<u>Center of Excellence for Vaccine Development – (Louisiana Vaccine Center)</u>

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Year 3 Annual Report 6/30/2010

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OVERVIEW

The Center of Excellence for Vaccine Development, now entitled: *The Louisiana Vaccine Center* (LVC), encompasses three major Louisiana campuses (LSUHSC-New Orleans, Tulane HSC, and Xavier University of Louisiana). The Center was created through a grant from the Louisiana Board of Regents post-Katrina support fund initiative (PKSFI) in order to focus 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 ultimate goal is to develop recognized local research strengths in infectious disease and vaccine development into a tower of strength in the region with a research and development infrastructure to support its future growth and the commercialization of new discoveries. The LVC would thereby provide a cornerstone for any future regional enterprise that could ultimately consolidate vaccines and therapeutics research and development in the South.

In June 2009, the Louisiana State University Board of Supervisors approved full 5-year Center of Excellence status for the LVC within the LSU system. The Center was subsequently ratified through 2012 as a Center of Excellence. These developments demonstrate strong Institutional and State support for our education, research and development programs.

Center programming continues to be implemented based on the performance measures and milestones laid out in our Center contract. The primary goal of the Center is the ongoing growth of a framework for research and development in infectious disease and vaccines that will, in turn, provide a focus for retention of established researchers and promising junior scientists. Through this approach in years 1 through 3, the Center has fostered research collaborations between scientific institutions in Louisiana and strengthened our capacity to compete for large-scale research and development grants and contracts, with some notable successes in year 3 of Center activity. Through our education programming, we are stimulating the interest of high school and college students and their future participation in higher education in related fields, through summer internships in vaccine-related research. We are also participating decisively in the development of an improved pool of potential research support staff locally through the Bioscience and Education Training program. Our commercialization initiatives are working towards the development of intellectual property in the form of patents and/or licenses, with significant outcomes in year 3. In these ways, the Center is playing a critical role in the development of the local infrastructure necessary for the development of novel vaccines for infectious disease.

Our External Advisory Committee (EAC), chaired by Lawrence Stanberry MD, Chairman of Pediatrics at Columbia University in New York, visited the Center for our Annual meetings in September of 2008 and 2009. After their most recent visit, the EAC saluted the Center for the progress that we have made in a relatively short time and were extremely positive about the strength of local vaccine-related research as developed and facilitated by the Center. EAC members voiced their positive assessment of the progress, productivity and impact of the Center in a memorandum addressed to the senior administration of the partner institutions (See **APPENDIX D** for the full text of the EAC Memorandum).

In year 3, our focus has been to build upon on the successes of the research, commercialization and education initiatives of the Center, and to promote their continued growth and development. A key recent feature of Center activity is the increasing development of linkages between these initiatives – research success increasingly feeds into commercialization and education of graduate students, postdocs and summer students), while the commercialization program helps to develop aspects of the research program towards technological development and educates both faculty and interns in entrepreneurial bioscience. The education program exposes trainees to careers in bioscience and trains future research support staff.

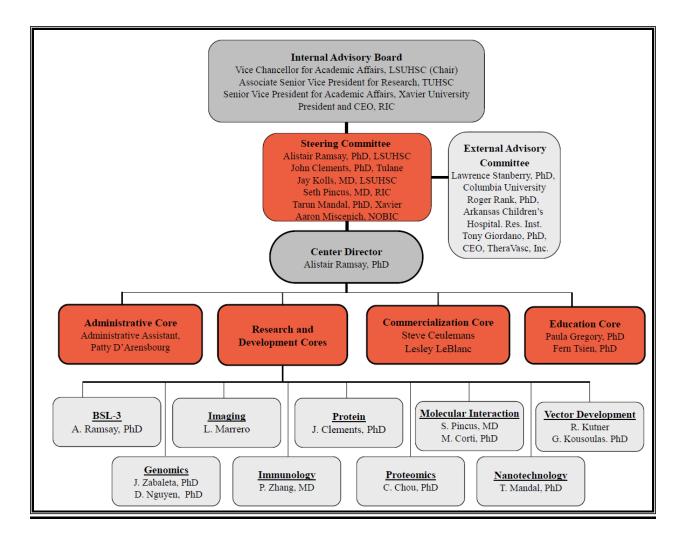
Our third year has been marked by significant progress in each of these areas – some key highlights are outlined below:

- Center investigators have been awarded over \$57 million dollars in new external grants from federal and private sources in year 3, primarily from the NIH. External grant applications for a further \$87 million were submitted.
- Center investigators have published 110 original papers in year 3 of Center activity, with a total of 232 publications since our inception.
- Our Collaborative Pilot Research Project Fund has led directly to the submission 40 new federal grant applications, while pilot grantees have been awarded 12 new federal grants (including several R01s and a Career Development award from NIH) and 5 grants from other external sources, and published 25 new papers arising from their funded research.
- The Center has continued to develop critical core infrastructure, contributing nearly \$600,000 for the purchase of new core equipment and supporting the employment of six research associates specifically to facilitate vaccine-related research in Center cores. The Biosafety Level 3 core, critical for NIH-funded Center research in TB vaccine development, is now fully functional.
- The Center Faculty Interview Program, conducted by teams of law and business student interns
 from LSU and Tulane, has now interviewed 39 Center faculty members, leading directly to the
 pursuit of 18 new invention disclosures which are highly focused in the area of infectious disease
 research and vaccine development.
- The Center commercialization program "Venture Development" process has led to directly to 5 new (international) provisional patents that are currently being pursued, while a framework for startup development has also been established for two business plans that are currently emerging from the Center with further potential developments in the pipeline.
- The Center Commercialization facilitator, Steven Ceulemans, was awarded the Governor's Technology Award for University Technology Leadership from the Louisiana Technology Council in March 2010, in recognition of his key role in the commercialization of research developed at our partner universities and other local institutions.

- Forty students from local high schools and from colleges nationwide have now participated in the
 Center's Summer Research Internship Program since 2008. The program exposes young students
 to a career in the biosciences, and also represents an important potential recruitment tool for
 bringing our undergraduates, who attend universities throughout the U.S., back to Louisiana for
 graduate or medical school training.
- The Center's Infection, Immunity and Vaccine Seminar Program featured eight high-profile national speakers in Year 3. The Center has now sponsored twenty-four visiting speakers sponsored to date, with significant outcomes for new collaborations and mentorship.
- The Bioscience and Education Training (BET) Program, designed to address a critical local and regional shortage of trained biomedical research support staff, has graduated its first six individuals. Three are now employed in research labs at LSUHSC, two have applied to graduate programs, and one has gained employment in a local biotechnology company. Six new students have now enrolled in the program, with recruitment underway for a third intake late in 2010.

1. PERSONNEL

The organizational structure of the Louisiana Vaccine Center is shown below.



Key Personnel in the Center include:

Alistair Ramsay PhD, is currently Professor of Medicine and Director of the Gene Therapy Program at LSU Health Sciences Center in New Orleans. He is Principal Investigator and Center Director, and a member of the Center Steering Committee. He recently accepted the position of Chairman of the Department of Microbiology, Immunology and Parasitology at LSU Health Sciences Center, a key unit within the overall LVC structure. Dr. Ramsay has been centrally involved in all of the Center's research, commercialization and education activities since inception. During Year 3, along with the members of the Steering Committee and EAC, his focus has been to build upon the foundation of the first two years of Center activity. He chaired the LVC's Annual Meeting and the External Advisory Committee (EAC) meeting and is also Director of the BSL-3 Bio-Containment Core Facility.

<u>John Clements PhD</u>, Professor and Chairman of the Department of Microbiology & Immunology and Director of the Center for Infectious Diseases at Tulane University HSC, is co-Principal Investigator (co-PI) and a **member of the Center Steering Committee**. He is also Director of the Protein Core.

<u>Jay Kolls MD</u>, Chairman of the Department of Genetics at LSU Health Sciences Center and a **member of** the Center Steering Committee.

<u>Tarun Mandal PhD</u>, McCaffrey Norwood Professor of Pharmacology at Xavier University of Louisiana, is co-PI and a **member of the Center Steering Committee**. He is also Director of the Nanotechnology Core Facility.

<u>Seth Pincus MD</u>, Nelson Ordway Professor of Pediatrics at LSU Health Sciences Center and Director of the Research Institute for Children (RIC) in New Orleans, is co-PI and a **member of the Center Steering Committee**. He is also Director of the Molecular Interaction Core Facility.

<u>Aaron Misenich</u> is Director of the New Orleans BioInnovation Center (NOBIC) and a **member of the Center Steering Committee**.

<u>Paula Gregory PhD</u>, Associate Professor of Genetics at LSUHSC, is Education Program Facilitator and is assisted by <u>Fern Tsien PhD</u>, Instructor of Genetics at LSUHSC. They have developed and implemented the Education Program that focuses on summer research internships for high school, undergraduate and medical students and other training programs.

Steven Ceulemans MS is the Commercialization Facilitator and is based at NOBIC. He oversees the LVC Faculty Interview Program and training of law and business interns in research commercialization; develops the Bioscience Technology Database; assists Center members with preparation of disclosure and preliminary patent documents, research commercialization grants and business plan development; and organizes educational and other outreach programs. His activities are supervised by Aaron Miscenich and partner university technology transfer directors.

<u>Lesley LeBlanc BS</u> is the Associate for Research and Development. She works closely with the Center Director, the research core directors, and the commercialization and education facilitators to coordinate and implement all Center research, education and commercialization strategies.

<u>Patricia D'Arensbourg</u> is the Administrative Coordinator. She assists the Director and the Steering Committee in all administrative and budgetary functions, including coordination of the LVC *Infection, Immunity, and Vaccine Seminar Program*.

2. <u>ACTIVITIES AND FINDINGS</u>

Our activities have focused on the development and support of programs in vaccine-related research across the three participating university campuses, with particular emphasis on collaborative studies. The Center has continued to develop an impressive network of Core facilities and research support programs to facilitate the seeding of new projects, the movement of existing programs towards clinical trials, and an impressive amount of new federal research funding, mostly from the NIH. Meanwhile, the Center commercialization program has assisted in the movement of many of these projects towards patenting and commercial development, while continuing to mine for new projects with potential for biotech development within the Center. This process includes educating both junior faculty and regional business and law interns in research commercialization. The education program has focused on training of summer high school students in vaccine-related research, the continued development of a first class seminar series featuring several distinguished visiting speakers, and the training of a technologically savvy local research support workforce. This section will discuss in detail the recent progress of the (a) research, (b) commercialization, and (c) education programs within the Center.

(a) Research program

The growth of essential research infrastructure and other support of vaccine-related research and development projects are hallmarks of the LVC Research Program. Highlights in Year 3 include the continued growth and development of Center core facilities (including expansion along the Southeast Louisiana corridor to develop core facilities at the LSU School of Veterinary Medicine that are now a complementary component of our Center core network); very positive outcomes both from our Cooperative Pilot Research Grant Fund awards and our Grant Seekers Meetings; and outstanding outcomes in both external grant awards and research publications for Center investigators.

i. Core Facilities: Expansion, Enhancement and Usage:

Central to our mission is the development and staffing of 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 towards the development and conducting of clinical trials. Importantly, the cores are situated across all of our Center campuses, and have opened up new research support infrastructure for Center researchers, trainees and students, as well as helping to facilitate new multi-institutional research collaborations.

The core facilities are all highly responsive to the needs of Center investigators. Their focus is to aid our researchers and students at every stage of their research from the bench to the clinic via state-of-the-art equipment, and also in the provision of services and support by personnel with specific training and expertise in vaccine-related research technology. Since 2008, the Center has contributed nearly \$600,000 for the purchase of new core equipment and has employed six research assistants to work in Center cores, all specifically to facilitate vaccine-related research.

Importantly, each of the Center cores also contributed directly in year 3 to the laboratory skills training component of the Bioscience and Education Training (BET) Program, developed in coordination with SLIIDR. The BET program has been developed to help promote an educated local workforce for placement in bioscience research and development labs – a major current need in Louisiana (see **Section 2 c. vi.**).

In addition, to increase general awareness of the facilities and services offered in our Cores, the Center has continued to develop "Core Awareness" slide shows – short informational PowerPoint presentations that are shown immediately prior to local speaker presentations in the LVC *Infection, Immunity and Vaccine Seminar Program* (see **APPENDIX A** for examples of Core Awareness Slide Shows). We have also now created a Core Usage Survey that has recently been sent out via e-mail to all Center investigators. Usage data and user comments will be analyzed in order to develop strategies to better serve Center investigators.

Below are descriptions of activities of each the Center core facilities in Year 3:

<u>Genomics Core:</u> Doan Nguyen PhD and Jovanny Zabaleta PhD (LSUHSC - Clinical Sciences Research Building)

The mission of the Genomics Core is to provide comprehensive genomics, microarray and bioinformatics support to Center investigators through 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.

In year 3, the Microarray and Bioinformatics division of the Genomics Core has directly supported the research projects of over 30 Center members across five campuses including: LSUHSC-NO, LSU Dental School New Orleans, Tulane University, Children's Hospital-Research Institute for Children and LSU-Baton Rouge. To help train researchers in new or updated technologies the core hosted several instructional seminars including: (i) Thermo Scientific-Knockdown University: An experimental guide to siRNA/shRNA/microRNA technologies, (ii) Affymetrix users update, and (iii) high throughput genome sequencing technology. The core also provided laboratory training to multiple research support trainees, including three from the Biosciences Education and Training (BET) program (see Education Program, section 2 c. vi. below). Two of these graduates subsequently received research job offers in local research laboratories as a direct result of the training they obtained in this core facility. The core also provided summer research opportunities and training for two high school summer students in year 3: Anushka Das and Thy Tran.

The DNA Sequencing component of the Genomics Core purchased an Illumina Genome Analyzer and Bead Express Reader in year 3, in part through Center support. This facilitates rapid, deep DNA and RNA sequencing for Center investigators. We are also contributing substantially to bioinformatics analyses for data mined in this way through the Genomics Core and will look to expand support for this critical development in subsequent years.

Proteomics Core: C. Chou PhD (LSUHSC - Clinical Sciences Research Building)

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 workstation for fast protein identification in quantization and biomarker discovery.

Protein Core: J. Clements PhD (Tulane University School of Medicine)

The mission of the Protein Core is to provide Center researchers with high quality, purified protein antigen for use in vaccine research. Personnel dedicated to Center projects have assisted researchers in the selection of optimal recombinant expression systems (prokaryotic and eukaryotic), sub-cloned genes of interest into expression vectors, and optimized 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.

During the year 3, the Protein Core cloned and purified recombinant proteins for NIH-supported projects in *Burkholderia* and in tuberculosis vaccine development, for Dept. of Defense-supported *Y. pestis* (plague) and nanocarrier adjuvant vaccine projects, and for a Gates Foundation PATH-EVI supported diarrheal disease project. The core trained multiple graduate students in use of core equipment in year 3, and has also recently upgraded equipment for protein preparation and production and for chromatography (see Section 4).

Nanotechnology Core: T. Mandal PhD (Xavier University of Louisiana)

It is the mission of the Vaccine Delivery/Nanotechnology Core, situated at Xavier, to support and advance vaccine research capacity through the provision of novel and innovative vaccine delivery formulations. The major goal of the core is to maintain a state-of-the-art innovative polymeric vaccine delivery research facility in order to support inter-disciplinary research. Core personnel provide leadership in planning, designing, and implementing innovative nanotechnology and will assist investigators in conducting preformulation and formulation studies of any potential novel vaccine delivery system for preclinical and NDA studies (New Drug Application following USFDA guidelines).

During year 3, the Nanotechnology core purchased one new piece of new equipment: a Labonco Freeze Dryer, required for lyophilization of vaccine and related formulations to store them as a dry powder. This is the core's second Freeze Dryer and will increase the core's productivity and capabilities. This is in addition to the Water Acquity SQDLC/MS System that was funded by the Center in year 2 to help more readily identify successful synthesis and product formulation.

Significant progress has also been made through collaborative Center research developed through the Nanotechnology core during year 3. The long-term goal is to develop safe and effective vaccines suitable for *mucosal immunization* in multiple Center tuberculosis and HIV vaccine projects, in collaboration with several Center investigators (including Ramsay, Luftig, Kozlowski). Five different lipid nanoparticle formulations containing pDNA vaccine have been prepared and each was separately filled into hard

gelatin capsules for oral administration. To prevent premature release of the enclosed vaccine in the stomach region, the capsules were coated with a specialized pH sensitive polymer. The formulations were evaluated for mucosal immunization efficacy following oral administration in monkeys. The pDNA was either encapsulated 100% within the non-human primates or adsorbed 100% on the surface of non-human primates through electrostatic force or 50% encapsulated or other remaining 50% absorbed. In one study, all five immunized non-human primates showed highly uniform particle size distribution with a median size around 200 nm. The zeta potential of the particles was between 6 and 32 mV. Similar collaborative approaches are currently being developed in the core specifically for delivery to the lungs.

Future plans of the Nanotechnology Core include development of various nanoparticle formulations loaded with DNA or viral vector-based vaccines. In year 3, the Nanotechnology Core also established a new partnership with Dr. Russell Wilson of AutoImmune Technologies Inc., a local biotechnology company. The goal of this collaboration is to develop novel formulations of Flufirvitide-3, an investigational drug for the treatment of influenza.

<u>Vector Development Core:</u> R. Kutner (LSUHSC – Medical Education Building) and Gus Kousoulas, PhD (LSU-Baton Rouge-School of Veterinary Medicine)

The Vector Core greatly facilitates co-operative Center research through the design, engineering, preparation and purification of new recombinant vaccine vectors and novel vector technology. The core is already equipped for manufacture of lentvirus, poxvirus/MVA, adenovirus and adeno-associated virus vector systems for Center investigators. To date in year 3, Center investigators from LSUHSC, Tulane, and the Research Institute for Children have received a total of 32 new, large-scale vaccine vector preparations that were generated in the Vector Core, with other researchers utilizing core facilities equipment and expertise to assist with their own preparations.

The Vector Core is also developing technologies based on new vector systems and other technologies in order to expand its portfolio to meet current needs of Center investigators. These include: (i) the engineering of all current core vector systems for compatibility with Gateway® recombinant technologies that greatly simplify recombinant selection – a key step in vector vaccine construction, (ii) a streamlined system for engineering, selection, and production of recombinant MVA vectors (an increasingly important vaccine vector system with potential for safe use in humans). The demand for vaccine-based vectors is increasing, the addition of modern production techniques has already been implemented, and the future addition of newer technologies, the core is well situated to cater for Center researcher's ongoing needs.

The acquisition of a lyophilizer, in response to requests by several Center researchers, allows the core to optimize conditions for preparing final products in a stable dried form. The initial goal is to be able to lyophilize rMVA vector products or DNA vaccine vectors prior to their encapsulation into gel coated pills for targeted oral vaccine delivery to the gut mucosa (in collaboration with the nanotechnology core).

The demand from Center researchers for recombinant DNA vaccine production (and also protein production) was addressed by purchase of a Gateway® compatible *E. coli* protein expression system. With the New Brunswick BIOFLO 310 bio-reactor already used for endotoxin-free plasmid DNA vaccine vector production, the adaptation of large-scale recombinant protein production in *E. coli* is now possible,

complementing the expertise available through the Protein Core.

In an important new development in year 3, the Center has engaged vaccine researchers along the Southeast Louisiana corridor in order to develop both the breadth of vector-related services available to Center investigators, and the potential for new collaborative vaccine research across the State. The Viral Vectors Laboratory at LSU-Baton Rouge, directed by Dr. Gus Kousoulas, has particular expertise in the construction, development and production of herpes simplex type-1 (HSV-1), vesicular stomatitis virus and baculovirus vectors for vaccine development, and this is clearly complementary to the Center Vector Core at LSUHSC. Support provided by the Center will also facilitate the development of new research collaborations with the Baton Rouge vaccine research group as an affiliate of the Center.

Immunology Core: P. Zhang MD, PhD (LSUHSC - Clinical Sciences Research Building)

The Immunology Core serves Center investigators in the measurement of immune responses and data analysis. State-of-the-art flow cytometry and immunoassay equipment (including bioplex and real-time PCR) has been purchased by a combination of LSUHSC and NIH funds, while the Core has a fully qualified FACS operator funded by institutional NIH grants (Constance Porretta MS) and additional technical support specifically for vaccine-related research and training provided by the Center. Full FACS acquisition services and immune assay development support and are provided to Center researchers.

The Core purchased a new BD FACSCanto II flow cytometer in year 3, and this is directly supported by a highly-trained LVC-funded technician. In the past year, the Immunology Core completed 9,282 sample analyses by flow cytometry, in addition to 24 separate sorting experiments, for Center investigators. The core has also trained multiple Center investigators, graduate students and research assistants in FACS technology, in addition to training in clinical research for affiliated medical students.

<u>Molecular Interaction Core:</u> S. Pincus MD and M. Corti PhD (Research Institute for Children-Children's Hospital)

This Core utilizes Biacore technology to study intermolecular interactions in real time and has proven 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.

In year 3, users of the Molecular Interaction Core include faculty from LSUHSC, University of Louisiana (Monroe), Ochsner Clinic and Research Foundation, University of New Orleans at Children's Hospital. In addition, the core has fielded enquiries and discussed potential experiments from investigators at Tulane, Xavier, and CAMD at LSU Baton Rouge. Major ongoing projects include:

- Anti-ricin antibodies (Seth Pincus, LSUHSC and Research Institute for Children)
- Identification of SCA-1 Ligand (Ping Zhang, LSUHSC)
- Binding of the AIRE transcription factor to insulin promoters (Michael Lan, LSUHSC and Research Institute for Children)

- Small molecule inhibitors of HER-2 signaling (Seetharama Jois, University of Louisiana at Monroe)
- Binding of mTOR pathway components (T. Cooper Woods, Ochsner Clinic and Research Foundation
- Affinity analysis of anti-HIV antibodies (S. Pincus and James Robinson, Tulane)
- Binding of vaccine induced antibodies to Candida albicans (Jim Cutler, Hong Xin LSUHSC, and RIC)

Imaging Core: L. Marrero (LSUHSC - Clinical Sciences Research Building)

The Imaging Core on the LSUHSC-NO campus is a comprehensive histopathology and specialized imaging center for use by the Louisiana Vaccine Center and partners. The MIC facilitates technical expertise in the fields of histology; immunological and chemical detection of gene expression; and imaging of cellular targets at the molecular level; underpinned by scientific input, advice in experimental design and interpretation of results. The core clientele includes over 25 Center investigators.

In year 3, Imaging Core staff collaborated in the design and execution of a wide array of experimental protocols including, but not limited to: investigations requiring isolation of mRNA transcripts from lungs treated with DNA vaccines via laser-micro dissection; ongoing deconvolution analysis of *Chlamydia trachomatis* persistence within endocervical cytobrushes; measurement of *Candida albicans* membrane transport dynamics; characterization of lymphocyte populations in lung granulomas by quadruple immunofluorescence; and monitoring of various nanoparticle delivery vehicles *in vivo* using biophotonic imaging technology. High-resolution photomicrographs include details to the order of a single chromosome and are often complemented with quantitative analyses.

The core exploits state-of-the-art technologies for 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 integrated 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.

BSL-3 Bio-Containment Core: A. Ramsay PhD (LSUHSC - Clinical Sciences Research Building)

This facility is critical for work with pathogens that require bio-containment. It was originally established with the aid of LEQSF Enhancement Funds from the Board of Regents and its further and focused development is now leveraged by the Center as well as investigator's NIH funding in tuberculosis vaccine research (made possible by the existence of the facility). The facility is compliant with all relevant guidelines of the Centers for Disease Control and is also approved, and is regularly inspected by, the Institutional Biosafety Committee. The laboratory is served by a dedicated air handling unit for cooling and heating. Siemens APOGEE automation controls consist of room pressurization controllers, constant volume exhaust boxes, and constant volume supply boxes. The primary control for automation is differential pressure and temperature is the secondary control. All controls are calibrated semi-annually. The exhaust is a redundant manifolded exhaust system with the stand-by fan programmed to activate to maintain exhaust pressure.

The facility totals 1040 ft² comprising separate rooms dedicated for animal care and use, pathogen infection and titration, and laboratory assays. Equipment within the facility includes: HEPA-filtered animal racks maintained under negative pressure, a HEPA-filtered animal bedding disposal station, a pass-through autoclave, class II biological safety cabinets, a glove box with airlock and dual exhaust HEPA filtration, a Glas-Col nebulizer, an ultracold freezer (-70°C), a standard freezer (-20°C), a refrigerator, CO2 incubators with HEPA filtration, a tabletop centrifuge with sealed canisters, and an inverted phase microscope. In addition, an experienced Core Manager oversees all issues of compliance, laboratory function and integrity, equipment function and maintenance, and experimental activity, and liaises with LSUHSC Facilities and outside contractors as required.

Studies in the BSL-3 laboratory in year 3 were focused on *Mycobacterium tuberculosis*—both in terms of the development of novel vaccines against TB and in studies of the interactions of this pathogen with the host, using animal models and clinical samples. These NIH-funded projects include: Vaccination Strategies Against Pulmonary Tuberculosis (Alistair Ramsay PhD, Principal Investigator), Immunomodulation in Tb infection (Carol Mason MD, PI), TB and regulatory T cells (Carol Mason MD, PI) and Mechanisms of immune response evasion in patients with tuberculosis (A. Zea PhD, PI).

ii. New research collaboration between LVC and LSU-Baton Rouge School of Veterinary Medicine:

As mentioned above, researchers from the LSU School of Veterinary Medicine in Baton Rouge became affiliates of the Center in year 3, expanding the breadth and geographical location of vaccine-related research supported by the LVC. The major objectives are: to expand current Center support core capabilities, to expand regional collaborative research and development in infectious disease and vaccine development in Louisiana, to provide a broader spectrum for retention of established researchers and promising junior scientists, to foster new collaborations between scientific institutions thereby strengthening our capacity to compete for large-scale research and development grants and contracts, and to aid in the development of local infrastructure necessary for the development and testing of novel vaccines.

Currently, the chief areas of research focus of this collaboration are Herpes Simplex Type-1 (HSV-1) and Type 2 (HSV-II), West Nile Virus, and Dengue virus. Two post-docs are currently supported, in part, to facilitate these collaborative projects that provide scope for new federal research funding and, importantly, applications for new funding for research commercialization (SBIR), an increasingly important component of our development strategy.

iii. Grant Seekers Meetings and Expert Grant Reviews:

A critical component of the ongoing success of the Center is the generation of new funding for research in infectious disease and vaccine development. The Grant Seekers Meetings and Expert Grant Reviews, held in coordination with the South Louisiana Institute for Infectious Disease Research (SLIIDR), are designed to aid researchers, through a constructive critical review process, as to the best approach to prepare or modify their grant application. All Center members are invited to contribute to this process, with strong emphasis on (and participation by) our junior faculty. Since their inception within the Center, thirteen

Grant Seekers sessions and two Expert Grant Review meetings have been held. To date, these meetings have facilitated the funding of three new NIH R01 project grants to Center faculty, along with the submission of five new NIH R01 applications whose development was facilitated at these sessions (see **APPENDIX B**).

iv. Cooperative Pilot Research Grant Fund Project Outcomes:

The Cooperative Pilot Research Grant Fund (established in conjunction with SLIIDR) is a major initiative of the Center that provides two-years of funding (up to \$75K per year), for new collaborative research projects. This fund was established to foster the development of projects in infectious disease, immunity and/or vaccine development that were required to be **novel**, **multidisciplinary and collaborative in nature**. The fund was established primarily to address our goals: (i) to generate new project and collaborative program 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, followed by peer review assessment, we were able to fund ten proposals, primarily from new and mid-career investigators (See **APPENDIX C** for a list of Pilot Grant Recipients). Post-award, there has been extensive feedback and interaction between pilot grantees and senior Center investigators, including presentations by all pilot grantees at each of the last two Annual Meetings of the center (which include the Center External Advisory committee meeting).

With the pilot funding period now coming to an end, we are in a position to begin to assess its impact. From an initial look at outcomes, it is clear that pilot fund has been has been highly successful in meeting our goals in a number of critical areas: developing and advancing new collaborative research projects, facilitating multi-institutional collaborations, providing a sound platform for the submission of new federal and private funding with notable new grant successes, the publication of manuscripts, and research presentations at national and international meetings – all raising the profile of Center investigators and the Center itself. To date, over the course of the pilot grant period, recipients have submitted a total of fifty-four new grant applications - 40 to federal funding agencies (primarily to the NIH) and 14 to industrial and private sources. As a result of these submissions, a total of new 17 grants have been awarded to pilot recipients, with 25 new publications arising from pilot grant-funded research (see **Table** immediately below).

LVC/SLIIDR Cooperative	ve Pilot Grant Research Fund				
Project Outcomes and Me	Project Outcomes and Metrics 2008-2010 (FY09 & FY10)				
Federal Grant	40				
Submissions	40				
Other Grant	14				
Submissions	14				
Federal Grant Awards	12				
Other Grant Awards	5				
Publications	25				

Such metrics are a critical determinant of the success of the Pilot Project Fund, however the feedback that we have received from pilot grantees reflects **additional important direct benefits, particularly to our early-career investigators** (including enhanced mentoring, opportunities for new collaborations including across Institutions, access to new research opportunities, access to improved core facilities, capacity to stabilize access to critical human patient cohorts). Several recipients have provided testimonials describing the impact of Center pilot funding on their research programs, including new grants and publications (See **APPENDIX** C for Pilot Grant Recipient Testimonials). Notable comments included:

"The Cooperative Pilot Research grant has significantly propelled my career as a new investigator and provided me with the initial support necessary to establish a successful independent research program. LVC helped to support [the] mentorship of 3 full-time graduate students . . . a research lab technician for 2 years and yielded 2 manuscripts receipt of the WRCE Career Development award from the NIH (\$480,000 directs) was a direct result of LVC funding and will enable me to expand my vaccine work".

- Lisa Morici PhD. of Tulane HSC

"With the assistance of this pilot research grant, we were able to re-establish a longitudinal clinical cohort of 70 HIV+ patients post-Katrina. Directly due to the establishment of this clinical cohort, we were able to successfully bid for the Merck Pharmaceutical clinical trial: "A study to evaluate Methods for Measurement of Oral HPV infection) ... and have allowed us to prepare a proposal for NIH funding (Identifying Risk Factors and Interventions to prevent oral warts and candidiasis in HIV disease), as part of a larger Program grant application to be submitted to NIH 8/15/10)."

- Michael Hagensee M.D Ph.D. of LSUHSC

"During these two years, my program received excellent mentoring from the LVC leadership. Such mentoring was critical in molding a young but inexperience investigator into one who could compete for independent funding. We have now used these pilot funds to secure a new R21 and a new R01 award they could not have been secured without the support of the LVC pilot grant."

- Deepak Kaushal Ph.D. of Tulane National Primate Research Center

"...pilot grant allowed me to hire excellent personnel and purchase key reagents, which rapidly moved our lab into a very productive phase. . . I have been hooked up with terrific colleagues and facilities spanning the Tulane and LSU campuses. We are taking every advantage of this burgeoning critical mass of research activity on infectious disease and vaccines in order to move our research to national prominence, including the award of a Gates Foundation grand challenges grant... and a new R01 award for HIV epitope engineering."

- Sam Landry Ph.D. of Tulane HSC

"In parallel with the development of our scientific program, LVC pilot funding will reap economic rewards for Louisiana. Funding has allowed us to employ and train a recent college graduate. With the skills she has acquired she now plans to pursue a PhD and a career in a scientific discipline. Equally important, LVC funding allowed us to generate the preliminary data to submit five new grants."

- David Welsh M.D. of LSUHSC

Additionally, in year 3, the Center supported the appointment of three post-doctoral fellows to projects in vaccine-related research programs as a direct result of pilot grant funding: Kyla Frolich, Ph.D., Maria Lewis, MD, and Miao Luo, Ph.D.

These outcomes illustrate clear and long-term benefits for vaccine-related research and education in the region. We will continue to monitor funding outcomes.

v. Research Development and Commercialization Pilot Grant Fund:

The next step, beyond the Cooperative Pilot Research Grant Fund and the Center Faculty Interviews (conducted within the Center Commercialization Program, (see Section 2 b. i) will be the identification of new Center projects with potential for research commercialization. We are in the process of: (i) preparing a request for proposals for pilot funding along these lines, and (ii) establishing a review panel that includes significant external expertise in research commercialization and that will review all applications and make funding recommendations to the Center Steering Committee. We anticipate making up to four such pilot awards in year 4, with the aim of providing a springboard for Center projects leading directly to patent applications, SBIR/STTR funding applications, and potential start-ups and/or linkages with biotechnology companies in vaccine-related research and development.

vi. External Funding Outcomes and Activity:

Vaccine Center faculty continued to have **great success in obtaining external funding for their research** in vaccine development and infectious disease in Year 3 of Center activity. Center Investigators were awarded over \$57 million in new federal and private foundation funding, primarily from the NIH.

Particular award highlights in year 3 include:

- a \$3.6 million, 3 year-SBIR grant awarded to Dr. Tarun Mandal of Xavier University of Louisiana (Center Steering Committee member and Nanotechnology Core Director) and AutoImmune Technologies, Inc., a local biotechnology company. This grant was awarded by NIAID to aid in the commercial development of novel formulations of an investigational drug for the treatment of influenza.
- a \$6.5 million, 5-year P20 Center grant from the NIH to LSUHSC-NO and Dillard University to
 investigate health disparities among minorities. In addition, Michael Hagensee MD (Center Pilot
 Grant recipient and Associate Professor of Medicine at LSUHSC) has an R01-level project in the
 overall grant that focuses on human papilloma virus (HPV) detection and prevention in minority
 groups.

A full list of external grants **awarded** to Center investigators during Year 3 is tabulated below:

LVC Faculty Grants Awarded-Year 3

	Type of		
Agency	Award	Title	PI
NIH	R01	Functions of EBNA1 in Replication and Partitioning of EBV (stipend)	Aiyar
NIH-NIAID	R21	Characterization and use of a novel AT-hook protein in Leishmania	Aiyar and Kelly
NIH	T32	Biomedical Alcohol Research Training Program	Bagby
Google Foundation	n/a	Global Pathogen Surveillance & Discovery - SUB with Columbia	Bausch
NIH-NIAID	U01	Multiplex MassTag PCR for African Hemorrhagic Fevers	Bausch
NIH-NIDICR	R01	Impact of ART on DC & Treg Responses in Oral Tissues - SUB with Pop Council	Blanchard
NIH-NNDS	R01	Pre-Clinical Trial of MSC-Based Therapy for CNS Disease - SUB with Scripps	Blanchard
NIH-NIAID	R37	Modulating Mucosal DCs & T Cells to Limit SIV Spread - SUB with Pop Council	Blanchard
NIH-NNDS	R01	Pre-Clinical Trial of MSC-Based Therapy for CNS Disease - SUB with Scripps	Blanchard
NIH-NIAID	R01	Assessment of Vaccine/Microbicide Combination Efficacy in the Macaque Model - SUB with ADARC	Blanchard
NIH-NCRR	U42	Maintenance of an SPF Macaque Breeding Colony for AIDS Research	Blanchard
NIH-NIAID	U19	ZCM: A Novel Broad Spectrum Microbiscide for STIs - SUB with Pop Council	Blanchard
NIH-NIAID	R01	R5 SHIV/Macaque Models for the Evaluation of T & B Cell-Based HIV-1 Vaccines	Blanchard
USAID	n/a	Testing Carrageenan-Based Microbicides - SUB with Pop Council	Blanchard
USAID	n/a	Testing Carrageenan-Based Microbicides - SUB with Pop Council E	
USAID	n/a	Macaque Mucosal Explant Models for Microbicide Testing - SUB with Pop Council	Blanchard
La BoR	n/a	Predoctoral Training in the Molecular Biomedical Sciences	Clements
NIH	C06	NCRR Recovery Act Construction of Science Facilities - JBJ	Clements
NIH	R01	Combustion generated pm0.1 and predisposition to asthma	Cormier
NIH-NIAID	U01	AIDS Clinical Trials Group Network (ACTG)	Fidel Jr.
NIH	P20	Mentoring oral health research in Louisiana (supplement)	Fidel Jr.
La BoR	n/a	Mechanisms of herpes virus proteins in hijacking and subverting host and cellular response pathways	Foster
NIH	P20	HSV-2 Subversion of the Innate Immune Response by Targeting Cell-Intrinsic Pathways (COBRE project)	Foster
Leukemia & Lymphoma Society	n/a	Graduate Student Support for Education & Training	Garry
La BoR	n/a	Predoctoral Training in Graduate Program in Biomedical Sciences Gar	
La BoR	n/a	Predoctoral Training in Graduate Program in Biomedical Sciences	Garry
NIH	Contract	Lassa Laboratory Solar Power Initiative - Coypu	Garry
NIH-NIAID	U01	Pre-Clinical Development of Recombinant Antigen Diagnostics for Lassa Fever	Garry

NIH-NIAID	R43	Recombinant Antigen Diagnostics for Filoviruses - SUB with Corgenix	Garry
NSF	n/a	CAREER: Synthesis, Characterization, and Applications of cyclic Polymer "Nanoloops"	Grayson
1,01	11/4	Interaction of ebv and hpv in the development of cervical	Grayson
NIH-NCI	R01	dyslasia in hiv+ women (admin supplement)	Hagensee
NIH-NCI	R01	Interaction of ebv and hpv in the development of cervical dyslasia in hiv+ women (competing supplement)	Hagensee
NIH	K08	Alcohol, pulmonary cytokines and host defense	Happel
NIH-NEI	R01	Ocular HSV-Latency, Reactivation, and Recurrence	Hill
NIH	P01	Determinants of Human Longevity & Healthy Aging The Design of Multifunctional Colloidal Nanostructures for	Jazwinski
NSF	n/a	the Remediation of Chlorinated Hydrocarbons	John
		NSF MRI ARRI-R2 Acquisition of a Field Emission	
NSF	n/a	Transmission Electron Microscope	John
NIIII	D21	Macaque Model of TB/AIDS Co-Infection Via Natural	W11
NIH	R21	Routes of Exposure Role of miRNA in Lung Damage During TB & TB/AIDS	Kaushal
NIH	R21	Co-Infection	Kaushal
		Genetic Requirements for the Survival of Tubercle Bacilli in	
NIH-NIAID	R01	Non-Human Primates	Kaushal
AMI AMI DI	P.50	Host Factors in Fungal Allergy and Fibrosis (SUB-	77 11
NIH-NHLBI	P50	University of Pittsburgh) The Role of IL-17 in RSV-induced Mucus and Airway (SUB)	Kolls
NIH-NIAID	R01	w/ VANDERBILT UNIV)	Kolls
NIH-NIAAA	R01	Alcohol, ROS, and Macrophage Epigenetics	Kolls
MDA	n/a	The Role of Histone Deacetylase 6 (HDAC6) in Spinal &	Kolls
NIH	R01	Non-CD4 Host Defense Against P. Carinii Pneumonia	Kolls
NIH	R01	Alcohol, ROS, and Macrophage Epigenetics Kolls	
NIH	R01	Th17 Cytokines and Lung Immunity	Kolls
1111	101	Mechanisms of protective immunity induced by live	Rons
NIH	R01	attenuated siv vaccines	Kozlowski
NIH/GeoVax		GM-CSF-adjuvanted clade c DNA/MVA & MVA/MVA	
Inc.	R01	vaccines	Kozlowski
NIH-NIAID	Contract	HIV vaccine design and development teams	Kozlowski
NIH	R01	Nasal DNA/Protein Vaccine for Anti-HIV Antibody and CTL	Kozlowski
NIH Gates	R01	HIV ENV Epitope Engineering	Landry
Foundation	n/a	Engineering Antigen Processing for Improved Immunity	Landry
		Substance P & NK1R Antagonists in Simian AIDS - SUB	
NIH	R01	with Children's Hospital of Phil	Lackner
NIII NIAID	D20	Penn Center for AIDS Research - Non-Human Primate Core	Lookaan
NIH-NIAID	P30	- SUB with U of Penn	Lackner
NIH-NCRR	T32	Research Training in Experimental Medicine & Pathology	Lackner
NIH	P20	COBRE - TNPRC - SUB with LSU	Lackner
NIH-NIAID	P01	Functional Analysis of NSV-Based HIV Vectors - NHP Core C - SUB with TJU	Lackner
MIT-MAID	101	Pathogenic Determinants in the SIV Envelope	Lackitti
NIH-NIAID	R01	Transmembrane Cytoplasmic Domain - SUB with U of Penn	Lackner
Robert Wood			
Johnson Foundation	n/o	Doham Wood Johnson Farmadation Harlift D. P Faller	Laiah
Foundation	n/a	Robert Wood Johnson Foundation Health Policy Fellows	Leigh

USAID	n/a	Design, Delivery & Development of Therapeutic Peptides	Luftig
NIH-NIAID	R43, R44	Peptide drug inhibitors of influenza virus entry (SUB with AutoImmune)	Manda
		, , , , , , , , , , , , , , , , , , ,	
NIH	N01	Sexually transmitted infections clinical trials group Microbial Correlates of Bacterial Vaginosis Treatment	Martin
NIH-NIAID	SC2	Failure	Martin
NIH-DHH	n/a	special projects to control std & school screening	Martin
HHS	n/a	HIV outpatient program research and services	Martin
DoD	n/a	Bioinformatics and Biotechnology Research Initiatives	Martin
Local Govt (LSUHSC- MCLNO			
Charity)	n/a	HIV outpatient clinic (HOP)	Martin
NIH	U19	Gulf South STI/Topical Microbicide Cooperative Research	Martin
NIH	WRCE Career Development Award	Immunogenicity & Protective Efficacy of Novel Burkholderia Pseudomallei Subunit Vaccines - SUB with U of TX	Morici
USAID	n/a	Design, Delivery & Development of Therapeutic Peptides	Nelson
NIH-NIAAA	P60	Alcohol, HIV Infection and Host Defense (supplement)	Nelson
NIH-NIAAA	P60	Alcohol infection & host response	Nelson
American Heart Assoc	n/a	Targeting Host and Fungal Eicosanoids During Candida	Novem
NIH	R01	Impact of Candida Oxylipins on Host Immunity and Fungal	Noven
NIH-NIAID	R21	Importance of Antigen Specific Immunoglobulin Responses in Controlling SIV Infection	Pahar
Children's Hospital Research Institute	n/a	Graduate Student Stipend- Ryan Craig	Pincus
Children's Hospital	n/a	Children's hospital research institute	Pincus
Mount Sinai Sch of Med	n/a	Defensins in STI-Mediated Enhanced HIV Infectivity	Quayle
NIH	R01	Vaccination strategies against pulmonary Tb	Ramsa
NIH	R01	Vaccination strategies against pulmonary Tb (student stipend)	Ramsa
Gates Foundation	n/a	Molecular Analysis & Modeling of HIV-1 Transmission, Containment & Escape - SUB with UAB	Robins
Gates Foundation	n/a	Comprehensive Antibody Vaccine Immune Monitoring - SUB with Duke	Robins
Gates		Broadly Reactive Neutralizing Antibodies: Novel Strategies	ъ
Foundation Gates	n/a	for Vaccine Design - SUB with Duke Rhesus Mabs From SHIV Infected Macaques - SUB with	Robins
Foundation Foundation	n/a	Seattle Biomed	Robins
Gates Foundation	n/a	Molecular Analysis & Modeling of HIV-1 Transmission, Containment & Escape - SUB with UAB	Robins
NIH	R01	AIM 3 Ontogeny of Anti-HIV B Cell Responses - SUB with Duke	Robins
NIH-NIAID	R01	Monitoring the Development of Anti-ENV Abs During HIV Infection - SUB with Seattle Biomed	Robins
NIH	Contract	B Cell Epitope Discovery & Mechanisms of Antibody Protection	Robins

		Project 4 Human & Monkey MAbs to Quaternary	
NIH-NIAID	P01	Neutralization Epitopes - SUB with UMDNJ	Robinson
		Inhaled Cidofovir Dry-Powder Formulation for Post	
		Exposure Prophylaxis & Treatment of Smallpox - SUB with	
NIH-NIAID	Contract	Nanotherapeutics	Roy
		Monoclonal Antibody SEB Immunoprotectant - SUB with	
NIH-NIAID	R43	MAPP	Roy
NIH	WRCE	Alphavirus Vaccines for Biodefense - SUB with WRCE	Roy
		Animal Models of Infectious Diseases - Part COI (Non-	
NIH-NIAID	T32	Human Primates)	Roy
United			
Kingdom			
Ministry of		Extra Mural Research Contract Ricin Antitoxin Efficacy	
Defense	n/a	Study	Roy
Canon Health			
Care	n/a	Canon health care	Ruiz
Lakeside			
Hospice	n/a	Associate medical director and patient home visit	Ruiz
NIH	P01	Host defense against hiv-related pulmonary infection	Shellito
CYTHERIS			
Inc.	n/a	IL-7 and Murine Pneumocystis Pneumonia	Shellito
NIH	R01	Analyses of sigma factor 28 of C. trachomatis	Shen
P.F. Taylor			Tsien-
Fdtn	n/a	Medical Research Opportunities for the Patrick F. Taylor	Miller
NIH	P01	Determinants of human longevity and healthy aging Wels	
NIH	R01	Mesenchymal stem cell homing to the lung in emphysema	Welsh
		Alcohol and Impairment of the Granulopoietic Response to	
NIH	R21	Pneumonia	Zhang

<u>New grant submissions in Year 3</u>: LVC investigators continue to be highly active in pursuing external funding for Center-related research. Grant applications for over \$87 million were submitted in year 3, primarily to the NIH. Grant submission highlights in Year 3 include:

- a large RC4 grant application to the NIH by Jay Kolls, MD (Center Steering Committee) and David Welsh, MD (Center pilot grant recipient) for \$5.25M over three years. This project will characterize the bronchial microbiota in HIV-positive individuals and the effects of their interaction with the host.
- multiple R01 and R21 submissions in key areas of Center research and development, including 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 T35 application to NIH/NHLBI was submitted in year 3 and a further T35 (to NIH/NIAID) is in the final stages of preparation by our Education Program Facilitator these will support the development and expansion of our Summer Internship Program.

A full list of external grant **applications** submitted by Center investigators during Year 3 is tabulated below:

LVC Faculty Grant Submissions-Year 3

Lve Facuity Grant Submissions-Tear 3			
Agency	Type of Award	Name of Project	PI
NIH-NIAID	R01	Probiotics as a novel prophylaxis to prevent HIV transmission via breastfeeding (new)	Amedee
NIH	ICIDR	Epidemiology and pathophysiology of Lassa fever	Bausch
USAID	n/a	Outbreak preparation and capacity	Bausch
World Bank	n/a	Training and capacity building for emerging infectious diseases in Nigeria, World Bank (co-investigator)	Bausch
NIH	WRCE	Training in patient management and clinical research on biosafety level four pathogens	Bausch (co-
USAID	n/a	Zoonotic disease prediction and surveillance	investigator)
USAID	n/a	Microbicides Containing Biodegradeable Nanoparticles Loaded with Antiviral Agents - SUB with Pop Council	Blanchard
NIH-NIAID	U19	ZCM: A Novel Broad Spectrum Microbiscide for STIs - SUB with Pop Council	Blanchard
NIH	R01	Pre-Clinical Trial of MSC-Based Therapy for CNS Disease - SUB with Scripps	Blanchard
NIH	R01	Blocking a4b7/gp120 Binding with an Aptamer-Based Microbicide - SUB with Pop Council	Blanchard
NIH	R01	Eliciting Immunity in the Vaginal Mucosa with an HIV-1 Envelope Cocktail Vaccine - SUB with St. Jude's	Blanchard
NIH	R01	Impact of T. Vaginalis on Epithelial Cell - T Cell Interactions During HIV Infection in Genital Mucosa - SUB with Pop Council	Blanchard
USAID	n/a	Macaque Mucosal Explant Models for Microbicide Testing - SUB with Pop Council	Blanchard
NIH	R01	Assessment of Vaccine/Microbicide Combination Efficacy in the Macaque Model - SUB with ADARC	Blanchard
NIH-NIAID	R01	R5 SHIV Macaque Models for T & B H1V1 - SUB with ADARC	
NIH-NCRR	U42	Maintenance of an SPF Macaque Breeding Colony for AIDS Research	Blanchard
NIH	R01	Adult MSC Universal Vaccine Platform	Clements
DoD	Military Infectious Disease Research Program	Tulane/Xavier Vaccine Development and Engineering Project	Clements & Mandal
NIH	Superfund	Health impacts of toxic combustion by-products	Cormier
NIH	R01	The role of α in neonatal RSV immunopathology	Cormier
Gates Foundation	n/a	Generation of an effective neonatal vaccine for RSV	Cormier
NIH-NIAAA	P60	Maternal alcohol and infant RSV Con	
NIH-NIEHS	P42	Environmentally persistent free radicals alter pulmonary immunologic homeostasis (Renewal) Corm	
Sandler/American Asthma			
Foundation	n/a	Th17 cytokines and steroid resistant asthma Dendritic Cell Response to Microsporidia - SUB with	
NIH-NIAID	R01	GWU Didier Dendritic Cell Response During Immunosenescene - SUB	
NIH-NIAID	R01	with GWU Host Immune Response to an In Vivo Vaginal C.	Didier
NIH-NIAID	R01	Albicans Mucosal Biofilm (resubmission) Fidel	

Gates Foundation	n/a	Protection Against Vaginal Yeast Infections in Women (new)	Fidel
NIH	P20	Mentoring translational researchers in Louisiana (COBRE)	Foster
NIH	R21	Identifying & Characterizing Host Genetic Factors in Resistance to Lassa Hemorrhagic Fever	Garry
NIH	Contract	Lassa Laboratory Solar Power Initiative - Coypu	Garry
NIH-NIAID	R43	Recombinant Antigen Diagnostics for Filoviruses - SUB with Corgenix	Garry
La BoR	n/a	Travel Grant to IUPAC World Polymer Conference	Grayson
NIH	R01	Genetic Obesity Testing Intervention Trial (GOT-IT) (new)	Gregory
NIH	T35	LSUHSC Summer Internship Program (new)	Gregory
Ladies Auxiliary to Veterans of Foreign Wars	n/a	Postdoctoral Cancer Research Fellowship (Nicolas Herrell) (new)	Hagensee
NIH-NHLBI	R15	A self-administered home sampling for high-risk HPV DNA testing of the cervix (PI Donna Williams)	Hagensee
NIH-NCI	R01	Interaction of EBV and HPV in the Development of Cervical Dysplasia in HIV+ Women ARRA supplement	Hagensee
NIH	P20	The role of EBV in HPV-related Cervical Dysplasia in HIV-negative women. (Dillard-LSUHSC Minority Health and Health Disparities Research Center)	Hagensee
NIH-NCI	R01	Interaction of EBV and HPV in the Development of Cervical Dysplasia in HIV+ Women (administrative supplement)	Hagensee
NIH-NCI	R01	Detection of EBV in Residual Pap Smear Fluid to Enhance Cervical Cancer Screening	Hagensee
NIH-NCI	R01	Interaction of EBV and HPV in the Development of Cervical Dysplasia in HIV+ Women (competing supplement)	Hagensee
NIH	R01	Nanocomposite Infection Resistant Orthopedic Materials (new) Hobden	
NIH-NIA	P01	Determinants of Human Longevity & Healthy Aging Jazwinski	
NIH	R37	Cellular Aging in a Yeast Model System	Jazwinski
NSF	n/a	NSF MRI ARRI-R2 Acquisition of a Field Emission Transmission Electron Microscope	John
NSF	n/a	NSF ARI-R2; Renovation of the Taylor Laboratory	John
EPA	n/a	Engineered Zero Valent Iron Carbon Nanocomposites for DNAPL's Remediation	John
EPA	n/a	Novel Multifunctional Materials (Subcontract from NanoFed, LLC)	John
NSF	n/a	Self Assembly of chemical Dispersant Systems	John
NIH-NIAID	R21	Role of miRNA in Lung Damage during TB and TB/AIDS Co-infection. Kaushal	
NIH-NIAID	R01	Genetic Requirements for the Survival of Tubercle Bacilli in Nonhuman Primates Kaushal	
NIH-NIAAA	P30	Alcohol and TB: A pilot study Kaushal	
NIH-NHLBI	R01	Transcriptomics of Tuberculosis Latency and Reactivation in Primates Kaushal	
NIH-NIAID	R01	Preclinical Evaluation of Novel Drugs against Multi-Drug Resistant Tuberculosis. Kaushal	
NIH-NIDDK	R01	Molecular Pathology of HIV/SIV Enteropathy	Kaushal
NIH-NIAID	R44	Novel Therapy for Pulmonary Anthrax. Kaushal	

NIH-NIAID	T32	Animal Models of Infectious Disease.	Kaushal	
		Clp Proteolysis in M. tuberculosis: Regulation, Role in		
NIH-NIAID	R01	Virulence and Targets.	Kaushal	
NIII	D21	Macaque Model of TB/AIDS Co-Infection Via Natural		
NIH	R21	Routes of Exposure	Kaushal	
I o DoD	m/o	Biomarkers for Acute & Latent Tuberculosis & for Co-	Vouchal	
La BoR	n/a	Infection with AIDS Cannabinoid Epigenomic and miRNA Interactions Impact	Kaushal Kaushal	
NIH-NID	R01	HIV/SIV Disease Progression.	(collaborator)	
TTT-TTD	Enhancement	THY/STY Discuse Progression.	(conaborator)	
La BoR	Fund	The Southeast Louisiana shRNA Screening Facility (new)	Kolls	
		Novel Macrolide Th17 Inhibitors for Lung Inflammation		
NIH	R21	(new)	Kolls	
		Create new ways to induce and measure mucosal		
Gates Foundation	n/a	immunity (new)	Kolls	
American Asthma				
Foundation	n/a	Th17 Cytokines and Steroid Resistant Asthma (new)	Kolls	
NIH-NHLBI	R01	T-Cells and P Carinii Pneumonia (renewal)	Kolls	
		The Role of IL-13 in Regulating TH17 Cytokine		
NIH	R21	Production (new)	Kolls	
		Nlrp3 Inflammasome Suppression by Cigarette Smoke		
NIH-NCI	R01	(new)	Kolls	
			Kolls and	
NIH	RC4	Respiratory Microbiota and Mucosal Immunity (new)	Welsh	
W.H. Keck	/ -	WILL World Contain for the Manager Links were	Kolls and	
Foundation	n/a	W.H. Keck Center for the Mucosal Interactome	Welsh Kozlowski &	
NIH-NIAID	R01	Targeted intestinal delivery of immunodeficiency virus vaccine (new)	Mandal	
MIT-MAID	KOI	GM-CSF-Adjuvanted Clade C DNA/MVA and	iviandai	
Geo-Vax Inc.	U19	MVA/MVA Vaccines (new)	Kozlowski	
		Single-Cycle SIV as an Experimental AIDS Vaccine		
NIH	R01	Approach (renewal)	Kozlowski	
		ASO for Optimizing Immune Responses to Oral or		
Gates Foundation	n/a	Sublingual HIV Vaccines in Infants (new)	Kozlowski	
		Recombinant Streptococcus as an Oral Mucosal Vaccine		
NIH	R01	for HIV (new)	Kozlowski	
	201	Optimization of Vaccine-Induced SIV Immunity in		
NIH	R01	Macaques (new)	Kozlowski	
NIII	DO1	Optimization of Vaccine-Induced SIV Immunity in	IZ11-:	
NIH	R01	Macaques (resubmission) Passive Antibody Therapy Following Exposure to Ricin	Kozlowski	
NIH	R01	Toxin (new)	Kozlowski	
14111	ROI	Enhanced Immunogenicity of Pediatric HIV Vaccines	ROZIOWSKI	
NIH	R01	Through Immune Modulation (new)	Kozlowski	
	-	Genetics of Simian Immunodeficiency Virus		
NIH	R01	Encephalopathy - SUB with U of Penn	Lackner	
		Pathogenic Determinants in the SIV Envelope		
		Transmembrane Cytoplasmic Domain - SUB with U of		
NIH-NIAID	R01	Penn	Lackner	
	Major	Confocal Microscope TCS SP5 II for the Tulane National		
NIH	Equipment	Primate Research Center	Lackner	
MILI	D20	HIV Vaccine Research & Drug (HIVRAD) Program -	Looknas	
NIH	P30	SUB with TJU	Lackner	
NIH	P20	COBRE - TNPRC - SUB with LSU	Lackner	
MILL MILL ID	D20	Penn Center for AIDS Research - Non-Human Primate	T 1	
NIH-NIAID	P30	Core - SUB with U of Penn	Lackner	

		Engineering the CD4+ T-cell response for improved	
Gates Foundation	n/a	immunity	Landry
NIH-NIAID	R01	HIV ENV Epitope Engineering	Landry
Gates Foundation	n/a	A Novel Therapeutic Strategy Against HIV Using Defective HIV Particles (new)	
		A Novel Interventional Strategy for Preventing HIV	Luftig a
Gates Foundation	n/a	Infection by using L-2 Particles (new)	Zhong
NIH	P30	BD LSRII Fortessa Flow Cytometer for Microbiology/Immunology Core Facility	McLachlan
	Scientist	Targeting Host and Fungal Eicosanoids During Candida	
American Heart	Development	albicans Bloodstream Infections (transfer from Wayne	
Association	Grant	State University)	Noverr
NIH-NIAID	R01	Impact of Candida Oxylipins on Host Immunity and Fungal Biology (new)	Noverr
NIII NIIIGID	D01	Fecal and Intestinal Tissue Bacteria in Premature Infants	
NIH-NIHCID	R21	with and without Necrotizing Enterocolitis	Penn
Thrasher	7/0	Fecal and Intestinal Tissue Bacteria in Premature Infants	Donn
Foundation	n/a	with and without Necrotizing Enterocolitis. Analysis of Intestinal Tissue Microbiota in Human	Penn Penn
NIH-NICHD	R21	Necrotizing Enterocolitis	(collaborato
MIII-MCIID	K21	Defensins in STI-Mediated Enhanced HIV Infectivity	(Collaborato
NIH	R01	(resubmission)	Quayle
	1101	Immune Signatures Induced by Influenza, VZV, and HPV	Zuujio
NIH	U19	(new)	Quayle
		C. Trachomatis Increases Transmission of HIV:	
NIH-NIAID	R21	Mechanisms (resubmission)	Quayle
Louisiana		, ,	
Biomedical		Role of Alternatively Activated Macrophages for	
Research Network	n/a	Chlamydial Pathogenesis (new)	Quayle
Gates Foundation	n/a	Broadly Reactive Neutralizing Antibodies: Novel Strategies for Vaccine Design - SUB with Duke	Robinson
Gates Foundation	n/a	Comprehensive Antibody Vaccine Immune Monitoring - SUB with Duke	Robinson
Gates Foundation	n/a	Broadly Reactive Neutralizing Antibodies: Novel Strategies for Vaccine Design - SUB with Duke	Robinson
		Development of Cell-Permeable scFvs for Post-Exposure	
NIH-NIAID	R21	Treatment in Ricin Toxicity - SUB with NYU	Roy
NIH-NIAID	Contract	Inhaled Gentamicin Dry-Powder Formulation for Postexposure Prophylaxis & Treatment of Aerosolized Pneumonic Plague & Tularemia - SUB with Nanotherapeutics	Roy
NIH-NIAID	T32	Animal Models of Infectious Diseases - Part COI (Non- Human Primates)	Roy
United Kingdom	134	Transmit Hillians)	NOy
Ministry of		Extra Mural Research Contract Ricin Antitoxin Efficacy	
Defense	n/a	Study	Roy
		Novel Vaccine Technology for Chikungunya - SUB with	•
NIH	R21	U of TX	Roy
		Development of Passive Antibody Therapy Following Exposure to Biological Toxins - SUB with Children's	_
NIH-NIAID	R21	Hospital	Roy
Infectious Diseases	,	11 (6)	0.1: 00.1:
Society of America	n/a	Identification of Vaccine targets Against Dengue Virus	Schieffelin
Infectious Diseases	n/o	Identification of Vaccine Tensets Assist Descriptive	Cohinee-1
Society of America	n/a	Identification of Vaccine Targets Against Dengue Virus LA CaTS (Louisiana Clinical and Translational Science	Schieffelin
		I A Call (Louisiana Clinical and Translational Valance	

			Shellito	and
NIH	R01	Vaccines Against Pneumocystis (new)	Kolls	
		The Link between transcription regulation and virulence		
NIH-NIAID	R01	in Chlamydia trachomatis (resubmission of renewal)	Shen	
		A Molecular Switch of Type III Secretion System in		
NIH	R01	Chlamydia Trachomatis (new)	Shen	
Patrick F. Taylor		Louisiana Genetics Education Center Interactive Website		
Foundation	n/a	for High School Students and Teachers (new) Tsien		
		Clinical Resource for Lung and Alcohol Investigations		
NIH-NIAAA	R24	(resubmission)	Welsh	
NIH-NIAAA	R01	Alcohol, Septecemia and the LKS Cell Response (new) Zhang		

vii. Center Faculty Publications:

Center investigators have published 110 new research papers in year 3, making a cumulative total of 232 Center publications in the first three years of Center activity. Many have resulted directly from new collaborations facilitated by Center activity. These publications help to raise the profile of Center investigators and of the Center itself. We now strongly encourage inclusion of the following statement by Center investigators as an acknowledgement on all relevant manuscripts or public/conference/seminar presentations: "This work was supported in part by the Louisiana Vaccine Center and the South Louisiana Institute of Infectious Disease Research sponsored by the Louisiana Board of Regents."

(NOTE: See Publications uploaded as a separate document as required for PKSFI reporting).

viii. 2nd Annual Meeting and External Advisory Committee (EAC) Meeting:

The Center's Second Annual Meeting, incorporating the EAC Meeting, was held on September 29th and 30th, 2009 at LSUHSC-NO campus. This event allows the management, administration and facilitators to give updates to attendees on the progress of the Center and provides a forum for feedback regarding current and future planning by the EAC and Steering Committee members. The agenda also included presentations by pilot grant recipients and a public seminar in the Center's "Infection, Immunity, and Vaccine Seminar Program" by Roger Rank, Ph.D, a member of our EAC, as the featured speaker (See **APPENDIX D** for agenda). The day concluded with a feedback session involving the Center Steering Committee and the EAC, which welcomed a new member, Anthony Giordano, Ph.D., with specific expertise in Research Commercialization. Distinguished members of the Center EAC include:

Lawrence R. Stanberry, M.D., Ph.D. (*EAC Chairman*)
Reuben S. Carpentier Professor and Chairman
Department of Pediatrics
College of Physicians and Surgeons, Columbia University
New York, NY

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

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

The EAC saluted the Center for the progress that has been made in a relatively short time and were extremely positive about the strength of local vaccine-related research as developed and facilitated by the Center. EAC members voiced their positive assessment of the progress, productivity and impact of the Center in a memorandum addressed to the senior administration of the partner institutions - LSUHSC, Tulane HSC, and Xavier University of Louisiana (See **APPENDIX D** for the full text of the EAC Memorandum).

Additional recommendations included:

*Establishment of metrics based on Core Usage amongst its investigators: the Center has now sent out surveys to all Center faculty to determine usage and additional feedback.

*The EAC praised our commercialization program describing it as "remarkably novel" and encouraged us to forge ahead with technology transfer, believing that our that our continued progress in this area this will considerably enhance the value of technology transfer in the partner universities. The Center has continued to expand our research commercialization and education programs.

*The EAC was extremely positive about the proposed Research Development and Commercialization Pilot Grant Fund, and suggested that tangible deliverables at the end of the grant period should be included as a requirement in the RFA. While this should not necessarily be intellectual property, outcomes such as a R01 or R21 applications, and particularly technology/development products should be included. The Center will include these recommendations as the new Research Development and Commercialization Pilot Grant Fund is developed.

*The EAC encouraged us to begin looking into fundraising and endowment as a way to fund the Center long term, in addition to continued expansion of external grant funding. The Center has begun discussions with the University Foundations to look into such of funding Opportunities and will continue to emphasize the development of both new external project and program/center-type funding.

ix. Other Research Activities and Initiatives:

Infection, Immunity and Vaccines Seminar Program (IIVSP):

The seminar program, developed in partnership with SLIIDR, continues to be one of the great successes of the Center Research and Education Programs. During year 3, the seminar program features eight high-profile national speakers from: the Mayo Clinic's Vaccine Research Group, The Scripps Research Institute, the University of San Antonio, Johns Hopkins University, the University of Alabama at Birmingham, Emory University School of Medicine, University of Florida Gainesville, and the University of California at San Francisco. Ten prominent local speakers from partner institutions also presented in Year 3. To date, we have hosted 24 national speakers and twenty-six speakers with local affiliations and the series continues to sustain regular attendances of over 100-150 attendees per session. The series has facilitated several new research collaborations and, importantly, the development of mentorship interactions with visiting speakers. It also clearly helps to raise the national and international profile of the Center and of research activity in Louisiana (See **APPENDIX J** for Seminar Programs in Years 1, 2,and 3; see also Education Program, section 2 c. v. for further details).

In an important development in Years 2-3, Louisiana State Access Grid technology has been implemented to allow for greater interaction between the Center members in New Orleans and outside groups, including Children's Hospital in New Orleans, LSU School of Dentistry in New Orleans, Tulane University National Primate Center in Covington LA, LSU main campus in Baton Rouge LA and LSU Health Sciences Center in Shreveport LA.

Website Development:

The Center launched its website, www.louisianavc.org, in the spring of 2009. The role of the website is to inform Center investigators and other visitors to the site about our mission, ongoing research projects, education and commercialization activities, membership, opportunities for collaboration, funding and employment, our core facilities, our seminar series, and other news and events. The website also helps the Center to establish a profile both within the local bioscience community and also the larger research and bioscience community. During year 3, the site continued to be upgraded to include additional activities and links.

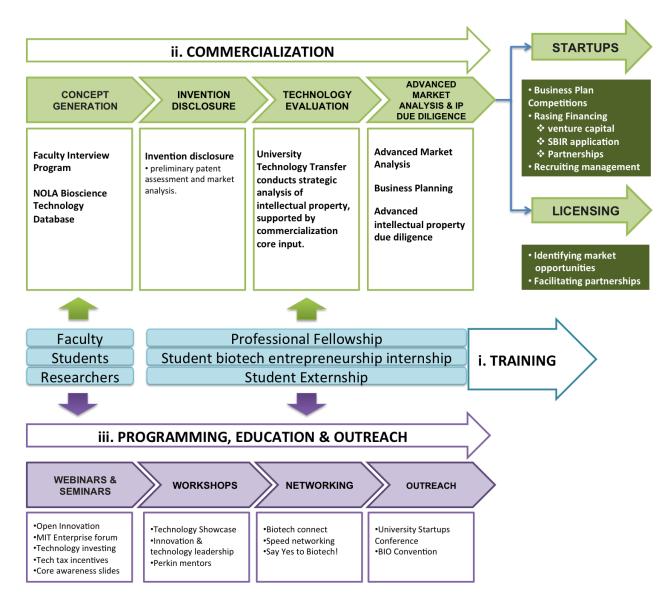
Center Outreach:

• in efforts to create partnerships with outside groups involved in vaccine awareness, the Center has reached out to several local organizations. Shots for Tots is a local organization that is affiliated with the Louisiana Office of Public Health and the New Orleans Health Department. They help to disseminate information regarding immunization in children to increase the likelihood of vaccination through education. The Greater New Orleans Immunization Network (GNOIN) is a location organization that provides mobile immunizations and services to aid in timely vaccination of infants and children in an accessible, inexpensive manner. The LVC sees our partnering with these organizations as a 'natural fit' in the broader regional biomedical community.

- the Center participated in several regional research days and scientific meetings in Year 3 in continuing efforts to establish linkages and collaborations with new partners. Alistair Ramsay (Center Director), gave the keynote "Grand Rounds Presentation" at the 20th Annual Medicine Research Day on January 8, 2010 at LSU School of Medicine in New Orleans. His talk, entitled *New Approaches to Vaccine Development*, discussed the past, present and future of vaccine development as well as current, on-going research projects in the Center, particularly in the areas area of tuberculosis infection and host immune response.
- the Center was an official participant in the Louisiana NCRR/IDeA 2010 Biomedical Research Symposium on January 22, 2010 in Baton Rouge, LA. The meeting was addressed by Dr Barbara Alving (Director of NCRR, NIH) and attended by several other NIH officials. The symposium was sponsored by several regional NIH-funded COBRE training programs, including the LSU INBRE-LBRN and the COBRE-CEIDR; the LSU School of Veterinary Medicine; the LSU College of Basic Sciences; Pennington Biomedical Research Foundation; and the LSU Office of Communications and University Relations. The purpose was to highlight research progress in the Louisiana NCRR/IDeA Community and promote collaboration and interactions among members (see APPENDIX E for LVC Abstract and Poster Presentation).

(b) Commercialization Program

An important goal of the *Louisiana Vaccine Center* is to promote the development of our research with the ultimate aim of clinical translation and commercialization. A schematic overview of our Program plan is outlined below, including: Commercialization Building Blocks, Commercialization Programming, and Education and Training resources. Details of this schematic are discussed in subsequent sections.



The Commercialization and Programming initiatives are designed to facilitate the translation of new inventions into commercially viable initiatives while raising awareness, collaboration, education and networking among Center members and outside life science professionals. Programming initiatives 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 potential interactions between Center members and different local stakeholders involved in research development

and commercialization. The commercialization track illustrated in the diagram above includes: concept generation (which typically entails invention identification and disclosure), technology evaluation, advanced market analysis and due diligence for intellectual property, as well as facilitating startups and licensing. Underlying Building Blocks include student training in bioscience entrepreneurship through internships, externships, and fellowships for young professionals; and interviews with Center faculty in order to raise awareness of the potential for research commercialization, and then to actively facilitate commercialization of Center research. Each of these building blocks is discussed below.

i. Training:

An important initiative in the commercialization strategy of the Vaccine Center is to expose local business and law students to research commercialization and biotechnology through internships and externships. By training students with interdisciplinary backgrounds in technology development and commercialization, they will aid in strengthening entrepreneurship in the Center and, potentially, Statewide. Typical student intern recruits are pursuing advanced degrees in business or law, and have a background in science with an interest in areas such as biotech business development, entrepreneurship and patent law. This training program allows them to interact meaningfully with Center researchers on novel inventions, and in turn, participate in research commercialization support for Center investigators and the technology transfer processes at the relevant partner universities. Over the life of the LVC student internship program, a total of 22 interns and 2 externs have been engaged within the various commercial initiatives of the Center. In year 3, eight student interns and one extern were engaged part time in the commercial projects of the Center, with some turnover between semesters based on the students' academic curriculum. The interns formed the basis of two interview teams, each composed of both law and business students, which conducted Faculty Interviews (see Section 2 b. ii. A, on p34-36) in an ongoing expansion of our efforts in Years 1 and 2.

The externship collaboration with the LSU Law School in Baton Rouge initiated in year 2 continued over the past year. Externs, typically senior level law students with a scientific background and interest in health/patent law, complete up to 100 hours of activities in their area of interest, for which they are supervised by their law school mentor and obtain course credit. Externs are typically involved in provisional patent writing, supervised by both their faculty mentor and the attorney that will ultimately draft the patent application for the technology in question. Engaging law students in provisional patent writing provides not only practical experience to the student externs but is an economical way for the Center to augment its level of due diligence related to invention patenting.

A novel initiative instituted by the Center in year 3 is a <u>technology development fellowship for young professionals</u>. Fellows are typically recent graduates with interdisciplinary backgrounds covering science, law, and/or business, who have completed a successful student internship or externship in research commercialization, and who also have a clear interest in technology entrepreneurship. Fellows will participate in the management of projects with commercial potential and will primarily be involved in activities such as writing business plans for startup ventures and facilitating commercial collaborations. The fellows will also manage small teams of above mentioned student interns and will guide them in venture planning and business plan writing, and will manage interaction between the student teams, academic inventors, any entrepreneurs who may be involved with specific projects, and the university

offices of technology development. In the event that an independent startup arises from this process, fellows will also facilitate its development through managing business plan competition entries, small business innovative research (SBIR) grant applications, and facilitating seed financing. They would then be well-positioned to be among the initial hires of the startup company to help drive the business forward. Over the past year, the Center engaged three fellows who were subsequently involved in a number of Center related commercial projects and startups as outlined below. Over the course of the past year, one of these fellows became the initial hire of a local startup companies initiated through NOBIC, and was therefore the first working example of a student intern from our program transitioning into a fellowship role and ultimately leading a local technology startup.

All activities of the student interns, externs and fellows are overseen by the commercialization facilitator and the NOBIC director (a member of the Center Steering Committee).

Year 3 training roster

Student Interns



Daniel Beuke

Daniel is a student intern specializing IP law and international patenting. He is completing a JD from the Tulane University Law School and holds a BFA from the university of Massachusetts. He has worked as Senior Editor in the Trademark and Patent Design Department for the Kim and Chang law office in Seoul, Korea.



Adaire Chatry

Adaire is a student intern specializing in technology needs assessments. She is completing an MPH in Epidemiology from the LSU School of Public Health and holds a BS in Biology and Business from the University of Dallas. Adaire has worked in technology development with the University of Dallas and had marketing experience in with Praxis.



Ashton Prat

Ashton is a student intern specializing in market analyses of technology related innovations. He is completing an MBA from the A.B. Freeman School of Business, Tulane University and holds a BS in Evolutionary Biology from Tulane University. He has worked as a General Manager with MLU Services, Inc. in Athens, GA.



Erin McLaughlin

Erin McLaughlin is a student intern specializing in intellectual property. Erin is a 3L law student at Tulane Law where her focus is intellectual property and corporate law. Erin holds a B.S. in Biology from Union College, NY. She has worked as a legal clerk with the United States International Trade Commission in Washington DC, focusing on patent litigation.



Cesar Solorzano

Cesar Solorzano is a student intern specializing in market analysis and corporate strategy. He is completing an MBA from the A.B. Freeman School of Business, Tulane University and holds an industrial engineering degree from Universidad Rafael Landivar in Guatemala City. Cesar has extensive experience in corporate development and has worked in corporate development at J&J, PepsiCo, and P&G.



Austin Ramsay

Austin is a student intern specializing in technology assessment and intellectual property. He is completing a J.D. from the Tulane University Law School and holds as BS in Neuroscience from Tulane University. Austin has over 3 years of research experience with Tulane School of medicine in the area of bone marrow derived stem cells.



Alexander Chan

Alexander is a student intern specializing in accounting, finance and financial forecasting and modeling. Alex is completing a Masters Degree in Accounting from Tulane University and holds a BS in finance accounting from Tufts University. Alex has experience in financial management with Deloitte.



Kristopher Ryals

Micah Fincher

Kris is a student intern working on the commercialization website design and the skills and capabilities database. He is currently pursuing an MS in computer science from UNO. His work experience includes developing in-house applications using C #, .Net and SQL,



Student externs

Micah is a student extern specializing in provisional patent writing. He is completing a JD from the Louisiana State University Law School and holds a BS in Biological Engineering from LSU. Micah has completed the USPTO patent bar examination and is a registered patent agent. He has completed 100 hours of provisional patent writing related to a novel photocaging hydrogel photopolymerization method invented by Center researchers. This invention was disclosed to the university tech transfer office prior to commercialization team inception, why it is not listed as a team-facilitated disclosure.

Young professional Fellowships



Justin Levy

Justin is currently a resident fellow in NOBIC/LVC specializing in legal research, intellectual property laws and patent prosecution. Justin holds Bachelor of Science in Biomedical Engineering from Boston University and a Juris Doctorate from Tulane University Law School. He has experience in copyright iteration and energy regulatory law from Entergy and Durationator, a copyright related startup.



Damon Bowe

Damon is currently a resident fellow in NOBIC/LVC specializing in legal research, intellectual property laws and patent prosecution. Damon holds a Ph.D. in Pharmacology & Toxicology from the University of Alabama at Birmingham. He has a J.D. from LSU Law. Damon has conducted research at Tulane, Memorial Sloan-Kettering Cancer Center, and the Medical University of South Carolina. He has experience working with Merck & Co. in Safety Assessment and has provided lectures to Tulane medical students on FDA Regulatory Law.



Justin Peno

Justin was a resident fellow in NOBIC specializing in the strategic development and market research of intellectual property. Justin holds an MBA from the A.B. Freeman School of Business, Tulane University. Justin has experience writing business plans and in the commercialization of several startup businesses. Justin has worked in the health care industry for several years and as a consultant for Booz Allen Hamilton, among others. He is currently director of business development for NuMe Health, a New Orleans startup company in the area of medicinal foods.

ii. Research Commercialization: Over the past three years, the Center has focused on building a comprehensive commercialization program to facilitate research development and to complement existing institutional technology transfer infrastructure. The process of commercial research development in the Center begins with concept generation facilitated by structured interaction between the commercialization team and Center researchers using a faculty interview process. The LVC commercialization program actively engages Center faculty in the identification of novel inventions related to their research using a systematic faculty interview outreach program to learn more about the ongoing research within the Center. This process aids in facilitating collaborations and in identifying novel inventions that can be put on a track towards commercialization. Inventions with commercial potential are ushered through the disclosure process by research commercialization teams including fellows, student interns, and student externs overseen by the Commercialization Program coordinators and NOBIC. A comprehensive invention disclosure is produced for the university technology transfer

and development office in order to initiate institutional technology transfer processes, and a customized commercial recommendation (including a prior-art search related to the underlying intellectual property and a marketability analysis) is presented to the relevant partner institutional tech transfer office for each identified invention. This process aids in the institutional decision making process of whether to invest in the relevant intellectual property. When appropriate, the invention is further evaluated through a detailed market analysis and evaluation of competing intellectual property as the basis for formulating a business or marketing plan. In subsequent steps, inventions will be supported with marketing plan development in the case of licensing, or technology-tailored business plans in the case of startups, to facilitate their commercial development.

The following sections (a through e) follow the upper (green) part of the diagram on page 29 in detail.

a. Concept Generation and Faculty Interview Program

CONCEPT GENERATION

Faculty Interview Program

NOLA Bioscience Technology Database Center researchers generate inventions and other commercial opportunities often as a byproduct of their academic research programs. Novel academic inventions with commercial potential are not always identified and actively pursued as commercially relevant projects within the universities, mainly due to a lack of awareness and/or different institutional emphasis. The Vaccine Center has now developed a rational process for identifying and supporting the inventions of its members. This includes a faculty interview program, an actively supported invention disclosure process, and creation of a collaborative biosciences technology database.

Faculty Interviews: This initiative continues to be a great strength within the Commercialization Program and is fueled by student interns. The purpose of these interviews is to consult with Center investigators on a regular basis to learn more about their ongoing research projects. In this effort we have, to date, been able to foster new research partnerships and explore and facilitate potential commercial opportunities. The development of research towards commercialization is a multi-step process and clearly, not all research is aimed in this direction. However, the Center emphasizes the importance of commercial and translational potential of its members work, including any funding opportunities that are available and might assist in this process. Examples include, identifying potentially novel inventions that have not yet been disclosed and possible sponsored research agreements, including SBIR and STTR grant opportunities. We also use the information compiled during the interview process to complete and verify information for a locally developed Bioscience Technology Database. This login and password protected online database provides a consolidated view of available biotechnology resources in the area. It provides insight into faculty members'

areas of expertise, key lab equipment, ongoing research projects and related intellectual property. Furthermore, it maps all available core lab resources, testing capabilities, clinical resources and expertise to establish avenues for the local bioscience and academic communities to take optimal advantage of them. All of these activities are coordinated through the Institutional Technology Transfer offices with their full support.

The interview process is multi-step and organized as follows (See **APPENDIX F** for supporting materials):

*Pre-interview includes updating and verifying a researcher's profile that appears on the Bioscience Technology Database. Faculty members are provided with an updated profile compiled using information from their Curriculum Vitae. Interns also use these resources to create background folders on each researcher prior to the interview to better understand their work before meeting with them.

*Interview of one hour in duration focuses on ongoing research, commercial plans and ambitions. The interview team has a set of questions they work from in order to give the interview structure and direction. Questions cover the general areas of research, commercialization and core facility topics. For the interview, a commercialization facilitator and one of the student intern teams visit with faculty in their offices. At this time, we reiterate the intellectual property policies of each institution and discuss the relevant disclosure procedures for new intellectual property.

*Post-interview focuses on future support related to topics identified through the interview process. These areas include assisting faculty to assess potential commercial viability of their discoveries and fully exploring commercialization options (e.g. assistance with SBIR grant applications, invention disclosures, research collaborations, etc). Each team also completes an interview summary in order to document matters discussed and to determine plans, if any, for follow up.

Through the initial and follow-up interviews with faculty, we obtain a comprehensive understanding of the research areas, ongoing projects and potentially novel inventions in Center labs. In order to obtain interview feedback and metrics in regards to researcher need for commercial support and education, a post-interview questionnaire is used to obtain feedback on the perceived value of the interview and to pole for topics of interest for future commercial education events and seminars. Responses to the questionnaire are anonymous.

To date, the commercialization teams have interviewed a total of 39 Center faculty members with expertise in the areas of infectious disease research and vaccine development, including 24 during Year 3. This effort has led directly to the pursuit of 25 inventions, 18 of which are relevant to the areas of infectious disease research and vaccine development. These invention disclosures are listed below under the invention disclosure segment of this report (see page 38).

The faculty interview process has been well received by Center researchers, and by partner university administration and technology transfer offices. This is reflected in the responses gathered by those interviewed in our anonymous feedback questionnaire. See the table below of feedback gathered from faculty members that have completed the interview multi-step process. See **APPENDIX G** for questionnaire response metrics.

Interview Feedback How would you rate the following aspects of the recent faculty interview?	Rating Score 1-Disagree; 2-Somewhat Disagree; 3-Neutral; 4-Somewhat Agree; 5-Agree
The goals of the interview were sufficiently clear	4.7
to me.	
The interview length was appropriate.	4.8
The interview team was friendly and courteous.	5.0
My questions were adequately answered.	5.0
My expectations were met.	4.9

A majority of Center faculty found this exercise to be extremely valuable. Many gained knowledge regarding the research commercialization process of which they were not previously aware. The interviews were highly productive and have added much to the interviews and follow-up. As a result of this initiative, we have found that many Center faculty members now actually take the initiative to seek us out when they have questions and potential commercial outcomes arising from their research. Moving forward, our plans are to focus efforts on developing promising projects resulting from faculty interviews in Years 2 and 3, with plans to continue the interview process in parallel with follow-up of all current projects with commercial potential.

b. Invention disclosure

INVENTION DISCLOSURE

192 Researchers captured in database

70 researchers identified to interview

39 interviews completed

e. 18 disclosures

To date, Bioscience Typically many marketable technologies are not reported to the institution where they were invented, often because of the sheer amount of discovery within the university, and the degree of emphasis on IP procurement and commercial development versus publication. The Vaccine Center has developed a systematic approach to the identification of potential inventions, based on directly interacting with each researcher. Often researchers are focused on the research implications of their discoveries to a degree that they overlook potentially marketable applications of their discoveries.

Center interview teams have captured 192 contacts in the Technology Database, out of which they selected 70

researchers as the initial group for interview. To date, interviews were conducted with 39 of them. Upon identification of promising inventions by the interview teams, teams 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 through the externship program with the LSU Law School in Baton Rouge. A market analysis is performed concurrently. A comprehensive market analysis is a critical tool for selecting inventions with the greatest commercial potential. This analysis examines the potential size of a particular market, the current status of the industry and technology, and the companies that are presently in the market. The market analysis also provides insight into additional steps that may be required for an invention to reach its commercial potential, and also whether additional R&D is required. To date, as a direct result of the faculty interview process, 18 new invention disclosures arising from Vaccine Center research have been made to the partner university technology transfer offices, as illustrated in the following chart.

New Vaccine Center Technology Transfer Invention Disclosures

Category	Technology	Summary	
Vaccine	Pneumocystis pneumonia vaccine	Vaccine to treat Pneumocystis pneumonia	
Therapeutic	Stable EBNA1 binding protein	A synthetic Epstein-Barr nuclear antigen 1 (EBNA1) binding protein that links the Epstein-Barr Virus (EBV) plasmids to human cellular chromosomes with high affinity inhibits the human immune response and also provides a cleavage point for drug delivery.	
Reagent	High Yield Plasma	A pBR322 plasmid derivative that has been shown to replicate at a much higher copy number than the parent and other derivatives.	
Therapeutic	Fusion Plasma	The current technology is a retroviral vector which combines all aspects needed for RNA interference into one vector.	
Diagnostics	Cell Penetrating Peptide	A novel cell penetrating peptidomimetic agent (CPP) that when combined with Fluorescein isothiocyanate (FITC) can be used intracellularly as a fluorescent labeling molecule.	
Diagnostics	Method to diagnose T. cruzi infection using LAMP	Method for diagnosis of <i>Trypanosoma cruzi</i> using loop-mediated isothermal amplification (LAMP)	
Diagnostics	HPV Serology Test	Method for detection of human papillomavirus (HPV)	
Diagnostics	T-Cell allocation prediction theorem for vaccine subunits	T-Cell allocation into antigen tridimensional structure prediction theorem	
Therapeutic	Arsenic Trioxide as a combined therapy to treat herpes virus	Arsenic Trioxide Herpes as a Viral Latency Mechanism	
Therapeutic	Monoclonal antibody against Dengue fever	antibody still in testing phase. Attempt to encourage use of in vivo testing was considered but eventually declined.	
Vaccine	TB Vaccine	Tuberculosis Vaccine Using HspX protein	
Diagnostics	GFP assay to measure effectiveness of protease inhibitors	A high-yield screening tool for effective protease inhibitors.	
Vaccine	Nanoparticle delivery for HIV vaccine (defective HIV particles)	Nucleic acid molecules and fragments thereof containing mutations in certain genes of the HIV-1 virus that may be used as a therapeutic or prophylactic HIV vaccine.	
Therapeutic	Peptide therapy for Herpes Simplex Virus	Two residues from apolipoprotein E protein (apoE) were found to have antiviral and anti-inflammatory effects to treat ocular HSV	

Category	Technology	Summary
Therapeutic	Trichostatin A to treat normal human lung fibroblasts	Trichostatin A (TSA) as an inhibitor of Transforming Growth Factor b1-mediated a-smooth muscle actin (a-SMA), and a1 type 1 collagen to treat normal human lung fibroblasts (NHLFs).
Therapeutic	Stem Cells for inflammation	Pro- or anti-inflammatory mesenchymal stem cells.
Device	Novel integrated rodent tail vein injection apparatus	Rodent restraining and warming device
Device	Novel rat denture as a model for studying biofilms / advanced materials	Removable intraoral device for rodent research

c. Evalution of Technology

TECHNOLOGY EVALUATION

University
Technology Transfer
conducts strategic
analysis of
intellectual property,
supported by
commercialization
core input.

Following the initial disclosure of intellectual property, the partner university technology transfer offices are responsible for determining whether the university will support patenting and commercial development of an invention. university technology transfer committed to investing in the intellectual property, the Center facilitates its commercial development and support. The Center has established a "Venture Development" process for facilitated commercialization of intellectual Based on the results of intellectual property due diligence and the market analysis, the commercialization team can suggest whether or not patent protection is valuable, the extent to which protection can be obtained, and whether a

researcher should continue development prior to public disclosure of the invention. These results are presented to the researcher and the research institution, which ultimately determine the path that will ultimately be pursued.

Even though invention disclosures typically follow a streamlined process taking only a matter of weeks to complete, the institutional assessment and (provisional) patenting process is typically more elaborate and lengthy and can take several months. For this reason, there is generally some lag time between the initial invention disclosure and an IP related outcome, especially in the form of an issued patent.

To date, 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. A table of the IP related outcomes to date and their current state of IP development is provided below.

New Vaccine Center Provisional Patents

Category	Technology	IP Stage
Therapeutic	Peptide therapy for Herpes Simplex Virus	PCT
Diagnostics	Method to diagnose <i>T. cruzi</i> infection using LAMP	Provisional Patent
Vaccine	Pneumocystis pneumonia vaccine	Provisional Patent
Diagnostics	HPV Serology Test	Provisional Patent
Therapeutic	Monoclonal antibody against Dengue fever	Provisional Patent

d. Market Analysis & Intellectual Property Due Diligence:

ADVANCED
MARKET
ANALYSIS & IP
DUE DILIGENCE

Advanced Market
Analysis
Business Planning
Advanced
intellectual property
due diligence

In order to facilitate the commercial development of Center inventions. viable technology a commercialization and marketing strategy that runs in parallel with IP procurement has been formulated. This strategy considers prevailing market forces in modeling the conceivable routes-to-market for each invention. Through market analysis, and advanced IP due diligence, the commercialization teams are able to formulate technology development roadmaps tailored to each specific invention. In collaboration with the inventors and the partner institution. the preferred route-to-market ultimately determined by consensus between the stakeholders and aligning expectations

including the level and type of involvement that the inventors want in commercialization of technology and expected Center and institutional returns on investment expectations.

Our advanced market analysis and IP due diligence also provides a useful tool for assessing the current stage of development of the technology in relation to its marketability. Even though an invention might be patentable, additional research work is often necessary to bring it to a point at which it can be licensed to either an established company or moved into a startup for final development and market launch. The research commercialization team assists in identifying the additional research steps that need to be taken to reach the next step of commercial development of

the technology, and helps identify mechanisms to achieve those research goals through identifying collaboration opportunities with either industry or academia and through identifying funding sources that can aid in supporting additional research.

Practical examples of Center related collaborative outcomes that were facilitated by the commercialization team include: (i) a drug development collaboration between the Center and the medicinal chemistry program at the University of New Orleans (UNO), (ii) a strategic collaboration with Thevac LLC, and (iii) a preferred relationship with Southern Research Institute:

- (i) UNO drug development collaboration: The faculty interview process recently facilitated a collaborative effort between a biology oriented research group in the Vaccine Center and a medicinal chemistry lab at UNO that were both investigating different aspects of a related family of compounds but were previously unaware of each other. Both groups are now collaborating on co-developing a series of novel anti-inflammatory agents with prime application in lung-related inflammatory modulating interventions like asthma treatment. This collaborative effort has already resulted in a recent R21 grant submission to NIH.
- (ii) Thevac LLC is a Baton Rouge-based biotech company focused on human vaccines and therapeutics for major infectious disease pathogens and cancer. Thevac is in the process of licensing work on vaccines for breast cancer and herpes simplex infections that is patented through LSU-BR. The Center now has an ongoing research collaboration with the Thevac, focused on furthering a flavivirus-related IP position and combined research interests, as well as co-developing novel vaccination strategies for a number of emerging infectious diseases. This collaboration has also created new SBIR grant-funding opportunities that are currently being evaluated as an avenue to support further research and development in the Center.
- (iii) Southern Research Institute (SRI) is a Birmingham, AL-based research and contract research organization with a very strong and established pre-clinical vaccine-validation program. SRI has recently established a satellite office at the New Orleans BioInnovation Center with the distinct goal of increasing its interactions in the region. This gives the Vaccine Center preferred access to SRI researchers and pre-clinical validation facilities for vaccine candidates emerging from its program. As the research commercialization program of the Center matures, the relationship with SRI is expected to result in the co-development and validation of new candidate vaccines.

e. Startups and Licensing:

Commercialization of scientific discoveries typically follows two distinct paths: licensing the technology to an established firm or creating a new venture. Successful technology transfer combines intellectual property due diligence with market research to identify the best path for new inventions. The Center commercialization teams, including fellows, interns and externs, support this process by facilitating the strategic development related decision-making process.

Licensing is favored when a technology is an incremental improvement over an existing product. These products have established markets, channels and customers that can more effectively be accessed through licensing to an existing company. The commercialization team supports technology licensing by generating shortlists of potential licensing partners, writing non-confidential technology summaries for marketing, and actively supporting the institutional offices of tech transfer in promoting and marketing technologies for licensing at industry venues like the BIO convention. These activities are discussed more in detail under the outreach segment below.



Platform technologies that form a basis for development of a range of products are the best candidates for venture creation. Because multiple products can be created, and multiple markets may be penetrated, there is greater investment security and greater opportunity for return, both factors that attract investors. The research conducted by the commercialization teams forms the basis for the development of Center-related intellectual property. Vaccine Center/NOBIC commercialization teams have now created business plans to support nascent local startup ventures. As part of this process, sharp-end venture opportunities are vetted by entering them into national business plan competitions. This is an invaluable and low-cost method for getting unbiased market feedback for a new technologies and potentially generating entrepreneurial and seed finance-related

contacts. Such contacts often include investors, advisors, or management for the startup.

By housing the LVC-related commercialization resources at the New Orleans BioInnovation Center, a local bioscience technology incubator aimed at supporting biotech related startups, interaction between LVC commercialization teams 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 two business plans that are now emerging from the LVC commercialization program, with further potential developments in the pipeline:

1. **HomePoint Testing** is a proposed startup company that will develop and commercialize home diagnostic kits based on proprietary in-licensed methods developed in the Louisiana Vaccine Center. The Company plans to develop kits to allow for the convenient, self-diagnosing of common but often serious conditions such as HPV, vaginal candidiasis, and others. HomePoint will employ a multi-stream revenue model including direct- to- consumer marketing of home diagnostic kits for consumer use as well as the out-licensing of proprietary methods for the development of clinical diagnostics for professional use. By providing users with a way to make a self-diagnosis in a private, inexpensive, and easy-to-use manner, HomePoint could lower both diagnostic and treatment costs while simultaneously improving outcomes.

The Company's first product will be a serological HPV test, the HPV-Inform, for both women and men either considering HPV vaccination or for those wishing to monitor protection from past HPV vaccination. Although approximately 75% of girls and women claim their interest in receiving the HPV vaccine, studies show that only 33% of women actually get vaccinated, indicating that nearly 50% of these "interested" women do not follow through with vaccination. The most common reasons cited for not getting vaccinated include lack of awareness about HPV infection, concern with vaccine safety, and cost of vaccination. The HPV-Inform will serve to increase awareness about HPV infection while eliminating the need to receive the vaccine for many women concerned with its safety and cost. Additionally, the HPV-Inform will validate the need for many women to receive the vaccine who otherwise would not have.

The HomePoint business plan is currently under development and will be entered in business plan competitions nationwide upon completion 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.

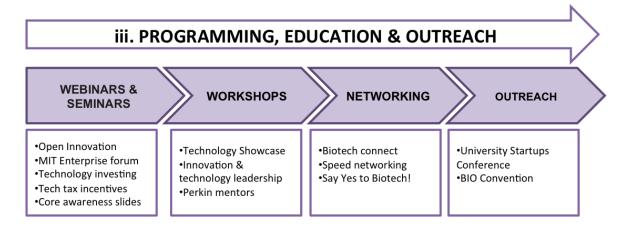
2. **MiniVax** is a proposed vaccine company that will develop vaccines for a variety of fungal pathogens including *Candida albicans*, *pneumocystis carinii*, and others. The company's vaccine platform will be based around a novel engineered antigen discovered at the Louisiana Vaccine Center and termed "mini-kexin". This platform will allow the company to address a range of fungal diseases for which effective treatments are lacking.

Fungal pathogens continue to be a major source of infection in the US with an absolute incidence rate above 1%; however, among viral, bacterial, and fungal diseases, the latter remain the only category without a vaccine. MiniVax will initially focus 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 immuno-suppressed individuals are treated prophylactically. MiniVax plans to utilize both strategic partners and the FDA's Orphan Drug Designation to bring the vaccine through clinical trials, scale manufacturing, and distribute worldwide.

The MiniVax business plan is currently in early stages of development and will be entered in business plan competitions nationwide upon completion either spring of 2011. Entrepreneurial interests and SBIR opportunities for this startup have been identified and are being pursued.

iii. Programming, Education and Outreach:

To better serve the educational goal of raising general awareness of research translation and commercialization as a logical outcome for academic research, particularly in the Vaccine Center, but also among other members of the local biomedical research community, the following four initiatives were conceived to bring local universities, the business community, and economic development professionals together (as illustrated in the following chart):



a. Webinars and seminars are organized to enable local university, business community, and economic development professionals in New Orleans to learn about different aspects associated with technology commercialization. Seminars are typically organized with local or visiting speakers, whereas webinars are broadcast at a local venue but typically feature remote-site speakers. Aside from providing educational content, these seminars and webinars also facilitate interactions between peers and stakeholders in the local technology commercialization ecosystem. Over the past year, the LVC commercialization team has organized 1 live seminar and 5 webinars which are described below (Full size event flyers are provided in APPENDIX H):

The R&D Tax Credit Seminar was presented by Susan Bigner from Louisiana Economic Development and was aimed at educating New Orleans' researchers, clinicians, entrepreneurs and industry representatives involved in R&D about tax credits available to promote the growth of the research and development industry in Louisiana.

The Open Innovation Webinar on government research funding programs that support university-industry collaborations at the National Institute of Standards and Technology (NIST) was presented by Dr. Lorel Wisniewski, the Deputy Director of the TIP Program at NIST, and was organized to educate the local community on collaboration opportunities with NIST.





The Open Innovation Webinar on building strategic relationships between industry and universities was presented by Helmut Traitler, V.P. Innovation Partnerships with Nestle and was organized to educate the local community on collaboration opportunities with industry.

The <u>Creating Value Through Sustainability</u> webinar was hosted by the MIT enterprise forum in Atlanta and discussed the effect of the green movement on business.

The Breakthrough Medical Technologies webinar hosted by the MIT enterprise forum was presented by MIT Institute professor Robert Langer and discussed the process of and excitement that comes from discovery, the challenge of acceptance from the scientific community, obtaining rights to your intellectual property, and the winding road to commercialization.

The <u>Tough to get growing</u>, <u>How to succeed</u> in a down economy webinar hosted by the MIT enterprise forum discussed how The current economic climate doesn't mean companies can't succeed. It just means the *WAY* a company succeeds has its own unique challenges. It discussed real-world experiences of entrepreneurs going from start-up to success story.



<u>Commercialization Program awareness slides</u>: as mentioned in the Research section, a successful program of the Core Awareness slides has been developed that display the mission, services and equipment available in Center Core Facilities. We therefore decided to develop a similar slide show to advertize the expertise of the Commercialization Program. This slide show will be shown prior to local

speaker presentations in the LVC/SLIIDR seminar program in order to better inform Center investigators of the technology transfer assistance that the Program can provide (see **APPENDIX I** for Commercialization Program slide show.)

b. Workshops are organized around defined topics to expose specific target groups related to tools that may be required to succeed in biomedical research commercialization. A new initiative that will be instituted by NOBIC and the Vaccine Center in the coming year is a business-mentoring workshop series. This industry-funded initiative will bring in technology experts and experienced entrepreneurs to share their insights and ideas with nascent startup companies to help them get going. Mentors will be selected based on their expertise that has to be closely related to the area of the planned Vaccine Center startups. Workshops organized over the past year include a 2-day workshop on Innovation and Technology Leadership, and a technology showcase workshop. Both of these workshops are described briefly below (full sized event flyers are shown in APPENDIX H).

The 2-day workshop on Innovation and Technology Leadership provided an insight into the dynamics of technology acquisition, and how the integration process is managed. The workshop also provides tools on how to structure successful deals and manage the relationships of integrating external technology sourcing into business processes.

The technology showcase VC open house workshop in which 3 local startups presented their business to a panel of experienced investors was geared towards the VC's sharing insights on how they perceive investment opportunities, and what makes deals attractive. Insights and learning aided presenting startups in optimizing their business plans and investor pitches.



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c. Networking events are organized by NOBIC in conjunction with the Vaccine Center to provide a forum for scientists, entrepreneurs, business facilitators, lawyers, and venture capitalists to interact. These groups do not usually mix, but their interaction is necessary and important for the economic development of local biotechnology. Over the past year, 3 networking events were organized including a speed networking session, a biotech-connect social, and a keynote luncheon termed "Say Yes to Biotech!" These events are described in more detail below (Full size event flyers are provided in **APPENDIX H**).

The <u>Speed networking reception</u> were aimed at overcoming the challenge of forming scientific and business relationships, and promoting interdisciplinary professional interaction in the science and technology arena in New Orleans.



The <u>Biotech Connect</u> networking event was focused on networking amongst life science professionals in the New Orleans area. Attendees included academic researchers, local entrepreneurs, attorneys and other stakeholders interested in technology commercialization.



- d. The Outreach program focuses on raising Center awareness and fostering collaborations nationwide. Over the past year, the Center was a participant at two major National/International research development and commercialization related events including the 2009 University Startups conference organized by the National Council on Entrepreneurial Tech Transfer in Washington DC and also the 2010 International Bio convention in Chicago, as a featured exhibitor. Building on past years, the Vaccine Center presence in the Louisiana delegation helped to build 'brand awareness' of the Center and facilitated interactions with opinion leaders in the areas of academic technology development and the biotechnology industry.
 - for its 2009 university startups conference, The National Council of Entrepreneurial Tech Transfer (NCET2) partnered with the Science and Technology officials at the various Washington Embassies to include international universities, investors and corporations in Council programs and activities. The NCET2 University Startups Conference is a unique conference dedicated exclusively to creating and funding globally-competitive, venture-backed university startups. It brings together universities creating startups with VCs, angel investors and Fortune 500 technology scouts funding them. The conference also includes NSF, NIH, NIST and other government agencies working on improving the Innovation Economy by increasing the quality and quantity of startups coming out of universities.
 - the 2010 BIO International Convention was held at the McCormick Conference Center in Chicago, IL from May $3^{rd} - 7^{th}$, 2010. BIO is recognized as the world's largest gathering of the biotechnology industry. The Vaccine Center had three members in attendance: Steve Ceulemans (Commercialization Coordinator), Damon Bowe (LVC Fellow), and Justin Levy (LVC Fellow). The Center also participated, in coordination with the New Orleans BioInnovation Center, for the second time as a member of the Louisiana Pavilion on the BIO exhibit floor. Several meetings were organized on both the exhibitor floor and at the business-partnering forum to facilitate collaboration between the Center and the biotech industry. Both of the LVC fellows were heavily involved in pre-conference preparation of technology documentation, scheduling meetings with industry representatives and partnering forum attendants. Through BIO, we were able to introduce three Center-related nonconfidential technology summaries in the fields of infectious disease treatment (dengue fever and herpes simplex virus) and modulation of inflammation by stem cells, to a shortlist of potential licensing partners and/or commercial collaborators identified in advance. Each technology was marketed to several major pharmaceutical players in the relevant area to raise technology interest and to facilitate a dialog. To date, one of these companies has confirmed active further interest in the stem cell immune modulation, and one investor group has expressed interest in co-developing the dengue therapeutic. participation at BIO, we plan to continue to gear our efforts towards specific BIO conference offerings especially in the area of business partnering. For our presence in the exhibitor hall as part of the Louisiana pavilion, we will continue focusing on key services and partnering opportunities our initiative has to offer. This would primarily include marketing Center member's technical capabilities and interests as well as affiliated laboratory (core facility) testing capabilities and their specialized equipment resources.

(c) Education Program

During Year 3, there have been several enhancements to the Education Program. The Summer Internship Program has continued to develop, providing research experiences for students from local high schools and also colleges throughout the country the opportunity under the direction of Center researchers. Many of the college students are home in Louisiana for the summer and the Summer Internship Program represents a potentially important recruitment tool for bringing them back to the State for graduate or medical school training. The Infection, Immunity and Vaccine Seminar Program is highly successful, with the presence of several high-profile outside speakers leading to increased opportunities for collaboration and mentorship. The goal of the Bioscience Education Training Program is to help develop an educated local workforce for placement in local bioscience research and development labs. The first round of graduates from the BET program have each found placement in local labs, some within the Center itself, or will undertake further study. Activity in each of these areas in Year 3 and overall impact is outlined below.

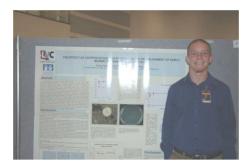
i. Summer Internship Program (SIP) – Education and Training in vaccine-related research:

Since its inception, a total of 40 students have participated in the Summer Internship Program. We have recruited some of the best and brightest Louisiana students to work side by side with LVC scientists over the summer. This program teaches the students about career options in science, keeping a lab notebook, how to analyze and present their data, and responsible conduct of research. The students all participate in a Summer Research Poster Session that is attended by all the interns, their mentors and the members of their lab. As is evident from the Table below, the undergraduate summer students attend universities throughout the United States. The Summer Internship Program is an important recruitment tool for bringing them back to Louisiana for graduate or medical school training. By forming mentoring relationships with the students, we strive to stay connected with them and cultivate their continued interest in research careers.

In the 2010 SIP, there are three high school students, 10 undergraduates, 6 medical students, and 1 MD/PhD student. Fifty-five percent of the participants are female and 5% are minority students. At least 25% of the students are eligible for the year-long scholarship that supports their continued research because they are from local universities.

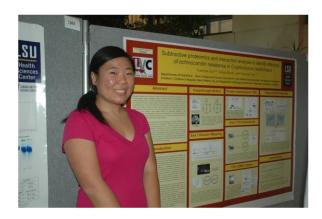
This year there are five additional students in the 2010 program. Funding for these students was obtained through NIH ARRA summer student supplements to LVC investigators' R01 grants (including Alistair Ramsay PhD, Center Director; Jay Kolls MD, Center Steering Committee). The education program facilitated the submission of these supplement applications. We also have six medical students funded by the Office of the Dean at LSUHSC who are working with LVC mentors. One of these, Michael Ripple, is enrolled in the LSUHSC M.D./Ph.D. program and plans to complete his Ph.D. research with LVC researcher, Jay Kolls.

Accomplishments of the student interns:



Examples of the impact that this program has had on the students include Phillip Calmes who participated in the summer of 2009. Phillip is now enrolled in the LSUHSC Interdisciplinary Graduate Program.

Betsy Bateman is completing her second summer as an intern. She was recently named Louisiana's female Presidential Scholar. The Presidential Scholars Award 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 will attend Tulane University in the fall.



Yuanyue Sun, who attends the University of Southern California, won for the best undergraduate poster presentation in the summer of 2009. She worked with Center investigator Dr. Deborah Fox on a project titled "Subtractive proteomics and interaction analysis to indentify effectors of echinocandin resistance in *Cryptococcus neoformans*".

ii. Post-Internship Evaluation:

Each year we conduct a Post-Internship Evaluation of the interns at the end of the summer. This measures students' satisfaction with their mentor, their lab and the impact of their experience has on their career goals. Students also 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. Goal Attainment Scaling is an outcomeoriented method of program evaluation that has been successfully used to evaluate other summer internship programs (1).

Data from the last Post-Internship Goal Attainment Scaling survey generated in 2009, are tabulated below. Students ranked their goal attainment in eight dimensions ranked into five different outcome

levels, 1-5 with 5 being the "Best Anticipated Success". The overall Goal Attainment score for the student group was 29.7. The Table below summarizes the scores by dimension.

Post-program mean dimension scores for the student interns

Dimension	Mean Score
Understanding of Project	3.7
2. Interest in Project	2.3
Conducting Independent Research	4.3
4. Knowledge of Research	3.4
5. Clarification of Career Plans	3.3
6. Personal Growth	4.5
7. Satisfaction with Program	4.5
8. Completion of Reporting Requirements	3.0

Based on these results, we will work to strengthen the interest the students have in their projects. The other dimensions are well within the range of those found in the published study.

In the current year, we will introduce 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 (2, 3). We will use a hard copy version of the survey for all our interns, high school, undergrads and medical students, which will be administered at the same time as the Goals Attainment Scaling tool.

- 1. The Use of Goal Attainment Scaling to evaluate a cancer research training program for high school and college students. Cookfair DL, Zevon MA, Mirand EA, Cancer Education Vol 1 (4) pp255-263, 1986.
- 2. Survey of Undergraduate Research Experiences (SURE): First Findings. Lopatto D, Cell Biology Education. Vol 3, pp270-277, 2004.
- 3. Undergraduate Research Experiences Support Science Career Decisions and Active Learning. Lopatto D, CBE-Life Sciences Education. Vol 6, pp297-306, 2007.

iii. Year Long Student Research Experience:

Each year we encourage LVC mentors to nominate student researchers whom they would like to continue working with throughout the year. In 2009, Tim Tate was chosen as the student who would continue his research. Tim is a New Orleans native who graduated with honors from Brother Martin 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 Kyle Happel MD entitled: "Ethanol intoxication and CXC chemokine response to *S. aureus* pneumonia". In both 2008 and 2009, he participated in the LVC summer program, working with Lisa Morici PhD (Center Investigator and Pilot Grantee) in the Department of Microbiology and Immunology at Tulane University Health Sciences Center. He worked on two projects - a collaborative effort between Morici and Vijay John PhD, and also with Morici on an antibiotic coated surgical mesh for use as a controlled drug release system. This research was presented the annual meeting of the American Institute of Chemical Engineers in November 2009. Tim was a co-

author on the abstract entitled: "Breath Figure Thin Films of Biodegradable Polymers for Controlled Antibiotic Release".

Tim has also been working with Morici on OmpW as an immunogenic protein that is present in the outer membrane of the gram-negative bacillus *Burkholderia thailandensis*. They believe that this immunogenic protein is a potential vaccine candidate against *Burkholderia pseudomallei*, a gram-negative pathogen capable of causing respiratory problems, septic shock, and/or death. Using a reverse vaccinology approach, Tim has assisted with the cloning and purification of a recombinant form of OmpW. Balb/C mice have been immunized with OmpW and adjuvant, using a prime-boost strategy. Serum from the mice was harvested for use in western blot experiments. Currently, Tim is using extracts from *B. thailandensis* total membrane protein on western blots probed with the OmpW-immunized mouse sera. The group plans to determine: a) whether the mouse was able to make antibodies against the recombinant form of OmpW, b) determine if OmpW is present in the TMP, c) Determine the highest concentration of sera/antibody capable of detecting OmpW in the TMP fraction. Tim is co-author on a paper published in Microbial Pathology (2010. Jan; 48(1):9-17): "Differential susceptibility of inbred mouse stains to Burkholderia thailandensis aerosol infection.



Timothy Tate and Dr. Lisa Morici

Tim is currently entering his junior year at Tulane University. His original plan prior to his LVC internship was to attend dental or medical school upon completing his college degree. Following his research experience, his plans have changed towards a future in basic science research, in particular vaccine research. He therefore plans to apply to a graduate program or an MD/PhD program after graduation from Tulane University. He described his LVC internship as having opened career opportunities which he had otherwise experienced. The Center considers that this is an ideal outcome of the Year Long Student Research Experience program.

2010 Summer Internship Student Participants

Student	LVC Mentor	Academic Level	School
*Srihasa Allam	Hobden LSUHSC-MIP	High School	Grace King H.S.
*Manal Awan	Aiyar LSUHSC-MIP	Undergrad	Loyola Univ.
Betsy Bateman	Marble Children's Hosp	H.S./Undergrad	Mandeville H.S./Tulane
Christina Chen	Cefalu LSUHSC-Endo	Undergrad	Univ of Chicago
*Patrick Cherry	Sturtevant LSUHSC-MIP	Undergrad	Hendrix College, AR
Milad Elhajj	Venuti LSUHSC-CB&A	Undergrad	Loyola Univ.
Rebecca Hron	Neumann LSUHSC-Ophth.	Undergrad	Tulane Univ.
Madeleine Jansen	Lasky TU-Pulm	Undergrad	Stanford Univ.
Hannah King	Pandey LSUHSC-Genetics	Undergrad	Univ. of Mass.
Tichelle Porch	McLachlan Tulane	High School	Patrick Taylor H.S.
Spencer Robichaux	Amedee LSUHSC-MIP	Undergrad	Spring Hill College
Anjelle Rogers	Morici Tulane	High School	St. Mary's Acad.
Donald Stewart	Jacob LSUHSC-Ophth	Undergrad	Virginia Tech
*Richard Tang	Ramsay LSUHSC-Gene Therapy	H.S./Undergrad	Ben Franklin H.S. /Tulane Univ
John McIntire	Pincus Children's Hosp	L1/LSU Med Sch	n/a
Justin Miller	Cormier LSUHSC-Pharm	L1/LSU Med Sch	n/a
Megan Poynot	Aiyar LSUHSC-MIP	L1/LSU Med Sch	n/a
Michael Ripple	Kolls LSUHSC-Genetics	L1/LSU Med Sch	n/a
Laura Roan	Dickinson Children's Hosp	L1/LSU Med Sch	n/a
Michael Rolfsen	Thompson LSUHSC-Ophth	L1/LSU Med Sch	n/a
*funded by NIH ARRA supplement			

iv. Plans for NIH funding:

To expand the scope of the Education Program through complementation of Center funding, the Program plans to submit two NIH grant applications in the fall of 2010, both to the NIH/NIAID:

- the T35 mechanism supports short-term research experiences for students in professional schools.
 This application will be 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.
- the R25 mechanism supports science education grants. This application is based on a former ARRA application "Rebuilding Science Education in New Orleans"; it would support partnerships between LVC faculty and New Orleans high school science teachers.

v. Infection, Immunity and Vaccine Seminar Program:

The IIVSP seminar program, developed in partnership with SLIIDR, is a major and ongoing success of the Center. During year 3, the seminar program features eight high-profile national speakers, including Gregory Poland, Director of the Mayo Clinic's Vaccine Research Group, and Bruce Beutler, Professor and Chairman of the Department of Genetics at The Scripps Research Institute. Other visiting speakers hail from the University of Texas at San Antonio, Johns Hopkins University, the University of Alabama at Birmingham, Emory University School of Medicine, University of Florida Gainesville, and the University of California at San Francisco. Ten prominent local speakers from partner institutions also presented in year 3. To date, we have hosted 24 national speakers and twenty-six speakers with local affiliations and the series continues to sustain regular attendances of over 100-150 attendees per session. The program has exposed large numbers of Center faculty, postdocs, graduate students and medical students to high-profile national and local researchers, with an extensive program of follow-up meetings with visiting speakers. The series has facilitated several new research collaborations and, importantly, the development of mentorship interactions with visiting speakers (see **APPENDIX J** for Seminar Programs in Years 1, 2, and 3).

In an important development in Years 2-3, Louisiana State Access Grid technology has been implemented to facilitate real-time broadcast of our seminars to multiple off-site locations in the State. This development has clearly facilitated greater interaction with researchers, trainees, and students at these sites, including the LSU main campus in Baton Rouge, LA, and LSU Health Sciences Center in Shreveport, LA. Local sites at which our seminars are broadcast include Children's Hospital in New Orleans, LSU School of Dentistry in New Orleans, and the Tulane University National Primate Center in Covington LA,

vi. The Bioscience and Education Training (BET) Program:

The primary goal of the Bioscience and Education Training (BET) Program, developed in coordination with SLIIDR, is to help develop an educated local workforce for potential placement in research labs in

local universities and biotech. There is a distinct shortage of quality research trainees available in the region and this has hampered local research and development initiatives in the biosciences.

The BET students undergo extensive training in biosafety, chemical safety, and radiation safety and the use of animals in bioscience research. They also rotate throughout five Center core labs during the semester 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 bioscience settings.

In 2008-2009, six individuals successfully completed the BET program. Three of these are now employed in research labs at LSUHSC, two have applied to graduate programs, and one has gained employment at a local biotechnology company, pointing to the success of the BET program against its immediate goals. In Year 3, there are six new students in the program and recruitment is ongoing for a third intake.

Problems encountered in Year 3:

No specific problems were encountered that had a major impact on Center activity in Year 3.

3. CONTRIBUTIONS

Our focus has been to build upon on the successes of the research, commercialization and education initiatives of the Center, and to promote their continued growth and development. Year 3 has been marked by significant progress in each of these areas.

Our objectives are 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 research commercialization. We also aim to educate a new generation of researchers and research support staff in this important area, which is a field of great current prominence world-wide. The ultimate goal is long-term sustainability of the Center and its key initiatives.

In June 2009, the Louisiana State University Board of Supervisors approved full 5-year Center status for the Center within the LSU system. Subsequently the Center was ratified through 2012 as a Center of Excellence by the Louisiana Board of Regents.

Specific highlights in year 3 of Center activity are outlined below. We are confident that these contributions in the areas of vaccine development and infectious disease will positively impact research and development, education and economic development locally and throughout the State.

RESEARCH

- Center investigators have been awarded over \$57 million dollars in new external grants from federal and private sources in year 3, primarily from the NIH. These awards include a small business innovation grant (SBIR) for over \$3.6 million over 3 years (a collaboration between Xavier University and AutoImmune Technologies Inc), and a NIH Center grant (P20) of \$6.5 million over 5 years (a collaboration between LSUHSC-NO and Dillard University).
- External grant submissions by Center investigators in year 3 total over \$87 million, primarily to the NIH. These include a RC4 application to the NIH with a potential value of \$5.25M over three years and numerous R01 and R21 submissions to NIH in key areas of Center research.
- Center investigators have published 110 original papers in Year 3 of Center activity. A total of 232 publications have been published by Center investigators since inception.
- The Center's two-year Collaborative Pilot Research Project Fund is intended to foster the development of novel local multidisciplinary and collaborative research projects in the areas of infectious disease, immunity and/or vaccine development. As a direct result of this fund, pilot grant recipients have submitted 40 new federal grant applications, and have been awarded 12 new federal grants (including several R01s and a Career Development award from NIH) and 5 grants from other external sources. Our pilot grantees have also published 25 new papers arising from their funded research.

- The Center supported the appointment of three postdoctoral fellows to projects in vaccine-related research programs as a direct result of Center pilot grant funding: Kyla Frolich, Ph.D., Maria Lewis, MD, and Miao Luo, Ph.D.
- The Center sponsored Grant Seekers Meetings and Expert Grant Reviews, developed in coordination with SLIIDR, have facilitated the funding of three new NIH R01 grants and the submission of five additional R01 applications.
- The Center has initiated a new collaboration with vaccine researchers in the LSU School of Veterinary Medicine in Baton Rouge. This collaboration complements our existing portfolio of research and development projects and also expands our current core capabilities. The Center sees this expansion as a logical extension of our activity along the Southeast Louisiana corridor that will further strengthen our capacity to compete for large-scale research and development grants and contracts and aid in the development of regional infrastructure necessary for the development and testing of novel vaccines.
- The Center has continued to develop critical core infrastructure, contributing nearly \$600,000 for the purchase of new core equipment and supporting the employment of six research associates specifically to facilitate vaccine-related research in Center cores.
- In year 3, the Biosafety Level 3 Facility has become fully functional, fulfilling all required operational guidelines. This core is critically important for the progress and further development of NIH-funded Center research on host-pathogen interactions in *Mycobacterium tuberculosis* infection and the development of novel vaccines against TB.

COMMERCIALIZATION

- A total of 22 interns, 2 externs and 3 professional Fellows all recent graduates with interdisciplinary backgrounds covering science, law, and/or business have been engaged in commercial initiatives of the Center, including our Faculty Interview program, designed to identify Center research projects with potential for commercialization. Established in partnership with NOBIC, these internships will aid in strengthening faculty awareness of research commercialization and entrepreneurship in the Center and, potentially, Statewide.
- The Center Faculty Interview Program, conducted by teams of law and business student interns from LSU and Tulane, as outlined above, continues to play a key role in identifying faculty projects that are commercially viable and helping to develop these towards commercialization. To date, the intern teams have interviewed a total of 39 faculty members including 24 during year 3. This interview process has led directly to the pursuit of 25 new inventions, 18 of which are highly focused in the area of infectious disease research and vaccine development.
- The Center has established a "Venture Development" process to facilitate commercialization of intellectual capital. To date, abovementioned Center-related invention disclosures have led to directly to 5 new (international) provisional patents that are currently being pursued.

- Housing of the LVC-related commercialization effort in the New Orleans BioInnovation Center, has created a synergy where nascent Vaccine Center startups can immediately be entered into an existing and productive startup framework. This will provide an ideal setting for two business plans that are currently emerging from the Center commercialization program, with further potential developments in the pipeline.
- Seminars, webinars, workshops and networking events have been organized by the Center, in
 conjunction with NOBIC, to educate Center faculty in research commercialization and also
 provide a forum for the interaction of local university, business community, and economic
 development professionals in New Orleans to learn about different aspects of technology
 commercialization.
- Steven Ceulemans, the Center Commercialization facilitator, was awarded the Governor's Technology Award for University Technology Leadership from the Louisiana Technology Council in March 2010, in recognition of his key role in the commercialization of research developed at our partner universities and other local institutions.

EDUCATION

- Including our current intake, forty students have now participated in the Center's Summer Internship Program since 2008. This program teaches students career options in science, how to analyze and present their data and responsible conduct of research. The program also represents an important recruitment tool for bringing our undergraduates, who attend universities throughout the U.S., back to Louisiana for graduate or medical school training.
- A T35 grant application was submitted to NIH/NHLBI late in year 3 with the aim of further enhancing the Education Program. Two further submissions to NIH/NIAID are under development for submission in the fall of 2010 a further T35 application to support short-term research experiences for students in professional schools and an R25 application to support science education grants and partnerships between LVC faculty and local high school science teachers. These applications aim to leverage current Center support in order to further develop our successful Summer Internship Program.
- The Center's Infection, Immunity and Vaccine Seminar Program featured eight high-profile national speakers in year 3, along with a number of local presenters. To date, the Center has sponsored twenty-four visiting speakers, with significant outcomes for new collaborations and mentorship. Access Grid technology has now afforded greater interaction between the Center and outside groups by facilitating our broadcast of the seminars to off-site locations in Baton Rouge and Shreveport.
- The Bioscience and Education Training (BET) Program, developed in coordination with SLIIDR, is designed to help train an educated local workforce for eventual placement in local bioscience research labs, in this way addressing a critical local and regional need. In 2008-2009, six

individuals successfully completed the program - three are now employed in research labs at LSUHSC, two have applied to graduate programs, and one has gained employment in a local biotechnology company. There are currently six new students in the BET program and recruitment is underway for a third intake late in 2010.

4. PROJECT REVISION

Revision of original equipment requests for the Protein Core and the Immunology Core was approved by the Board of Regents on 5/17/10. The revision was necessitated by changing technologies and the needs of Center investigators.

The addition of the New Orleans BioInnovation Center (NOBIC) as a sub-contractor to the original Center contract was also approved by the Board of Regents on 5/17/10. This revision was made in order to further the goals of the Center and to meet requirements of the Office of Contractual Review.

Center of Excellence for Vaccine Development-(Louisiana Vaccine Center)

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

Year 3 Annual Report 6/30/2010

APPENDICES

APPENDIX A: LVC Core Awareness Slide Presentations

APPENDIX B: LVC Grant Seekers Meetings and Expert Grant Reviews-Listings and Outcomes

APPENDIX C: Cooperative Pilot Research Grant Fund

APPENDIX D: LVC 2nd Annual Research Meeting and EAC Meeting

APPENDIX E: Louisiana NCRR/IDeA 2010 Biomedical Research Symposium

APPENDIX F: Interview Guide

APPENDIX G: Post-Interview Feedback Questionnaire Metrics

APPENDIX H: LVC Commercialization Event Announcements: Webinars, Seminars, Workshops and Networking Events

APPENDIX I: Commercialization Core Awareness Slide Show

APPENDIX J: LVC Infection, Immunity and Vaccine Seminar Program Schedule 2010-2008

APPENDIX A: LVC Core Awareness Slide Presentations

- A1. BSL-3 Core
- A2. Genomics Core: Microarray and Bioinformatics
- A3. Vector Development Core
- A4. Molecular Interaction Core
- A5. Imaging Core
- A6. Protein Core
- A7. Nanotechnology Core

A1. BSL-3 Core







Biosafety Level 3 (BSL-3) Facility









Biosafety Level 3 (BSL-3) Facility

Objective

- To provide support for work with pathogens that require bio-containment
- Facilitate Level 3 preclinical vaccine development studies in the area of Mycobacterium tuberculosis (MTb)





Biosafety Level 3 (BSL-3) Facility

- •1040 total square feet with separate rooms dedicated to animal care and use, pathogen infection/titration and laboratory assays
- •Compliant with relevant guidelines of the Centers for Disease Control (CDC)
- •Approved and inspected by the Institutional Biosafety Committee (IBC)
- •Served by a dedicated air handling unit for cooling and heating
- •Automation controls consisting of room pressurization controllers, constant volume exhaust boxes, constant volume supply boxes





Biosafety Level 3 (BSL-3) **Facility**

Equipment

- Negative pressure HEPAfiltered animal racks
- HEPA-filtered animal bedding
 Glove box with airlock and disposal station
- Pass-through autoclave
- CO₂ Incubators

- Class II Biological Safety Cabinets
- dual exhaust HEPA filtration
- · Glass-Col nebulizer
- Ultra cold freezer (-70°C)





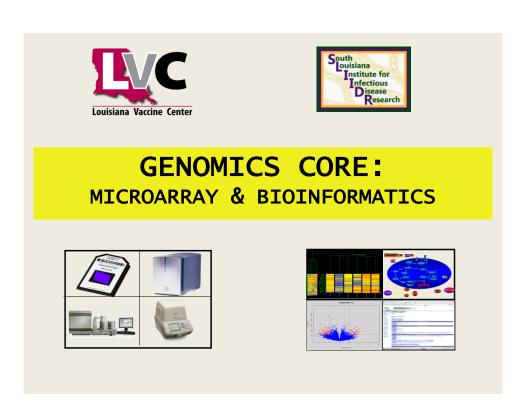
Biosafety Level 3 (BSL-3) **Facility**

For more information:

Amy Pierce MS, RLAT apierc@lsuhsc.edu

A2. Genomics Core: Microarray and Bioinformatics









GENOMICS CORE:MICROARRAY & BIOINFORMATICS

Objective

 to provide investigators with the expertise and instrumentation necessary for RNA transcript profiling, data analysis and mining.

Services

- Consultation
- RNA Sample Preparation
- Gene Expression Profiling
- Data Analysis & Mining
- Database Development





GENOMICS CORE: MICROARRAY & BIOINFORMATICS

Microarray Services Available

- -3' expression arrays → surrogate, most expression arrays to date
- -**Exon arrays** → better annotations, splice variants
- -miRNA array → microRNA profiling from multiple organisms
- **Gene arrays** \rightarrow most economical, whole genome profiling
- -Made-to-Order arrays → custom designed to meet your needs







Bioinformatics Services Available

- Rosetta Resolver software → allows researchers to analyze microarray gene expression data
- Functional and Pathway Mapping → enables data integration and pathway mapping of gene expression and proteomics data into specific metabolic and signal transduction pathways, as well as gene network analysis.
- Gene2Function.com

 customized online database which allows users to build and mine Omics-related data & share collected data
- "Omics-Working Group" → high-level analysis group consisting of statisticians & computational biologists available for consultation and collaboration





GENOMICS CORE:MICROARRAY & BIOINFORMATICS

For more information, please contact:

Doan Nguyen (504) 568-4552 dnguye@lsuhsc.edu

Room 539 CSRB 533 Bolivar Street LSU Health Sciences Center

A3. <u>Vector Development Core</u>

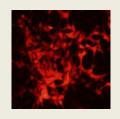




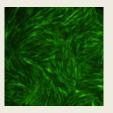


Featured Core Facility

VECTOR DEVELOPMENT







Contact: ROBERT KUTNER; (504)568-3337; rkutne@lsuhsc.edu





VECTOR DEVELOPMENT CORE

Objective

 To provide investigators access to new recombinant vaccine vectors and novel technology for basic research applications and other preclinical studies

Services

- Consultation
- Vector Construction
- Vector Production
- Molecular Assays
- Biological Assays
- Chromatography

Contact: ROBERT KUTNER: (504)568-3337: rkutne@lsuhsc.edu





VECTOR DEVELOPMENT CORE

VECTOR SYSTEMS AVAILABLE

ADENOVIRUS

- Efficient high titer viral vectors for gene delivery
- Broad range for in vivo and in vitro uses

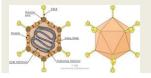
LENTIVIRUS

- > Provides long-term stable gene expression
- Modifiable tissue tropism

ADENO-ASSOCIATED

VIRUS

- Wide range host of the virus due to serotypes available
- Low immunogenicity













VECTOR DEVELOPMENT CORE

REPORTER TRANSGENES



Ideal for microscopy:

- ***ZsGreen** → brighter, more stable version of *EGFP*
- *TurboRFP → brighter, more stable version of DsRed express
- *LacZ(co) → Codon optimized βgalactosidase which reports more robust expression than traditional LacZ

Ideal for animal studies:

- *Katushka → protein of choice for visualization within animals; well suited for bioimaging
- *Luc2→ brighter more stable version of Luciferase
- *LacZ(co) → Codon optimized βgalactosidase which reports more robust expression than traditional LacZ

Contact: ROBERT KUTNER; (504)568-3337; rkutne@lsuhsc.edu





VECTOR DEVELOPMENT CORE

For more information, please contact:

ROBERT KUTNER

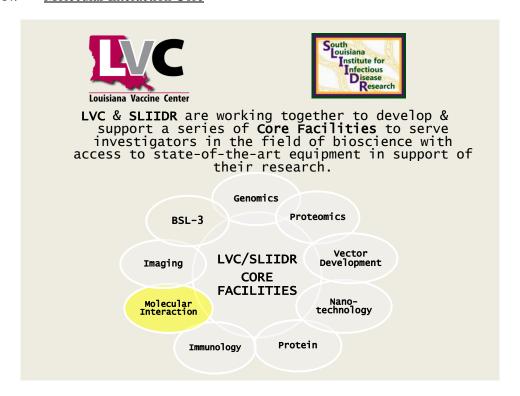
(504)568-3337

rkutne@lsuhsc.edu





A4. <u>Molecular Interaction Core</u>







Featured Core Facility

Molecular Interaction







Molecular Interaction Core

Objective

 To visualize and analyze label-free molecular interactions in real time using surface plasmon resonance technology

Services

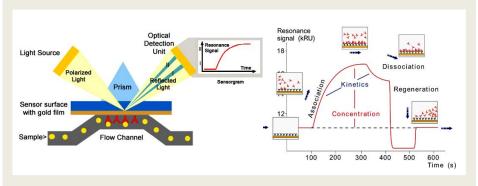
- Sensor surface preparation.
- Optimization of experimental conditions and sensor surface regeneration conditions.
- Generation of ligand-analyte interaction curves.
- · Analysis of data.





Molecular Interaction Core

Surface Plasmon Resonance







Molecular Interaction Core

How can the surface plasmon resonance technology be applied to biomedical research?

- · Binding specificity.
- · Interaction kinetics.
- Concentration in complex samples.
- Monoclonal antibody screening.
- Antibody-antigen affinity.
- · Epitope mapping.
- Receptor ligand interactions.
- Multiple complex formation.
- Ligand fishing for MS analysis.

- Proteins
- Carbohydrates
- Nucleic acids
- Lipid bilayers
- · Intact cell membranes
- Cell/tissue lysates
- Serum/plasma
- Viruses
- Whole cells





Molecular Interaction Core Sensor Surface Chips



<u>Chip</u>	<u>Dextran</u>	Modification	<u>Application</u>
CM5	100 nm	100% carboxylation	General (amine, thiol, aldehyde, maleamide coupling)
CM4	100 nm	30% carboxylation	Cell extracts / serum samples (decreased charg
CM3	30 nm	100% carboxylation	Cell extracts / serum samples (increased sensitivity)
C1	None	100% carboxylation	Phage binding
NTA	100 nm	Nitrilotriacetic acid	Capturing poly-HIS tags
HPA	None	Hydrophobic	Capturing Lipids
L1	100 nm	Lipophilic substances	Forming bilayers that mimic membranes
SA	100 nm	Streptavidin	Capturing biotin
AU/J1	None	None	User defined surface chemistry





Molecular Interaction Core

Contact Information

Miriam Corti, Ph.D. mcorti@chnola-research.org 504-896-2824

A5. <u>Imaging Core</u>

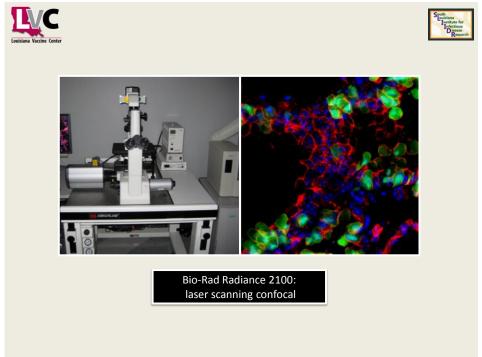




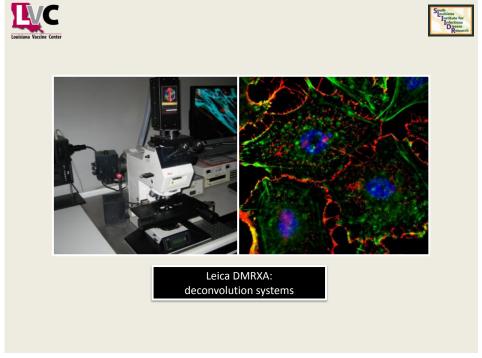


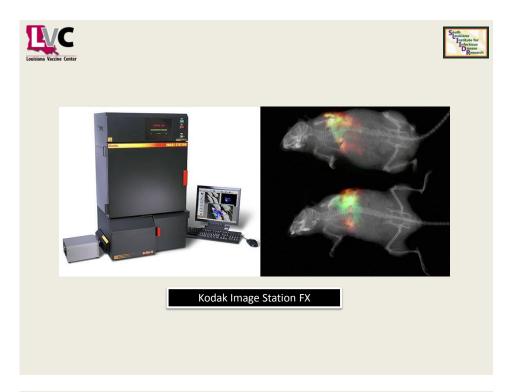


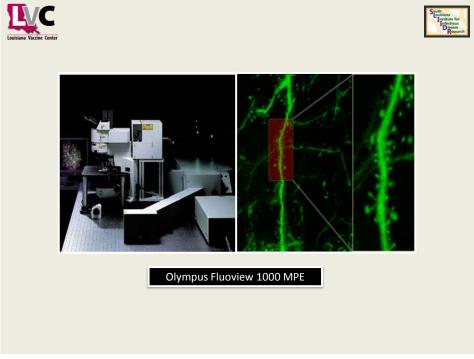


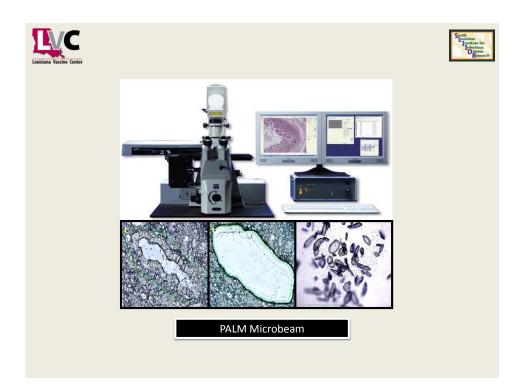


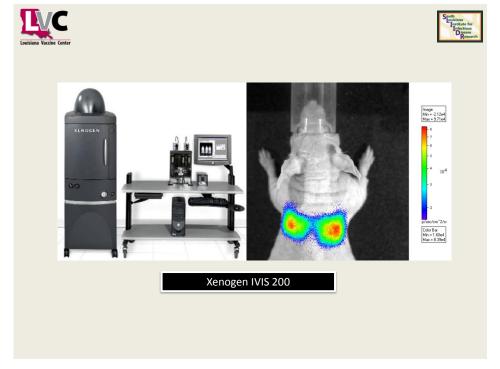
















Services

Routine Histopathology	Special Preparations	Microscopy & Analysis
Paraffin processing Paraffin embedding Paraffin sectioning Frozen sections Vibratome sections Whole mounts H&E stain Organ dissection	Immunohistochemistry (peroxidase / AP) Immunofluorescence (single to quadruple) In situ hybridization (DNA / RNA) Whole mount detections Multiple special stains (chemical / dye based) Enzyme histochemistry Antibody optimization	Brightfield Description of the state of th

A6. <u>Protein Core</u>







PROTEIN CORE











PROTEIN CORE

Aim

- · Facilitate protein purification for onsite or offsite Investigators
- Produce high quality protein for down-stream applications

Services

- Cloning & overexpression of protein in *E.coli*
- Large scale expression of native or tagged proteins
- Analytical or Preparative protein purification
- · Lyophilization

Contact: 504-988-2171





PROTEIN CORE

Automated Fermentation

High volume capacity 1-10 liters



Chromatography Options

- Σ0μm Ceramic
 Hydroxyapatite

Gelfiltration

► Affinity

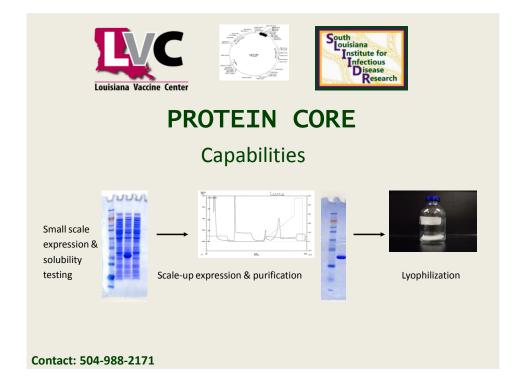
∇ (Ni²⁺) Sepharose High Performance

BioRad BioLogic Duoflow

High flow rates, Gradient elution capabilities



Contact: 504-988-2171







PROTEIN CORE

TULANE UNIVERSITY

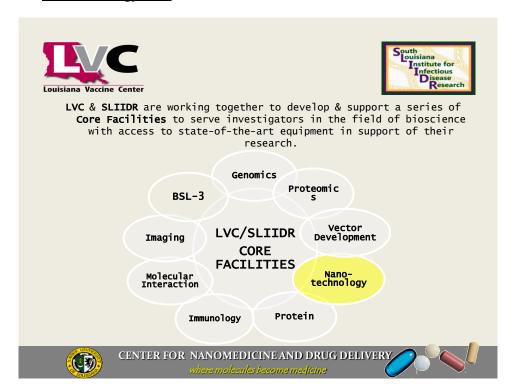
School of Medicine

Protein Purification Core

504-988-2171



A7. Nanotechnology Core







Nanotechnology

MISSION

It is the mission of the Vaccine Delivery/Nanotechnology Core facility to support and advance vaccine research capacity by providing novel and innovative vaccine formulations



CENTER FOR NANOMEDICINE AND DRUG DELIVERY
where molecules become medicine







Nanotechnology

Objective

The major goal of the Core is to maintain a state-of-the-art innovative polymeric vaccine delivery research facility in order to support interdisciplinary research.

Services

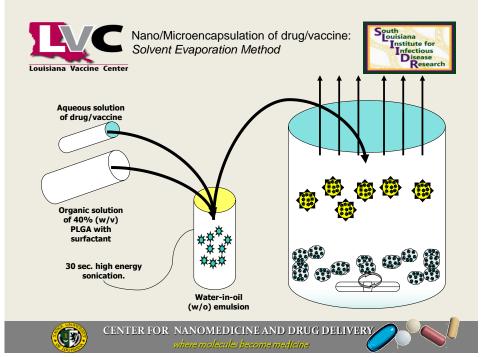
- Plan, design, and implement innovative vaccine formulations.
- Conduct pre-formulation and formulation studies of any potential novel vaccine for preclinical and NDA studies (New Drug Application following USFDA guidelines).

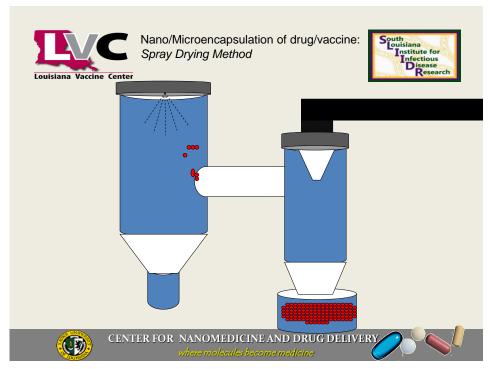


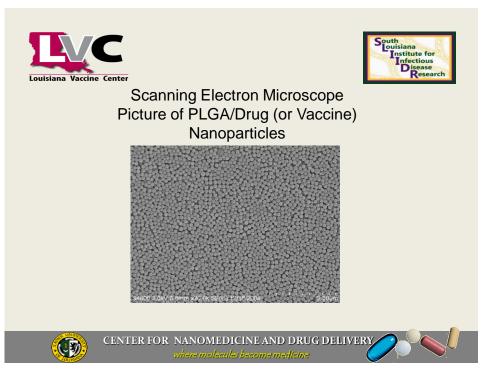
CENTER FOR NANOMEDICINE AND DRUG DELIVERY
where molecules become medicine















Molecules to Medicine









Nanotechnology

CONTACT INFO

Tarun Mandal, PhD (tmandal@xula.edu)
Phone: (504) 520-7442

Richard A. Graves, MS (rgraves@xula.edu)



CENTER FOR NANOMEDICINE AND DRUG DELIVERY



APPENDIX B: LVC Grant Seekers Meetings and Expert Grant Reviews-Listings and Outcomes

Grant Seeker's Meetings

Date	Name	Project Title	Outcome
June 4, 2010	Dr. Paul Fidel	"Identifying risk factors and interventions to prevent oral warts and candidiasis in HIV disease"	
May 21, 2010	Dr. Li Shen	"Control of type III secretion in Chlamydia trachomatis"	
February 19, 2010	Dr. Glen Palmer	"Endosomal trafficking in Candida albicans hyphal growth and pathogenesis"	Submitted R01
December 4, 2009	Dr. Jennifer Cameron	"Cervical Dysplasia and miRNA"	Submitted R01
March 6, 2009	Dr. Victor Hsia	"Thyroid Hormone (T3) and T3 Receptors Use Epigenetics to Control HSV-1 Gene Expression"	
December 5, 2008	Drs. Jim Hill and Walter Lukiw	"Age, gender, ApoE allele and HSV-1 reactivation phenotype are linked to Alzheimer's"	
December 1, 2008	Drs. Angela Amedee and Patty Kissinger	"Alcohol use and shedding of HIV-1 in the female genital tract"	
October 3, 2008	Dr. Li Shen	"Linkage between transcription regulation and virulence in <i>Chlamydia trachomatis</i> "	Submitted R01
September 29, 2008	Dr. Paul Fidel	"Host response against vaginal candidiasis"	Submitted R01
August 22, 2008	Dr. Bonny Dickinson	"Cholera toxin regulation of dendritic cell chemotaxis"	
August 11, 2008	Dr. Sam Landry	"HIV ENV epitope engineering" (R01 awarded)	NIAID-R01 Awarded
July 14, 2008	Dr. Tom Wen	"BrpA in virulence modulation of Streptococcus mutans" (R01 awarded)	NIDCR-R01 Awarded
April 19, 2008	Dr. Bonny Dickinson	"Role of toll-like receptors and FcRn in carcinoid cancer"	

Expert Grant Reviews

Date	Name	Reviewers	Outcome
July 14, 2008	Dr. Xu	Dr. Wen	R01-NIDCR Awarded
October 20, 2008	Dr. Li Shen	Dr. Hollenbach and Dr. Haas	R01 Submitted

APPENDIX C: Cooperative Pilot Research Grant Fund

- C1. Cooperative Pilot Research Grant Fund Recipients
- C2. Cooperative Pilot Research Grant Fund Recipient Testimonials

(Hagensee, Kaushal, Landry, Morici and Welsh)





C1. Cooperative Pilot Research Grant Fund Recipients

Principal Investigator Daniel G Bausch, M.D., MPH & TM Co-Investigators Christopher N. Mores, SM ScD	osal Title "	tiology of Arbovirus Infections in Guinea, West Africa"
Co-Investigators Christopher N. Mores, SM ScD	ipal Investigator	PH & TM
	vestigators	1 ScD
Institution TUHSC	ution T	

Proposal Title	"Natural History of Oral HPV Infections in HIV+ individuals"
Principal Investigator	Michael Hagensee, M.D., Ph.D.
Co-Investigators	Janet Leigh, B.D.S., D.M.D & Jeevan Yenugenti, D.D.S.
Institution	LSUHSC

Proposal Title	"Correlates of Immune Protection against Tuberculosis in BCG Vaccinated Nonhuman Primates"
Principal Investigator	Deepak Kaushal, Ph.D.
Co-Investigators	Andrew Lackner, DVM, Ph.D.; James Blanchard, DVM, Ph.D.; Peter Didier, DVM, Ph.D and Bapi
	Pahar,Ph.D.
Institution	TUNPRC

Proposal Title	"HIV ENV Epitope Engineering"
Principal Investigator	Samuel J. Landry, Ph.D.
Institution	TUHSC

Proposal Title	"A Novel Approach to HIV Vaccine Development: Spontaneously Derived L-2 Defective Particles
	with 8 Essential Mutants"
Principal Investigator	Ronald Luftig, Ph.D.
Co-Investigators	Angela Amedee, Ph.D.& Qiu Zhong, M.D., Ph.D.
Institution LSUHSC	

Proposal Title	"The role of small non-coding RNAs in controlling Mycoplasma genitalium virulence factors"
Principal Investigator	Liang Ma, M.D., Ph.D.
Co-Investigators	Oliver Wessely, Ph.D.
Institution	LSUHSC

Proposal Title	"Characterization and Evaluation of Novel Subunit Vaccines Against B. pseudomallei"
Principal Investigator	Lisa Morici, Ph.D.
Co-Investigators	Dr. Lucy Freytag, Dr. Chad Roy, and Dr. Pam Kozlowski
Institution	TUHSC

Proposal Title	"Fecal Microbiota in Infants with and Without Necrotizing Enterocolitis"
Principal Investigator	Duna Penn, M.D., MS
Co-Investigators	Lynn Tran, MD; Raegan Wetzel, MD; Michael Ferris, Ph.D.
Institution	LSUHSC

Proposal Title	"Cellular Envelope Homeostasis Of Chlamydia Trachomatis"			
Principal Investigators	Li Shen, M.D., Ph.D.& Alison J Quayle, Ph.D.			
Institution	LSUHSC			

Proposal Title	"Pneumocystis Colonization, Inflammation and Frailty"			
Principal Investigators	David A Welsh, M.D. & Judd E Shellito, M.D.			
Co-Investigators	Marco Ruiz, M.D.; Stephanie Broyles, Ph.D.; Michael Jazwinski, Ph.D.; Kyle Happel, M.D.; Kurt			
	Varner, M.D.; and Salman Arain, M.D.			
Institution	LSUHSC			

C2. Cooperative Pilot Research Grant Fund Recipient Testimonials

LVC Cooperative Pilot Research Fund Project Michael E. Hagensee Natural History of Oral HPV Infections in HIV+ Individuals

The LVC/SLIIDR cooperative pilot research grant has **greatly assisted in resurrecting** this exciting project trying to better understand how human papillomavirus causing pathology in the oral cavity of HIV+ individuals. Prior to hurricane Katrina, this project was in full swing with funding from a R21 grant (1R21DE015051) which investigated the prevalence of oral HPV in a cross-sectional study design, supplemented with R03 funding (5R03CA111327) to examine more closely a rare HPV type 32 which was found in the majority of oral warts in these patients. These projects led to a funded CoBRE project in which I was the mentor for Dr. Janet Leigh. We had developed a cohort of HIV+ individuals that we were following longitudinally. Unfortunately the hurricane not only dispersed our clinical cohort but Dr. Leigh was subsequently promoted to chairman of Oral Medicine. This move required her to forego her research interests and the funding for this research was abruptly lost. With the assistance of this pilot research grant, we were able to re-establish a longitudinal clinical cohort of about 70 HIV+ subjects some of whom we have been following for 18 months.

We were able to develop a high-throughput PCR-based assay for HPV-32 and **published this method**. We also discovered that about 50% of all HPV-16 and 32 oral infections are persistent for at least 6 months. In addition, further analysis of these data revealed that anti-retroviral therapy (ART) was a risk factor for HPV-32 infection (**manuscript in preparation**). Indeed, our focus over the last 12 months of this grant has been to enroll and follow those HIV+ individuals not on ART. We are focused on examining the changes that occur with the initiation of these medications to obtain a better understanding of the mechanism involved. These critical pieces of preliminary data have allowed us to prepare a proposal to the NIH as part of a Oral Program Project from LSU named "Identifying Risk Factors and Interventions to prevent Oral Warts and Candidiasis in HIV Disease," to be submitted on August 15, 2010.

In addition, directly due to the establishment of this clinical cohort, we were able to successfully bid for the Merck Pharmaceutical clinical trials named "A Study to Evaluate Methods for Measurement of Oral HPV Infection (\$46,000 in direct costs)". This not only provided national exposure to our research endeavors on oral HPV but also provided partial funding to maintain this clinical cohort. The pilot funds from the LVC also provided salary support for a research technician who assisted the development of the HPV-32 assay as well as testing these clinical samples. These data has and will be presented at 2 international meetings, the 25th International Papillomavirus Conference in Malmo, Sweden, 5-09 and the upcoming 26th International Papillomavirus Conference in Montreal, Cancer, 7-10.

Poster Presentations:

24th International Papillomavirus Conference, 5-09 - Sweden

"Oral HPV-32 infection in HIV+ Individuals is associated with HAART." M. E. Hagensee, N. Herrel, C. Cheeks and J. Leigh

25th International Papillomavirus Conference, 7/10, Montreal Canada

"Anti-retroviral Therapy Increases the Risk of Oral HPV-32 Infection." Herrel, N., K. Sutton, J Hagan, and Hagensee, M.E.

Manuscripts:

Herrel, N.R., Johnson, N.L., Cameron, J.E., Leigh, J., and Hagensee, M.E., Development and Validation of a HPV-32 Specific PCR Assay. *Virology Journal* 6:90 (1-7), 2009.

Herrel, NR, NL Johnson, J Leigh, J Hagan, ME Hagensee, Antiretroviral Therapy Increases the Prevalence of HPV-32 Infection. *STD* manuscript submitted.

LVC/SLIIDR Cooperative Pilot Research Fund Project: Testimonial Highlights Dr. Deepak Kaushal

Correlates of Immune Protection Against TB in BCG Vaccinated Nonhuman Primates

The LVC-supported pilot project was tremendously successful. We recently performed experiments proposed in both year 1 and year 2 of the project. While we were significantly delayed by the unavailability of the BSL3 animal space, our experiments worked as well as possible and have generated a plethora of interesting data.

The premise of our proposal was that Bacille Calmette-Guerin vaccination of nonhuman primates (NHPs) would result in protective immunity against a lethal challenge with Mycobacterium tuberculosis. We were indeed able to document protection using an array of clinical, pathological, microbiological and immunological metrics. We then analyzed the cellular composition of granulomatous lesions in the lungs of both vaccinated and non-vaccinated NHPs. We identified significant differences in the recruitment of CD8* Natural Killer cells in these lesions, with higher numbers being found in the lesions of vaccinated NHPs. We then generated transcriptomic profiles of both lesion types and have identified i) Mtb infection specific genes and pathways as well as ii) Protective vaccination specific panel of genes and pathways. These data generated a panel of candidate biomarkers of protection against TB, which can be tested in humans.

We have used these data in part, to successfully secure federal research funding from NIH. This includes an RO1 grant with \$ 3.3 million total costs over the course of the next five years, funded by NIAID, and two R21 grants totaling nearly \$ 1 million over the next two years. These grants could not have been secured without the invaluable support of the LVC proposal. The LVC support has also been instrumental in the publication of a number of manuscripts by my lab. Two manuscripts directly arising from the work performed using these funds are currently under review. Furthermore, an NIAID RO1 grant proposal based entirely on these data is being prepared for initial submission in the fall of 2010. During these two years, my program received excellent mentoring from the LVC leadership and Dr. Alistair Ramsay in particular. Such mentoring was critical in molding a young but inexperienced investigator into one who could compete for independent funding. Apart from providing the funds necessary to perform pilot experiments, and the advice to write productive NIH grant applications directly, the LVC program was helpful in many other ways. The program invited national leaders in infectious diseases to speak, allowing young investigators and members of their labs, access to top-quality research. The LVC program also organized the popular Grant Seekers meetings. Finally, the excellent staff that supported this program allowed the pilot grant recipients to focus on work by providing exceptional administrative and grants management support. I deeply appreciate the support of LVC. I hope that the LVC initiative will be able to continue to its good work in supporting infectious disease research in Louisiana.

Grant Awards with the direct support of the LVC.

- Macaque model of TB/AIDS Co-infection Using Natural Routes of Infection. (PI = Kaushal, D), NCRR R21RR026006-01. Year 1 direct costs = \$ 150,000. Total award (all years) = \$ 495,000. 09/28/09 - 08/31/11.
- Mycobacterium tuberculosis o^H and its Regulon in the Immunopathology of Tuberculosis. (Kaushal D is the PI of project 1). NCRR P20RR020159. Year 1 direct costs = \$ 207,000. Total award (all years) = \$ 1,026,808. 06/01/09 - 05/31/12.

 3. Role of miRNA in Lung Damage during TB and TB/AIDS Co-infection. (PI = Kaushal D). NIAID R21AI091457-01.
- Year 1 direct costs = \$ 150,000. Total award (all years) = \$ 453,000.
- Genetic Requirements for the Survival of Tubercle Bacilli in Nonhuman Primates. (PI = Kaushal D). NIAID. RO1AI089323. Year 1 direct costs = \$ 343,256. Total award (all years) = \$ 3,355,238.
- NanogentTM Inhaled Gentamycin Dry Powder as a Treatment for Tuberculosis (PI = Roy C, co-investigator = Kaushal D). NIH-NHLBI. 01/01/2009-12/31/2009. Total costs: \$ 89,000.

Publications arising from the direct support of the LVC

- 1. Mehra S, Pahar B, Dutta NK, Conerly C, Philippi-Falkenstein K, Alvarez X & Kaushal D. 2010. Transcriptional Reprogramming in Nonhuman Primate (Rhesus Macaque) Tuberculosis Granulomas. PloS ONE. In Press.
- 2. Mehra S, Dutta NK & Kaushal D. 2010. MT2816 encodes a key Mycobacterium tuberculosis stress response factor. J Infect Dis. In Press.
- 3. Dutta NK, Mehra S & Kaushal D. 2010. A Mycobacterium tuberculosis Sigma factor network responds to Cell-envelope Damage by the Promising Anti-mycobacterial Thioridazine. PLoS ONE. 5:e10069.
- Dutta NK, Mehra S, Didier PJ, Roy CJ, Doyle LA, Ratterree M, Alvarez X, Be N, Lamichhane G, Jain SK, Lacey MR, Lackner AA & Kaushal D. 2010. Genetic requirements for the survival of tubercle bacilli in primates, J Infect Dis. 201 (11): 1743-52.
- Mehra S & Kaushal D. 2009. Functional genomics reveals extended roles of the Mycobacterium tuberculosis stress response factor σ^H. J Bacteriol. 191: 3965-3980.

6-22-10

Deepak Kaushal, PhD Assistant Professor, Tulane National Primate Research Center

LVC/SLIIDR Cooperative Pilot Research Fund Project: Testimonial Highlights Dr. Samuel Landry

HIV ENV Epitope Engineering

Recent progress in our research and success in obtaining federal grant support would not have been possible without the LVC/SLIIDR Cooperative Pilot Grant. In the first year of LVC support, the Pilot Grant allowed me to hire excellent personnel and purchase state-of-the-art reagents, which rapidly moved our lab into a very productive phase. With the lab-work underway, I was able to focus my own efforts on amending my application to NIH, which was eventually awarded and also to writing papers (grants and papers listed below). In the second year of LVC support, we were able to expand our research into a new area, for which I am now planning to seek additional NIH grant support. As an LVC/SLIIDR grant recipient, I have been hooked up with terrific colleagues and facilities spanning the Tulane and LSU campuses. We are taking every advantage of this burgeoning critical mass of research activity on infectious disease and vaccines in order to move our research to national prominence.

Grant Awards

Bill and Melinda Gates Foundation, Grand Challenges Explorations, Phase I, "Engineering Antigen Processing for Improved Immunity," 10/1/08-9/30/09, \$100,000 total costs

Tulane National Primate Research Center, Pilot Research Program, "HIV ENV Epitope Engineering," 3/1/09-2/28/10, \$50,000 total costs.

National Institutes of Health (R01-Al080367) "HIV ENV Epitope Engineering," 6/19/2009 – 5/31/2012, \$250,000 direct costs per year.

Further Grant Submission

Gates Grand Challenges Explorations (phase II), Landry (PI), Engineering the CD4+ T-cell response for improved immunity, 12/1/2009-11/30/2011, \$984,443 total costs

Publications

Influence of disulfide-stabilized structure on the specificity of helper T-cell and antibody responses to HIV envelope glycoprotein gp120.

Mirano-Bascos D, Steede NK, Robinson JE, Landry SJ. J Virol. 2010 Apr;84(7):3303-11. Epub 2010 Jan 20. PMID: 20089653

Three dimensional structure directs T-cell epitope dominance associated with allergy. Melton SJ, Landry SJ.

Clin Mol Allergy. 2008 Sep 15; 6:9.

Proximal glycans outside of the epitopes regulate the presentation of HIV-1 envelope gp120 helper epitopes.

Li H, Xu CF, Blais S, Wan Q, Zhang HT, Landry SJ, Hioe CE.

J Immunol. 2009 May 15; 182(10):6369-78.

Samuel J. Landry, Ph.D.

Professor

LVC Cooperative Pilot Research Fund Project: Testimonial Highlights Lisa A. Morici

Characterization and Evaluation of Novel Subunit Vaccines Against B. pseudomallei

The LVC/SLIIDR cooperative pilot research grant has significantly propelled my career as a new investigator and provided me with the initial support necessary to establish a successful independent research program. During this 2 year project period, we have identified novel protein antigens that can be utilized as mucosal vaccines against B. pseudomallei. Furthermore, we have data to support the protective efficacy of mucosal vaccination against aerosol biothreat agents. With the currently established NIH/NIAID R21 and R03 paylines, it would have been difficult for me to out-compete more established investigators for start-up funds for my pilot project. Support from the LVC enabled me to submit a highly competitive 3 year grant proposal to the Western Regional Center for Excellence in Biodefense and Emerging Infectious Diseases (WRCE). Receipt of the Career Development Award (\$480,000 in total direct costs) in September 2009 was a direct result of LVC support and will enable me to continue and expand my vaccine development work. LVC support has also directly afforded me numerous professional development opportunities as a junior faculty member (2 oral presentations and 4 poster presentations of my work; mentorship of 3 full-time graduate students; and management of my own independent research lab). This has led to rank promotion (research to tenure-track), increased laboratory space, and additional collaborative research with other investigators. Furthermore, the work supported a research lab technician for 2 years and yielded 2 manuscripts. I am sincerely grateful for the LVC and truly believe its senior mentorship, networking and educational opportunities (seminars), and pilot funding have been essential for the success of young investigators in this highly competitive era.

Oral and poster presentations

May 2009 "Characterization and Evaluation of novel subunit vaccines against *Burkholderia* pseudomallei"; Louisiana State University Health Sciences Center; Louisiana Vaccine Center Seminar Series; New Orleans, LA.

Feb. 2009 "Characterization and Evaluation of novel subunit vaccines against *Burkholderia* pseudomallei"; Louisiana State University School of Veterinary Medicine, National Hansen's Disease Laboratory; Baton Rouge, LA.

- 2 Poster presentations at the 109th General Meeting of the American Society for Microbiology.
- 2 Poster presentations at the 110th General Meeting of the American Society for Microbiology.

1 Published and 1 Submitted Manuscript (directly related to project)

Heang J, Nieves W, Honer zu Bentrup K, Roy C, and L.A. Morici. 2010. Specific and potent immunogenicity of bacterial elongation factor Tu following immunization and during *Burkholderia* infection. Submitted.

Morici, LA, Heang J, Tate T, Didier P and C.J. Roy. **2010**. Differential susceptibility of inbred mouse strains to *Burkholderia thailandensis* aerosol infection. Microbial Pathogenesis. **48**(1) 9-17.

Lisa Morici, Ph.D.

Date

6/22/10

LVC Cooperative Pilot Research Fund Project David A. Welsh. MD Pneumocystis Colonization, Inflammation & Frailty

Thank you for the opportunity to communicate my appreciation for LVC/SLIIDR pilot research funding. Without hesitation I can attest that this program, and more specifically, funding for our project, has nurtured the development of a new research agenda and positioned us for success. Although not evident from our project title, we are focused on the interaction between communities of resident microbes (the microbiota) in the lung and mucosal immunity. We believe that microbial community structure and diversity informs mucosal responses and that HIV and aging are examples in which the relationship is perturbed. A better understanding of this paradigm will certainly impact vaccination strategies.

LVC support has expedited the maturation of many components of our research program. In order to illustrate the benefits of LVC funding to us, and to Louisiana I will highlight two specific areas:

Scientific Development: During the funding period we have developed protocols, infrastructure, and new collaborations that have created the scientific environment necessary for investigations examining the interaction between the microbiota and host mucosal responses. For example, we have refined bronchoscopy sampling protocols that allow assessment of the lower airway without upper airway contamination. Our technique is unmatched among groups examining airway colonization. Establishing new collaborations is another example of the benefits of LVC funding. This has occurred on the local level with Children's Hospital and Tulane investigators but also nationally (we now have ongoing studies with investigators at the Joint Genome Institute in California).

Economic Development: In parallel with the development of our scientific program, LVC pilot funding will reap economic rewards for Louisiana. Funding has allowed us to employ and train a recent college graduate previously in the low paying, unskilled workforce. With the skills she has acquired during the past two years she now plans to pursue a PhD and a career in a scientific discipline. Equally important, LVC funding allowed us to generate the preliminary data that enabled us to submit five grants:

RFA HL-09-006 - NIH/NHLBI

Unfunded (1 priority point above payline)

Respiratory Microbiota, Inflammation & HIV

RC4HL106743 - NIH

Requested budget \$1,673,320 / yr

Respiratory Microbiota and Mucosal Immunity

W. H. Keck Foundation

Budget requested \$1,169,915

W. H. Keck Center for the Mucosal Interactome

PO1 AG022064 - NIH / NIA

Dr Welsh's Subproject's Requested budget \$423,234 / yr

Determinants of Human Longevity and Healthy Aging

NIH / NIAAA

Dr Welsh's Subproject's Budget requested \$127,566

Clinical Resource for Lung and Alcohol Investigations

Thus, LVC/SLIIDR pilot research funding has contributed to the development of an exciting new area of scientific investigation while contributing to Louisiana economic growth.

Thank you.

David A Welsh, MD

Associate Professor of Medicine

X ELSH MUS

APPENDIX D: LVC 2nd Annual Research Meeting and EAC Meeting

- D1. Agenda
- D2. Photos
- D3. EAC Letter of Recommendation

D1. Agenda



ANNUAL RESEARCH MEETING SEPTEMBER 29-30, 2009 AGENDA

Genetics Conference Room 665A

8:15 a.m. – 8:45 a.m. Continental Breakfast

8:50 a.m. – 9:10 a.m. Introduction by LVC Director

9:15 a.m. – 10:30 LVC EAC Meeting

Presentation by Facilitators (Education, Research and

Commercialization)

Pilot Grant Recipients (CSRB 563 Conference Room) - Shared session with SLIIDR

10:35 a.m. – 10:55 a.m. Lisa Morici, Ph.D.

11:00 a.m. – 11:20 a.m. Deepak Kaushal, Ph.D.

11:30 a.m. – 12:00 p.m. Lunch

12:00 p.m. – 1:10 p.m. IIVSP Seminar by Dr. Roger G. Rank – "The critical role of the

inflammatory response in chlamydial genital infection - "the good,

the bad, and the ugly"

1:15 p.m. – 1:20 p.m. Timothy Tate, LVC Scholar Recipient

1:25 p.m. – 1:45 p.m. Samuel Landry, Ph.D. 1:50 p.m. – 2:10 p.m. Ronald Luftig, Ph.D.

Genetics Conference Room 665A

2:15 p.m. – 3:15 p.m. LVC EAC deliberations

3:20 p.m. – 4:20 p.m. LVC EAC briefing

6:00 p.m. Pre-dinner drinks - Ralph's on the Park (EAC and Guests)

7:00 p.m. Dinner - Ralph's on the Park (EAC and Guests)

In Partnership with







Wednesday, September 30 (CSRB Conference Room 563) - Shared session with SLIIDR

10:35 – 1:00 p.m. Five additional LVC/SLIIDR pilot grant presentations will be made on

9/30 as part of the Annual Meeting of our partner program, the South Louisiana Institute for Infectious Disease Research (SLIIDR) either side of lunch, as detailed below. You are welcome to attend these if

available.

10:35 a.m. – 10:55 a.m. Daniel G. Bausch, MD, MPH & TM

11:00 a.m. – 11:20 a.m. Lynn Tran, MD

11:25 a.m. – 11:45 a.m. David A. Welsh, MD & Judd E. Shellito, MD

11:50 a.m. – 12:10 p.m. Lunch Break

12:15 p.m. – 12:35 p.m. Li Shen, MD, PhD & Alison J. Quayle, PhD

12:40 p.m. – 1:00 p.m. Michael Hagensee, MD, PhD

In Partnership with





D2. Photos





D3. EAC Letter of Recommendation

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 Comm

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. TheraV:

anthry Those

President and CEO, TheraVasc, Inc. Assistant Dean of Research and

Business Development LSUHSC, Shreveport, LA

APPENDIX E: Louisiana NCRR/IDeA 2010 Biomedical Research Symposium

- E1. Abstract
- E2. Photo

E1. Abstract

Poster Presentation Abstracts

Other Related Programs

Louisiana Vaccine Center

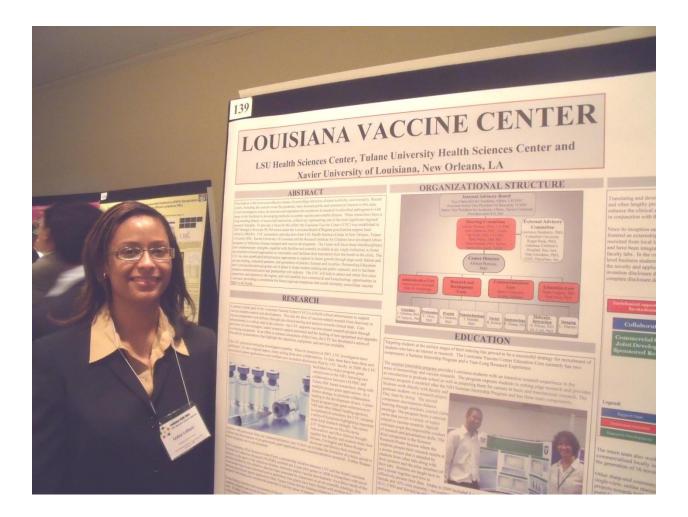
139 Louisiana Vaccine Center

Alistair Ramsay LSUHSC-New Orleans

Vaccination is the most cost-effective means of controlling infectious disease morbidity and mortality. Recent events, including the current swine flu pandemic, have focused public and commercial interest in this area. Local investigators enjoy an international reputation for excellence in research in microbial pathogenesis with many at the forefront in developing methods to combat vaccine-preventable disease. These researchers have a long-standing history of successful interaction, collectively representing one of the most significant regional research strengths. To provide a focus for this effort, the *Louisiana Vaccine Center* (LVC) was established in 2007 through a five-year \$5.5M award under the Louisiana Board of Regents post-Katrina support fund initiative (PKSFI). LVC researchers and educators from LSU Health Sciences Center in New Orleans, Tulane University HSC, Xavier University of Louisiana and the Research Institute for Children have developed robust programs of infectious disease research and vaccine development. The Center will focus these interdisciplinary and complementary strengths, together with facilities not currently available at any single institution, to foster development of novel approaches to vaccination and facilitate their translation from the bench to the clinic. The LVC has also established infrastructure appropriate to support its future growth through large-scale federal and private funding, industrial partners, and generation of patents, licenses and royalties. Outstanding Education and Commercialization programs are in place to foster student training and public outreach, and to facilitate research commercialization and partnership with industry. The LVC will help to attract and retain first class researchers and trainees to the region, and will establish new commercial and biotechnology opportunities in Louisiana, providing a cornerstone for future regional enterprises that could ultimately consolidate vaccine R&D in the South.

Louisiana NCRR/IDeA 2010 Biomedical Research Symposium ~ January 22, 2010 ~ 65

E2. Photo



APPENDIX F: Interview Guide

Interview Guide: Follow-up Interview

Invention disclosure questions

- 1. What technical details constitute this invention?
- 2. When/where did you make this invention exactly?
- 3. What is the history leading to this invention?
- 4. Were there any other inventors involved in this discovery? Please note that inventorship requires an intellectual contribution directly related to the discovery, not just executing an experiment.
- 5. What are the possible areas of commercial application of the invention?
- 6. Is any material used in this invention covered by a material transfer agreement and if so, in which context?
- 7. Have you made a patent or literature search? Has it yielded any related inventions? If so, what are the details of these technologies?
- 8. Has the invention been reduced to practice (assembled, tested or modeled)?
- 9. Have you made any public disclosure of the invention or submitted it for publication (public disclosure includes published article or abstract in a journal or proceedings; a presentation or poster at a conference; preprints distributed outside the institution; a thesis or dissertation catalogued and shelved in a public library; prototype exhibit; posting on internet; etc)? If so, what are the details and exact dates of disclosure?
- 10. When is your earliest planned publication of this invention?
- 11. Do you have an interest to personally take a license under this invention from the institution, with the intention to develop/commercialize it yourself?
- 12. Do you know of any firms that might be interested in licensing this technology, please elaborate?

Post-Interview Questionnaire

Interview follow-up: questionnaire

Introductory email:

Thank you for allowing our Interview Team to meet with you about your past and current research projects. Our team is looking forward to following-up with you in the near future as we begin to review and assess all that we learned from our meeting. At this time, we ask that you please fill out our brief Faculty Interview Feedback Questionnaire at your convenience by utilizing the link below. Your responses will not only allow us to be able to better serve you, the investigator, but to apply what we learn from you to our future meetings with others. All information gathered from this questionnaire will be used for commercial support purposes and will be anonymous. Thank you so much for your time and responses.

http://survey.constantcontact.com/survey/a07e2hnfowafsnobuwg/start

APPENDIX G: Post-Interview Feedback Questionnaire Metrics





CTRECP

Clinical & Translational Research, Education and Commercialization Project



Constant Contact Survey Results

Survey Name: Faculty Interview Questionnaire Response Status: Partial & Completed

Filter: None

May 28, 2010 4:38:37 PM

Interview Feedback:

How would you rate the following aspects of the recent faculty interview

1 = Disagree, 2 = Somewhat Disagree, 3 = Neutral, 4 = Somewhat Agree, 5 = Agree

Answer	1	2	3	4	5	Number of Response(s)	Rating Score ¹
The goals of the interview were sufficiently clear to me						22	4.7
The interview length was appropriate						22	4.8
The interview team was friendly and courteous						22	5.0
My questions were adequately answered						22	5.0
My expectations were met						22	4.9

[&]quot;The Rating Score is the weighted average calculated by dividing the sum of all weighted ratings by the number of total responses.

Please provide your comments/suggestions to improve future interview.

6 Response(s)

Page 1



Programming Feedback:

Have you ever participated in any of the following programs or events (check all that apply)

Answer	0%		100%	Number of Response(s)	Response Ratio
Biotech Networking Evens (NOBING)				5	21.7 %
Industry Outreach Meetings				4	17.3 %
NOBIC Mentor Program				0	0.0 %
Entrepreneur SBIR/STTR Workshops				3	13.0 %
SLIIDR/LVC grant seekers Meeting				15	65.2 %
SLIIDR/LVC Invited speakers series				19	82.6 %
Commercial awareness for researcher's seminar.				2	8.6 %
None of the Above				2	8.6 %
			Totals	23	100%

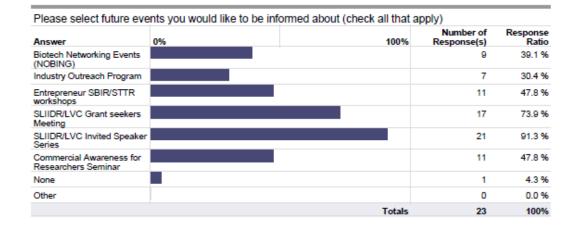
Do you feel this cu	rent offering of programming me	ets your needs?		
Answer	0%	100%	Number of Response(s)	Response Ratio
Yes Completely			14	60.8 %
Somewhat			6	26.0 %
Neutral			2	8.6 %
No, not at all			0	0.0 %
		Totals	23	100%

Page 2

Do you have any suggestions for future commercially oriented event/seminars to better meet your needs? Please provide suggestions below:

3 Response(s)

Would you like to	stay informed about fut	ture events?		
Answer	0%	100%	Number of Response(s)	Response Ratio
yes			21	91.3 %
No			1	4.3 %
No Response(s)			1	4.3 %
		Totals	23	100%



Page 3

APPENDIX H: LVC Commercialization Event Announcements: Webinars, Seminars, Workshops and Networking Events

Seminars & Webinars

- 1. R&D Tax Credit Seminar **December 9, 2009**
- 2. Open Innovation Webinar on government research funding programs through NIST **January 20, 2010**
- 3. Open Innovation Webinar on building strategic relationships between industry and universities –**September 8, 2009**
- 4. Creating Value Through Sustainability webinar **April 20, 2010**
- 5. Breakthrough Medical Technologies webinar **September 22, 2009**
- 6. Tough to get growing, How to succeed in a down economy webinar **November 16**, **2009**

Workshops

- 1. 2-Day Workshop on Innovation and Technology Leadership June 25-26, 2009
- 2. Technology showcase & VC open house workshop May 10, 2010

Networking Events

- 1. Speed networking reception **June 26, 2009**
- 2. Biotech Connect networking event **October 21, 2009**
- 3. "Yes! to Business" Biotech Luncheon Forum October 22, 2009



Wednesday, December 9th 10:30AM - Noon NEW ORLEANS BIOINNOVATION CENTER 134 LaSalle St. – New Orleans

For Information, Please Contact: info@neworleansbio.com

FREE TO ATTEND, PLEASE RSVP AT

Highlights of the Tax Credit

- Taxpayers who receive a federal SBIR grant shall be allowed a refundable tax credit against income and franchisee taxes due.
- Taxpayer who employs up to fifty LA residents and incurs QRE (Qualified Research Expenditures) as defined in 26 USC 41. (b) (inhouse research expenses and contract research expenses) shall be allowed a refundable tax credit against income and franchise taxes due.
- Taxpayer who employs more than 50 LA residents and claims a federal income tax credit under 26 USC 41 (a) for increasing research activities (Form 6765) shall be allowed a refundable tax credit against income and franchise taxes due.

FEATURED SPEAKER



SUSAN BIGNER
Business Development Officer II
Louisiana Economic Development

Susan Bigner is the Program Manager for several State incentive programs, including the Research & Development Tax Credit Program; Technology Commercialization Credit & Jobs Program; Industry Assistance Program; and the Tax Equalization Program. She also assists with other programs at LED.















Open Innovation Webinar

Broadcast by the University-Industry Demonstration Partnership (UIDP) & National Council of Entrepreneurial Tech Transfer (NCET2)



SPEAKER:

Dr. Lorel Wisniewski Deputy Director, TIP Program NIST

WHO SHOULD ATTEND:

These webinars are open and free to attend for anyone interested in how universities and industry can better collaborate to commercialize R&D.

GOVERNMENT RESEARCH FUNDING PROGRAMS THAT SUPPORT UNIVERSITY — INDUSTRY COLLABORATIONS AT THE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY (NIST)

As federal and state investments in research and development grow, universities have sought to bolster the funding they receive from these sources. Increasingly, companies are looking to exploit these opportunities and are turning to universities as logical partners in pursuit of funding. In order to increase the awareness of these programs, the UIDP and NCET2 will hold a series of regularly scheduled webinars that highlight specific agencies and their programs that support university-industry collaborations.









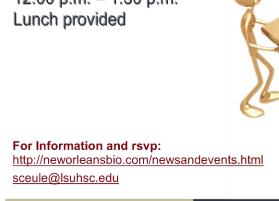






Open Innovation Webinar





SPEAKER:

Helmut Traitler V.P. Innovation Partnerships, Nestle

WHO SHOULD ATTEND:

These webinars are open to anyone interested in how universities and industry can better collaborate to commercialize R&D.

Broadcast by:

National
Council of
Entrepreneurial
Tech
Transfer

BUILDING STRATEGIC RELATIONSHIPS BETWEEN INDUSTRY AND UNIVERSITIES

This webinar series is about how companies work or want to work with universities to create value for both themselves and the universities. The ecology of innovation is undergoing a profound change where a collaborative set of activities need to effectively connect academic institutions with the business community. Universities are becoming key sources of discovery and are playing an ever increasing role in how industry innovates. Global competition, rising R&D costs and thus the need to get more products to the market sooner are some factors forcing companies to reach out to research universities for new ideas and capability. Licensing, corporate sponsored research, consulting engagements, venture capital investment, gifts, and employment are just some of the ways used to build strategic relationships between industry and universities, and are becoming a regular part of the developing open innovation environment. Helmut will discuss the challenge of creating innovation partnerships in a large corporation using the example of Nestlé. His initiatives have led to the build up of a network of more than a million researchers worldwide, including science universities, venture capital, strategic suppliers and government laboratories, that supports the 4,500 people in Nestlé Food and Beverages R&D.















And The MIT Club of Louisiana

Present

Creating Value Through Sustainability

A worldwide satellite broadcast and webcast

Tuesday, April 20, 2010

New Orleans BioInnovation Center

134 LaSalle Street, New Orleans, LA 70112

Program: 6:00 – 7:30 P.M.

Networking reception: 7:30 – 8:30 P.M.

Refreshments will be provided.

How will the green movement affect your business?

While many organizations are struggling to differentiate among the myriad of products and services that promise a path to "sustainability", a number of leading companies are creating real, tangible value by integrating environmentally and socially sensitive considerations into key business practices.

Join us as the keynote speaker and panelists address how to:

- successfully integrate sustainability strategy in everyday business decisions;
- create financial value while meeting societal and environmental needs....the "triple bottom line";
- determine the key sustainability drivers impacting business; and
- increase business success through an effective sustainability strategy

Keynote speaker: Matt Kistler Senior Vice President, Sustainability, Wal-Mart

Panelists: Eric Hespenheide Global Leader, Climate Change and Sustainability, Audit and Enterprise

Risk Services, Deloitte & Touche, LLP

Paul Murray Director, Environmental Safety and Sustainability, Herman Miller, Inc.

James Modak Chief Financial Officer, Suniva, Inc.

For more information about the event, contact Jenna Matheny: imatheny@neworleansbic.com

For more information about the MIT Enterprise Forum Global Network, visit: http://enterpriselonum.mit.edu/about/
For more information about the speakers, visit: http://ewww.mitefa.org/events/2010/04_20_10_bio.php#1
With special thanks to broadcast partner, GREENGUARD Environmental Institute













The MIT Club of Louisiana





An MIT Enterprise Forum Live Global Broadcast

Presented in association with Technology Review's EmTech09 Conference

Tuesday, September 22, 2009

New Orleans BioInnovation Center 134 LaSalle Street, New Orleans, LA 70112 4:15 - 5:00 pm - Program 5:00 - 7:00 pm - Networking Reception Refreshments will be provided.



"Breakthrough Medical Technologies"

A Keynote by MIT Institute Professor Robert Langer

Robert Langer discusses winning the 2008 Millennium Technology Prize

Langer is the world's most cited engineer with over 750 issued or pending patents worldwide, licensed to 220 pharma, chemical, biotech, or medical device companies. He will share case studies and lessons learned on:

- the process of and excitement that comes from discovery
- the challenge of acceptance from the scientific community and obtaining rights to your intellectual property
- · the winding road to commercialization

For more information and to RSVP:

http://www.neworleansbio.com/newsandevents.html Or contact Jenna Matheny: jmatheny@neworleansbio.com

Further details regarding Dr. Langer and MIT Enterprise Forum Global Broadcasts may be found at www.mitenterpriseforum.org













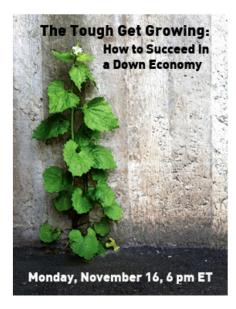
The MIT Club of Louisiana and New Orleans BioInnovation Center Present



An MIT Enterprise Forum Live Global Broadcast

Presented in Celebration of Global Entrepreneurship Week

Monday, November 16, 2009
New Orleans BioInnovation Center
134 LaSalle Street, New Orleans, LA 70112
5:00 – 6:30 PM – Program
6:30 - 8:00 pm - Networking Reception
Refreshments will be provided.



The current economic climate doesn't mean companies can't succeed. It just means the WAY a company succeeds has its own unique challenges.

Hear the real-world experiences of entrepreneurs from today, the lessons learned going from start-up to success story, and the research and best practices that will help YOU get growing.

Introductory remarks by MIT President
Susan Hockfield
Speakers: Bo Fishback
VP, Entrepreneurship
Ewing Marion Kauffman Foundation
Helen Greiner '89, SM '90
CEO, The Droid Works
Daphne Zohar
Founder, Managing Partner

Pure Tech Ventures

For more information and to RSVP:

http://www.neworleansbio.com/newsandevents.html
Or contact Jenna Matheny: jmatheny@neworleansbio.com
Further details regarding the speakers and MIT Enterprise Forum Global
Broadcasts may be found at www.mitenterpriseforum.org













Acquiring External Technology to Drive Innovation

BUSINESS ISSUES ADDRESSED

Innovate rapidly by scouting and acquiring external technology. Obtain the tools to manage the acquisition process. Learn how to structure successful deals and manage the relationships. Integrate external technology sourcing into your business processes.

KEY BENEFITS

Identify when outside technology is needed, how to find what you need, and how to manage the integration process.

KEY TOPICS

Accelerating Innovation Through External Technology

- Becoming more innovative by moving to an 'open innovation' business model
- Accelerating the product development cycle using limited technical resources
- Managing risks and controlling costs

Balancing External and Internal Development Efforts

- Using the WFGMSM model of technology acquisition: determining **W**hat you need; Finding it; **G**etting it; **M**anaging relationships
- Developing a comprehensive technology strategy that involves acquisition, cross-supply, and co-development

Determining Your External Technology Acquisition Goals

- Candidate criteria: seeking value, filling gaps, managing complexity, addressing competitors, reducing costs, and hedging your bets (the portfolio concept)
- Incorporating technology roadmaps
- Establishing priorities among technology acquisition needs

Finding What You're Looking for

- Looking in other companies
- Searching in start-up companies
- Working with university faculty and tech transfer offices
- Going global: problems and considerations

Structuring the Deal

- Transitioning from one-on-one arrangements to alliance networks
- Moving from cost and supply chain management to more strategic integrated external networks
- Considering the open innovation model

Integrating External Technology Sourcing Into Your Business Processes and Managing Resulting Relationships

- Using the external technology sourcing concept to overcome traditional corporate boundaries
- Making it work: top management involvement
- Risk management

Impact of Intellectual Property Law on External Technology Sourcing

- Structuring relationships with intellectual property in mind
- Understanding the role of patent and copyright in enhancing/impeding external innovation acquisition
- Assessing the impact of IP law on external sourcing

SPEAKER BIO

Ora Smith, JD, consults on projects in the technology sector. His clients include companies, organizations, and universities engaged in technology development, commercialization, and transfer. Previously, he was CEO of Illinois Superconductor Corporation, (now ISCO International) a leader in using external innovation to bring high temperature superconductors into the commercial wireless equipment marketplace.

Mr. Smith served as vice president and chief marketing officer at Conductus. Both ISCO and Conductus were cited in the April 2005 Spectrum magazine as among the top seven most innovative IPO's out of 823 companies that went public from 1993-2002.

At Rockwell International, Mr. Smith was a corporate R&D lab director and the company's corporate director of external technology development. He also served as the Industrial Research Institute (IRI) Fellow in the White House Science Office while at Rockwell.

Mr. Smith was president of the Science and Technology Campus Corporation for over five years. This organization operates a research park and provides technology commercialization functions in affiliation with Ohio State University. He has served on various boards of directors and advisory boards.

Mr. Smith received his SB and SM degrees in mechanical engineering from MIT and his JD from Harvard Law School

VC OPEN HOUSE

New Orleans BioInnovation Center

MAY 10th 2010

New Orleans BioInnovation Center 134 LaSalle St.

New Orleans, LA

For more information: stevenc@neworleansbio.com



NanoFex



Agenda

8 20 - 9 00 am Introduction

9.00 - 10.00 am

9.00 - 9.20 am 9.20 - 9.40 am

Nanofex

Presentation VC open deliberation Feedback and O&A

10.00 - 11.00 am

10.00 – 10.20 am 10.20 – 10.40 am

Durationator

Presentation /C open deliberation Feedback and O&A

11.00 - 12.00 pm

11.00 – 11.20 am 11.20 – 11.40 am

Safesnip

Presentation C open deliberation Feedback and O&A

Session Goals

Sharing insights into how venture capitalists perceive investment opportunities, and what makes deals attractive to VCs.

Insight and leanings will aid presenting startups in optimizing their business plans and investor pitches, and aid them in raising future venture funding.

Investor Advisor Panel

Tullis-Dickerson & Co., Inc

- · Gloria M. Skigen
- · Thomas P. Dickerson
- · Lyle A. Hohnke
- · Joan P. Neuscheler

Shippan Point Advisors, LLC

- · Richard J. Miller
- Robert Vialardi

Presenting Startups

Nanofex

Nano-ex LLC manufactures and distributes a non-toxic micro-particle that cleans dangerous pollutants in our groundwater.

Durationator

The Durationator is a software tool that can determine the copyright duration of any work anywhere in the world by asking the user a series of questions.

Safe Snip

NOvate Medical Lechnologies manufactures and distributes SafeSnip, an inexpensive device that cuts, clamps and disinfects umbilical cords.















VC Open House











Bios of Venture Capitalist Advisors

Gloria M. Skigen

Gloria M. Skigen practices in the areas of business and general corporate law, venture capital and private equity financings, mergers and acquisitions, corporate, limited liability and partnership law matters, employment arrangements and joint venture formation.

Gloria was a Partner and General Counsel to Tullis-Dickerson, a healthcare venture capital firm (1998-08). Prior to 1998, Ms. Skigen was with the firm of Battle Fowler LLP (1988-98) and

Thomas P. Dickerson

Thomas P. Dickerson specialized in working with Tullis-Dickerson's portfolio companies to develop effective communication strategies and led the firm's relationships with Wall Street. He played a central role in the development of Tullis-Dickerson's relationships in developing entrepreneurial environments, and has written and spoken extensively on that topic. He has been a director of numerous portfolio companies and non-profit organizations.

Lyle A. Hohnke

Lyle A. Hahnke is a partner at the Tulli Dickerson & Company with full investment responsibility for identifyin structuring, monitoring and exiting investments in life sciences, healthcare and biotechnology (Birmingham, AL office). Total funds under her management include Javelin Capital (\$31MM), TD II (\$195MM) and TD III (\$130MM). Some of her successes include: Sensus, Scandipharm, ViaCell Adams Respiratory, BioRexis, LivHomand Atritech.

(continued)















VC Open House

New Orleans BioInnovation Center

Joan P. Neyscheler

Joan Neuscheler has more than 25 years of venture investing, fundraising, finanicial, and operations management experience. Ms. Neuscheler is Co-founder and Partner of Aura Equity Partners, which provides advisory services to private equity firms and portfolio companies. Prior to forming Aura Equity, Ms. Neuscheler spent 18 years as a General Partner of multiple Tullis-Dickerson healthcare venture capital funds with particular focus on healthcare IT/services, medical devices and specialty pharmaceuticals. From 1998 to 2008 she served as President of Tullis-Dickerson & Co., Inc ("TD"), the management company, and from 1989 to 2000 as Chief Financial Officer.

Richard J. Miller

Rick Miller has nineteen years of private equity investment experience and is the founder and Managing Member of Shippan Point Advisors LLC, a private equity advisory firm. As part of his private equity advisory work, Rick was a member of the general partnership of Tullis-Dickerson Capital Focus III, L.P. (2002-2006) and served as the Chairman and subsequently Chief Executive Officer of SupplyPro, Inc., an automated supply chain company for the manufacturing sector (2003-2006). Prior to founding Shippan Point Advisors in 2001, Rick was an executive at Onsite Access, Inc., a telecommunications company. Beginning in 1999, Rick was the Executive Vice President of Business Development and then added the role of Chief Financial Officer (2000) before becoming Chief Executive Officer in 2001 where he led successful strategic private equity investments in healthcare companies (1995-1999).

Robert V. Vialardi

Rob Vialardi has thirteen years of private equity investment experience. Since 2001, Rob has been a Partner with Shippan Point Advisors LLC, a private equity advisory firm, where he has responsibility for identifying new investment opportunities, working directly with portfolio companies and creating liquidity events for clients. In 2000, Rob was a Vice President of Investments at FrontLine Capital Group, an investment firm with \$400 million under management. Before joining FrontLine, Rob was part of GE Equity from 1996 through 1999, where he was involved in making strategic private equity investments in healthcare and business services companies. Rob began his professional career in 1992 as part of the Acquisition Finance Group of Chemical Securities Inc. (now J.P. Morgan) where he focused on financing leveraged buyouts.

New Orleans BioInnovation Center

134 La Salle St. New Orleans, LA70112

For additional information: stevenc@neworleansbio.com



BIOTECH CONNECT



Please rsvp at http://www.neworleansbio.com/newsandevents.html

EVENT AGENDA

WEDNESDAY, OCT 21ST

3PM PERKIN MENTORS SEMINAR Daniel DiLorenzo

@ NOBIC, New Orleans 4PM

Free to Attend, rsvp at neworleansbio.com

5:30PM BIOTECH CONNECT NETWORKING RECEPTION

7PM @ Roosevelt Hotel, New Orleans. Free to Attend, rsvp at neworleansbio.com

THURSDAY, OCT 22ND

YES! TO BUSINESS: BIOTECH 11:30AM Luncheon Forum with James Greenwood, BIO president and CEO
@ Roosevelt Hotel, New Orleans.
\$45/guest, registration at
acglouisiana@acg.org 1:30PM

2:PM 1 ON 1 WITH DANIEL DILORENZO Personal meetings with Daniel are 4PM available, please schedule in advance at stevenc@neworleansbio.com

END

NEW ORLEANS BIOTECH CONNECT

COME ENJOY FREE FOOD AND A CASH BAR!



Where?

The Roosevelt Hotel "Blue Room" 123 Baronne St. New Orleans, LA (504) 648-1200

Biotech Connect is a social event organized to provide a relaxed forum for scientists, entrepreneurs, business facilitators, lawyers, and venture capitalists to interact. These people do not usually mix, but their interaction is necessary and important for the economic development of biotechnology in New Orleans.

For More Information Contact info@neworleansbio.com























Making N.O. The City of YES!

in association with



Greater New Orleans Biosciences Economic Development District



"YES! to Business" Biotech

Thursday, October 22, 2009

11:30 A.M. TO 2 P.M.

Roosevelt Hotel



123 BARONNE STREET

SPECIAL GUEST SPEAKERS



James C. Greenwood
President and CEO
Biotechnology Industry Organization
Washington, D.C.



James P. McNamara
President and CEO
Greater New Orleans Biosciences
Economic Development District

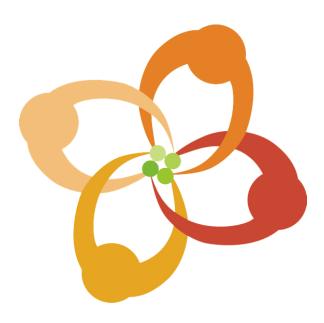
Guests: \$45

Table of Eight: \$350

RSVP: acglouisiana@acg.org

Ph: 504 348-3500 or 504 680-2973

APPENDIX I: Commercialization Core Awareness Slide Show



















Research Commercialization

Steven Ceulemans

Commercialization Coordinator

sceule@lsuhsc.edu



LVC/SLIIDR Commercialization Core

Mission

Establish pathways to more efficiently translate new discoveries into cures and treatments, create new partnerships between the institutions and existing biotech companies, and create bioscience business training opportunities for students.



Aims

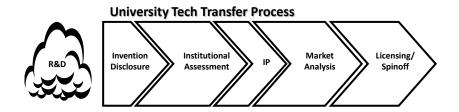
- (Student) exposure to the bioscience industry.
- · Inventory of capabilities & discoveries.
- · Commercial assessment and marketing of discoveries and IP.

Resources available for researchers:

Contact Steven Ceulemans at sceule@lsuhsc.edu

We are a link between academic researchers and the university technology development office and provide support with:

- · Invention disclosures.
- Collaborative R&D.
- Spinoffs (Business Plans, SBIR Grants, venture acceleration, ...)
- · Commercial assessment and marketing of discoveries and IP.



Seminar, Workshop, and Networking Opportunities

Objective:

 Bring local universities, business community, legal community, and economic development professionals together and raise awareness for research translation/commercialization as a potential outcome for academic research.

Sign-up for email confirmations and newsletter at www.neworleansbio.com

APPENDIX J: LVC Infection, Immunity and Vaccine Seminar Program Schedule 2010-2008





Infection, Immunity, and Vaccine Seminar Program – 2010 12:00 p.m.

LSUHSC Campus, CSRB Room 563, 533 Bolivar St. ◆

TUHSC Campus, School of Medicine Room 6065, 1430 Tulane Ave. ■

January 28 ♦	Gregory Poland, M.D., MACP, FIDSA
, ,	Mary Lowell Leary Endowed Professor of Medicine, Infectious Diseases, Molecular
	Pharmacology and Experimental Therapeutics Director, Mayo Vaccine Research
	Group Director
February 25 ♦	Alistair Ramsay, Ph.D.
•	Professor of Medicine
	Director, Gene Therapy Program
	LSU Health Sciences Center
March 11 ■	Mairi Noverr Ph.D
	Associate Professor, Department of Oral & Craniofacial Biology
	LSUHSC School of Dentistry
March 25 ♦	Tom Gillis, Ph.D.
	Chief, Laboratory Research Branch
	National Hansen's Disease Programs
	LSU School of Veterinary Medicine
April 8 ♦	Floyd L. Wormley Jr., Ph.D.
•	Assistant Professor of Microbiology & Immunology
	Department of Biology
	University of Texas at San Antonio
April 22 ■	Thomas Voss, Ph.D.
	Department of Microbiology and Immunology
	Tulane University School of Medicine
May 17 ♦	William R. Bishai, M.D., Ph.D.
-	Professor, Department of Medicine,
	The Johns Hopkins University
	Baltimore, MD
May 27 ♦	Patricia Kissinger, Ph.D.
•	Professor, Department of Epidemiology
	Tulane University School of Public Health and Tropical Medicine
June 10 ■	Alison Quayle, Ph.D.
	Associate Professor, Department of Microbiology, Immunology, and Parasitology
	LSU Health Sciences Center

August 12 ♦	James McLachlan, Ph.D.
	Assistant Professor
	Department of Microbiology and Immunology
	Tulane University School of Medicine
August 26 ■	John A. Vanchiere, M.D., Ph.D.
	Associate Professor
	Chief, Section of Pediatric Infectious Diseases
	LSU Health Science Center - Shreveport
September 9 ♦	Nirbhay Kumar, Ph.D.
	Professor and Head, Department of Tropical Medicine
	Tulane University School of Public Health and Tropical Medicine
September 23 ■	Chad Steele, Ph.D.
	Associate Professor, Department of Medicine, Division of Pulmonary, Allergy and
	Critical Care
	University of Alabama at Birmingham
October 14 ■	Rama Rao Amara, Ph.D.
	Emory Vaccine Center
	Associate Professor, Dept. Microbiology and Immunology
	Emory University School of Medicine
	Atlanta, GA
October 28 ♦	Robert Burne, Ph.D.
	Professor and Chair, Department of Oral Biology
	University of Florida, College of Dentistry
	Gainesville, FL
November 11 ♦	Bruce Beutler, M.D.
	Professor and Chairman
	The Department of Genetics
	The Scripps Research Institute
December 2♦	Joel Palefsky, M.D.
MEB 3209	University of California at San Francisco
	San Francisco, CA
December 9 ■	Angela Amedee, Ph.D.
	Associate Professor, Department of Microbiology, Immunology, and Parasitology
	LSU Health Sciences Center





Infection, Immunity, and Vaccine Seminar Program – 2009

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

January 29	"Nonhuman Primate Models for AIDS Research"
,	Ron Veazey, D.V.M., Ph.D.
	Chair, Division of Comparative Pathology and Professor of Pathology
	Tulane National Primate Research Center & Tulane University School of Medicine
February 12	"The pathogenesis of Staphylococcus aureus infection: the battle between sarA and
•	agr"
	Mark S. Smeltzer, Ph.D.
	Professor, Department of Microbiology and Immunology
	University of Arkansas for Medical Sciences
March 12	"Prevention of mother-to-child transmission of HIV: past successes and current
	challenges"
	Russell Van Dyke M.D.
	Department of Pediatrics, Section of Infectious Diseases
	Tulane University Health Sciences Center
March 26	A "Toll" Bridge for T cells: A novel mechanism of T cell costimulation
	Eduardo Davila, Ph.D.
	Assistant Professor, Department of Pediatrics
	LSU Health Sciences Center
April 9	" Th1 and Th17 pathway in intracellular bacterial infections"
	Shabaana A. Khader, PhD
	Division of Medicine, Allergy and Immunology
	Children's Hospital of Pittsburgh
	Pittsburgh, PA
April 23	"Antigen Structure and Epitope Dominance"
	Samuel Landry, Ph.D.
	Professor, Department of Biochemistry
	Tulane University School of Medicine
May 14	"Characterization and Evaluation of Novel Subunit Vaccines against Burkholderia
	pseudomallei"
	Lisa Morici, Ph.D.
	Research Assistant Professor, Department of Microbiology and Immunology
	Tulane University Health Sciences Center
May 28	"The Normal Vaginal Microbiome: Define "Normal""
	Michael Ferris, Ph.D.
	Assistant Professor, Department of Pediatrics & Microbiology, Immunology and
	Parasitology
	LSU Health Sciences Center

June 11	Christopher A. Hunter, Ph.D.
	"The Role of IL-27 in Modifying Infection-Induced Inflammation."
	Professor and Chair, Department of Pathobiology
	University of Pennsylvania, School Veterinary Medicine
August 13	Surojit Sarkar, Ph.D.
	"Differentiation of T cell Memory to Pathogens and Vaccines"
	Post-Doctoral Research Associate
	Department of Microbiology and Immunology
	Emory University School of Medicine
	Atlanta, GA
November 12	Martin Blaser M.D.
	"How Helicobacter pylori varies phenotypes important in host interactions."
	Chair, Department of Medicine
	New York University Medical Center
September 29	Roger G. Rank, Ph.D.
	"The critical role of the inflammatory response in chlamydial genital infection
	– 'the good, the bad, and the ugly'"
	Professor
	Chlamydia Research Group
	Arkansas Children's Hospital Research Institute
October 22	David Koelle, M.D.
	"Human T-Cell Responses to DS DNA Virus Infections at the Local and Systemic Level"
	Associate Professor of Medicine, Division of Allergy and Infectious Diseases
	University of Washington School of Medicine
	Seattle, WA
2 1 10	hosted by Drs. Hagensee and Quayle
December 10	Marshall E. Bloom, M.D.
	"Putting the Bite on Tick-Borne Flavivirus Infections"
	Division of Intramural Research
	Rocky Mountain Laboratories
	National Institutes of Health
	Hamilton, Montana





Infection, Immunity, and Vaccine Seminar Program - 2008

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

February 14	"Weak AIDS Vaccines, Safe AIDS Vaccines, and Some That May Even Work"
-	Preston Marx, Ph.D.
	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	"The Potential of Cyberinfrastructure for Complex Problem Solving in the Biomedical
	Sciences"
	Edward Seidel, Ph.D.
	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	"Ricin: Mechanisms of Toxicity and Protective Efficacy of Antibodies"
	Seth Pincus, M.D.
	Director, Research Institute for Children, New Orleans, LA and Professor, Pediatrics and
	Microbiology, Immunology, & Parasitology, LSUHSC, New Orleans, LA
March 12	"Current Status of HIV Vaccine Development"
	Barney S. Graham, M.D., Ph.D.
	Director of Clinical Studies, Dale and Betty Bumpers Vaccine Research Center (VRC),
April 10	NIH, Bethesda, Maryland (TENTATIVE) "Polymeric Nanoparticles: Novel Carriers for Vaccine Delivery"
April 10	Tarun K. Mandal, Ph.D.
	Professor of Pharmaceutics, College of Pharmacy, Xavier University of Louisiana, New
	Orleans, LA
April 24	"HIV Neutralizing Antibodies: Obstacles in HIV Vaccine Development"
•	James Robinson, M.D.
	Professor, Section of Pediatric Infectious Diseases, Department of Pediatrics, Tulane
	Hospital for Children, New Orleans, LA
May 8	"Novel Adjuvants and Delivery Systems for Transdermal Immunization"
	John D. Clements, Ph.D
	Professor and Chairman of Microbiology & Immunology, Tulane University HSC.
May 22	"The latest on host defense against mucosal yeast infections: It's all about the site."
-	Paul Fidel, Ph.D.
	Director, SLIIDR, 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	"A new genetic vaccine for West Nile Virus."
	K. Gus Kousoulas PhD
	Director, Division of Biotechnology & Molecular Medicine LSU School of Vet Medicine
June 26	"Regulatory T cells and Infectious Disease"
	Barry Rouse, Ph.D.
	Lindsay Young Distinguished Professor, UT Knoxville, TN
July 23	"Genetic Design and Manipulation of Salmonella Recombinant Vaccines."
	Roy Curtiss III, Ph.D.
	Director, The Biodesign Institute, Center for Infectious Diseases and Vaccinology
	Arizona State University
September 11	"The Human Immunology of Lassa Fever"
	Robert F. Garry, Jr. Ph.D.
	Department of Microbiology & Immunology Tulane University Health Sciences Center
September 25	"Thoughts on the Origin of Microbial Virulence"
	Arturo Casadevall, M.D., Ph.D.
	Professor, Department of Medicine (Infectious Diseases), Chair, Department of
	Microbiology & Immunology, Albert Einstein College of Medicine of Jeshiva University,
	New York, NY
October 9	"Modulation of the Host Response to Pneumocystis"
	Judd Shellito, M.D.
	Lowenstein Professor of Medicine
	Chief, Section of Pulmonary/Critical Care Medicine
	LSU Health Sciences Center- New Orleans
October 23	"Poxvirus Tropism is Linked to Immune Evasion"
	Grant McFadden, Ph.D.
	Professor, Department of Molecular Genetics & Microbiology
_	College of Medicine, University of Florida
November 6	"Immunization Route Modulates the Quality of HIV-Specific Cytolytic T Cell
	Responses"
	Charani Ranasinghe PhD
	John Curtin School of Medical Research
	Australian National University
November 13	"Perturbation, resilience, and the human microbiome"
	David Relman, M.D.
	Professor of Medicine (Infectious Diseases and Geographic Medicine) and of
	Microbiology and Immunology, Stanford University, Stanford, CA
December 11	"Mycoplasma genitalium: An Emerging Sexually Transmitted Pathogen"
	David Martin, M.D.
	Chief, Section of Infectious Diseases; Harry E. Dascomb Professor of Medicine
	Professor of Microbiology, LSU Health Sciences Center