SYMPOSIUM

Building and Supporting Effective Academic Clinical Research Programs in Today's Market-Driven Health Care Environment: Is Research Valued and How Much and by Whom?

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Academic medical centers today face unprecedented and growing financial pressures. Typically, even public state-supported centers must now generate 85% to 95% of their annual operating funds through patient care revenues, research grants, tuition, and philanthropy. Most centers operate both outpatient and inpatient physician services through faculty practice plans. They may either own or have operational agreements with hospitals where patient care, teaching, and clinical research occurs. Patient care revenue from hospital and physician services typically makes up most of a center's total operating revenue.

These income sources are subject to negotiated or mandated third-party reimbursement reductions, including government and private insurers. The public also expects academic medical centers to provide a disproportionate amount of uncompensated care for individuals who are underinsured. Many centers now operate with minimum operating cash reserves. Patient care income is subject to acute unplanned budget reductions that may occur in a matter of weeks creating significant cash flow problems. Salaries for all faculty and staff, including those who are not directly involved in patient care, are the major recurring institutional expense and are not easily reduced when income declines.

Research-related internal expenses also face academic medical centers as they strive to support their clinical research missions. Central is the need for costly protected research time for clinician-scientists. While engaged in and planning research, faculty members are less available to perform patient care services that will generate income. Time is also required to maintain clinical proficiency, particularly in rapidly advancing surgical specialties. There is a nationally recognized shortage of fully trained clinician-scientists entering the profession. This requires a significant institutional investment in mentored faculty development for new clinical faculty who are interested in expanding their involvement in research. Complicating these issues are the mixed cultures within these centers that value clinical research differently.

In addition to faculty time, there is a significant research infrastructural cost to establish and maintain clinical research programs. State-of-the-art research support core facilities require major items of multi-user specialized equipment and professional staff to provide research support services. There are additional start-up costs for recruiting new faculty and assisting them to establish and maintain competitive sponsored research programs. Finally, there is a relatively high drop-out rate for clinician-scientists, particularly at the time of their first competing grant renewal. This drop-out rate results in loss of the institution's investment in faculty who subsequently decide to concentrate their efforts on patient care instead of continuing their research interests.

Further complicating clinical faculty time and salary considerations are granting agency caps on faculty salary base compensation. For example, the current NIH cap is $172,900 per year for a full-time effort for an investigator who receives salary support from grants. Faculty in some surgical and critical care disciplines may have annual salaries well in excess of this limited base. For such clinician-scientists, spending even part-time conducting sponsored research within the range of the lower salary cap may actually limit personal compensation because of today's in-

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centive-based clinical practice salary plans. To fully support competitive salaries for such faculty, institutions or departments increasingly find it necessary to subsidize their investigator-related salaries.

In recruiting clinician-scientists into some of these higher-income disciplines, institutions and departments must consider many issues. For example, can a procedurally oriented surgeon maintain "cutting-edge" surgical skills while working half-time in a research lab? What is the best fit for clinical specialty-related research—applied translational research or clinically inspired basic research? How much pay are clinician-scientists willing to forgo for the privilege of pursuing their research interests? How much income are clinical colleagues who fill the coffers of their departmental practice plan willing to give up so a clinician-scientist in their department can do research—what's in it for them? Do the chairs, dean, and hospital director truly value and foster clinical research or do they merely give lip service?

In addition to directing and conducting the actual research, there are major research-related time demands placed on clinician-scientists. Most gladly accept their responsibilities to develop and perform routine laboratory procedures, write manuscripts, and attend scientific meetings, but they must also face many other less desirable responsibilities. They must write research grants and shepherd them through the peer review process, and they must prepare research protocols and applications to meet a growing number of institutional compliance requirements. These include the statutory requirements defined for institutional review boards for human investigations, institutional animal care and use committees, laboratory biohazard and biosafety regulations, conflict of interest certifications, and most recently HIPAA privacy issues. Further compounding the process of conducting sponsored research, the investigator must also deal with research accounting, purchasing, and personnel issues in a system that often seems unsympathetic to the research mission relative to the much larger patient care and traditional educational missions.

Increasing the efficiency and effectiveness of a researcher's time is one thing an institution can do to improve both the economics and productivity of clinician-scientists. Institutions can support the recruitment and general training of effective research support staff to minimize the training time required by the investigator. They can develop a set of core research support facilities that will provide advisory, assay, and procedural support for clinical research objectives. Human subject participation in research can be facilitated by the presence of a general clinical research center staffed by professional research nurses and technical support staff. A clinical trials office can assist faculty in contract negotiations, provide staff support in the recruitment of research subjects, and provide grant writing and compliance application assistance. Finally, building and maintaining a general institutional research culture that regularly brings together clinician and basic scientists can facilitate cross-fertilization and collaboration among researchers. Seminar programs, research colloquia, research advisory groups, and program project initiatives are excellent forums to encourage such interactions.

An effective way to re-energize the research mission is to utilize research training programs to further enhance research objectives. Mentoring clinical research fellows, basic science research fellows, Ph.D. students, and M.D./Ph.D. students, and providing research opportunities for medical students and residents create unique opportunities to both maintain research vitality and to train future biomedical scientists.

Building and maintaining a supportive institutional research culture must be a continuously active process to sustain a vibrant research mission. Some administrative activities that can contribute to this goal are as follows:

- Promoting selected interdisciplinary areas of research within the institution to achieve national prominence in a few areas
- Encouraging and rewarding productive collaborations and partnerships among faculty and departments
- Promoting a "helpful" rather than an "obstructionist" institutional attitude among all business and compliance offices that interface with researchers
- Creating funding safety nets or bridge funding programs to help investigators through unsuccessful grant renewal cycles
- Introducing institutional research programs to peers at other institutions, particularly those sitting on grant review panels, and
- Promoting institutional respect for research and researchers, particularly among clinicians and educators who are not themselves engaged in research

It is important that institutions make sure that newly hired faculty members understand the institutional expectations that they will conduct research. This can be done by:

- Including research expectations in letters of academic expectations at the time of initial faculty appointments
- Providing adequate start-up packages that include protected research time to enable the researcher to become fully established and self-sustaining
- Making conceptual research advances and development of a sustainable sponsored research program an important component of academic promotion decisions
- Conducting workshops on grantsmanship and authoring scientific papers for beginning faculty, and
- Emphasizing the importance of mentoring-beginning faculty by established investigators

Once established, keeping the clinical research system financially healthy can be a real challenge. The most effective approach typically involves establishment of various incentive programs that allow researchers and departments to earn their own opportunity for continuing programmatic

and professional growth and development. The institution can reinvest funds recovered through indirect cost recovery to maintain and upgrade support for the research infrastructure. It can develop financial reserves from this source to match or augment major equipment grants and it can declare and distribute dividends to departments when institutional income and cost recovery from research exceeds costs. At the departmental level, the institution can allow departments to reinvest base salaries recovered on grants to expand their research enterprise, create a faculty development fund fueled by either indirect cost or base salary recovery, and develop a system of bonuses based on research productivity or levels of base salary recovery. To facilitate use of these leveraged incentive programs, institutions may need to develop a financial reserve and time-limited financial safety nets for grant supported salaries and programmatic costs that are of a recurring nature.

No single institution supports their research mission in the same manner. Faculty, particularly clinician-scientists, who are considering research careers at a specific institution must carefully evaluate the culture and institutional infrastructure that supports their research mission. Selecting the right institution will have a major impact on the success of a clinician-scientist's career.