

Administration and Infrastructure for the Translational and Clinical Research Enterprise

Advances in biomedical research provide medical researchers with unprecedented opportunities to understand and interdict human diseases. To seize these opportunities, U.S. medical schools and teaching hospitals must produce and support sufficient cadres of translational and clinical physician-scientists to propel scientific advances into better diagnostics, treatments, and preventatives of disease. Yet concerns are widespread that organizational and cultural barriers in academic medical institutions are impeding these outcomes.

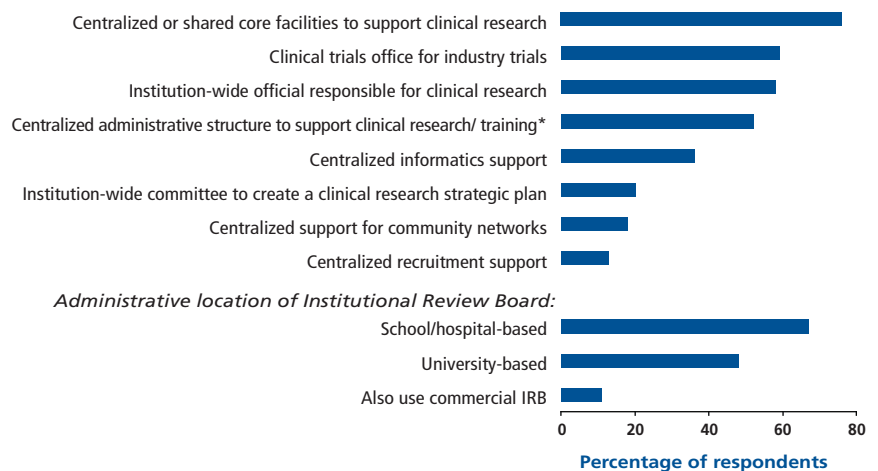
One way to remove these organizational barriers is in the centralization of research governance and infrastructure. Based upon the work of the AAMC's Clinical Research Task Force II, this Analysis in Brief examines the degree to which academic medical centers have centralized their translational and clinical research enterprises, as well as the models and benefits of centralization.

Method

In 2005, we surveyed 65 program directors of NIH General Clinical Research Centers (GCRCs).¹ Forty-six institutions (71 percent) responded to the survey. Additional information and insight came from pertinent literature reviews and examinations of best practices by the members of the AAMC's Clinical Research Task Force II.

¹ NIH General Clinical Research Centers are a national network of centers that provide settings for medical investigators to conduct both inpatient and outpatient clinical and translational research studies. GCRCs also provide infrastructure and resources that support several career development opportunities.

Figure 1
Institutional Organization, Administration, and Governance of Clinical Research, 2005



* Many are actually in the planning stages. In 2005, only seven institutions had a centralized structure supporting all or almost all aspects of clinical research.

Results

Survey responses indicate that medical schools are moving toward administrative centralization of their translational and clinical research enterprises (Figure 1). Slightly more than half (58 percent) of respondents had an institutional official responsible for clinical research across the institution; 52 percent had, or were in the process of establishing, a specific, centralized administrative structure to support/facilitate clinical research and training; 76 percent provided centralized or shared core facilities to support clinical research; and 57 percent had established a clinical trials office for industry trials. Institutional review boards were

generally centralized and based either in the school or hospital (67 percent) and/or the university (48 percent). Less centralization was evident in other areas, such as informatics (36 percent), research subject recruitment (13 percent), and community networks (18 percent).

Approaches to Centralization

Our analysis identified three general approaches to the centralization of clinical and translational research (Table 1). The first model centralizes the enterprise as a clinical research office within the Office of the Dean. Second, some institutions have created a separate Department of Clinical and

Table 1.
Three Approaches to Centralization of the Translational and Clinical Research Enterprise

	Dean's office	Separate department	Center (matrix)
Administrative home	Office of clinical research in dean's office	Department of clinical research	Center for clinical research
Leadership	Associate dean for clinical research (or equivalent)	Chair of the department of clinical research	Director of the center for clinical research
Appointment of investigators	Discipline department	<i>Primary:</i> department of clinical research <i>Secondary:</i> discipline department	<i>Primary:</i> discipline department <i>Secondary:</i> center for clinical research
Location of investigators	Discipline department	Department of clinical research	Either discipline department or center for clinical research
Oversight of resources supporting investigators	Discipline department	Department of clinical research	Both discipline department and center for clinical research
Location of essential clinical research components	Co-localization is possible	Department of clinical research	Center for clinical research
Oversight of resources supporting essential clinical research components	Dean's office	Department of clinical research	Either or both discipline department or center for clinical research

Translational Research. The third approach creates a Center for Clinical and Translational Research.

Many institutions are employing these approaches or hybrid variations of them. Whichever the approach, all include a leader who most often reports to the dean of the medical school, but in some cases may report to a higher university official, such as the vice president/vice chancellor for medical affairs or for research.

Essential core components of this centralized translational and clinical research enterprise include research training and degree-granting programs; the GCRC(s) that provide participant and clinical interactions resources; the clinical trials office; bioinformatics and protocol development (research design, biostatistics, and regulatory support); and support for community collaborations and linkages.

Benefits to Centralization

Based on the survey results and research of the AAMC's Clinical Research Task Force II, we believe many benefits can emerge from greater centralization of the translational and clinical research enterprise. Centralized leadership aided by strategic planning and targeted investment of resources can promote cohesion among the various components and partnerships with and between departments and other schools. It also can ensure that appropriate investments are made to maintain continuity of cutting-edge research infrastructure and retention of key non-faculty research staff, who are often vital to the success of these programs.

Centralization also may help produce a culture in which translational and clinical research is vibrant and visible and can strengthen the identity and morale of translational and clinical scientists. If feasible, co-localization of

infrastructure components may increase spontaneous meetings of clinical investigators and promote scientific interactions. Locating the training programs in the midst of the research enterprise can create a sense of excitement and mission among the trainees, and importantly, increase their chances to encounter role models.

Centralized oversight and support of core resources can enhance their usage by providing fair and unimpeded access for any faculty member who needs their services. Centralized oversight also can help ensure that institutional leaders learn of any issues or problems immediately, and can respond to them quickly. Additional advantages include efficiency, cost savings, continuity of funding, availability of backup personnel, uniform operating procedures and training that improve compliance, and uniform standards for the qualifications and experience of support personnel.

The call for central oversight, administration, and support for translational and clinical science is consistent with the intent of the recently issued NIH Clinical and Translational Science Award (CTSA) initiative² that seeks to create "academic homes" for translational and clinical science. This initiative provides a powerful incentive for greater institutional attention to, and centralization of, oversight and support of translational and clinical research.

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² See www.ncrr.nih.gov/clinicaldiscipline.asp for more information.