What Can Be Done to Protect the Translational Investigator?

THE ENVIRONMENT FOR INVESTIGATOR-INITIATED CLINICAL RESEARCH IS CHANGING

KARL E. ANDERSON, MD¹

The Association for Patient-Oriented Research (APOR) arose from concerns expressed beginning in the late 1970s about a growing shortage of investigators interested and well trained in conducting research on human subjects. Educational debt, difficulties in securing grant funding, and greater financial rewards in clinical practice continue to discourage young practitioners from pursuing careers in clinical research. Academic medical centers have seen their margins from clinical earnings decline and have asked potential clinician-investigators to contribute to the bottom line by seeing more patients. There was also an assumption, mostly unspoken, that basic research should be the focus of support and training, and that self-evident clinical and public health applications of basic research findings would be developed without much support from government or academic institutions. But the translation of basic research knowledge to the clinic and community has proven to be challenging and complex, and the rate by which the pharmaceutical industry has been developing significant new drugs is disappointing.

An especially endangered species is the clinical investigator who asks questions at the bedside, and may then pursue answers initially in the laboratory and animal models before returning to the patient with a scientifically meaningful and ethical research protocol. This bidirectional aspect has been recognized as an essential and exciting aspect of patient-oriented research for many years, as exemplified by the comments of John Oates in 1982 (Figure 1). The career development of effective investigators who are comfortable both at the bedside and in the laboratory requires many years of mentoring and experience as well as stable research funding and institutional support.

Lack of Funding

Since the 1950s, the National Institutes of Health (NIH) has provided basic infrastructure for patient-oriented research in academic medical centers through the General Clinical Research Center (GCRC) program. GCRCs were also important for training patient-oriented investigators. In the 1990s, the NIH initiated K30 grants, which supported development of curricula for clinical research education, and individual K grants for trainees (NCRR

Figure 1. Integral role of patient-oriented clinical investigation both in the discovery of new knowledge and development of new therapies (from Oates JA. Presidential address: Clinical investigation: a pathway to discovery. *Trans Assoc Am Physicians.* 1982; 95: lxxviii-xc).

K12), young investigators (K23, K08, etc.), and mentors (K24). The NIH Roadmap proposed by former NIH Director Elias Zerhouni, MD, emphasized clinical research and culminated in the Institutional Clinical and Translational Science Awards (ICTSAs).

APOR supports the ICTSA program, which aims to expand support across the broad spectrum of translational research—from bench to bedside and the community—and for training at multiple levels. Unfortunately, this comprehensive program is being implemented at a time when NIH funding is limited. There are no progress reports yet on ICTSAs, but concerns have been expressed that at some institutions infrastructure for patient-oriented research has been

downsized and that support has shifted to more basic research in the translational spectrum. If so, this will impede development of patient-oriented researchers. Current plans are for fewer ICTSAs than the number of previous GCRCs, which may mean that students and junior faculty at many academic health centers will have little exposure to hypothesis-driven, investigator-initiated clinical research. Clinical research at such institutions may be visible only as clinical trials sponsored by the pharma. While partnering with pharma is a key component of the NIH Roadmap, academic centers must also provide an environment favorable to patient-oriented research that investigators pursue based on hypotheses generated at the bedside.

APOR Supports Patient-Oriented Research

APOR will continue to promote patient-oriented research in a rapidly changing healthcare and clinical research environment. Because patient-oriented research represents a partnership between all practitioners and patients affected by disease, APOR welcomes all who are interested in CTS research to join in this effort. APOR is partnering with other organizations with complementary goals, such as the Society for Clinical and Translational Science (SCTS) and the Association for Clinical Research Training (ACRT), in planning an annual spring meeting that will benefit members of all these organizations. APOR and SCTS are also partners in supporting CTS. APOR will continue to provide further information about its activities in future issues of this journal, as well as in our newsletter (<http://www.apor.org>). **CTS**

¹President, Association for Patient-Oriented Research.

Correspondence: K. Anderson (kanderso@utmb.edu)

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