

Wake Forest Institute for Regenerative Medicine

ORGANIZATION OVERVIEW AND IMPACT

1. MISSION & PROGRAMS

The mission of the Wake Forest Institute for Regenerative Medicine (WFIRM) is **to improve patients' lives by developing regenerative medicine therapies and support technologies.**

The Wake Forest Institute for Regenerative Medicine (www.wfirm.org) is an international leader in translating scientific discoveries into therapies to benefit patients. Its physicians and scientists were the first in the world to engineer laboratory grown organs that were successfully implanted into humans. Today, this team, which has grown to almost 300 scientists and staff, is working to engineer replacement tissues and organs and develop healing cell therapies for more than 30 different areas of the body.

The U. S. Department of Health and Human Services (HHS) calls regenerative medicine the "next evolution of medical treatments." Regenerative medicine is not just a future promise, but is already making its mark on health care. Skin and cartilage substitutes are available through regenerative medicine techniques and laboratory-grown bladders, tracheas, blood vessels and other tissues have been implanted in patients. In addition to the medical benefits, regenerative medicine also represents the potential for economic benefit through the growth of companies and research institutions dedicated to its technologies.

Once a new technology has been thoroughly tested and is ready for clinical studies, WFIRM is equipped for efficient "translation" from the bench to the bedside. A current good manufacturing practices (cGMP) facility, which manufactures replacement tissues and organs under guidelines of the U.S. Food and Drug Administration, ensures that a reproducible process is in place. And when the technology is ready to be licensed to a company that can commercialize it for widespread use, WFIRM has the unique infrastructure and resources to create companies and develop partnerships to expedite the delivery of the technology to patients.

WFIRM was established in 2004 to catalyze the multidisciplinary collaborations needed to realize the promise of regenerative medicine, to provide the infrastructure necessary to support and energize these collaborations, and to accelerate the clinical translation of their fruits. The WFIRM mission is supported with four strategic objectives:

- ***Advance research and discovery*** with a multidisciplinary structure
 - Innovative engagement across disciplines, departments, and institutions, for profit and nonprofit, national and international
 - Enhance funding through multi-investigator and multi-institution program initiatives
- ***Train and educate***
 - Ensure the future of regenerative medicine through training of next generation of scientists, physicians, healthcare providers in the knowledge base and skills required to both lead and participate in multidisciplinary research teams
 - Outreach programs educating the elementary, middle and high school students and the public

- ***Accelerate clinical translation***
 - Integrated teams for the development and translation of specific therapies
 - GMP-grade operating facilities
 - Intellectual capital for the transfer of technologies
- ***Serve as a magnet for regenerative medicine***
 - National and international collaborations
 - Clinical partnerships worldwide
 - Leading and supporting organizations whose mission is to advance regenerative technologies
 - Licenses, joint ventures, and start-ups in North Carolina

Key among the collaborative, multidisciplinary programs at WFIRM is the Armed Forces Institute for Regenerative Medicine, a \$100 million virtual institute that develops regenerative therapies for our wounded warriors. The Department of Defense established the AFIRM in 2008 with the mission of developing new products and therapies to treat severe injuries suffered by U.S. service members. WFIRM at Wake Forest Baptist Medical Center heads one of the two consortia established within AFIRM to accelerate the delivery of regenerative medicine therapies to these severely injured U.S. service members, with the second headed by Rutgers University.

DoD last year issued a solicitation to continue the AFIRM program. WFIRM was selected by its peer institutions to lead the Warrior Restoration Consortium as the prime contractor in response to the AFIRM II solicitation. The Warrior Restoration Consortium proposes a comprehensive program of \$75 million in research over 5 years, with more than 60 projects in 5 program areas, with more than 30 participating institutions. AFIRM II is expected to be funded in the fall of 2013.

2. CUSTOMER/ TARGET POPULATION

The mission of WFIRM is to benefit the public through improvements in human health and enhancements to the quality of life. Key among those who will benefit are those with chronic illnesses for which organ transplant is the only hope for survival. Regenerative medicine holds the promise of overcoming organ shortages through use of engineered tissues and organs. Through the AFIRM, WFIRM serves our wounded warriors, developing regenerative therapies to address burn, craniofacial, and compartment syndrome related injuries, limb and digit regeneration and healing without scarring.

Development of regenerative medicine therapies from bench to bedside is an extensive, pain-staking process that requires satisfying significant technical, medical and regulatory hurdles. In the process of developing these therapies, WFIRM activities generate benefits in terms of education and training, economic development, and tax revenue.

3. ORGANIZATION INCEPTION

WFIRM was established in 2004 and has been actively engaged in research, education and clinical translation since that time.

4. FOOTPRINT

WFIRM operates from a single location in Winston-Salem, Forsyth County. The WFIRM facility is located in the Piedmont Triad Research Park. WFIRM collaborates with researchers, institutions, and industry – regionally, nationally, and internationally.

5. BUDGET

WFIRM operates on a fiscal year budget of July 1 to June 30. The five year history of the WFIRM organizational budget is provided below.

Income Sources	Year Ending 06/30/08	Year Ending 06/30/09	Year Ending 06/30/10	Year Ending 06/30/11	Year Ending 06/30/12
Extramural Sources					
Federal	2,472,516	11,544,089	16,832,500	23,549,947	24,764,480
State	8,000,000	4,006,300	218	9,706,718	8,050,623
Industry	2,310,356	1,763,486	1,704,800	2,172,128	639,473
Philanthropic	828,023	2,836,488	3,145,981	1,627,910	2,424,154
Institutional Sources	2,261,009	2,242,720	2,633,323	2,959,621	2,633,650
Total	15,871,904	22,393,083	24,316,822	40,016,324	38,512,380

6. SALARY COMPLIANCE

Of approximately 300 scientists and staff at WFIRM, 253 are full time employees, and of these, sixteen who receive salary support earn an annual salary of \$120,000 or more. Other sources of support for employees that exceed the State salary cap include grants and contracts from the U.S. government (Department of Defense, including Armed Forces Institute for Regenerative Medicine, and the National Institutes of Health), grants and contracts from industry, grants from foundations and philanthropic donors, and institutional support from Wake Forest Baptist Medical Center.

Position	Salary	State	Other	Position	Salary	State	Other
Faculty	138,456	6,923	131,533	Faculty	225,000	33,750	191,250
Faculty	120,000	70,800	49,200	Faculty	201,610	41,330	160,280
Faculty	120,000	21,600	98,400	Faculty	197,880	18,403	179,477
Faculty	192,216	9,611	182,605	Faculty	192,146	17,293	174,853
Faculty	237,384	11,869	225,515	IP Mgmt	229,500	103,275	126,225
Faculty	150,000	55,500	94,500	Staff			
Faculty	231,750	119,351	112,399	Scientist	153,000	7,650	145,350
Faculty	160,000	25,600	134,400	Translation	120,000	108,000	12,000
				Translation	132,600	66,300	66,300

WFIRM employees receive benefits from other sources. Benefits include paid vacation time, health plan, dental plan, retirement savings plan contribution, disability and life insurance and health care and dependent care spending accounts.

7. LOBBYING SERVICES

Outside lobbying firm: John Bode, Esq., Bode, Call & Stroupe, LLP Raleigh, NC 27612

Amount of Retainer: \$3,300 for the last 12 months.

No employee is a registered lobbyist with the NC Secretary of State.

8. KEY PERFORMANCE INDICATORS

The mission of WFIRM is to improve patients' lives by developing regenerative medicine therapies and support technologies. The ultimate performance indicator for WFIRM will be implementation of regenerative medicine therapies and the resulting improvements in human health and enhancements to the quality of life. The development of therapies from bench to bedside is a pain-staking process, and requires satisfying significant technical, medical and regulatory challenges. Interim performance measures that indicate progress toward the goal of approved therapies in the clinic include extramural funding received, collaborations established, scientific papers published, individuals trained, inventions and patent applications made, as well as projects progressing through the development process. Key performance indicators for the last five years are provided below.

Metric	Year Ending 06/30/08	Year Ending 06/30/09	Year Ending 06/30/10	Year Ending 06/30/11	Year Ending 06/30/12
Full time members	127	176	247	260	253
Graduate Students	15	15	25	35	28
Collaborations			147	194	209
Visitor Groups	86	107	210	351	589
Scientific Publications	111	111	107	146	177
Inventions (cumulative)			85	100	150
Patent Applications (cumulative)			175	200	225
Translational Programs			5	10	12
Extramural Awards			\$22 million	\$30 million	\$32 million

9. SIMILAR ORGANIZATIONS

There is not a similar organization in the state of North Carolina. State funding programs exist in other states to promote the development of regenerative medicine therapies, the largest of which is the California Institute for Regenerative Medicine, established in 2004 by the State of California with, a \$300 million per year commitment to support regenerative medicine research and related medical technologies. Other states, including New York, Maryland, and Connecticut also have regenerative medicine-related state funding programs.

While regenerative medicine research initiatives are under way globally, few areas have the critical mass and infrastructure that North Carolina has to engage in the full spectrum of activities required to move from basic research to commercialization and the clinic.

10. BUDGETARY IMPACT

As a nonprofit research institute, WFIRM obtains funding for all of its programs from extramural sources. WFIRM has been very fortunate to have top performing scientists and staff who are well funded. Scientists are able to take advantage of the multidisciplinary structure for individual clinical

translational research advancement, as well as for the team research opportunities available within WFIRM.

While WFIRM's funding portfolio has grown yearly, the cost of translating technologies for clinical use is very high, and maintaining funding in the current very challenging funding environment has required redoubling of efforts. WFIRM continues to increase the volume of grants submitted, and continues to partner with nationally and internationally recognized programs, institutions and industry to enhance competitiveness for extramural funding. While pursuing extramural funding is a requirement for world class translational science, there is no question that these efforts take time away from scientific progress, and translational programs can be delayed.

Resources to support the translation of scientific discoveries into therapies to benefit patients, like those provided by the State of North Carolina, are critical in the current environment, and help to leverage added federal funds into the state, such as the current programs awarded to WFIRM, including the Armed Forces Institute for Regenerative Medicine, and the newly awarded \$25 million Space and Naval Warfare Systems Center program, in which WFIRM will lead a team to develop a "body on a chip" that could be used to predict safety and effectiveness of potential medical countermeasures against biological and chemical agents. WFIRM continues its track record of bringing large federal investments into the state, and to keep our mission central to what we do, **to improve patients' lives by developing regenerative medicine therapies and support technologies.**