10. Serruys PW, Foley DP, Kirkeeide RL, King SB. Restenosis revisited: Insights provided by quantitative coronary angiography. American Heart Journal. 1993;126:1243–1267.

11. Duda SH, Pusich B, Richter G, et al. Sirolimus-eluting stents for the treatment of obstructive superficial femoral artery disease: six-month results. Circulation. 2002 Sep 17;106(12):1505–9.

5:10 p.m.

Clinical Follow-up of Femoropopliteal Disease; Economic Impact for Your IR Practice

James L. Swischuk, MD
OSF Saint Francis Medical Center
Peoria, IL

5:20 p.m.

POINT / COUNTERPOINT (Case Review):
Claudication and Long Segment SFA Disease; Stretch It, Freeze It, Stent It, Cover It, Shave It, or Cut It

5:40 p.m.

POINT / COUNTERPOINT (Case Review): *Limb Salvage: When All You Have Is a Hammer, Everything Looks Like a Nail*

Research (SY)

Coordinator / Moderator: Gordon McLennan, MD

Objectives: Upon completion of this symposium, the attendee should be able to:

1. Examine the role of corporate service research in the development of a long-term research career.
2. Interpret the role of foundation grants to initiate research programs or to sustain ongoing research between federal funding.
3. Employ the application and review process for NIH grants.

12:00 p.m.

Introduction—"Practical Case Studies in Extramural Research Funding"

Gordon McLennan, MD
The Western Pennsylvania Hospital
Pittsburgh, PA

Research and innovation has been the basis for the rapid explosion of interventional radiology services provided over the last 25 years. The growing pressure for competition from non Interventional Radiologists performing Interventional radiology procedures is a testament to the success of Interventional Radiology therapy but also highlights the importance of research in the future development of our specialty. To better compete in the future, it will be necessary for Interventional Radiologists to become involved in research & to learn how to incorporate research into their clinical practices.

This symposium will illustrate three pathways to develop research as part of an Interventional Radiology Career. The first will be a discussion of how Corporate investment in Research and Development has become a major component of many research programs. While Corporate interests are focused on bringing a product to market, the means by which a medical product gets to market requires a substantial investment in basic research, pre-clinical safety trials, and clinical efficacy trials. For this reason, involvement with research in support of corporate interests may become the basis for a research program. The second discussion will illustrate how the use of small foundation grants can enable a researcher early in their research career to develop pilot data that will form the basis for future NIH grant submissions. The third discussion will center on the NIH programs for researcher training. The K-series of grants offered by NIH are highly competitive but they provide a multi-year pathway for involvement in the NIH process and can jump start an early researcher into the NIH grant process.

Finally, we will conclude the symposium with a discussion of the NIH grant application process and provide a Mock Study section for the participants in the symposium. By hearing from a representative of the NIH how the process works & then working through some grants in the review process, participants will gain an appreciation for the grant review process to better help them prepare grant submissions and start them on the "road to a research career."

Corporate Service

While the NIH represents a sizeable source of medical research funding with over 21 Billion dollars of funding in 2003, there is increased interest in medical research from the private sector. According to the report of the Office of Technology Assessment in 1993, Research and development investment by the pharmaceutical Industry was approximately $65 million for drugs reaching the market in the 1980s but the returns on the investment exceeded the cost of the R & D by 4.3%.(1) Similar to the pharmaceutical industry, the growing medical device industry has a vested interest in the conduct of research and development of new devices for medical therapy. The investment in research by corporations represents an opportunity for researchers in interventional radiology to partner with device companies to advance science while assessing the efficacy and safety of medical devices prior to their use in humans.

For example, many new devices will require preclinical research to establish the safety of the device prior to clinical trial. This represents an opportunity for research labs with access to animal facilities and imaging suites to perform the safety trials mandated by the FDA to get a product to market. Strictly speaking, these are purely service functions for many corporations but the

investigator has the opportunity to influence the design of these preclinical studies such that the outcomes yield some scientific data. It is important as an investigator in these situations to be cognizant that a good scientific design will help get research studies published. This will help the company get better promotion of their product when it finally comes to market.

Once the preclinical work is done, clinical trials will be required for FDA approval of many new devices. Devices that fall under the 510 (K) process because they are substantially similar to other devices may undergo clinical trials to compare the efficacy of one device versus another. In either case, it is common for clinical trials of devices to be funded by private companies. While the funding source may raise the specter of bias, it is important for investigators to recognize that high quality prospective randomized trials are the most accepted form of data. For this reason, it is important for investigators to focus on the design of these clinical trials. If the science is good, it doesn't matter where the money came from.

Through participation in corporate sponsored research, it is possible for investigators to develop a fulfilling career that focuses as much on science as it does on providing service to device manufacturers. The relationships built through such collaborative research projects can result in long-term partnerships that enable high quality scientific projects to be designed by investigators and sponsored by companies in order to further science, patient welfare, and also the welfare of the companies we partner with.

Foundation Support

For many investigators, the major obstacle to initiating a research program is the lack of funding for early pilot studies that can eventually lead to large competitive research grants such as the NIH R-01. While some small pilot information can be gleaned from the resources within a department, to gain enough preliminary data for a competitive NIH submission requires the development of techniques that are novel and efficient and you must demonstrate that you can complete the research proposed. To develop this level of data will usually require a more substantial amount of money than can be obtained from a radiology department. To fund these initial projects, investigators can pursue early funding through research foundations such as the SIR Foundation, the RSNA Research & Education Foundation, and disease specific societies such as American Heart Association or the American Cancer Society.

Foundation support will generally be for a limited time (usually 1 to 2 years) and for a limited amount of money (typically < $100,000/year). For example, the SIRF pilot grant is for $25,000 for 1 year's worth of work. This type of pilot grant will generally provide enough funding to form a basic hypothesis & develop enough preliminary data to generate sample sizes for larger experiments. The data from these grants should be used to apply for larger grants from foundations or the NIH. If the pilot data is strong enough for NIH submission then that is an excellent place to apply. NIH funding is, however, extremely competitive so even pilot data may need to be further developed. For the committed researcher, application for investigator development grants such as the Ring grant offered by the SIR Foundation may offer enough funding to initiate a program that can eventually lead to NIH funding.

Through careful planning, an early investigator can develop a series of grants that build upon each other to initiate an NIH funded research program.

The NIH Training program

For those investigators who have developed relationships with good scientific mentors, the NIH offers a number of training awards to help develop young investigators. The training awards, known as the K-series grants, provide funding for investigator development. The grants most applicable to early investigators are the K-08, designed to train a clinician in the conduct of basic scientific research and the K-23, designed to train applicants in clinical research.

For each of these grants, the application material must have a complete description of the training program proposed for the applicant. This should include a discussion of the courses to be taken by the applicant, a discussion of what type of meetings will take place with the mentor, and a clear delineation of how the applicant will be trained to become a productive researcher. The application material on the project itself is as much a reflection of the mentorship as it is of the applicant. Since only $25,000/ year can be spent on the materials for the project and education of the applicant, it is important to develop a research program that is not too ambitious.

The focus of the NIH training grants is to develop early researcher so that they can become independent researchers that run programs that move medical research forward over the long term. As such, it is expected that the recipients of K awards will ultimately translate their research into R-01 grants.

Grant Writing

Grant writing, and the subsequent award of a grant, is a test of one's knowledge of and contribution to a given field, research and analytical skills, writing ability, and grantsmanship skills. Today grant writing is a regular activity at most academic departments, with some institutions drawing a substantial portion of their annual budget from federal and private research dollars. Many institutions and even some departments have staff dedicated to the grant procurement process. This introduction to grant writing consists of six sections: 1) mechanisms of support 2) funding sources 3) components of a grant application 4) review process 5) resubmitting and 6) resources.

I. Mechanisms of Support

There are a number of mechanisms to fund research including but not limited to: grants, contracts, cooperative agreements, gifts, and in-kind contributions. Grants