NATIONAL CENTER FOR
RESEARCH RESOURCES
NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH
AND HUMAN SERVICES

General Clinical Research Centers

General Clinical Research Centers make it possible to translate knowledge gained through basic research to the development of new approaches to prevent, diagnose, and treat diseases and disabilities that affect the health of the nation's people. Researchers are provided resources to accelerate the pace of new discoveries to bring drugs, devices, and therapies to the people who need them.

The National Center for Research Resources ensures that essential tools and research resources are readily available to NIH-supported investigators nationwide. NCRR-supported resources—a comprehensive range of human, animal, technology, and more—enable biomedical research advances.

The Division for Clinical Research Resources at the National Center for Research Resources (NCRR) funds a network of more than 80 General Clinical Research Centers (GCRCs), distributed across the United States and located mostly at academic medical centers and teaching hospitals. The GCRC program began in 1959 to provide clinical investigators with specialized environments that have the infrastructure needed to conduct sophisticated patient-oriented research. More than 40 years later, these research settings have enabled countless investigations of human diseases, both rare and common. In the last year, the GCRCs supported approximately 11,000 research scientists who pursued more than 7,400 studies.

Each GCRC has unique characteristics that reflect the host institution's research strengths and the needs of its researchers. Major areas of investigation include pulmonary disorders, cardiovascular diseases, endocrinology, cancer, diabetes, and immunology. In recent years, a special emphasis has been placed on supporting pediatric studies. Because the GCRCs support a full spectrum of patient-oriented scientific inquiry, researchers who use these centers participate in multidisciplinary collaborations.

GCRCs began as discrete inpatient units in university hospitals with research nurses as their principal resource. But, over a 40-year evolution, research at the GCRCs has come to rely more on outpatient than inpatient facilities, and the resources have expanded to include biostatistics and bioinformatics units; enhanced nutrition and laboratory cores; and imaging facilities. To accommodate this trend, a number of GCRCs have established satellite sites, which expand outpatient study populations and broaden scientific collaborations. In addition, resources may be used at off-site locations, such as schools and community centers, for research activities that carry little medical risk.

GCRC Funding and Management

Typically, GCRCs are funded in 5-year cycles, with continued funding contingent upon competitive renewals. The principal investigator (PI) of a GCRC, usually the Dean of the medical school, is responsible to NCRR for research conducted within the institution's GCRC. The program director, an established physician-scientist who holds peer-reviewed grant support, supervises the day-to-day activities of the GCRC. The PI appoints an institutional GCRC Advisory Committee (GAC) drawn from the institution's faculty. GAC members supervise GCRC management, approve research projects, and set admission policies and priorities for patient research.

In addition to the PI, a number of GCRC key staff members are supported by NCRR funding. Their roles and responsibilities are described below in the table entitled, "The GCRC ResearchTeam."

NCRR recently began funding the Research Subject Advocate (RSA) position to further enhance Federal regulations and policies that protect patients in clinical research protocols. The RSA's role is to assist clinical researchers to meet the increasingly complex research consent and oversight procedures. To this end, RSAs monitor the steps taken to maximize patient safety as detailed in the protocols approved by the Institutional Review Board (IRB). The RSA must understand the research protocols and have sufficient stature within the institutional community to achieve the goals of the program. Although typically an RSA's background is in medicine, research nursing, pharmacy, or ethics, other relevant areas also may be appropriate.

The GCRC Research Team

Team member	Role and responsibilities
Program Director	Senior physician-investigator and a medically-licensed, full-time member of the institution's faculty Supervises the operation of the GCRC and must be familiar with all GCRC research protocols, which could be as many as 200 or more depending on the GCRC's capacity Teaches the concepts and methods of clinical research to fellows, residents, interns, and students
Administrative Director/Manager	Responsible for the day-to-day management of administration, fiscal matters, and records of activities Coordinates with Principal Investigator, institutional officials, and staff to ensure the efficient operation of the center
Biostatistician	Plans, designs, and evaluates all clinical research protocols for statistical soundness and is a voting member of the GCRC Advisory Committee (GAC) Consults and may collaborate with investigators on study design, implementation, analysis, interpretation, and dissemination of results

The GCRC Research Team (continued)

Core Laboratory Director	Supervises the core laboratory Establishes laboratory procedures for complex and routine research assays, and trains GCRC investigators and junior faculty or fellows in advanced lab techniques Supported by staff who have expertise in research analysis
Head Nurse	Manages the administrative organization of the nursing staff, including training, patient care delivery, and interactions with investigators to assure that research projects are carried out as approved by the IRB and the GAC Supported by nursing staff, who are trained to make complex research observations and perform precise collections of specimens while providing exemplary patient care Assisted by an Associate Head Nurse in those GCRCs that have many complex research projects or a large number of outpatient research visits
Nutrition Research Manager	Manages nutritional aspects of metabolic or other protocols that demand sophisticated nutritional support Works closely with GCRC nurses to provide optimal service to research patients and investigators
Informatics Core Manager	Ensures that current technologies are available and are employed to meet GCRC informatics goals Uses an array of methods to organize and analyze research data, and collaborates with GCRC investigators to design and develop methodologies that meet accepted standards for research data management of approved protocols
Research Subject Advocate	Serves as an unbiased observer during the consent process when requested by either the patient/volunteer or investigator Provides information to patients/volunteers participating in Phase I or Phase II clinical trials and other research that is above minimal risk Assists GCRC investigators to formulate, and the GAC to review, data and safety monitoring plans Assures that GCRC studies are performed in accordance with IRB-approved protocol and monitoring plan Facilitates the reporting of Serious Adverse Events and Conflicts of Interest to appropriate local committees and Federal agencies Assures that GCRC investigators are appropriately trained and remain current on their regulatory and patient safety responsibilities

Training Opportunities

The future of clinical research depends on a continuous stream of well-trained investigators. To help maintain the nation's cadre of clinical researchers, NCRR supports several career development programs that are GCRC based. Information about the programs is available on-line at www.ncrr.nih.gov/clinical/cr_crcd.asp and from a fact sheet, entitled *Clinical Research Career Development*, also available on-line or from NCRR.

Investigator Access to GCRCs

Investigators whose projects are supported by the NIH, other Federal agencies, state and local entities, the private sector, or other peer-reviewed sources are eligible to apply to use the GCRCs. (However, priority is given to investigators who have received grant funding from NIH.) To ensure research diversity at the GCRCs, no single group of investigators studying a specific disease may utilize more than 33 percent of the resources at a center. This limit may be temporarily exceeded in unusual circumstances to benefit the public's health.

Top Four NIH Institutes Supporting GCRC Investigators:

- National Heart, Lung, and Blood Institute
- National Cancer Institute
- National Institute of Diabetes & Digestive & Kidney Diseases
- National Institute of Allergy and Infectious Diseases

An eligible clinical investigator who wants to gain access to a GCRC for research should contact the resource staff listed for that GCRC in the *Clinical Research Resources Directory*, which is available on-line at www.ncrr.nih.gov/ncrrprog/clindir/crdirectory.asp. The directory lists key staff members, center resources, and major areas of investigation for each of the GCRCs. Copies of the directory also can be obtained from NCRR.

For further information:

Director, Division for Clinical Research Resources
National Center for Research Resources
6701 Democracy Boulevard, Room 906
Bethesda, MD 20892-4874
Telephone: (301) 435-0790
Fax: (301) 480-3661
E-mail: CRADIR@ncrr.nih.gov

For general NCRR information:
Telephone: (301) 435-0888
Fax: (301) 480-3558
E-mail: info@ncrr.nih.gov
NCRR Web site: www.ncrr.nih.gov

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