Navigating the Biomedical Research System as a Full Participant: Strategies and Opportunities for the Nuclear Medicine Technologist

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After a quick look at the *New England Journal of Medicine*, *Radiology*, or for that matter, *The Journal of Nuclear Medicine (JNM)*, one is inundated with research reports. These range from esoteric and highly specialized methods to more broadly applied and clinically useful findings. Despite daily pressures to complete clinic workloads, train students, and manage overtime hours, many allied health professionals also find time to participate in research. As the field of nuclear medicine technology evolves, this research can be equipment-based, such as validating scatter correction methods or testing renal scan software, or can involve after-hours imaging of animals during the development of new radiopharmaceuticals. Clinical research, historically the measurement of the effects of some medical intervention on human subjects, is more broadly defined to include epidemiological studies, behavioral observations, or outcomes and health services research. All of these must first undergo peer review for funding, for publication or presentation at scientific meetings, and for administrative approvals.

RADIOLOGICAL AND NUCLEAR MEDICINE RESEARCH

What exactly comprises imaging research? Academic leaders have periodically attempted to set the research agenda for radiology and nuclear medicine. As described by Holman, these domains have included description of structural or functional changes in a disease, standardization (e.g., methods or safety protocols), exam validation (e.g., sensitivity, specificity, predictive values, receiver operator characteristic, efficacy), as well as tasks more broadly associated with public health and other types of research, (e.g., cost/benefit analyses, observational [case control and cohort] studies), and outcomes related to new instrumentation and procedures (*1*). A familiar example for nuclear medicine technologists (NMT) is the quality control review of myocardial or phantom studies in multicenter trials such as the "Thrombolysis in Myocardial Infarction" (TIMI) study.

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TRAINING IN RESEARCH METHODS

These days many more skills (e.g., fluency with molecular biology techniques, statistical design, and evidence-based validation) are required to sustain a viable research career. At bedside, one must be familiar with regulatory issues, human subject protections, and the elements of sound experimental design. Universities, hospitals, and professional societies have made efforts to creatively address the "training gap," and to provide the necessary skills and credentials to those interested in conducting, or required to conduct, clinical research. In response, the American College of Radiology (ACR) and the Canadian Association of Radiologists published a series of articles in the *American Journal of Roentgenology*, with topics ranging from basic statistics, such as sampling size and descriptive measures, to fairly sophisticated methods, including survival analysis and multivariate techniques (*2*). While helpful, these were not meant to supplant formal training. Postdoctoral training fellowships, as well as certificates and degree programs in clinical investigation, are available at schools of medicine and public health, with coursework often available in a distance-learning format (*3–5*). Hospitals and health care systems also offer inhouse seminars and courses on biostatistics, research ethics, and grant writing, which are essential tools for their medical and allied health staff and trainees. NMTs may find that these are offered free of charge, or in the case of certificate studies, at least partially supported by tuition reimbursement programs. These options provide an important function, as research methods are not listed as training requirements in the *Essentials for Nuclear Medicine Technology Training Programs* nor described as skills or responsibilities in the *Scope of Practice for Nuclear Medicine Technologists*, established by a task force of the SNM Technologist Section (SNMTS) in 2001 and revised this year (*6–7*).

An immediate benefit that technologists gain from attending these courses is a more critical and knowledgeable eye towards the research literature. SNM and SNMTS also support training grants for technologists, scientists, and physicians, having granted over $100,000 in 2005 (*8–9*). Clearly, resources are available for those interested in expanding their research skills portfolio. The next, most crucial

step is to find a meritable project, a step often referred to as "the research question."

DEFINING THE RESEARCH PROJECT

One of the most important steps is to identify the research question. The question might come up in daily clinical practice, (e.g.: "How do we make our elderly patients more comfortable during the procedure?" "Why did we find an altered distribution of radiopharmaceutical in this group of patients," or "How much time should we wait after a fatty meal to image gall bladder contraction?") Other times, the question is narrowly proscribed by a funding agency in a request for proposals, with specified objectives within a specified subject population, for example, the utility of ^{18}F-FDG PET in the pre-operative staging of esophageal cancers.

The research question may also arise from a completely accidental discovery. Meyers describes this inversion of an empirical observation ("I have the answer! What is the question?") as a creative process, often guided by luck (*10*). His examples include bread mold in Alexander Fleming's lab leading to the discovery of penicillin's potential use, and closer to our own discipline, Roentgen's observations of unexpected fluorescence from an energized Crooke's tube. Thus, while science has its dogmas, standards, and reproducible methods, an open and inquisitive mind may challenge and shift the prevailing wisdom.

Once an idea or question has been determined, the litmus test (frequently referred to as the "*so what?*" test) must be passed. That is to say, "Is anyone interested in the findings?" Would any reasonable person or group commit money or time to answer this question? If a positive answer to the above is at least probable, then one can proceed to develop a proposal and outline of the research project.

TABLE 1
Common Elements of a Research Project Outline/Proposal (*40–42*)

I. The Research Project
  A. Title
  B. Abstract
II. The Research Plan
  A. Specific aims
  B. Research hypotheses
  C. Timeline for specific objectives
III. Background and Significance
  A. Rationale and supporting theories for the project
  B. Existing knowledge and related studies
  C. Uniqueness of proposed methods
  D. Prior experience/qualifications of the investigator that support the project
IV. Research Design and Methods
  A. Subjects
    1. Characteristics
    2. Sampling methods
    3. Exclusion/inclusion
  B. Materials
    1. Instruments
    2. Validation/reliability
  C. Procedures and Methods
    1. Overview of study design
    2. Specific interventions or observations
    3. Data collection and storage
    4. Potential limitations, alternative procedures, precautions
  D. Data analysis/reduction
V. Budget justification
  A. Personnel
  B. Equipment
  C. Space
  D. Direct Costs
  E. Overhead
VI. Assurances
  A. Human subject protections, IRB
  B. Animal use, IACUC
  C. Administrative/Institutional approval

THE RESEARCH PROPOSAL

In organizing the project, a survey of the existing literature, the so-called background information, is critical. Reviewers at funding agencies and publications will ask how this question has been addressed by others. How does the proposed project differ from existing research? Concisely stating how the unique aims of the project may meet existing needs or unanswered questions influences the design and possible success of the project. Furthermore, the research proposal must be formulated in terms of a succinct and measurable hypothesis, choosing appropriate statistical methods to evaluate the findings (*11*). Table 1 illustrates the common elements found in a project outline or clinical trial proposal.

Much of this work should be completed months before submitting a proposal. Reviewing the pertinent literature and speaking with colleagues helps to clarify the research question and identify potential components of the study design. Feedback from others may help the novice investigator to rethink and restate the specific aims, goals, and significance of the study in more concise and articulate terms. Experienced investigators can give advice on what is truly achievable within the specified deadlines or limited resources, be it subject enrollment, institutional approvals, publication of results, and so on. Pilot studies, preclinical trials, or computer simulations help to "shape" the design or scope of the larger proposed work. Another essential task is to determine in advance which outcome measurements (findings or results) are important when selecting evaluation criteria and statistical methods (*12*). A preliminary consultation with a biostatistician can help in selecting the correct statistical tests.

Reviewing the grant writing process, Inouye and Fiellin found that while the specific aims and hypotheses are the most important pieces of the grant, the methods (study design, instruments, and materials) are frequently rated as the most underdeveloped by scientific review panels (*13*). The authors give clear examples and advice on improving a proposal. One must consider the reviewers' unique perspectives,

be thoroughly familiar with the funding agency's stated objectives, and if possible, examine previously successful proposals. Additional guidance can be sought from the sponsor. More commonly, the sponsor will provide a complete template, specifying content length, supporting documentation requirements, timelines for objectives, budget justifications, and other necessary items. For an example, see the grant application forms of the SNMTS Professional Development and Education Fund (PDEF) (*14*).

FEDERAL REGULATIONS AND GUIDANCE

All researchers should be prepared to provide documentation of ethical and regulatory compliance by the institution, the investigator, and the study staff. These include signed agreements to adhere to sound scientific methods, disclose potential conflicts-of-interest, and stay current, via mandatory training and refresher courses, with human and animal subject protections. The investigator also holds overall responsibility for the safety and informed consent of the trial subjects. NMTs interested in performing research should contact their institutional review board (IRB) or research administration department to enroll in human subjects protections courses in advance of their participation in clinical research. Additional credentials (e.g., medical degree, board certification, faculty or staff appointment) are often required in order to serve as a principal investigator on interventional studies, though technical, pharmacy, and nursing staff often initiate their own quality improvement or outcomes research.

The *Declaration of Helsinki*, the *International Ethical Guidelines for Biomedical Research Involving Human Subjects,* the *Belmont Report,* and other publications provide ethical direction to regulators, administrators, and oversight committees such as the IRB (*15–17*). Several other well-written texts offer extensive coverage of research and biomedical ethics (*18–20*). In the U.S., federal legislation covering human subject research is found in two sections of the *Code of Federal Regulations*. The common rule guidelines are found in 45 CFR 46 (*21*). Regulations covering research that involves biologics (e.g., monoclonal antibody fragments, peptides, and genes), medications (including radiopharmaceuticals), or investigational devices are listed in 21 CFR 50, otherwise known as the FDA regulations (*22*). As codified in these regulations, the IRB and administrative entities must approve the proposed research and all associated materials, such as the consent form, advertisements, and survey questionnaires (and if applicable, all translated copies), prior to subject recruitment. Research funds are usually not released until these approvals are documented. In Table 2, a timeline from an actual SNM-funded project demonstrates three different approval dates. The grant was conditionally awarded in early September, pending IRB approval, which was not secured until mid-November. Additional institutional approvals were received in February of the next year, thus producing a lag time of five months between funding approval and subject recruitment. Here, as elsewhere, concurrent submissions to the IRB, Office of Sponsored Research, and granting agencies greatly speed up the approval process.

FUNDING SOURCES

After deciding upon a worthwhile project, where does one find financial support to answer the research question? In the U.S., a staggering 79.9 billion dollars were spent on drug discovery and pharmaceutical research in 2005, with 36% coming from the National Institutes of Health (NIH), the premiere public funding agency for biomedical research (*23*). Extramural research sponsored by the NIH involves

TABLE 2
SNMTS Grant Project Timeline

Task	2004	2005	2006
Proposal submitted to SNMTS	May 20		
Submit to research administration	May 20		
Grant awarded by SNMTS	Sep 8		
IRB submissions	Sep 25, Oct 17		
IRB approval	Nov 17		
Quarterly funding disbursements	Dec 14	Mar 31, June 30	Held for research results
Subjects recruited		Jan 6	
Preliminary testing of equipment		Jan 25, Apr 4	
Research administration approval		Feb 7	
Subject pre-test		Apr 11–30	
Subject dosimetry		Apr 11–Jun 10	
Training intervention		Jun 11–Aug 11	
Subject post-test		Aug 12–31	
Subject dosimetry		Sep 1–Nov 30	
Submit first paper		Oct 18	
Data Analysis		Dec 1–31	
Submit meeting abstract			Feb 20
Present at annual conference			Jun 28

over 200,000 scientists in over 3,100 organizations throughout the world (*24*). In late 2002, Elias Zerhouni, MD, the newly appointed director of the NIH, convened a number of strategic meetings with research leaders culminating in the NIH Roadmap for Medical Research, which identified key research focus areas for the 21st century—molecular imaging, nanomedicine, clinical outcomes assessment, clinical research training grants, etc. (*25*).

In that same year the National Institute for Biomedical Imaging and Bioengineering (NIBIB) received its first budget allocation ($112 million) from Congress (*26*). NIBIB has supported research in PET, SPECT/CT, gene therapy and delivery systems, computed radiography, and many other areas that fall within the domain of imaging or image-guided research (*27*).

Federal funding opportunities are readily available through the U.S. government's E-grant initiative web site, www.grants.gov, which lists over 1,000 grant programs, with access to approximately $400 billion in annual awards (*28*). One can search categories with potential relevance to nuclear medicine through topics such as health, science and technology, and education. Grants specifically funded by the NIH can be found through the Office of Extramural Research (*29*). Most of those funds are specifically earmarked for scientists and physicians. Allied health professionals also have additional resources. For example, nurses can find support for basic and clinical research within the NIH at the National Institute of Nursing Research (*30*). The U.S. Agency for Healthcare Research and Quality, with strategic research goals in patient safety and quality of care, efficiency of health care services, and effectiveness of procedures also funds research (*31*). Past awardees have received funds to study "Prescribing Practices of Nurse Practitioners" and "Access to Mammography for Older Women of Color." Clearly, nuclear medicine technologists pursuing graduate studies in health services management, health policy, or public health could develop similar projects.

Private sources include foundations, nongovernmental organizations, charitable groups such as the Wellcome Trust, and organizations classed by disease, (e.g., the American Cancer Society, the Cystic Fibrosis Foundation.) Websites for some key funding sources are listed in Table 3.

Professional societies also have a vested interest in promoting excellence in and recruitment for their professions, and often sponsor work in their fields. For example, the American Nuclear Society sponsors student research in radiochemistry and analytical applications of nuclear science (*32*). The American Society of Health-System Pharmacists (ASHP) supports research in medication use and outcomes and also sponsors Young Investigator awards (*33*).

What is specifically available to imaging technologists? Through its Education and Research Foundation, the American Society of Radiologic Technologists (ASRT) has funded research for technologists working on theses or doctoral dissertations in topics as diverse as "Radiation Exposure and CR Image Quality, " "Projected Supply and Demand of Radiography Educational Faculty," and "Career Burnout Among Radiologic Technologists" (*34*).

In nuclear medicine, the Professional Development and Education Fund (PDEF) of the SNMTS was created to advance the following goals:

- Ensure an adequate supply of qualified nuclear medicine technologists;
- Encourage research studies, publications, and papers in nuclear medicine technology that promote the development of best-practice techniques; and
- Advance the educational background of clinical nuclear medicine instructors, practicing nuclear medicine technologists, and those just entering the field.

In 2005, the PDEF granted close to $68,000 in grants and scholarships (including grants to pursue advanced degrees) to nuclear medicine technologists and students (*35*). Funded proposals have included, "Testing of DU Collimator for Removal of Tl/Tc Dual-Isotope Cross-talk" and "Reduction of Occupational PET Exposures by a Best Practices Training Program." Building upon their expertise and interest in radiation detection and exposure, NMTs might also find interested sponsors and projects involving occupational or patient exposures, operational health physics, and radiation disaster/homeland security.

Seasoned investigators often advise trainees not to be discouraged if their initial proposals are not funded. Grant proposal writing is an acquired skill that takes time to develop, and each proposal or investigator is often competing with many others. In fact only 15–25% of all proposals are actually supported by funding agencies (*36*). A partial solution to this dilemma is to become more entrepreneurial. For example, a group of Australian nurses with very limited institutional support found corporate sponsors to fund a full-time oncology research position throughout a several-year project in their hospital (*37*).

REPORTING RESULTS

While successfully competing for grants, developing a research team, and finding an answer to your research question are admirable accomplishments; the project is incomplete without presentation of results. Scientific abstracts, journals, or foundation meetings are possible avenues for reporting the findings. In fact, many sponsors will list exactly which journals or conferences are acceptable for publication. As with developing the grant proposal itself, conversations with mentors will assist junior investigators in becoming first-time authors (*38*). Most scientific periodicals also provide an "Instructions to Authors" guide, or reference the *Uniform Requirements of the International Committee of Medical Journal Editors* (*39*).

CONCLUSION

Although clinical research skills are currently not a routine part of nuclear medicine technologists' education,

TABLE 3
Funding Sources for Biomedical and Clinical Research

U.S. Government
General web directory of all government funding sources http://www.grants.gov/index.jsp
U.S. Department of Energy. Office of Science http://www.sc.doe.gov/grants/grants.html
US. Department of Health and Human Services. Agency for Healthcare Research and Quality http://www.ahcpr.gov/fund
U.S. Department of Education http://www.ed.gov/fund/landing.jhtml?src=ln
U.S. Department of Homeland Security. *Research* http:www.dhs.gov/xres
National Institute of Health (NIH) Office of Extramural Research. http://grants.nih.gov/training/extramural.htm
National Institute of Biomedical Imaging and Bioengineering http://www.nibib.nih.gov
National Institute of Nursing Research http://ninr.nih.gov/ninr
Foundations
American Association for the Advancement of Science. ''grants.net'' http://sciencecareers.sciencemag.org/funding
National Science Foundation and American Psychological Association http://www.decadeofbehavior.org/fundsource/index.cfmTechnical
The Foundation Center http://www.foundationcenter.org/findfunders/fundingsources/fdo.html
Northern California Community Foundation, Inc. http://foundations.org/
Society of Research Administrators International http://www.srainternational.org/newweb/resources/index.cfm
Professional Societies—Allied Health
Society of Nuclear Medicine Technologists Section, Professional Development and Education Foundation http://www.snm.org
American Society of Radiologic Technologists, Education and Research Foundation http://www.asrt.org/content/ASRTFoundation/Grants/Grants.aspx
American Society of Health-System Pharmacists, Research and Education Foundation http://www.ashpfoundation.org/Research/index.cfm

many institutions do provide training in biomedical ethics, statistical analysis, study design, and grant writing, subjects useful to successful investigators. With some of these skills, NMTs might join the IRB, Radiation Safety, or other committees to familiarize themselves with the research infrastructure within their institution. In addition to governmental agencies, professional societies, private industry, and hospitals also provide possible sources of funding. With creativity and a willing mentor, nuclear medicine technologists and other allied health personnel may discover that research opportunities are open to them. Playing a more active role as a member of the research community often contributes to professional growth, respect from peers, and increased career satisfaction.

ACKNOWLEDGEMENTS

In 2005–2006, the author was a recipient of funding through the Professional Development and Education Fund (PDEF) of SNMTS.

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