

## Complementary Programs

The RBHS strategic plan will support the development of four complementary programs. These complementary programs focus on areas that, while relatively strong, are not of sufficient strength currently to have the potential to be among the best in the nation within the next five years. However, they are essential for the growth and development of RBHS as well as the success of signature and emerging programs throughout RBHS. Each is critical to the RBHS mission more broadly.

### *Clinical Research*

Rutgers' mission includes providing education and instruction, conducting cutting-edge research, and performing public service in support of the needs of New Jersey's citizens. Clinical research is necessary to improve treatments and the health status of populations. Expanding clinical research will provide access to novel treatments to the state's citizens, and in particular disseminate the benefits of Rutgers biomedical research to the RBHS clinical enterprise and, specifically, to its health care providers, benefiting patients throughout New Jersey. It also will help advance one of the major industries in the state. For these reasons, the expansion of clinical research was also an important motivation for the Rutgers-UMDNJ integration. While Rutgers does not have the depth and breadth of the strongest clinical research programs nationally, considerable clinical research is being conducted at Rutgers. This includes a large number of IRB-approved active clinical protocols (3,394), peer-reviewed grant funding (\$21.65 million in 2013; \$112.85 million since 2009), and high impact peer-reviewed publications (73 in high impact clinical journals (impact factor >8) and 7,062 publications cited in PubMed from 2009 through 2013). Rutgers-wide, at least 60 faculty members currently receive NIH funding for clinical research. More than 65 faculty members who responded to a survey distributed to all Rutgers faculty in February 2014, reported that they currently receive extramural funding to support their clinical research activities.

Further, considerable clinical resources are available through the large hospital and community-based centers in Newark and New Brunswick, as well as through over 16 integrated medical centers throughout the state. RBHS has the capacity to provide leadership and oversight for a clinical research infrastructure sufficient to support signature programs and has the potential to expand the signature programs through foundation- and government-sponsored clinical research programs and partnership with biotechnology and pharmaceutical companies, and building clinical research bridges that would allow Rutgers to become a significant national leader.

*Two major initiatives* will be undertaken to support the mission of clinical research for the signature programs, the emerging signature program, and other RBHS research programs. *The first initiative* is the development of the infrastructure needed to support a NIH application for a Clinical and Translational Science Award (CTSA). When awarded, the CTSA would be a resource accessible to and supportive of research programs within all RBHS schools and units, and all schools and units Rutgers-wide with health-related research programs. The CTSA would provide expanded core resources in key areas, including biostatistics, bioinformatics, data management, clinical trials and epidemiology, research nursing, and pharmacy and pharmacology.

*The second initiative* would be a collaboration with Rutgers University Cell and DNA Repository (RUCDR) Infinite Biologics, the world's largest university-based biorepository. In operation since 1999, RUCDR has perfected the science of biobanking, bioprocessing, gene sequencing, and analytics. RUCDR currently works with several centers and institutes at Rutgers. The collaboration would enable RUCDR to support RBHS researchers focusing on the genetic causes of common, complex human diseases and enable genomic discoveries that would lead to diagnoses, treatments, and cures for these diseases. The collaboration with RUCDR will also enable us to advance our ability to determine individual/genetic susceptibility to the benefits or risks of therapies. Through this collaboration with

RUCDR, resources would be available to assist investigators and provide access to high quality biomaterials, technical consultation, and logistical support.

Discussion is underway to address the clinical research infrastructure campus-wide. An initial step would include the creation of a biostatistics consulting service that would merge existing services and coordinate activities university-wide and, in particular, clinical research in the School of Public Health, RU-New Brunswick, and RU-Newark.

The following tasks will be conducted in year 1:

- identifying a leader for this program who, with other senior clinical researchers, will visit academic sites with similar centers in development;
- establishing a CTSA Advisory Committee;
- recruiting a CTSA director;
- beginning recruitment for nursing, pharmacy, and other relevant staff from internal and external sources;
- identifying clinical research unit space for CTSA development at both New Brunswick and Newark campuses;
- developing a financial model for CTSA support; and
- initiating work with the cancer signature program to recruit new clinical investigators.

Additional critical tasks in year 1 will include efforts to improve and increase clinical research activity and infrastructure to streamline clinical trial negotiations with pharmaceutical companies and enforcing competitive timelines attractive to the pharmaceutical industry, in an effort to increase activity and preliminary data necessary for a CTSA application.

The following tasks will begin or be conducted in year 2:

- providing CTSA services across Rutgers;
- recruiting core staff and developing organizational structure (continued);
- establishing standard operating procedures;
- integrating IRB services across network;
- developing informatics for integrated databases;
- establishing new cores in biostatistics, bioinformatics, and pharmacy as dictated by the Advisory Committee and CTSA Director;
- identifying current faculty for integration into the center;
- developing a plan for integration with RUCDR and biorepository; and
- working with the neuroscience signature program to recruit new clinical investigators.

In year 3:

- a preliminary application for a CTSA award will be developed;
- strategic recruitment of new faculty in specialized centers to enhance faculty critical mass in clinical investigations will be conducted; and
- three to five collaborative research grants (e.g. PO1, SPORE, etc.) will be submitted;
- concurrently, new clinical investigators will be recruited jointly with the infection and inflammation signature program; and
- a pilot grant program in clinical investigation will be developed.

In year 4:

- the CTSA application will be submitted;
- the recruitment of new clinical investigators will be conducted jointly with the environmental and occupational health sciences program; and
- a major industry partnership will be established.

In year 5:

- the CTSA award will be established;
- Rutgers will be identified as a national leader in clinical research in each of the signature programs; and
- development of clinical programs in other health-related disciplines Rutgers-wide will begin.