funding for a number of initiatives in which molecular imaging and therapy play key roles. Most of these funding mechanisms are re-releases of prior offerings, with a renewed focus on molecular aspects of medical and biologic research. Most are also Program Announcements with regular NIH submission dates and the possibility of new grants under these announcements in coming years.

The National Cancer Institute has solicited proposals for research into the effects of emerging cellular, molecular, and genomic technologies (CMG) on cancer health care delivery (http://grants.nih.gov/grants/guide/pa-files/PA-07-260.html). Examples of CMG technologies include: molecular profiling and imaging of tumors to target cancer therapy to the biological characteristics of the tumor, biomarker tests for detection of recurrence, and treatment. This is an R01 funding mechanism, with the next cycle's due date on June 5 and subsequent due dates on a 4-month cycle thereafter.

"Nanoscience and Nanotechnology in Biology and Medicine" is a multi-institute–sponsored effort to encourage studies on (1) early detection of disease using imaging; (2) in vitro early diagnostics, including multiplexed sensitive and specific sensors; (3) multifunctional therapeutics and localized therapy delivery; and (4) tools and approaches to interrogate, understand, and manipulate single cells, structures, and molecules. This effort includes R01 (http://grants.nih.gov/grants/guide/pa-files/PAR-07-270.html) and R21 (http://grants.nih.gov/grants/guide/pa-files/PAR-07-271.html) funding. The next due dates are June 5 and June 16, respectively, with due dates on 4-month cycles thereafter.

The National Center for Research Resources' Shared Instrumentation Grant program reopened its cyclical funding initiative, soliciting applications from groups of NIH-supported investigators who wish to purchase or upgrade commercially available instruments ($100,000–$500,000) in support of current and ongoing research. Types of instruments supported include confocal and electron microscopes, biomedical imagers, mass spectrometers, DNA sequencers, biosensors, cell sorters, X-ray diffraction systems, and NMR spectrometers, as well as nuclear medicine instrumentation, including small animal imaging devices. The complete proposal, which requires individual documentation of need from the various researchers who will be sharing the instrument, is due on March 21 (http://grants.nih.gov/grants/guide/pa-files/PAR-07-105.html).

Other recently announced R01 solicitations target molecular therapy research and include Pathogenesis and Treatment of Lymphedema and Lymphatic Diseases (http://grants.nih.gov/grants/guide/pa-files/PA-07-165.html); Etiology, Prevention, and Treatment of Hepatocellular Carcinoma (http://grants.nih.gov/grants/guide/pa-files/PA-07-258.html); and Noninvasive Methods for Diagnosis and Progression of Diabetes, Kidney, Urological, Hematological, and Digestive Diseases (http://grants.nih.gov/grants/guide/pa-files/PA-07-025.html).

Training awards, including NIH K grants, the Ruth L. Kirschstein National Research Service Awards, and others, are available for physicians and scientists at all career levels. Imaging is usually underrepresented in the pools of applicants for these awards, and nuclear medicine professionals are urged to encourage their colleagues, particularly those at the beginning of their careers, to consider applying. Among the Kirchstein awards are those for Individual Senior Fellows (http://grants.nih.gov/grants/guide/pa-files/PA-07-172.html), an F33 mechanism; Predoctoral Fellows to Promote Diversity in Health-Related Research (http://grants.nih.gov/grants/guide/pa-files/PA-07-106.html), an F31 mechanism; and Individual Postdoctoral Fellows (http://grants.nih.gov/grants/guide/pa-files/PA-07-107.html), an F32 mechanism. Although the next due date for application submissions for each of these awards is in April, interested applicants and their departments are urged to check the Kirchstein Award site at http://grants.nih.gov/training/nrsa.htm#policy for changing requirements for timely filing.

National Institutes of Health

Cancer Tracer Synthesis Resources

The Cancer Imaging Program of the National Cancer Institute (NCI) reported in January on work in creating Investigational New Drug Applications (INDs) for imaging agents in an effort to encourage multicenter clinical trials of these materials. A subset of the documents filed is being made available to the research community to implement routine synthesis of tracers at their own facilities and to assist investigators with the filing of their own INDs. The first of these document sets is for ^{18}F-fluorothymidine (^{18}F-FLT). Component documents for the IND include a full set of manufacturing and quality control documents and an Investigator Drug Brochure, all of which have been accepted by the U.S. Food and Drug Administration (FDA) as part of the NCI IND. The synthetic method implemented in these documents was reported in an abstract by Blocher et al. (*J Nucl Med.* 2001;42:257P). An automated synthesis has been reported recently by the same

group using the same precursor (Reischl et al. *Radiochim Acta.* 2006;94:447–451). Investigators can use these documents to implement synthesis and testing in their own radiochemistry laboratories. The document set includes a chemistry, manufacturing, and controls (CMC) template that can be modified to be consistent with local procedures (e.g., with specific brands of equipment). Investigators can then write and file their own INDs with the FDA by modifying the CMC section to fit local conditions and adding the investigator's proposed clinical protocol. NCI will provide a letter to cross-reference the NCI IND file at FDA for pharmacology, toxicology, dosimetry, and previous human experience. NCI also provides a file of frequently asked questions relative to these procedures, as well as a copy of the transfer agreement by which NCI legally assigns the production documents to the investigator and his or her facility. This agreement stipulates, among other clauses, that the recipient will use the production documents for research only and not for commercial purposes.

The agreement can be read online, and, after agreement, documents can be downloaded from: http://imaging.cancer.gov/programsandresources/Cancer-Tracer-Synthesis-Resources.

National Cancer Institute

NRC 313A Forms and Guidance

On January 12, the U.S. Nuclear Regulatory Commission (NRC) announced the availability of new "Training and Experience and Preceptor Attestation" forms (313A) for those seeking recognition as radiation safety officers (RSOs), authorized medical physicists (AMPs), authorized nuclear pharmacists (ANPs), or authorized users (AUs). The NRC also released guidance documentation for the completion of these forms. The previous single form will be replaced by 6 distinct versions of NRC Form 313A with the following titles and corresponding *Code of Federal Regulations* (CFR) references: NRC Form 313A (RSO): Radiation Safety Officer Training and Experience and Preceptor Attestation [10 CFR 35.50]; NRC FORM 313A (AMP): Authorized Medical Physicist Training and Experience and Preceptor Attestation [10 CFR 35.51]; NRC FORM 313A (ANP): Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]; NRC FORM 313A (AUD): Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]; NRC FORM 313A (AUT): Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]; and NRC FORM 313A (AUS): Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690].

NRC Form 313 must be submitted by all applicants seeking a license for the use of byproduct material. The new NRC Form 313A series may be used by medical use applicants to document training and experience and preceptor attestations for individuals seeking recognition as RSOs, AMPs, ANPs, or AUs. The information required to complete the forms is unchanged from that required for the old form and is aligned with requirements in the 2005 revision of 10 CFR Part 35. Medical use applicants may elect to use the appropriate form from the NRC Form 313A series for each new individual; the first time that individual is seeking to be identified as an RSO, AMP, ANP, or AU; or when one of these individuals is seeking to be identified for a new authorization on a limited specific medical license. Broad-scope medical use applicants may use the NRC Form 313A (RSO), when requesting an individual be identified as a new RSO or when adding an additional RSO authorization for the individual. Commercial nuclear pharmacy applicants may also use NRC Form 313A (ANP) when requesting that an individual be identified for the first time as an ANP.

The complete 11-MB NRC Regulatory Issue Summary may be downloaded from www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200627.pdf. Updated NRC forms are available at: www.nrc.gov/reading-rm/doc-collections/forms and from the Medical Uses Licensee Toolkit page at: www.nrc.gov/materials/miau/med-use-toolkit.html.

Nuclear Regulatory Commission

New *Nuclear Medicine: Cardiology* Self-Study Volume

The SNM announced on January 10 the publication of the latest and final book in the *Nuclear Medicine: Cardiology* self-study series, covering Radionuclide Angiography (Ventriculography)—Equilibrium and First Pass Methods (Topic 7) and Myocardial Infarction—'Infarct Avid' Scintigraphy (Topic 8). This popular series proceeds from the basics through the latest high-tech applications in nuclear medicine cardiology, using high-quality illustrations, case-based questions and answers, and annotated references. The series is designed for a broad segment of the nuclear medicine and cardiology community, including residents, program directors, technologists, and technologist students. The cardiology self study series is especially useful for those preparing for certification examinations. Continuing education credit is also available. The series editor is Elias H. Botvinick, MD, professor of medicine and radiology and co-director of the Adult Cardiology Non-Invasive Laboratory at the University of California Medical Center in San Francisco. Previous series topics include Physical and Technical Aspects of Nuclear Cardiology (Topic 1), Pharmacologic Stress (Topic 2), Cardiac PET Imaging and Radionuclide Assessment of Congenital Heart Disease (Topics 3 and 4), Myocardial Perfusion Scintigraphy: Technical Aspects (Topic 5); and Myocardial Perfusion Scintigraphy: Clinical Aspects (Topic 6). Information on purchasing the new volume or the entire set is available at www.snm.org/shop.

SNM

Yale PET Center Opens

The Yale PET Research Center (New Haven, CT) opened on January 18 with a ceremony and reception. The 22,000 square foot center, a part of the Yale University Department of Diagnostic Radiology is situated near both the Yale School of Medicine and the Pfizer Clinical Research Unit, with which center staff will collaborate on drug development projects. "Clinical trials to determine a drug's effectiveness often fail because a drug doesn't reach its target or there isn't a sufficient amount of the drug to treat the disease," said PET Center Director J. James Frost, MD, professor of diagnostic radiology and psychiatry and chief of nuclear medicine at Yale–New Haven Hospital. "PET can now be used to determine this very early on. This knowledge will help cut down on large, costly clinical trials, and research can be focused on alternative drugs."

The opening ceremony included a keynote address by George Mills, MD, director of the Division of Medical Imaging and Radiopharmaceutical Drug Products of the U.S. Food and Drug Administration Center for Drug Evaluation and Research. His topic was "PET Imaging: The Essential Foundation for the Imaging Critical Path."

Yale University

Past SNM Historian Dennis Patton, MD, Dies

Dennis Patton, MD, a past historian of the SNM, died on January 23 at his home in Oakland, CA, at the age of 76. A noted teacher, historian of science, accomplished musician and composer, and indefatigable world traveler, he also performed both official and unofficial duties in preserving the history of nuclear medicine and allied sciences. He received his undergraduate degree in physics from the University of California at Berkeley and his medical degree from the University of California at Los Angeles. He was trained in diagnostic radiology at the University of California at Irvine, where he established the nuclear medicine service. In 1970 he joined the faculty at Vanderbilt University (Nashville, TN), where he became a professor and co-director of nuclear medicine. Five years later, he became a professor of radiology and director of nuclear medicine at the University of Arizona (Tucson), where he remained for more than a quarter of a century. In 2003 he moved back to his birthplace, the San Francisco bay area, as a clinical professor of radiology at the University of California, San Francisco and part-time medical director of PET Imaging of San Francisco and PET/CT Imaging of Berkeley. He was active in many professional organizations, including SNM, the American College of Nuclear Physicians, and the American College of Radiology and was a founding member of the Society for Medical Decision Making. For more than 6 years he served as SNM Historian and was instrumental in initiating a movement to preserve historical books, documents, and miscellany as part of the SNM Archives. At the time of his death he was working on a biography of German physicist Philipp Lenard, a series of vignettes on nuclear medicine, and a textbook on decision analysis for medical students. A memorial service was held on February 4 in Oakland. A more detailed In Memoriam is being prepared for the April issue of Newsline.

SNM

Global Science Agreement Signed

In London, UK, on January 22, Dr. Raymond L. Orbach, under secretary for science at the U.S. Department of Energy (DOE), signed an agreement with Lynne Brindley, chief executive of the British Library, to partner on the development of a global science gateway. The gateway would eventually make science information resources of many nations accessible via a single Internet portal. "It is timely to make the science offerings of all nations searchable through one global gateway," Orbach said. "Science is international, and centralizing access will enhance the rate of scientific discovery."

Dubbed "Science.world," the planned resource would be available to scientists in all nations and to anyone interested in science. The approach will capitalize on existing technology to search vast collections of science information distributed around the globe, enabling much-needed access to smaller, less well-known sources of highly valuable science. Following the model of Science.gov, the U.S. interagency science portal that relies on content published by each participating agency, Science.world will rely on scientific resources published by each participating nation. Other countries have been invited to participate in this international effort. The objectives of the initiative are to: search dispersed, electronic collections in various science disciplines; provide direct, seamless, and free searching of open-source collections and portals; build upon existing and already successful national models for searching; complement existing information collections and systems; and raise the visibility and usage of individual sources of quality science information. DOE's Office of Scientific and Technical Information will work with the British Library and international counterparts to develop a prototype of Science.world in 2007.

U.S. Department of Energy

U.S. Cancer Deaths Continue to Drop

An American Cancer Society (ACS) report released on January 17 showed a drop of 3,014 cancer deaths in the United States from 2003 to 2004, the most recent year for which mortality data are available from the National Center for Health Statistics. This drop was significantly larger than the 369 fewer deaths reported for the previous time period (2002–2003), which itself marked the first decline in actual number of cancer deaths in the more than 70 years since nationwide data began to be compiled. These figures, as well as estimates for the current year, come from *Cancer Statistics 2007*, published in the January/February issue of *CA: A Cancer Journal for Clinicians*, as well as in the 56th edition of its companion publication, *Cancer Facts & Figures 2007*. Based on the latest data, ACS epidemiologists predict that approximately 1.44 million Americans will be diagnosed

with cancer and 560,000 will die from the disease in 2007.

In 2004, 553,888 individuals in the United States died from cancer, compared with 556,902 in 2003. Drops in cancer deaths were seen across all 4 major cancer sites (lung, breast, prostate, and colorectal) in 2004, except for lung cancer among women. Colorectal cancer showed the largest decrease in the number of deaths. Although the death rate for all cancers combined has decreased in the United States since 1991, not until 2003 was the decrease large enough to outpace the aging and growth of the U.S. population, resulting in 2 consecutive years of dropping cancer deaths. The larger drop in cancer deaths in 2004 is evidence that the decline may continue. Although progress continues to be made in reducing mortality rates, cancer remains the top cause of death in Americans under age 85.

"This second consecutive drop in the number of actual cancer deaths, much steeper than the first, shows last year's historic drop was no fluke," said John R. Seffrin, PhD, ACS chief executive officer. "Everyone involved in the fight against cancer should be proud of this remarkable achievement. The hard work towards preventing cancer, catching it early, and making treatment more effective is paying dramatic, lifesaving dividends. Thirteen years of continuing drops in the overall cancer death rate have now overtaken trends in aging and growth of the U.S. population, resulting in decreased numbers of deaths."

The ACS predicts 1,444,920 new cases of cancer in 2007: 766,860 among men and 678,060 among women. Beginning with this year's estimated new cancer cases, the ACS introduced a new, more accurate projection method developed by researchers at the National Cancer Institute that accounts for cancer incidence in more than 86% of the U.S. population by drawing from more diverse and authoritative epidemiologic sources.

Highlights from this year's publications included the following facts and figures:

- Among men, cancers of the prostate, lung and bronchus, and colon and rectum account for more than half (54%) of all newly diagnosed cancers. Prostate cancer alone accounts for nearly a third (29%) of cancer cases in men.
- The 3 most commonly diagnosed types of cancer among women in 2007 will be cancers of the breast, lung and bronchus, and colon and rectum, accounting for more than half (52%) of estimated cancer cases in women. Breast cancer alone is expected to account for a fourth (26%) of new cancer cases among women.
- Lung cancer surpassed breast cancer as the leading cause of cancer death in women in 20 years ago. Lung cancer is expected to account for 26% of all female cancer deaths in 2007.
- Cancer incidence rates stabilized in men from 1995 to 2003 and increased in women by 0.3% per year from 1987 to 2003. Death rates for all cancer sites combined decreased by 1.6% per year from 1993 to 2003 in males and by 0.8% per year in females from 1992 to 2003.
- Mortality rates have continued to decrease across all 4 major cancer sites in men and in women except for female lung cancer, in which rates continued to increase by 0.3% per year from 1995 to 2003.
- Death rates from all cancers combined peaked in 1990 for men and in 1991 for women. Between 1990/1991 and 2003, death rates from cancer decreased by 16.3% among men and by 8.5% among women.
- Colorectal cancer incidence rates decreased from 1998 through 2003 in both males and in females.
- Female breast cancer incidence rates leveled off from 2001 to 2003 after increasing since 1980, which may reflect the saturation of mammography utilization and dramatic reduction in hormone replacement therapy.
- Among males under age 40 years, leukemia is the most common fatal cancer, whereas cancer of the lung and bronchus predominates in men aged 40 years and older.
- Among females, leukemia is the leading cause of cancer death before age 20 years, breast cancer ranks first at 20–59 years, and lung cancer ranks first at age 60 and older.
- From 2003 to 2004, the number of recorded cancer deaths decreased by 1,160 in men and by 1,854 in women. The largest change in number of deaths from the major cancers was for colorectal cancer in both men and women.
- African American men have a 15% higher incidence rate and 38% higher death rate than white men. African American women have a 9% lower incidence rate, but an 18% higher death rate than white women for all cancer sites combined.
- Among other racial and ethnic groups, cancer incidence and death rates are lower than those in whites and African Americans for all cancer sites combined and for the 4 most common cancer sites.
- After accidents, cancer is the second leading cause of death among children between ages 1 and 14 years in the United States. The 5-year relative survival rate among children for all cancer sites combined improved from 58% for patients diagnosed from 1975 to 1977 to 79% for those diagnosed from 1996 to 2002.

American Cancer Society

2008 IRIST Congress Announced

The International Research Group in Immuno-Scintigraphy and Therapy (IRIST) has announced that its 19th International Congress will be held in Krakow, Poland, June 18–21, 2008. The congress will be hosted by Jagiellonian University, one of the oldest institutions of higher learning in the world. IRIST was founded in 1986 by European investigators who hoped to stimulate and intensify international interaction and collaboration between investigators working with radionuclide targeting of cancer. Today, IRIST members come from countries around the world to attend

its scientific symposia. The 2008 meeting will feature presentations and invited lectures on immunoscintigraphy and nuclear medicine therapy as well as the official members' assembly, all within the setting of Krakow's historic district and within walking distance of the main market square and Czartoryski Museum. Abstracts of presented papers will be published in the official journal of IRIST, the *Quarterly Journal of Nuclear Medicine and Molecular Imaging*. For additional information, visit www.irist.org or e-mail info@irist.org or Dr. Alicja Hubalewska-Dydejczyk, Local Organizing Committee, at alahub@cm-uj.krakow.pl.

IRIST

(Continued from page 16N)

for those in preclinical and clinical molecular imaging. In addition to the task forces, the MICoE Editorial Board is developing a new quarterly newsletter, periodic e-mail blasts, this monthly contribution to Newsline, and a monthly review of the molecular imaging literature.

Investments in Research

The MICoE Task Force on Standard Definitions has developed a working definition of molecular imaging and related terms that will serve as the foundation for all future SNM activities. After approval by the SNM Board of Directors, these definitions will be printed in Newsline. A series of 4 key workshops is planned for 2007. The first, "Bringing Molecular Imaging from Bench to Bedside," will focus on what can be done in the short term (<5 years) to realize molecular imaging benefits in the clinical environment. Output from this workshop will include a list of molecular imaging technologies that can move quickly to demonstrate clinical utility and an identification of what is needed to accomplish this. The second workshop will be a working retreat that will broadly review emerging molecular imaging technologies and evaluate issues associated with each. The goals are to develop a list of technologies that could benefit clinicians in the next 5–10 years. Using the results of the first 2 meetings, a third phase will evaluate specific future molecular imaging technologies and agents to determine what is needed to validate them for clinical use. The final workshop, "Leading Technologies Advancement," will bring together the ideas generated in the first 3 workshop phases to examine the pathways for gaining acceptance of new molecular imaging technologies and identify key barriers to moving from the research environment to the bedside.

All of these activities are geared toward making molecular imaging a clinical reality, if not a household term. Through the combined efforts of the MICoE and the SNM membership and with attention to the goals of the Bench to Bedside Campaign, we can make the most convincing argument for continued investment in molecular imaging research: improvement in patient care. As SNM staff director of the MICoE, I am charged with managing the various groups within the center. I am always available for comments and suggestions regarding MICoE and how we can better serve the SNM membership. Feel free to contact me at MHowlett@snm.org with any comments or suggestions regarding the MICoE effort. I look forward to working with you.

Marybeth Howlett, MEM
Director, Molecular Imaging Campaign, SNM

(Continued from page 16N)

2. Lifelong learning and self-assessment: evidence of a commitment to lifelong learning and involvement in a periodic self-assessment process to guide continuing learning. Beginning in 2006, the ABNM required each diplomate to complete a minimum of 8 self-assessment credits per year to be eligible for the recertification exam (for a total of at least 80 credits over the 10 years of the recertification cycle). These credit hours may be obtained by completing the SNM Lifelong Learning & Self-Assessment Program modules.
3. Cognitive expertise: evidence of cognitive expertise based on performance on the ABNM recertification examination every 10 years. The test, per ABMS requirements, contains questions on fundamental knowledge, up-to-date practice-related knowledge, and other issues, such as ethics and professionalism.
4. Performance in practice evaluation: evidence of evaluation of performance in practice, including the medical care provided for common/major health conditions, and physician behaviors. ABMS is developing tools to assist physicians in documenting outcomes measures for practice performance, and SNM plans to develop management modules.

All 4 components of the ABNM MOC rules take effect this year, with the ABNM requiring MOC participation for its diplomates with time-limited certificates beginning in 2007. The ABNM also strongly encourages all of its diplomates to participate in MOC programs as these are developed.

The SNM is actively developing a range of approaches to assist nuclear medicine physicians in MOC efforts. This is the first in a series of articles in Newsline that will present these efforts in more detail. For more information, visit www.snm.org/llsap or www.abnm.org.

Lynn Barnes, MEd
Director of Education, SNM