



Louisiana Vaccine Center

**LEQSF (2007-12)-ENH-PKSFI-PRS-02
Mid-Course Report
September 30, 2010**

OVERVIEW

The Center of Excellence for Vaccine Development, now entitled: *The Louisiana Vaccine Center (LVC)*, is a critical mass of investigators based at three major Louisiana university campuses (LSUHSC-New Orleans, Tulane HSC, and Xavier University of Louisiana). The Center was funded by the Louisiana Board of Regents through the PKSFI in recognition of the breadth and strength of regional research in infectious disease and vaccines. Our primary goal has been to develop and focus these local interdisciplinary strengths in the basic and translational sciences of microbial pathogenesis, host immunity and vaccine research in order to foster the development of novel approaches to vaccination against infectious disease, with appropriate infrastructure to support our future growth and the commercialization of new discoveries. Detailed information and regular updates on the Center and its activities are posted on our website at: <http://www.louisianavc.org>

In our first three years, the LVC has focused on the development of a framework for education, research and commercialization in infectious disease and vaccine research. The Center has fostered research collaborations between scientific institutions in Louisiana; demonstrably strengthened local capacity to compete for and obtain large-scale research and development grants and contracts; and provided a focus for retention of established researchers and promising junior scientists. Through our education program, we are stimulating the interest of high school and college students and their future participation in higher education in related fields. We have also participated decisively in the development of an improved pool of potential research support staff locally through the Bioscience and Education Training program. Our commercialization initiatives have, to date, led directly to the development of new intellectual property in vaccine-related research, and the development of three new business plans for start-ups. Thus, the Center is playing a critical role in the establishment of infrastructure necessary to develop local vaccine research and is taking significant steps towards Center sustainability.

Central to the progress of the Center are our research, commercialization and education programs. The focus provided by these programs has underpinned significant progress in each of these areas, as detailed in our Annual Reports. Key advances include:

- the generation of over \$51 million dollars in new external grants for vaccine-related research from federal and private sources, primarily from NIH - including research project and center/program grants, and research commercialization and education awards
- 232 new publications by LVC investigators in the 2008-2010 period
- the LVC pilot grant program has underpinned 40 new federal grant applications – with 12 new federal grants awarded to our pilot grantees, primarily junior faculty at LVC partner institutions
- the development of critical core infrastructure for vaccine-related research comprising a network of nine core labs across partner institutions
- participation of over 40 students from local high schools and from colleges nationwide in the Center's Summer Research Internship Program since 2008, including 'year-long' research experiences in LVC labs
- our Bioscience and Education Training (BET) Program, designed to address a critical regional shortage of

trained biomedical research support staff, has graduated 12 students to date – all are currently employed in local research or biotech labs or have advanced to further professional or graduate training

- our Commercialization Core, based in the New Orleans BioInnovation Center (NOBIC) has identified and fostered vaccine-related research projects with commercial potential in LVC labs leading to 18 new invention disclosures to technology transfer offices in LVC partner institutions. To date, this process has resulted in 4 new provisional patents and 1 international PCT application.
- further development of vaccine-related intellectual property through the LVC commercialization core has led, to date, to one incorporated start-up, two additional start-up business plans under development, one SBIR grant, and three SBIR/STTR applications in preparation.

This mid-course report presents an overview of the organizational structure of the Center, and summarizes how we have successfully addressed our major objectives and met annual performance measures set forth in the Center contract and work plan. The report is organized to emphasize progress against our goals in five key areas including: (i) Research Capacity and Infrastructure, (ii) Education, (iii) Efforts to Secure External/Federal Funding, (iv) Contributions to Economic Development, and (v) Project Sustainability.

ORGANIZATIONAL STRUCTURE OF THE LOUISIANA VACCINE CENTER

The organizational structure of the Center, including a steering committee and internal/external advisory committees, was established in year 1 to guide our growth and development (see **Fig. 1**).

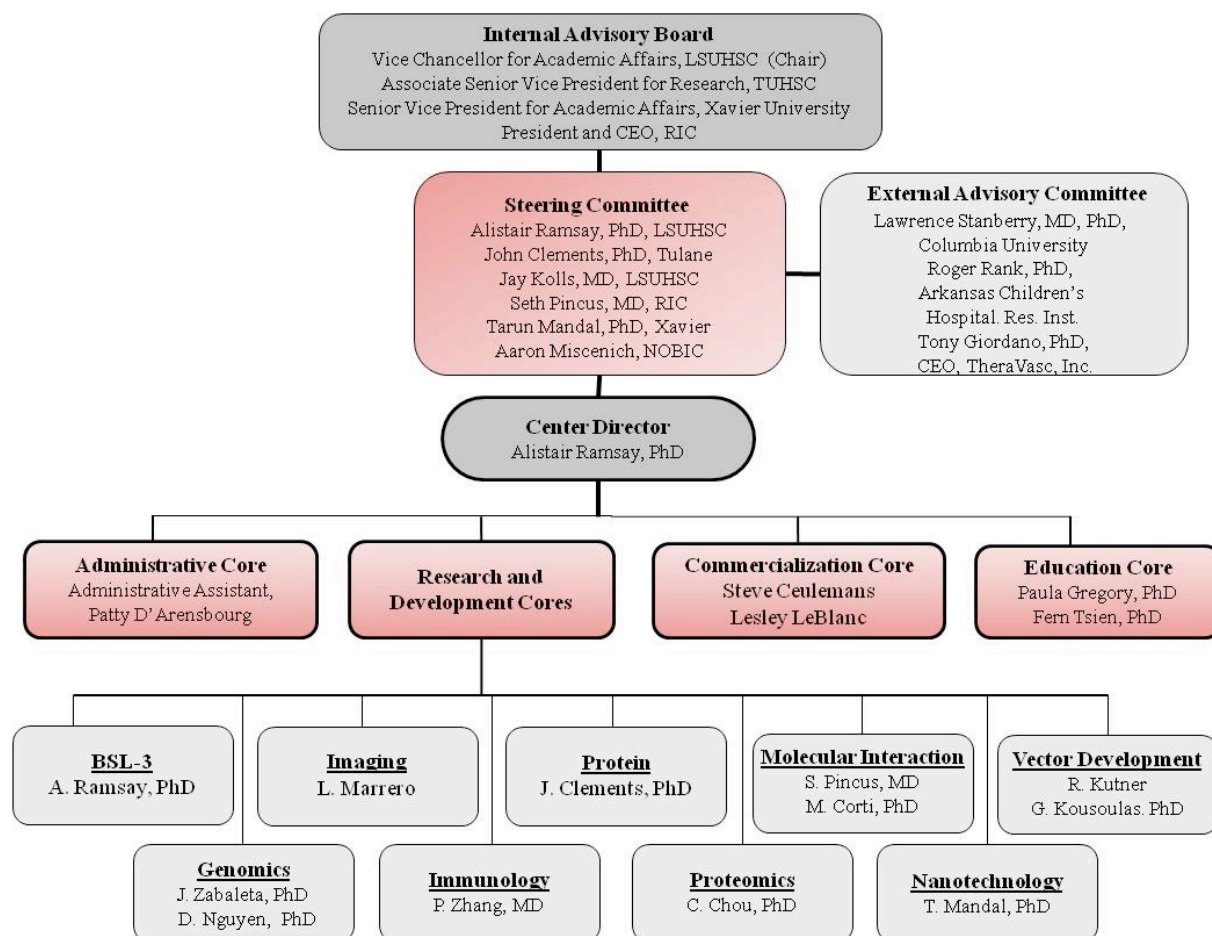


Figure 1. Organizational Structure of the LVC

Members of the LVC External Advisory Committee (EAC) were selected for their experience and national profile in research in infectious disease and vaccine/therapeutics, and in research commercialization. Our EAC comprises:

- **Lawrence R. Stanberry, MD, PhD**, Reuben S. Carpentier Professor and Chairman, Department of Pediatrics, College of Physicians and Surgeons, Columbia University, New York, NY
- **Roger G. Rank, PhD**, Professor, Chlamydia Research Group, Arkansas Children's Hospital Research Institute, Little Rock, AR
- **Anthony Giordano, PhD**, President and CEO, TheraVasc, Inc., Assistant Dean of Research and Business Development, LSUHSC Shreveport, Shreveport, LA

The Center held Annual/EAC Meetings in New Orleans in September of 2008 and 2009. Our next EAC Meeting will be held in the Spring of 2011. These meetings provide an excellent formal setting for feedback by our EAC and Steering Committee members. In addition, we are in regular informal contact with individual EAC members for discussion of Center activities. Following the Year 2 Annual Meeting, our EAC commented very favorably on the progress made in the Center in a relatively short time. The EAC continues to be extremely positive about the strength of the local vaccine-related research, education, and commercialization efforts that have been facilitated by the Center. Their positive assessment of our progress, productivity and impact was embodied in a memorandum addressed to the senior administration of our partner institutions - LSUHSC, Tulane HSC, and Xavier University of Louisiana (see **Fig. 2** below).

MEMORANDUM

Date: September 30, 2009

To: The Leadership, LSU Health Sciences Center, Tulane Health Sciences Center, Xavier University of Louisiana

From: The External Advisory Committee of the Louisiana Vaccine Center (LVC)

Re: LVC

The External Advisory Committee of the **Louisiana Vaccine Center** write this letter of support regarding the progress, productivity and impact of this LA Board of Regents sponsored program.

The LVC program has made tremendous strides in providing a new and enriched culture for infectious disease and vaccine research and development in the state of Louisiana. Having managed and worked through the challenges that Hurricane Katrina forced upon the City and its investigators, the demonstrable strength of this group of researchers prior to the disaster have, in our opinion, been significantly enhanced through the efforts of this program. It is also our opinion that LVC functions extremely well in a manner following the Clinical and Translational Science Award (CTSA) model focusing on infectious diseases, therapies, and preventives. The education, research, and commercialization components complement each other extremely well and, together, provide a giant resource for future funding and enhanced national and international reputation.

As the external advisory committee members overseeing and evaluating the LVC, we feel that the administration of LSUHSC, Tulane HSC, and Xavier University should be aware of the efforts put forth and the successful outcomes that have and will continue to follow from this program. We encourage the respective administrations to continue and expand their institutional support for this program as a means to sustain it alongside the external funding that its members generate. We also feel the unifying effect that the LVC has on the respective schools is extremely impressive and should continue to be fostered in the spirit of the original award.

Respectfully,



Lawrence R. Stanberry, M.D., Ph.D.
Chairman, LVC External Advisory Committee
Reuben S. Carpentier Professor and Chairman
Department of Pediatrics
Columbia University, New York, NY



Roger Rank, Ph.D.
Professor and Head, Chlamydia Research Group
Arkansas Children's Hospital Research Institute
Little Rock, AR



Anthony Giordano, Ph.D.
President and CEO, TheraVasc, Inc.
Assistant Dean of Research and
Business Development
LSUHSC, Shreveport, LA

Figure 2. Memo from the LVC External Advisory Committee to the Leadership of our Partner Institutions

PROGRESS AGAINST CENTER GOALS

(i). Research Capacity and Infrastructure

- Central to our mission has been the development and staffing of nine research core facilities designed to aid the flow of vaccine-related research from discovery to vaccine preparation and delivery and through pre-clinical testing and analysis, with a direct entry point at any stage in this pathway and ongoing support for Center investigators' research. The Center continues to develop critical core infrastructure, contributing nearly \$600,000 for the purchase of new core equipment and supporting the employment of six research associates. Our cores have opened up new research support infrastructure for Center researchers, trainees and students, as well as helping to facilitate new, multi-institutional research collaborations and enhancing our capacity to retain existing faculty and to recruit new faculty to the partner Institutions. The cores have also facilitated training of Center postdoctoral fellows and graduate students in advanced technologies, as well as trainees in the Bioscience and Education Training (BET) Program (see section ii below).

To publicize the facilities and services offered in our cores for Center researchers, and also to the broader local bioscience community, a guide map of vaccine-related core laboratory facilities has been developed, including "Core Awareness" slide shows. These are short, informational PowerPoint presentations which are shown immediately prior to local speaker presentations in the *LVC Infection, Immunity and Vaccine Seminar Program* and are linked through our website. Feedback from a Core Usage Survey sent out to all Center investigators is regularly analyzed in order to develop strategies to better serve Center investigators.

- The Cooperative Pilot Research Grant Fund is a major initiative of the Center that has provided up to two-years of funding (at up to \$75K per year) for new, collaborative vaccine-related research projects. The fund was established primarily to address our goals: (i) to promote the generation of new project and collaborative program applications (including interdisciplinary and/or multi-institutional applications) for extramural funding, (ii) to promote new discoveries with potential for clinical application and/or commercial development, and (iii) to develop the research programs of junior faculty. Through a process of RFP development and distribution and peer review assessment, eleven proposals have been funded, primarily from new and mid-career investigators. The pilot fund has been highly successful in meeting our goals and raising the profile of Center investigators.
 - pilot grant recipients have, to date, submitted 40 new funding applications to federal funding agencies (primarily to the NIH) and 14 to industrial and private sources.
 - 17 new grants have been awarded to pilot grant recipients arising in whole or in part from LVC pilot funding, including: four new R01s, three R21s, a U01 award, an NIH U54 Career Development Award, projects within two distinct Cooperative Center (P20) awards, and a Gates Grand Challenges Exploration Award.
 - 25 new publications have arisen directly from pilot grant-funded research.
 - 6 new postdoctoral fellows have been appointed to vaccine-related projects as a direct result of LVC pilot grant funding.
- The Center has fostered several new collaborations between scientific institutions in Louisiana and beyond in vaccine-related research with the effect of strengthening: (i) our research capacity and infrastructure for the development and testing of novel vaccines for infectious disease and (ii) our capacity to compete for large-scale research and development grants and contracts; all critical to the long-term sustainability of the LVC beyond the PKSFI funding period. Examples include:
 - Vaccine researchers in the Division of Biotechnology and Molecular Medicine at LSU School of Veterinary Medicine in Baton Rouge became affiliates of the Center during year 3, expanding the breadth of vaccine-related research now supported by the LVC. This partnership has allowed us to increase the breadth of Center core capabilities (eg. vector and antibody production) and collaborative research and development in infectious disease and vaccine

development and testing in Louisiana.

- Southern Research Institute (SRI) is a Birmingham, AL-based research and contract research organization with a strong, established pre-clinical vaccine-validation program. SRI has very recently established a satellite office at the New Orleans BioInnovation Center with the goal of increasing its interactions in the region. This partnership will give the Center preferred access to SRI researchers and pre-clinical validation facilities for vaccine candidates. With current developments in our research commercialization program (see section iv), the relationship with SRI will be beneficial for the co-development and validation of new candidate vaccines arising from Center research programs.
- Louisiana State Access Grid technology has been implemented into our Infection, Immunity and Vaccine Seminar Program, to facilitate interaction between the Center members in New Orleans and other groups, including Children's Hospital in New Orleans, LSU School of Dentistry in New Orleans, Tulane University National Primate Center in Covington, LA, the LSU main campus in Baton Rouge, LA and LSU Health Sciences Center in Shreveport, LA. To date, we have hosted 24 nationally recognized visiting speakers, along with 26 local speakers, for a total of 50 presenters since inception. These seminars continue to sustain attendances of over 100-150 per session. The seminar program has exposed large numbers of Center postdocs and graduate students to high-profile national and local research, including follow-up meetings with visiting speakers, and has also led to formal external mentorship arrangements in vaccine-related research. The series also serves to raise the profile of the LVC and of research activity in Louisiana, through exposure of distinguished visitors to our work. It represents a significant and highly successful component of our Research and Education Programs.
- Center investigators have published a total of 232 original research publications in the first three years of our activity. Many have resulted from new collaborations directly facilitated by the Center. Twenty-five of these papers arose directly from research funded by our Cooperative Pilot Research Grant.
- A major goal of the Center is to foster the recruitment of faculty in vaccine-related research in the post-Katrina phase. To date, the LVC has played a key role in recruitment of the following individuals through assistance with start-up funding and seed funding for specific research projects. **Five of these six individuals have since won new, independent NIH funding** (R01s, or as Project PIs within a Program Grant). Our development of vaccine-related research and development infrastructure has contributed to the ongoing success of these recruits, and other Center researchers.

LSU Health Sciences Center

- **Timothy Foster**, Ph.D., Assistant Professor of Microbiology, Immunology, Parasitology
- **Douglas Johnston**, Ph.D., Assistant Professor of Microbiology, Immunology, Parasitology
- **Li Shen**, Ph.D., Assistant Professor of Microbiology, Immunology, Parasitology

Tulane University Health Sciences Center

- **James McLachlan**, Ph.D., Assistant Professor, Department of Microbiology and Immunology
- **Lisa Morici**, Ph.D., Assistant Professor, Department of Microbiology and Immunology

Tulane University National Primate Research Center

- **Deepak Kaushal**, Ph.D., Assistant Professor, Division of Bacteriology and Parasitology

(ii). Education

- A major educational goal of the Center is to stimulate the interest of high school and college students in vaccine-related research, and encourage their future participation in higher education in related fields through a project internship program. To this end, a total of 40 students have participated in the LVC Summer Research Internship Program since 2008. We have recruited some of the best and brightest Louisiana students to work side by side with LVC scientists over the past three summers. 55% of the participants are female and 5% are minority students. This program teaches the students about career options in science, keeping lab records, how to analyze and present data, and responsible conduct of research. The students participate in a Summer Research Poster Session attended by all the interns, their mentors and the members of their lab. The undergraduate summer students attend universities throughout the United States. The Summer Internship Program plays an important role in making them aware of graduate training opportunities here in Louisiana. By forming mentoring relationships with the students, we strive to stay connected with them and cultivate their continued interest in research careers.
- The LVC also supports a Year Long Research Experience Program. Based on their successes in the LVC's Summer Research Internship Program, a select number of students are nominated by their mentors and chosen by the Center to be supported throughout the year to continue work on their research projects. This course gives students a concept of graduate school. To date, a total of four undergraduate students have participated in this experience, two involved in projects that began in 2008 and two new recruits starting in September 2010.
- It is instructive to briefly outline examples of the impact of these programs on participating students and their plans for future participation in higher education in related fields:
 - **Betsy Bateman** completed two summers as an intern in 2009-10 and was this year's Louisiana Female Presidential Scholar. This is one of the nation's highest honors for graduating seniors, presented to one male and one female student from each state. Betsy graduated first in her class from Mandeville High School and now attends Tulane University with intentions to pursue a career in biomedical research.
 - **Phillip Calmes** participated in the Summer Internship Program in 2009. As a direct result of his experience in the program, he is now enrolled in the LSUHSC Interdisciplinary Graduate Program and intends to pursue infectious disease research.
 - **Tim Tate** was selected for a Yearlong LVC Research Experience in 2009. Tim is a New Orleans native and minority student who graduated with honors from high school and received a full academic scholarship to Tulane University. While still in high school, Tim worked on a summer research project with Center investigator Lisa Morici. In 2008 and 2009, he participated in the LVC summer program, resulting in him presenting his work at the annual meeting of the American Institute of Chemical Engineers in November 2009 (*Thin Films of Biodegradable Polymers for Controlled Antibiotic Release*) and attaining co-authorship on a paper published in *Microbial Pathology* (2010) 48:9: *Differential susceptibility of inbred mouse strains to Burkholderia thailandensis aerosol infection*. Tim is now entering his junior year at Tulane University with plans to apply to a graduate or MD/PhD program after graduation. He described his LVC internship as having opened career opportunities that he would have not otherwise anticipated or experienced.
 - **Sharon George** is a New Orleans native and minority graduate of Tulane University, where she majored in Neuroscience and Spanish. She entered the summer internship program in 2008 with no laboratory experience. She had previously performed extensive community service work in under-privileged communities where she initially became interested in immunology and vaccine studies. Sharon worked with James Cutler during the summer of 2008 and remained in his lab, to continue her research project in our Yearlong LVC Research Experience Program. The focus of her work was to investigate

established and novel adjuvant systems that could be useful in humans for initiation of clinical trials for a putative vaccine against candidiasis, which she presented at the Southwest Medical Mycology Meetings held in New Orleans in 2009.

- A Post-Internship Evaluation of summer interns is conducted annually to measure the students' satisfaction with their mentor and project, their lab and the impact of their experience on career goals. Students complete a Post-Internship Goals Attainment Scaling survey. This is a validated measurement tool that provides us with formative evaluation data concerning how much the student feels they have accomplished during their internship. In year 3, we introduced an additional evaluation tool, the Survey of Undergraduate Research Experiences (SURE), a validated evaluation tool developed to assess the impact of student research experiences funded by Howard Hughes Medical Institute. The survey consists of 44 items, including demographics, learning gains and evaluation of aspects of summer programs. The data gathered from the students allows us to improve and build upon the strengths of the program.

- The LVC seeks to educate and train a knowledgeable scientific workforce through the Bioscience and Education Training (BET) Program, developed in collaboration with the RC/EEP-funded South Louisiana Institute of Infectious Disease Research (SLIIDR). There is a distinct shortage of quality research trainees available in the region which has hampered local research and development initiatives in the biosciences. The primary goal of the BET Program is to help develop an educated workforce for potential placement in research labs in local universities and for the fledgling local biotechnology industry.

BET students undergo extensive training in biosafety, chemical safety, and radiation safety and the use of animals in bioscience research. They also rotate through Center core labs in anticipation of their permanent placement into a scientific laboratory or core facility for the duration of their participation in the BET Program. BET participants learn skills unique to that lab under the direct supervision of Core directors or LVC/SLIIDR investigators. It is anticipated that BET graduates will be well placed to gain future employment either in a Center research or core lab, or other local research or biotech settings.

The BET Program has graduated 12 students to date – all are now employed in local research or biotech labs (8), or have advanced to further professional or graduate training (4), admirably fulfilling our goals.

- It is important to continue to develop the Summer Internship Program and the BET Program through complementation of Center funding, and to plan for sustainability of these educational programs beyond the Center PKSFI funding period. In this context, several grant applications have been submitted or are in preparation for submission in the fall of 2010, including:
 - a T35 application to the NIH-NHLBI that supports short-term research experiences for students in professional schools. This application is based on the success of the students in our existing summer program and would allow us to expand our annual intake to fund 15 medical students to gain research experience in LVC labs. *Application received a fundable priority score and JIT information requested by NIH.*
 - a T35 application to the NIH-NIAID that supports short-term research experiences for students in professional schools. This application is based on the success of the students in our existing summer program and would allow us to expand our annual intake to fund an additional 15 medical students to gain research experience in LVC labs. *Submitted in September 2010.*
 - an R25 application also to the NIH-NIAID that supports science education grants. This application is based on a former ARRA application: *Rebuilding Science Education in New Orleans*, and would support partnerships between LVC faculty and New Orleans high school science teachers. *Submission planned for Fall 2010 / Spring 2011.*
 - the strength and track records of our Summer Internship Program and BET Program has led to the development of an Advanced Technological Education (ATE) grant application to the National Science Foundation (NSF). The aim is the establishment of local and

regional partnerships between 2-year and 4-year universities alongside industry. The objective is to produce a cadre of individuals at 2-year colleges that can transition into a highly qualified workforce in the area of bioscience. Our regional center application will use as its model the successful structure of the Summer Internship Program and the BET Program. This is a collaborative effort between, LSUHSC-NO, Delgado Community College in NO, and the Greater New Orleans Bioscience Development District. *Due for submission in October 2010.*

(iii). Efforts to Secure External / Federal Funding

- The Center is aware that our development and sustainability beyond the PKSFI depends, in large part, on the ability of the Center and its investigators to secure external funding. A major goal of the Center is to continue to strengthen our capacity to compete for large-scale research and development project and program grants and contracts. The LVC was established through the PKSFI as one of the most significant regional research strengths, with an extensive history of leveraging State investments to bring in large amounts of external and private funding. **The establishment of the Center has greatly facilitated an increased focus of these efforts in key areas of vaccine-related research. The award of these grants also strengthens our capacity to sustain key Core activities and other Center infrastructure.**

Center investigators continue to be active in submitting external grant applications with tangible success. In year 3, Center investigators were awarded over \$51 million dollars in new external grants from federal and private sources, primarily from the NIH. These are outlined below by category in **Table 1** below.

Table 1. LVC Grant Awards by Category - Year 3

Funding Agency	Type of Award	Total Number of Awards	Potential Value
NIH	R01	25	\$6,446,714
	R21	5	\$1,089,975
	P01	5	\$1,689,436
	P20	3	\$1,008,200
	R43, R44 (SBIR)	3	\$3,705,296
	C06	1	\$13,533,254
	K08	1	\$179,353
	N01	1	\$15,832
	P30	1	\$280,720
	P50	1	\$74,298
	P60	2	\$1,942,000
	R37	1	\$416,348
	SC2	1	\$266,171
	T32	3	\$653,886
	U01	3	\$1,808,833
	U19	2	\$2,190,384
	U42	1	\$1,302,208
	Contract	4	\$5,330,612
	WRCE-Career Development	2	\$468,606
Department of Defense	-	1	\$346,278
Department of Defense (UK)	-	1	\$2,481,561
USAID	-	5	\$1,928,428
Gates Foundation	-	6	\$1,710,761
NSF	-	3	\$1,954,996
Foundations-Other	-	6	\$590,685
TOTAL		87	\$51,414,835

Specific highlights of some new awards are summarized in **Table 2** below, and emphasize a high level of local collaboration. They clearly demonstrate activity and success in each of our Research, Education and Commercialization programs and include:

- multiple NIH R01 and R21 awards in key areas of Center research and development (HIV immunity; vaccine research and transmission; Tb immunity and vaccine research; viral respiratory infection including influenza; infection and immunity in the genital-urinary tract including human papilloma virus and Epstein-Barr virus, Candida, and Chlamydia; and fundamentals of host immunity).
- a \$3.6 million, 3 year-SBIR award from the NIH-NIAID to Xavier University and AutoImmune Technologies (a local biotechnology company).
- a \$6.5 million, 5-year P20 Center award from the NIH-NCMHD to LSUHSC-NO and Dillard University to study health disparities in minorities.
- a T35 application to NIH/NHLBI from LSU and Tulane investigators, also submitted during year 3, to support the development and expansion of our Summer Internship Program was given a priority score in the fundable range and the award is pending.
- an RC4 grant application to the NIH-NIAID by for \$5.25M over three years, submitted during year 3, was scored in the 10th percentile. This project will use high-throughput genomic approaches characterize the bronchial microbiota in HIV-positive individuals and the effects if their interaction with the host.

Table 2. Notable Recent Grant Awards to LVC investigators

Funding Agency	Type of Award	Title	Budget	Comment
Research Awards:				
NIH-NCMHD	P20 (COBRE)	Dillard-LSUHSC Minority Health and Health Disparities Research Center	\$6.5 million	awarded in 2010
NIH-NCRR	P20 (COBRE)	Mentoring Translational Researchers in Louisiana	\$10 million	awarded in 2010
NIH-NCRR	C06	NCRR Recovery Act Construction-JBJ Tulane (Renovation and Interdisciplinary Research Infrastructure)	\$13.5 million	awarded in 2010
NIH-NHLBI	R01	Transcriptomics of Tuberculosis Latency and Reactivation in Primates	\$2.9 million	awarded in 2010
NIH-NCRR	P20 (COBRE)	Mentoring Translational Research in Medical Mycology	\$10 million	Pending; fundable priority score of 23
NIH-NHLBI	RC4	Respiratory Microbiota and Mucosal Immunity	\$5.3 million	Scored in 10 th percentile
Research Commercialization and Education Awards:				
NIH-NIAID	R43,R44 (SBIR Phase I & 2)	Peptide Drug Inhibitors of Influenza Virus Entry	\$3.6 million	awarded in 2010
NIH-NHLBI	T35	LSUHSC Summer Internship Program	\$108,000	Fundable priority score (JIT requested)

- The Center's Grant Seekers Meetings and Expert Grant Reviews are designed to aid researchers to more effectively prepare their grant submissions, through a constructive critical review process. Since their inception, 15 Grant Seekers or Expert Grant Review meetings have been held. To date, these have

facilitated funding of three new NIH R01 project grants to Center faculty, along with the modification/development of five new NIH R01 applications. Center-driven initiatives such as these utilize the experience of a broad range of senior faculty to improve the national competitiveness of all Center researchers, particularly our junior faculty.

(iv). Contributions to Local Economic Development

The Center, through its commercialization core, has worked effectively towards economic development in the local area, with initiatives that provide a focus for the commercial development of Center research through the development of intellectual property in the form of patents and licenses, assistance with market analyses and business plans, the development of partnerships with industry, and the preparation of commercial funding applications including SBIR and STTR applications. Programming initiatives also include webinars, seminars, workshops and networking events aimed at raising the general level of awareness of avenues for academic research commercialization, providing information and tools relevant to projects and startups in different stages of commercial development, and facilitating interactions between Center members and different local stakeholders involved in research development locally and throughout the State and the Gulf region. These initiatives have led to some highly significant successes against our stated goals in a relatively short period of time, as summarized in **Table 3**. Our robust technology commercialization strategy, developed in collaboration with NOBIC, has met and indeed exceeded our stated performance measures as outlined in the Center work plan. Further details of outcomes are outlined elsewhere in this section.

Table 3: LVC Commercialization Outcomes

Performance Measures	Results Achieved and Outcomes
Complete survey of all IP and patents submitted or owned by project researchers.	39 faculty interviews, 18 novel core invention disclosures in vaccine-related research
1 IP seminar	4 live seminars, 5 webinars
1 Workshop on academic-industry partnerships	1 two-day workshop, 3 networking events, and a keynote luncheon
1 patent disclosure from vaccine-related research	4 US provisional patents and 1 international PCT
Develop IP into patents and licenses	1 incorporated startup, 2 additional business plans under development, 4 established industry collaborations, 1 SBIR/STTR grant.

- In Year 1 of Center activity, a complete survey was performed of all intellectual property disclosures and patents submitted or owned by project researchers, as well as an in depth inventory and related commercialization assessment of the inventions affiliated with Vaccine Center investigators. Local business, law, engineering and basic science students from LSU, Tulane and Loyola were recruited to assist in this process as LVC-supported interns. These individuals, in turn, received training in research commercialization. Training students with interdisciplinary backgrounds in technology development and commercialization will aid in strengthening entrepreneurship in the Center and, potentially, statewide. To date, 24 interns have been supported to assist with the commercialization initiatives of the Center.
- Significant steps were taken soon after the establishment of the LVC to establish a commercialization pipeline for Center research. These steps were taken in concert with the development of essential core infrastructure and the funding of multidisciplinary, collaborative pilot awards with a view to the generation both of new external funding and the development of discoveries with potential for clinical application and/or commercial development. Student interns play a critical role in the research commercialization program. Supervised by the Commercialization Core leader, they formed the basis of the Center's Faculty Interview Program that works to coordinate information about Center researcher's projects, to identify projects with potential for commercialization, and then to help develop these projects. In addition, over the course of the past year, one of these interns became the initial hire of a local startup company initiated through NOBIC, and was thus the first example of a student intern from our program transitioning into a leadership role with a local technology startup.

- The student intern commercialization teams have interviewed 39 Center faculty members to date. As part of this process, the team also assists in identifying additional steps that should be taken to reach the next stage of commercial development of the technology. It also helps to identify mechanisms to achieve those research goals through identifying collaborative opportunities in industry or academia and funding sources that can aid in supporting additional research. Upon identification of promising inventions by the interview teams, they work with the inventor to disclose the invention to the university technology transfer office by providing a technical summary of the invention, along with a preliminary marketability analysis and a prior-art patent search. If there is a commercial opportunity in the field, the commercialization team will aid in drafting a provisional patent application, with a concurrent market analysis. To date, as a direct result of this faculty interview process, 18 new invention disclosures arising from Vaccine Center research have been made to the partner university technology transfer offices. Furthermore, Center-related invention disclosures have led to five new IP-related outcomes in the form of (international) provisional patents that are currently being pursued. With further inventions in the pipeline, this number is expected to increase in the future. The success of this program initiative has worked to strengthen the foundation of IP held by Center investigators.
- The LVC commercialization core is housed at the New Orleans BioInnovation Center, a local bioscience technology incubator aimed at supporting biotech related startups. Resultant interactions between the LVC commercialization team and NOBIC programs has created a synergy where nascent Vaccine Center startups could immediately be entered into an existing and productive startup framework. NOBIC has an established track-record in this area, fostering 7 startup companies in the past 2 years, and facilitating the submission of 5 recent SBIR grant applications. This background should provide an ideal setting for the following three business plans, recently developed from Center research projects:
 - **MiniVax** is a proposed vaccine company that will develop vaccines for a variety of fungal pathogens including *Candida albicans* and *pneumocystis carinii*. The vaccine platform of the company is based on a novel engineered antigen, termed “mini-kexin”, that was discovered in the LVC. This platform will allow the company to address a range of fungal diseases for which effective treatments are lacking. MiniVax will focus initially on the development of a prophylactic vaccine for *pneumocystis carinii*, a disease that infects over 1 million people worldwide and for which an additional 5 million immune suppressed individuals are treated prophylactically. MiniVax plans to utilize both strategic partners and also the FDA’s Orphan Drug Designation to help bring the vaccine through clinical trials, scale manufacturing, and distribution. The MiniVax business plan is currently in the early stages of development and will be entered in business plan competitions nationwide upon its completion in the spring of 2011. Entrepreneurial interests and SBIR opportunities for this startup have been identified and are being pursued.
 - **Home Point Testing** is a proposed startup company that will develop and commercialize home diagnostic kits based on proprietary methods developed in the LVC. The Company will develop kits to allow for convenient self-diagnosis of common but often serious conditions such as HPV infection and vaginal candidiasis. HomePoint will employ a multi-stream revenue model including direct-to-consumer marketing of home diagnostic kits as well as the out-licensing of proprietary methods for the development of clinical diagnostics for professional use. The initial product will be a serological HPV test, the HPV-Inform. The HomePoint business plan is currently under development and will be entered in business plan competitions nationwide either in the fall of 2010 or the spring of 2011. This process will also function as a networking tool to attract seed investors and entrepreneurs to the project prior to official incorporation.
 - **enVivatech, LLC** is a new New Orleans-based life sciences venture specializing in the rational design and production of peptide compositions and methods for inhibiting herpes virus infection, such as human cytomegalovirus infection. The peptides invented by enVivatech are useful for impairing the fusion of the virus with cells. The company recently incorporated and applied for its first STTR grant in collaboration with the academic inventors. The business plan is in advanced development and will be used for raising seed financing early in 2011.

- Additional LVC-related collaborative outcomes with potential for commercialization that have been facilitated by the commercialization core include:
 - a drug development collaboration between an LVC investigator and the medicinal chemistry program at the University of New Orleans (UNO)
 - a strategic R&D collaboration with TheVac LLC, a Baton Rouge-based vaccine startup focused on the co-development of veterinary and human vaccines using common platforms
 - a preferred relationship with Southern Research Institute, a contract research organization specializing in pre-clinical vaccine validation
 - joint commercial grant applications and/or direct commercial funding for vaccine exploration and development with Genocera and Pfizer in *Chlamydia*, and with Biological Mimetics in TB, *Chlamydia* and dengue
- A variety of programming has been developed to address our educational goals of raising awareness of research translation and commercialization as a logical outcome of academic research in the Center. The aim is to bring together Center researchers in the partner universities, the business community, and economic development professionals. Programming includes multiple webinars, seminars, workshops and networking events aimed at providing education in technology commercialization and also a forum for interactions between scientists, entrepreneurs, business facilitators, lawyers, and venture capitalists. There have, to date, been few local opportunities for these groups to interact, however this may be a necessary step for the further development of local biotechnology. A further planned initiative will bring in technology experts and experienced entrepreneurs to share insights and ideas with nascent startup companies, with mentors selected on the basis of expertise related to the focus area of the planned Vaccine Center startups.
- In summary, we have clearly met our LVC performance indicators in the commercialization core, and these efforts have realized a tangible impact on the biotechnology environment in New Orleans. Overall, the Vaccine Center faculty interview and IP awareness initiatives outlined above have increased the volume of institutional invention disclosures at LSU Health Sciences Center and Tulane by nearly 25%. Particularly noteworthy has been the generation of 3 new startup ventures that are currently at different stages of development - previously there had been none in this area of R&D. This spinoff activity should help to form one of the nuclei for a planned regional innovation cluster and also contribute to sustainable, high-value job creation. The generation of 3 LVC startups during the past year places New Orleans close to the national average of 3.5 startups annually.

v. Project Sustainability

The Center realizes the importance of planning for future development beyond the PKSFI funding period, in order to continue to provide a focus for local vaccine-related research, education and commercial development. It will be particularly important to continue to develop and focus each of the following:

- our programs in vaccine research
- our vaccine-related research infrastructure, including both new technologies and pipelines to clinical testing
- our support for recruitment of new faculty in this area
- our highly successful seminar program
- our core education and training initiatives for high school students, college students and medical students
- our internships in research commercialization
- our core efforts in commercialization of Center research in partnership with NOBIC

Our **primary strategy** to achieve these outcomes is to continue to generate external funding from federal agencies, private foundations and industry, and to expand this funding base. Our investigators and core leaders have multiple avenues for federal funding through RFAs issued by National Institutes of Health and the Department of Defense, Private Foundations including the Gates Foundation, and industrial partners, and these opportunities will continue to

be vigorously pursued. As detailed above, Center investigators have been highly successful in obtaining project, program and contract funding from each of these agencies during the first three years of Center activity, with **\$51M awarded in year 3 (ie. to 5/31/10), while an additional \$17M in external grants have been awarded since that date with a further \$18M pending.** It is important to note that the majority of these awards will contribute to the ongoing development of our overall Center infrastructure in vaccine-related research.

Thanks to the focus that the Center has provided in key areas of research strength, we are now in an ideal position to pursue collective, Center-based awards for new research programs focused on particular pathogens or disease groups (eg. pathogenic fungi, tuberculosis, sexually-transmitted disease). Several RFPs of this nature have recently been released, eg. NIH PAR-10-271 *NIAID Investigator Initiated Program Project Applications (P01)*. A P01 application in host/pathogen interactions and therapy of pathogenic mucosal fungus infection is currently in development and planning is underway for further Center-driven program applications.

It is also highly encouraging that we are now enjoying specialized grant success in both our Education and Research Commercialization Cores (as shown in Tables 2 and 3):

- our Education Core has recently generated a T35 award to support short-term research experiences for students in professional schools, with further NIH education grants pending. The strength and proven track record of our Summer Internship Program and BET Program has also led to the development of an Advanced Technological Education (ATE) grant application to the National Science Foundation (NSF) for a 3-5 year funding period. This is a collaborative effort between LSUHSC-NO, Delgado Community College and the Greater New Orleans Bioscience Development District to support the development and expansion of our education programs.
- our Commercialization Core was instrumental in developing a recent successful phase 1 & 2 SBIR award of \$3.6M for the commercial development of inhibitors of influenza virus entry, and is currently working on three additional SBIR or STTR applications based on technologies developed in the Vaccine Center. We anticipate increasing numbers of similar applications, based on the expanding portfolio of Center IP disclosures and patent applications facilitated by the Core. These will have downstream effects on the development of local biotechnology, including sustainable job creation and, potentially, recruitment of additional expertise into the region. The Commercialization Core is now also focused on generating external funding to support our ongoing research development initiatives, eg. an August 2010 application to the Louisiana Innovation Loan and Technical Assistance Program (CBDG funded) - Topic: *Technical assistance and convertible loans for biotechnology start-up businesses*.

Secondarily to new external funding, the Center also recognizes the importance of institutional support and endorsement of our research, commercialization and education initiatives as critical to our long-term success. The Center has obtained commitments in terms of space and faculty start-up packages from participating institutions. Both LSUHSC and Tulane HSC have indicated that research into infectious disease and vaccines is a high-priority area and will be directly supported with recruitment packages for faculty who will become members of the Center. The success of the Center will clearly benefit all three participating institutions in terms of their research profile and external funding levels, and the attraction of outstanding new faculty recruits and support staff. LSUHSC has also committed to support the Center through the availability of a portion of the indirect cost returns from external grants and salary release from extramural funding - this will assist the Center's continued growth and development.

In summary, the generation of new external funding for our research and education programs and the development of Center IP leading to patents and commercial licensing opportunities are central to our long-term sustainability. We have an excellent track record of external funding and have established an effective pipeline for the commercial development of Center research. Housing our commercialization core within NOBIC has created a synergy whereby nascent Vaccine Center startups can immediately be entered into an existing and productive startup framework.

The long-term goal of the Center is to establish Louisiana as a Center of Excellence in vaccine research and development with appropriate infrastructure to support its future growth and expansion through large-scale national, international, and private funding, commercial and industrial partners, patents, licenses, and royalties - and to provide a focus for vaccine research and development in the Gulf South.