Center of Excellence for Vaccine Development

LEQSF(2007-12)-ENH-PKSFI-PRS-02

Year 1 Annual Report

The Center of Excellence for Vaccine Development (Vaccine Center) encompasses three major Louisiana university campuses and was created in order to focus existing interdisciplinary strengths in the basic and translational science of microbial pathogenesis, host immunity and vaccine research to foster development of novel approaches to vaccination against infectious disease. The goal is to establish a tower of strength in Louisiana with a research and development infrastructure to support its future growth and expansion. This is a field of great current prominence worldwide, but not one that is well organized as yet in Louisiana, despite local researchers in this field clearly representing one of the most significant regional research strengths. To achieve this, the primary requirement is a coordinated approach to the problems of vaccine development together with appropriate supporting infrastructure.

The primary focus of the Center in Year 1 was, therefore, to establish the necessary infrastructure and also to begin to develop research, educational and, ultimately commercialization strategies necessary for the Center to achieve our goals and objectives, as detailed in our original application. Excellent progress has been made on each of these fronts in our first year, as outlined below.

1. Personnel

Key personnel in the Center in Year 1 include:

Alistair Ramsay PhD (Professor of Medicine and Director of the Gene Therapy Program at LSU Health Sciences Center). He is Principal Investigator, Center Director, and a member of the Center Steering Committee. Dr Ramsay has been centrally involved in all Center activities in Year 1. He has chaired three formal meetings of the Center Steering Committee during this period, at which progress reports were presented by research, education and commercialization coordinators and development strategies were discussed and appropriate actions were initiated. In particular, these initiatives included the establishment and support of Center Research Cores, the Summer Internship Education Program, the development of a first class seminar program with a number of high-profile visiting speakers already having visited the Center, and the development of a Pilot Research Grant Program that has recently funded 10 pilot awards from a total of 35 applications, all as detailed below. He was also a member of the peer review study section for the Pilot Research Grant Program and is Director of the BSL-3 Bio-Containment Core Facility.

John Clements PhD (Professor and Chairman of Microbiology & Immunology at Tulane University HSC). He is co-PI and a member of the Center Steering Committee. He has attended three formal meetings of the Center Steering Committee during this period and participated in the development and implementation of research, education and commercialization strategies. He was also a member of the peer review study section for the Pilot Research Grant Program and is Director of the Protein Core Facility.

Seth Pincus MD (Nelson Ordway Professor of Pediatrics at LSU Health Sciences Center and Director of the Research Institute for Children in New Orleans). He is co-PI and a member of the Center Steering Committee. He has attended three formal meetings of the Center Steering Committee during this period and participated in the development and implementation of research, education and commercialization strategies. He was also a member of the peer review study section for the Pilot Research Grant Program and is Director of the Molecular Interaction Core Facility.

Tarun Mandal PhD (He is McCaffrey Norwood Professor of Pharmacology at Xavier University of Louisiana). He is co-PI and a member of the Center Steering Committee. He has attended three formal meetings of the Center Steering Committee during this period and participated in the development and implementation of research, education and commercialization strategies. He is also Director of the Nanotechnology Core Facility.

Paula Gregory PhD (Associate Professor of Genetics at LSUHSC) is Education Program coordinator and Fern Tsien PhD (Instructor of Genetics at LSUHSC) is Assistant Education Program coordinator. They have attended three formal meetings of the Center Steering Committee during this period. Together, they have developed and implemented the Center Education Program that focuses initially on summer research internships for college and undergraduate students.

Thomas Lallier PhD (Associate Professor of Anatomy and Cell Biology at LSUHSC) is Research Program facilitator. He has attended three formal meetings of the Center Steering Committee during this period and was also a member of the peer review study section for the Pilot Research Grant Program. He has played a key role in integrating and coordinating the development of the Center Research Core Facilities and, now that the cores have been established, he will coordinate and facilitate their use by Center investigators.

Steven Ceulemans MS is the Commercialization Facilitator. He has attended two formal meetings of the Center Steering Committee during this period and has begun to develop a commercialization strategy for the Center, beginning with a full inventory of grants and intellectual property held by Center members. His activities are overseen by Aaron Miscenic (Director of the New Orleans BioInnovation Center), in partnership with the Vaccine Center.

Patricia D'Arensbourg is the Administrative Coordinator. She assisted the Director and the Steering Committee with all administrative functions in the Center.

In terms of controls in place, Center activities including the status of key personnel during Year 1 have been reviewed by the Head of the Internal Advisory Board, Dr. Joseph Moerschbaecher (Vice-Chancellor for Academic Affairs and Dean of the Graduate school at LSUHSC) and determined to be in accordance with the project's requirements. In addition, the Center's External Advisory Board, chaired by Professor Lawrence R. Stanberry MD, PhD (Columbia University, NY) have been advised of Center progress to date and will attend our first Annual Meeting planned for September 24th and 25th, 2008 to review our progress.

2. Activities and Findings

Central to the development of the Center are (i) the growth of essential research and development infrastructure, (ii) the development and support of vaccine-related research and development projects that are multi-disciplinary, collaborative, novel and that have clear potential for progress to clinical trials and commercialization, and (iii) education and training in vaccine-related research and development. The primary focus of the Center in Year 1 was, therefore, in these key areas.

(i) Essential research and development infrastructure - the plan for Core growth and development was designed specifically to aid the flow of vaccine-related research from discovery to vaccine preparation and delivery and through pre-clinical testing and analysis towards the development and conduct of clinical trials (and at any entry point in this continuum). To this end, a series of Core Lab Facilities have now either been established anew or were developed through enhancement of existing facilities as follows:

1) Genomics Core
2) Proteomics Core
3) Protein Core
4). Nanotechnology Core
5) Vector Development Core
6) Immunology Core
7) Molecular Interaction Core
8) Imaging Core
9) BSL3 Containment Lab Core

Each of these Cores is at a different stage of development with regard to its Center-related research support activities, as outlined below. Enhancement of these facilities will continue in Year 2.

The following is a full summary of progress to date in the development of each of these facilities:

1). Genomics Core

Core Directors: Doan Nguyen PhD and Jovanny Zabaleta PhD

Location: LSUHSC – CSRB

The mission of the Genomics Core is to provide comprehensive genomics, microarray and bioinformatics support to Center investigators through a wide array of state-of-the-art analytical equipment and data analysis capabilities. Services include assistance in microarray experimental design and data analysis, protein and nucleotide sequence analysis, functional analysis of high-throughput data, data mining, data organization and repository, whole microbial and mammalian genome mapping, and database development.

Vaccine Center enhancements in Year 1:

To enhance the capacity for Vaccine Center-related studies, upgrades of the Affymetrix scanner, of two Dual Core Xeon Workstations for Affymetrix users, of Rosetta Resolver bioinformatics software, of the Resolver server and workstations, and also an Illumina BeadXpress Reader have been purchased by the Center, also facilitating the use of protein and antibody arrays. The Center will also fund a technician dedicated to Center activities in order to facilitate investigator's research in the Genomics Core now that exemption from the La State Government hiring freeze has been obtained.

2). Proteomics Core

Core Director: Chau-Wen Chou, PhD

Location: LSUHSC - CSRB

The Proteomics Core was established at LSUHSC through institutional and State funding. As a result, extensive equipment is available for 2D Gel Electrophoresis analyses, fluorescent tags and special purposed stains (phosphorylation, glycosylation), high performance liquid chromatography, mass spectrometry and a Global Proteome Server Explorer workstatio for fast protein identification in quantization and biomarker discovery. The Center plans to fund a technician dedicated to Center activities in order to facilitate investigator's research in the Genomics Core now that exemption from the La State Government hiring freeze has been obtained.

3). Protein Core

Core Director: John Clements PhD

Location: Tulane School of Medicine

The Protein Core is located at Tulane HSC and its major goal is to provide Center researchers with purified protein antigen for use in vaccine research. Personnel dedicated to Center projects assist researchers in the selection of optimal recombinant expression systems (prokaryotic and eukaryotic), will sub-clone genes of interest into expression vectors, and will optimize protein expression and purification. The core also assists in generating site-directed mutants of proteins

of interest and in scaling up of recombinant protein production. Emphasis is placed on purity, with removal of bacterial endotoxin and contaminating immunogens from protein preparations, while minimizing degradation.

Vaccine Center enhancements in Year 1:

To facilitate Center research, a BioRad BioLogic Douflow chromatography system has been purchased. The Center has also supported an expert research position in the Core to support vaccine-related research projects – Anders Frisk PhD. Anders received his doctorate from Göteborg University in Göteborg, Sweden in 1998. While in Göteborg, Anders studied the pathogenesis of and host response to the sexually transmitted disease pathogen *Haemophilus ducreyi*. In 1999, Anders entered a postdoctoral fellowship at the University of Florida in Gainesville, where he identified and characterized genes encoding an anti-sigma factor in *Pseudomonas aeruginosa.* In 2001, Dr. Frisk joined the laboratory of Dr. Mike Schurr in the Department of Microbiology and Immunology at Tulane University School of Medicine as a Postdoctoral Fellow. Under Dr. Schurr's guidance, Dr. Frisk has studies transcriptional regulation of pathogenesis associated genes in *Pseudomonas aeruginosa*. His research findings have been published in excellent journals (Journal of Bacteriology, Infection and Immunity, Microbial Pathogenesis). In 2006, Dr. Frisk was appointed as a research Instructor in the Department of Microbiology prior to his appointment as manager of the Vaccine Center Protein Core. The Core has successfully expressed and purified three proteins for use by Center investigators in Year 1, including the recombinant Yersinia pestis antigen F1-V, the mucosal adjuvant LT(R192G/L211A), and recombinant HspX.

4). Nanotechnology Core

Core Director: Tarun Mandal PhD,

Location: Xavier University of Louisiana

The major goal of this Core is to maintain a state-of-the-art innovative polymeric vaccine delivery research facility in order to support inter-disciplinary research within the Vaccine Center. Core personnel will provide leadership in planning, designing, and implementing innovative nanotechnology and will also assist investigators in conducting pre-formulation and formulation studies of any potential novel vaccine delivery system for preclinical and NDA studies (New Drug Application following USFDA guidelines). Nano-delivery technology is being developed and/or adapted, in collaboration with Center researchers, to address the special requirements of either systemic or mucosal (ie. intranasal, pulmonary, oral, or intra-vaginal) particle-mediated delivery of peptides, proteins and/or recombinant DNA vaccines in preclinical and, ultimately, clinical studies. Targeted particle- or lipid-mediated delivery either of proteins via novel routes (eg. transcutaneous) or of alternative recombinant vaccine vectors is already under development in the Core and this technology will also be made available to other Center investigators.

Currently, the NIH-funded nanotechnology research laboratory is equipped with R&D-scale pharmaceutical formulation equipment, with research staff who have developed unique skills in micro-encapsulation for controlled release.

Vaccine Center enhancements in Year 1:
We have recruited Mr. Richard Graves on Vaccine Center funds as a senior research associate for the core. Mr. Graves has a BS degree in chemistry from LSU, Baton Rouge and a MS degree in chemical engineering from Tulane. He has over fifteen years experience in laboratory research including eight years in Dr. Mandal's lab at Xavier. We have purchased a new ultra pressure liquid chromatography/mass spectroscopy (UPLC/MS). The equipment was installed in February 2008 and is available for use by Center investigators.

Center-related research development activity in the Nanotechnology Core:

PEGylated PLGA nanoparticles for targeted vaccine delivery: one of the most important objectives for vaccine loaded nanoparticles targeted for cellular immunization is to impart these particles with the ability to cross barriers which block their access to cells. We are currently comparing four copolymers of PLGA and PEG used to prepare nanoparticles. The copolymers used were PLGA-PEG-PLGA triblock (10% PEG), PLGA-PEG diblock (5% PEG), PLGA-PEG diblock (10% PEG), and PLGA-PEG diblock (15% PEG) (Boehringer Ingelheim, Germany). The four different formulations of particles will be evaluated for surface morphology, particle size, and zeta potential, and for cellular uptake which ismeasured both qualitatively and quantitatively by fluorescent microscopy and flow cytometry, respectively. Assessment of these formulations with a view to optimizing uptake into cells will greatly increase the efficacy of naonparticle-mediated vaccine delivery.

In Vaccine Center-related collaborative developmental studies, we have recently begun to develop various nanoparticle formulations loaded with plasmid DNA vaccines. These nanoparticles will be prepared mostly using Spray Drying technique and will be tested in tuberculosis vaccine development studies in collaboration with Alistair Ramsay PhD (Center Director). We have also established collaboration with Dr. Ronald Luftig PhD (a Center Investigator from LSUHSC). The goal of this collaboration is to develop protein conjugated and encapsulated polymeric nanoparticles containing virus-like particles suitable for HIV vaccination.

5). Vector Development Core

Core Director: Robert Kutner

Location: LSUHSC - MEB

This Core greatly facilitates co-operative Center research through the design, engineering, preparation and purification of new recombinant vaccine vectors and novel vector technology in a variety of new vaccine vector systems. The Core is already equipped for manufacture of lentvirus, poxvirus, adenovirus and adeno-associated virus vector systems for Center investigators through LSUHSC, Gene Therapy Consortium and NIH funding.

To date in Year 1, Center investigators from LSUHSC and the Research Institute for Children have received a total of 12 vaccine-based vector preparations generated in the Core, while

another researcher was aided in HPLC purification of an antibody of interest. The Vector Core has also been investigating newer vaccine technologies to expand its portfolio to better suit infectious disease-related research. Newer technologies include implementing double stranded AAV production, large-scale batch-fed endotoxin-free plasmid production, and development of a fowl pox-producing helper cell line. With demand for vaccine-based vectors increasing, the addition of modern production techniques already implemented, and the future addition of newer technologies, the Core is now well situated to cater for Center researcher's needs.

Vaccine Center enhancements in Year 1:
An electroporator device for *in vivo* inoculation of DNA vaccines has been purchased by the Center to support pre-clinical studies. The Center will also fund a technician dedicated to Center activities in order to facilitate investigator's research in the Vector Core now that exemption from the La State Government hiring freeze has been obtained. The position has been advertised and we expect to make an appointment in July/August of this year.

6). Immunology Core

Core Director: Ping Zhang MD

Location: LSUHSC – CSRB

The Immunology Core serves Center investigators in the measurement of immune responses in vaccine-related studies and data analysis. State-of–the–art Flow Cytometry and Immunoassay equipment has been purchased by LSUHSC and NIH funds, while the Core is directed by and has a fully qualified FACS operator (Constance Porretta MS). Full FACS acquisition services and immune assay development support are provided to Center researchers and the Core has also trained several new investigators, medical students, graduate students and research assistants have been trained to perform analyses using equipment and procedures in the Core in Year 1. An experienced Vaccine Center-funded research technician, Olha Nicholls MS, has recently been employed in the Core to assist with all aspects of Center investigator's research.

7). Molecular Interaction Core

Core Director: Seth Pincus MD and M. Corti Ph.D.

Location: Research Institute for Children, Children's Hospital

This new Core utilizes Biacore technology to study intermolecular interactions in real time and is extremely useful in determining affinities of monoclonal antibodies and polyclonal antisera, activities important for many of the Center investigator's research projects. Because antibody affinity is often a correlate of protective activity, this presents a method for analyzing the quality of the antibody response elicited by experimental vaccines.

Vaccine Center enhancements in Year 1: the Center will fund a research support position in the Core to facilitate the work of Center investigators now that exemption from the La State Government hiring freeze has been obtained. After consultation with the Core, investigators will

provide paired antibody/antigen, receptor/ligand, or enzyme/substrate, for analysis by Core scientists.

8). Imaging Core

Core Director: Luis Marrero

Location: LSUHSC – CSRB

The mission of the Imaging Core is to provide sophisticated histology, microcopy and imaging services to support and advance Center research activities. The Core offers expert advice on experimental design and interpretation of results.

During the past year, Core staff have been involved in designing and executing a large array of experimental protocols for Center investigators including: investigations requiring phenotyping of inflammatory responses and organism burden in models of tuberculosis; characterization of *Chlamydia trachomatis* persistence in aging endocervix through deconvolution microscopy; visualization of *Pseudomonas aeruginosa* ocular infection by routine histological stains; detection of lymphocyte death in lungs afflicted with *Pneumocystis Carinii* infection using triple immunofluorescence labels of apoptosis; and descriptive analysis of cellular uptake of biotoxins such as ricin during timelapse imaging. High-resolution photomicrographs include details to the order of a single chromosome and are often complemented with quantitative analyses.

The Imaging Core has recently implemented new state-of-the-art technologies for use by Center investigators, including a laser micro-dissection system to allow for functional and molecular analysis of cells dissected and isolated from precise regions of tissue sections; and two real-time imaging chambers to non-invasively monitor and record cellular and genetic activity within a living organism. In addition, an infrared illumination based, multi-photon microscope has been recently incorporated to allow high resolution imaging of fluorescently labeled serum, microorganisms, cells, and tissues in fixed or live samples, with minimal sample degradation, and at 200 times greater depth than conventional microscopes. The Core thus significantly leverages previous significant State-funded investments in sophisticated imaging equipment through LSUHSC and the Louisiana Gene Therapy Research Consortium for Vaccine Center Investigators. Enhanced technical support for Vaccine Center research activities is also available in the Core.

9). BSL-3 Bio-Containment Core

Core Director: Alistair Ramsay PhD

Location: LSUHSC

This facility that is critical for work with pathogens that require bio-containment was originally established through LSUHSC and LEQSF Enhancement Funds. Vaccine Center enhancements in Year 1 have greatly enhanced the utility of this facility for Center Investigators through the purchase of specialized Animal Containment housing modules and direct research support

through the planned hiring of a Center-funded research technician trained in bio-containment now that exemption from the La State Government hiring freeze has been obtained.

In summary, the development of these Core facilities in Year 1 of Center activity has significantly leveraged previous State-funded investments and is a critical step in the creation of a coordinated series of facilities that will greatly aid the flow of vaccine research from antigen discovery to vaccine preparation and delivery and through pre-clinical testing and analysis towards the development and, ultimately, the conduct of clinical trials. Notably, the employment of Center-funded staff dedicated to vaccine Center-related activity within each Core now provides a direct entry point and an ongoing support pathway for Center investigators' research.

It is also clear that the development of a sophisticated chain of Cores with state-of-the-art equipment and technical support for Vaccine Center projects will greatly enhance our capacity to retain existing faculty, to recruit new faculty to the partner Institutions and to initiate new collaborative research programs. These Cores have also begun to facilitate training of Vaccine Center postdoctoral fellow and graduate students in advanced technologies and procedures central to Center-related research activities.

An additional research and development activity in Year 1 has been the establishment of a Commercialization Program. Steven Ceulemans MS is the Commercialization Facilitator and his activities are overseen by Aaron Miscenic, Director of the New Orleans BioInnovation Center, in partnership with the Vaccine Center.

In an effort to foster the local bioscience industry, to educate local researchers and trainees and, ultimately, to establish a commercialization pipeline for Center research and development programs, the Center has partnered with the South Louisiana Institute for Infectious Disease Research (SLIIDR) and the Clinical and Translational Research, Education and Commercialization Project (CTRECP) - all Board of Regents funded, Joint LSU – Tulane Health Sciences Center initiatives - and have joined forces with the New Orleans BioInnovation Center (NOBIC) to develop a systematic approach for transforming local bioscience discoveries into viable business opportunities. The consolidation of the commercialization goals and resources related to the above mentioned grants led to this establishment of a central research commercialization office housed at NOBIC. Mr. Ceulemans leads a team of student interns in this office. The first commercialization office project has been the development of a comprehensive commercialization strategy targeting all New Orleans based university-developed bioscience products and processes. Implementation of this strategy to date includes:

(a) pro-active student recruitment using a targeted awareness outreach effort. Through direct interaction with local University business, law, engineering and basic science programs, the most talented students with an interest in research commercialization were identified and attracted. This resulted in the recruitment of 6 summer interns from a variety of these local programs to support and implement various aspects of the commercialization strategy. Ultimately it is hoped

that this internship training will contribute to the development of a new generation of local bioscience entrepreneurs.

(b) inventory and assessment of the intellectual property (IP) assets with commercial potential available at the local Health Sciences Centers. A team of 4 students is currently completing an in depth inventory and related commercialization assessment of the inventions affiliated with Vaccine Center, SLIIDR and CTRECP investigators, as well as other local researchers having an extensive research commercialization history or that have recently disclosed high potential inventions. To date, this effort has resulted in a shortlist of a dozen technologies with commercialization potential that have not been exploited to date. So far, the student teams have performed commercialization analysis work on six of those technologies, leading to the generation of two non-confidential invention summaries.

(c) the development of a commercialization-oriented database has also now commenced. This database is aimed at providing a single-view of available biotechnology resources in the region, and will provide an overview of faculty members' key areas of expertise, key lab equipment as well as ongoing research projects and related IP. Furthermore, it will map all available core lab resources and capabilities, with a view to optimizing avenues of access to these for the local bioscience industry. Ultimately, it is planned that this database will also help support the national/international marketing of local resources to the local academic and bioscience business communities, thereby providing access to these unique skill sets and equipment. The database framework is in its final stage of development, the comprehensive data set is planned to be available as a web accessible tool to be operational late in 2008.

(ii) Development and support of vaccine-related research and development projects.

Another major initiative undertaken by the Center in Year 1 was the development of a Cooperative Pilot Research Grant Fund in partnership with the RC/EEP-funded South Louisiana Institute for Infectious Disease Research (SLIIDR).

This initiative is intended to foster the development of novel local multidisciplinary and collaborative research projects in the fields of infectious disease, immunity, and/or vaccine development. This clearly addresses our medium and long-term goals that include the generation of new project and collaborative program applications funded extramurally, and discoveries with potential for clinical application and/or commercial development.

We were particularly interested in supporting applications that:

- addressed key issues in the scientific fields of vaccine development, microbiology, immunology, infectious disease and the host response to infection
- proposed novel approaches

• were collaborative and multidisciplinary in nature, and

• made use of the Core Facilities developed/enhanced by the Center

Emphasis was also be placed on those applications that support high quality translational research. Applications from new investigators and those from established investigators that propose new research directions were particularly encouraged.

A Request for Proposals was circulated to all Faculty working in relevant Departments and Centers at LSUHSC, Tulane HSC and Xavier in April 2008. Thirty-five applications were received and were all peer reviewed by at least three reviewers with background in the area. Reviewers were drawn both from within and from outside of the three participating Institutions. Ten of these applications have now been identified for funding based on peer review scores and on their responsiveness to the RFP that embodied medium and long-term goals of the Center. Successful projects will be funded up to $75K/year for 2 years beginning in Year 2. These awards will foster the development of collaborative projects by new investigators and will also allow established investigators to explore new research directions, often in collaboration with junior researchers.

(iii) <u>Education and training in vaccine-related research and development</u>.

The Education Program is an integral component of the Vaccine Center. In Year 1 we have focused on the establishment of our <u>Summer Internship Program</u> and this is now underway.

The internship program is an intensive summer research experience open to talented students interested in a variety of areas related to immunology and vaccines. The program was created to expose students to state of the art research in immunology and infectious disease, to provide an introduction to graduate work and to motivate and prepare them for career opportunities in biomedical research. Students work with a Vaccine Center mentor in a laboratory for the summer and are encouraged to attend seminars and lab meetings. The program emphasizes the scientific process, bench experience, data analysis, and experimental design.

The program has three main components. The first and most important component is a hands-on research project, where the students work directly with faculty on cutting edge vaccine research. The second component is a summer seminar series, where students learn about the latest findings in a variety of research areas. The seminars also provide students with a forum for networking with students who are in programs with other funding sources. During the seminar series, summer interns learn about responsible conduct of research and how to prepare and present their data in a poster. The third component of the program is the Poster Session. At the end of the summer, the students will present their research results at a poster session attended by all the summer interns (totaling about 40) and the mentors and lab members. Students have an educational session on how to put together their poster and are given a poster template and posters are printed for them.

Currently, there are ten students who have been accepted to the program and these are listed in the Table below, along with their mentors - all Vaccine Center Investigators. The students include medical students, undergraduates and a high school student, at least two are minority students and eight are women. There are three medical students, who we hope will consider the M.D., Ph.D. degree program. The undergraduate interns are from Tulane University (3), MIT, Columbia University, Spellman College. We have targeted Tulane undergrads to participate, in an effort to identify candidates for the 2 individual year long research projects. These students would be able to continue research throughout the year, since they are at a local campus.

Vaccine Center summer students	**School**	**Academic level**	**Mentor**
Amy Cammarata	LSU Baton Rouge	Undergrad	Paul Fidel (LSU)
Sharon George	Tulane	Undergrad	Jim Cutler (LSU/ Children's Hospital)
Hannah Jarrell	MIT	undergrad	Michael Hagensee (LSU)
Mira John	Columbia	Undergrad	Alistair Ramsay (LSU)
KaTerri Kelly	Spelman College, Atlanta, GA	Undergrad	Joy Sturtevant (LSU)
McKenzie Mayo	LSU Medical School	Med Student, Possibly MD/PhD	Vijay John (Tulane)
Daniella Miller	Tulane Med School, Public Heath and Tropical Medicine	Med student, MD/MPH	Angela Amedee (LSU)
Anisha Ravichandran	LA School for Math, Science, and Arts HS	High school senior	Lucy Freytag (Tulane)
Tim Tate	Tulane	Undergrad	Lisa Morici (Tulane)
Bolong You	Tulane	Undergrad	Yan Cui (LSU)

The second major focus of our Education activities has been the development of a first-rate seminar program in Infection, Immunity and Vaccines, also in partnership with SLIIDR. Clearly, this program is also a central focus of our research development activities.

Beginning in the middle of Year 1, the initial seminar program features nine high-profile national speakers (from NIH, University of Tennessee, Arizona State University, Albert

Einstein College in New York, the Mayo Clinic, Ottawa, Stanford and LSU-Baton Rouge) and eight prominent local speakers from all partner Institutions. These sessions have proven to be an outstanding success, with an average of over 100 attendees per session to date. The program has exposed large numbers of Center postdocs and graduate students to high-profile national and local research, often with follow-up meetings with the visiting speakers. Importantly, the series also serves to raise the profile of the Vaccine Center and of research activity in general in Louisiana, through exposure of eminent visitors to our work. All have expressed great enthusiasm for Center activities and have commended its establishment through the PKSFI. A summary of the initial seminar program is reproduced below:

Infection, Immunity, and Vaccine Seminar Program - 2008

12:00 p.m. – CSRB Room 563, 533 Bolivar St., LSUHSC Campus

February 14	**Preston Marx, Ph.D.** ***"Weak AIDS Vaccines, Safe AIDS Vaccines, and Some that may even Work"*** Chair, Division of Microbiology and Immunology, Tulane National Primate Research Center, Tulane University Health Sciences Center, Covington, LA. and Professor, Department of Tropical Medicine, School of Public Health and Tropical Medicine, Tulane University Health Sciences Center, New Orleans, LA.
February 25	**Edward Seidel, Ph.D.** ***"Computational Science for Complex Problem Solving"*** Chief Scientist, Louisiana Optical Network Initiative, Director of the Center for Computation & Technology, Floating Point Systems Professor, Departments of Physics & Astronomy and Computer Science, Louisiana State University, Baton Rouge, LA
February 28	**Seth Pincus, M.D.** ***"Ricin: Mechanisms of Toxicity and Protective Efficacy of Antibodies"*** Director, Research Institute for Children, New Orleans, LA and Professor, Pediatrics and Microbiology, Immunology, & Parasitology, LSUHSC, New Orleans, LA
March 12	**Barney S. Graham, M.D., Ph.D.** ***"Rational Design of a Vaccine for Respiratory Syncytial Virus"*** Director of Clinical Studies, Dale and Betty Bumpers Vaccine Research Center (VRC), NIH, Bethesda, Maryland
April 10	**Tarun K. Mandal, Ph.D.** **"Polymeric Nanoparticles: Novel Carriers for Vaccine Delivery "** Professor of Pharmaceutics, College of Pharmacy, Xavier University of Louisiana, New Orleans, LA
April 24	**James Robinson, M.D.** ***"HIV Neutralizing Antibodies: Obstacles in HIV Vaccine Development"*** Professor, Section of Pediatric Infectious Diseases, Department of Pediatrics, Tulane Hospital for Children, New Orleans, LA
May 8	**John D. Clements, Ph.D** **"*Novel Adjuvants and Delivery Systems for Transdemal Immunization*"** Professor and Chairman of Microbiology & Immunology, Tulane University HSC.
May 22	**Paul Fidel, Ph.D.** ***"The latest on host defense against mucosal yeast infections: It's all about the site."*** Director, South Louisiana Institute for Infectious Disease Research, Director, Center of Excellence in Oral & Craniofacial Biology, Associate Dean for Research, School of Dentistry, and Professor, Microbiology, Immunology, & Parasitology, LSUHSC, New Orleans, LA

June 12	**K. Gus Kousoulas PhD** ***"A new genetic vaccine for West Nile Virus"*** Director, Division of Biotechnology & Molecular Medicine LSU School of Veterinary Medicine
June 26	**Barry Rouse, Ph.D.** ***"Regulatory T cells and Infectious disease"*** Lindsay Young Distinguished Professor, UT Knoxville, TN
July 23	**Roy Curtiss III, Ph.D.** Director, The Biodesign Institute, Center for Infectious Diseases and Vaccinology Arizona State University
August 28	To be announced
September 11	**Robert F. Garry, Jr. Ph.D.** ***"Virology, Molecular mechanisms of viral pathogenesis"*** Department of Microbiology & Immunology Tulane University Health Sciences Center
September 24	Annual Mtg/Research Fair - LVC/SLIIDR
September 25	**Arturo Casadevall**, **M.D., Ph.D.** Professor, Department of Medicine (Infectious Diseases), Chair, Department of Microbiology & Immunology, Albert Einstein College of Medicine of Yeshiva University, New York, NY
October 9	**Gregory Poland, M.D.,** Divisions of General Internal Medicine and Infectious Diseases, Mayo Clinic College of Medicine, Rochester, Minnesota
October 23	**Grant McFadden, Ph.D.** - Ottawa Health Research Institute, Ottawa, Ontario, Canada professor at the University of Western Ontario and the Robarts Research Institute in London, Ontario, Canada.
November 13	**David Relman, M.D.** Professor of Medicine (Infectious Diseases and Geographic Medicine) and of Microbiology and Immunology, Stanford University, Stanford, CA

Problems encountered in Year 1

The only problems encountered in Year 1 concerned the unfortunate State-imposed hiring freeze that impacted negatively on our appointing Core support research assistant positions at LSUHSC. Two exemptions were received in May 2008 and we have since proceeded with the relevant appointments, as outlined above. With the freeze due to expire on 6/30/08 we should now be able to proceed with the remaining LSUHSC appointments. Should the freeze be extended for any reason we will proceed with further exemption requests.

3. Contributions

As emphasized in the preceding section, the primary focus of the Center in Year 1 has been to establish the necessary research Core infrastructure to support vaccine-related work, and then to begin to develop research, educational and, ultimately commercialization strategies necessary for the Center to achieve our goals and objectives. Each of these initiatives has been described in detail above. The following is a brief summary of these efforts under the categories indicated in the this sub-section of the report.

Research and Education Capacity and Infrastructure:

In Year 1, we have focused primarily on the growth of *nine* essential research and development Core facilities designed specifically to aid the flow of vaccine-related research from discovery to vaccine preparation and delivery and through pre-clinical testing and analysis towards the development and conduct of clinical trials (and at any entry point in this continuum). Key items of enabling equipment have been purchased in the Cores to complement existing resources for vaccine related research and we have begun to place technical support staff in the Cores dedicated to Center research.

We have also developed a Cooperative Pilot Research Grant fund in partnership with SLIIDR in order to develop and support vaccine-related research and development projects that are multi-disciplinary, collaborative, novel and that have clear potential for progress to clinical trials and commercialization. Ten projects have recently been identified for funding through this mechanism.

We have also initiated our Education program in vaccine-related research and development through a summer research internship program (10 students currently enrolled in Center labs with Center researchers as mentors). In addition, the "Infection, Immunity, and Vaccine" Seminar Program has programmed nine high-profile national speakers (from NIH, University of Tennessee, Arizona State University, Albert Einstein College in New York, the Mayo Clinic, Ottawa, Stanford and LSU-Baton Rouge) and eight prominent local speakers from all partner Institutions. We have also begun to train students from local University business, law, engineering and basic science programs who have an interest in research commercialization. Thus, 6 summer interns from a variety of these local programs have begun to support and implement various aspects of the commercialization strategy, as outlined above.

Contribution to economic development and project sustainability, and efforts to secure external federal and private sector funding:

In Year 1 we have also established a Commercialization Program, in partnership with SLIIDR and the Clinical and Translational Research, Education and Commercialization Project (CTRECP) - other Board of Regents funded, Joint LSU – Tulane Health Sciences Center initiatives - and the New Orleans BioInnovation Center (NOBIC). The aims of this program are to foster the local bioscience industry, to educate local researchers and trainees and, ultimately, to establish a commercialization pipeline for Center research and development programs.

Year 1 activities include the development of a comprehensive commercialization strategy targeting all New Orleans based university-developed bioscience products and processes, involving: inventory and assessment of the intellectual property (IP) assets with commercial potential available at the local Health Sciences Centers; the development of a commercialization-oriented database; and the recruitment of local business, law, engineering and basic science students to assist in this process while receiving training in research commercialization.

Thus, in Year 1we have taken significant steps in the establishment of a commercialization pipeline for Center research, together with the development of essential Core infrastructure and the funding of multidisciplinary, collaborative pilot awards with a view to the generation both of new project and collaborative program applications funded extramurally, and of discoveries with potential for clinical application and/or commercial development. These are key platforms for future project sustainability and broader economic development.

4. Project Revision

In our original proposal we requested funding to support a BSL-3 containment Core lab for the Center based at the Research Institute for Children (RIC). We have subsequently determined that it is more appropriate to establish the BSL-3 Core lab within existing, purpose-built space on the LSUHSC-New Orleans campus, given the guidelines that we follow for containment and maintenance of such facilities.

We have also now established a Molecular Interaction Core at RIC (as detailed in section 2(i) above) that will utilize their existing Biacore technology to study intermolecular interactions in real time. Using the principle of surface plasmon resonance, this technique can be used to determine association and dissociation kinetics, and perform concentration analyses. This technology has proven extremely useful in determining affinities of monoclonal antibodies and of polyclonal antisera and will be of great benefit for researchers in the Vaccine Center.

Additionally, we are requesting a rebudget of the BSL-3 Year 1 funds to support Project Development proposals for the LVC. $157,570 will support new multi-disciplinary Center vaccine pilot research projects on the recommendation of our Center Steering Committee (CSC).

We are also requesting that carry forward Year 1 funds be used to support Project Development proposals for the Vaccine Center. Funding for Year 1 was affected by the initial delay and execution of the contract and subsequent hiring freeze imposed on State agencies. The resulting carryover enabled the Center Steering Committee to recommend enhancement of the Project Development Program (multi-disciplinary Center pilot research awards, as detailed in section 2(ii) above).

All budget and program documentation pertaining to these revisions has been submitted to the Board of Regents for review.