



CENTERS OF EXCELLENCE APPLICATION
NORTH DAKOTA DEPARTMENT OF COMMERCE
 SFN 59095 (1/10)

Centers of Excellence Application

Approved by the Centers of Excellence Commission July 14, 2010

I. Requesting Institution or Foundation:

NOTE: Boxes will expand as information is entered.

Name of Requesting Institution or Foundation: North Dakota State University

Project Title: CBRP 2.0: Development of devices for transplantation, RNA interference for live vaccines, Vaccines based on molecular breeding and Product Development of Immunotherapeutic agents

Amount of Request: \$3,015,000

Amount of Matching Funds: \$6,630,000

Number of New Private Sector Jobs to be Created: Approximately 40-60 jobs are anticipated to be created

List Private Sector Participants: Somahlution, Avianax, Aldevron, Altravax

Campus contact person or principal investigator

Name: Satishchandran
Chandrasekhar

Title or Position: Director, Center for
Biopharmaceutical Research
& Production and Professor,
Pharmaceutical Sciences,
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Name of local developer (if any) familiar with project: Mary Batcheller, GFMEDC
Jim Carlson
Gerald Finken, CSM

Essential Qualifying Factors:

1. The center must be an institution of higher education under the control of the State Board of Higher Education or a non-profit university-related or college-related foundation of an institution of higher education under the control of the board. All applications must go through the process established by their university or college and be signed by their institution's president. Each campus may submit up to two applications per round of funding.
2. The institution or foundation must be working in partnership with the private sector and create high value private sector employment opportunities.
3. Two dollars of matching funds are required for each dollar of state funds. These matching funds cannot be state funds and must be either funds from private sector partners or funds facilitated through the collaboration of the private sector partners with other funding entities. Of the two dollars of matching funds, at least one dollar must be cash, of which at least fifty cents must be from the private sector.
4. Funds cannot be used for infrastructure, to supplant funding for current operations or academic instructions, or to pay indirect costs.
5. Workforce may not be the primary need addressed by a Center.

II. Approval by Institution:

The approval and recommendation by the president/dean of the university or college is required to insure the funding request is consistent with the mission and development plans of the institution. Please sign below to indicate your approval and recommendation.
(Please type in name of President/Dean when submitting electronic copies)



Signature of President / Dean

October 15, 2010
Date

III. Executive Summary (limited to one page)

In 2008, the North Dakota Economic Development Center of Excellence Commission established the Center for Biopharmaceutical Research and Production (CBRP) to perform economically significant and market-driven research and development of vaccines that address unmet medical needs in commercially relevant areas. To date, the Center has hired a world renowned Director to head the program, and has established relationships with three North Dakota biotechnology companies to move their products to commercially viable clinical programs, established collaborations with NDSU researchers, UND, UNDRF and with the CoE at UND, the Center for Passive Immunotherapy.

The Center is currently seeking additional funds to further its initial successes, as well as complement them by developing internal capabilities in non-vaccine related biotherapeutics. The Center will move the most innovative research from NDSU, UND, and other area institutions into businesses to create new high-tech jobs for North Dakota. CBRP efforts will lead to new and/or enhanced products that will advance through clinical development, with the ultimate goal of commercialization and sale in the marketplace.

The CBRP will work with both in-state and out-of-state biotech companies on drug development. This work will increase revenue, market share, and profitability for the CBRP's private partners, which, in turn, will stimulate corporate growth and biotechnology entrepreneurship in the state, promote the creation of new jobs, and lead to further economic development. Work with out-of-state companies will encourage them to locate drug product manufacturing and research activities to North Dakota.

The CBRP will facilitate the near-term creation of over 40 new professional and technical jobs both in the private sector and at the Center itself. Many more jobs will be created in a longer term. The Center's objective is to become self-sustaining by generating and maintaining multiple revenue streams from both public and private sectors. The Center's synergistic relationship with academia, industry, federal funding agencies and the community will fuel biopharmaceutical R&D in N.D. to discover and develop new biopharmaceuticals to treat some of the most challenging diseases facing humankind.

IV. Private Sector Partner(s):

A completed "Verification of Private Sector Participation" form from every private sector partner should be attached to the proposal.

V. Center Description:

- Proposals shall include a description of the center and the purpose(s) toward which the requested funds will be applied.

The mission of the CBRP is to perform economically significant and market-driven research and development of vaccines that address unmet medical needs in commercially relevant areas. The vision of the CBRP is to create a biotechnology hub in the Red River Valley by generating an interactive industry cluster with seamless integration of academic research, biotechnology companies, Contract Research Organizations (CROs) and venture funds. The Center, through its participation with all players at all levels, will act as the catalyst to achieve this vision.

Biopharmaceuticals are derivatives of natural compounds and invoke biological responses in humans similar to responses in humans who recover from diseases. Unlike traditional small molecule drugs, biopharmaceuticals hold tremendous promise: despite the drawbacks of drug delivery and stability, a significantly greater number of biopharmaceuticals finish the race to marketplace, and those that do often realize far greater returns on investment than traditional drugs. Therefore, there is significant excitement surrounding biopharmaceuticals among biotech companies, pharmaceutical companies and venture capitalists. The industry provides tremendous potential to create investment, jobs and economic growth in N.D.

Biopharmaceuticals have been vital in reducing morbidity and mortality. Some of the greatest public health milestones have been attributed to research and development of biopharmaceuticals such as vaccines for smallpox, polio, mumps, measles, rubella, chickenpox, pertussis, influenza, meningitis, and Hepatitis-B, and therapeutics for transplant medicine, and autoimmune, inflammatory, infectious, neurologic, metabolic and cardiovascular diseases. Yet despite these victories, the world is currently being threatened at an alarming rate with new and re-emerging diseases, the need for better and

improved cures, and safe and effective vaccines. Because of this, the U.S. government and National Institutes of Health (NIH) have established vaccine research and development as a critical priority for future emphasis in healthcare research.

The process by which biopharmaceuticals and vaccines are designed and developed is complex and requires multiple partners to be successful. Most currently available biopharmaceuticals have resulted from collaborative partnerships between the public and private sector, including small and large businesses, academic research institutions, state and federal governments, non-profits, and global organizations. The importance of utilizing these strong cross-sector partnerships is recognized, emphasized, and encouraged by the various funding agencies which support current biopharmaceutical and vaccine research. In addition, new technological advances in life sciences, coupled with recent advances in bio-nanotechnology have created tremendous opportunities in recent years for advancing biopharmaceutical research. Such opportunities include identifying and designing novel candidates, improving safety and efficacy of existing biopharmaceuticals, and developing and implementing novel vaccine approaches, such as novel antigenic variants, new adjuvants and immunomodulators. These will help advance the development of novel drugs for prevention and treatment of diseases. The appropriate partnerships leveraging the use of the latest technologies in science and engineering will enable the design, development, evaluation, and production of a new generation of prophylactic and therapeutic biopharmaceuticals for diseases with significant public health consequences. Concomitantly, it will produce a very rich environment for attracting additional public and private sector partners and funding, and will have a profound impact on economic development.

Utilizing North Dakota resources and business partnerships, the Center would provide opportunities for the Fargo/Cass County community, the Red River Valley Research Corridor and the State of North Dakota to: (a) promote the creation of new, high-paying jobs in the life sciences sector; (b) provide opportunities to spin out new business start-ups; (c) assist in building economic development within the

state and region, including boosting the growth and development of local private business partners as well as the recruitment of business from outside the state; (d) provide educational and training opportunities for undergraduate and graduate students, postdoctoral fellows and employees of local businesses; (e) become a model and a foundation for developing the life sciences focus in the Fargo/Cass County community, North Dakota, the region and the nation; (f) attract major research grants from the federal government, including the National Institutes of Health (NIH), Department of Defense (DoD), and National Science Foundation (NSF), as well as private foundations and other potential non-profit partners (Bill Gates Foundation, World Health Organization, etc.); and (g) provide opportunities for NDSU and its private sector partners to generate new, novel, high-value intellectual property, including novel vaccine and biopharmaceutical products for commercialization.

The Center will be built upon existing capabilities and capacity to create economic value, especially through high technology and knowledge-intensive activities. The Center will develop or will help develop competitive and leading biopharmaceutical and biotechnology industries with increased employment and wealth creation, leading to enhanced social well being of the people of North Dakota. Additionally, the Center will be supported by the private sector partners and through grants and contracts from the state and federal funding agencies and foundations. We believe that the Center would be self-funded within approximately four years through a combination of such grants, contracts and sponsored research and through revenue participation with the private sector. In addition, the Center expects to generate additional revenues through licensure of patented technologies and products. Personnel associated with the Center will also be encouraged and incentivized to “spin off” biopharmaceutical companies based on product development and contracted research in the region.

The personnel, equipment and facilities needed to launch CBRP would come from the North Dakota Center of Excellence funds as well as from the resources provided from various private sector partners. One of the primary needs for developing such a Center is the recruitment of additional talents in the

diverse areas of biopharmaceutical research, in drug delivery, discovery of novel adjuvants, RNA interference, biopharmaceutical manufacturing, regulatory and clinical strategy development. Another primary need is the creation of a new, major research laboratory on the NDSU campus with sufficient space, equipment and personnel to support the growth of the Center. Such a world-class facility would complement North Dakota's investment in the Center, should it receive ED-COE funding, and enable the Center to be far more competitive in procuring grants and contracts and generating high value IP and products capable of significant licensing revenue.

The College of Pharmacy, Nursing, and Allied Sciences at NDSU has taken the lead in developing the Center thus far, and this relationship has been productive and fruitful. The Center's research activities will continue to focus on the critical gaps in developing high value biopharmaceutical products, and in conjunction with its private partners focusing on developing products through to clinical evaluation. The Center proposes to complement its current programs in vaccines by developing additional research programs in three biopharmaceutical areas of research: transplant medicine, molecular breeding-based vaccines and immunotherapy. As the drug development modules are assembled at the Center to enable biotech company partners to develop their products, the Center will focus its internal discovery and product development efforts on unmet and high economic impact areas; in vaccines such as Norwalk, West Nile virus and dengue, and in disease areas such as lupus, multiple sclerosis, diabetes and cardiovascular, and Duchene's Muscular Dystrophy.

Avianax: Through collaboration with a ND-based company, Avianax, the Center will co-develop and assist in the development of immunotherapeutic agents against infectious agents and toxins for use in humans following exposure to disease causing agent(s). Advancing these into the clinic and demonstration of safety of these product candidates is expected to be sufficient to develop products for use in acute settings, such as against DoD's list of bioterrorism agents. Avianax has obtained federal Dept. of Energy grants which will be used as matching funds in cash to the Center (\$380,000).

Altravax: Altravax's technology of molecular breeding provides a unique strategy to develop novel classes of antigens, particularly against chronic infections, and the Center will use Altravax's technologies to develop therapeutic vaccine candidates. Altravax's contribution of \$3,000,000 (in kind) to the Center will be used as matching private sector funds. This "in-kind" contribution is in the form of a license of their patent portfolio for one indication that the Center will name at a later date. The value of this contribution is based on previous transactions involving the molecular breeding technology.

SomahLution: The Center will collaborate with SomahLution, a company that functions semi-virtually, with operations in Pennsylvania, Maryland and Massachusetts. The Company will provide matching funds (\$750,000) to enable product and clinical development of its product candidates at the Center. Additionally, SomahLution, Inc. will expend \$500,000 in contracts for manufacturing in the State of North Dakota, for a cash reserved match. SomahLution is focused on transplant technologies that enable the extension of organ preservation time by 10-50 times what is currently possible. The Center is proposing to participate in developing the company's product through manufacture and clinical development. The Center will also develop RNAi strategies to enable transplantation of organs into recipients who are currently not eligible to receive organs for transplantation. Furthermore, the Center will develop RNAi strategies to prevent anti-graft responses by the host, a major issue in transplant medicine. The Center will also actively pursue locating SomahLution's manufacturing capabilities, and possibly their R&D activities, to N.D. to create new jobs for local citizens.

The Center will also provide guidance and develop strategies to enable its partners' products to enter clinical evaluation through research at either Sanford Health Fargo and/or Cetero. Aldevron is a major player in this, since much of commercial product manufacture will be carried out in Aldevron's facilities. CSM (Clinical supply Management) will be an active partner in the supply of products advanced from the Center and products advanced through collaborations with the Center. Such collaboration will build additional relationships between companies both within and outside the state, benefiting the North

Dakota economy and generating high-value biotech jobs in these other (secondary) participating institutions/companies. Furthermore, such relationships will also significantly enhance the biotechnology activities in the region.

With the additional funds that are being sought from ED-COE, along with matching funds from private and public sources, CBRP efforts will lead to new or enhanced products that can increase revenue, market share and profitability for ED-COE partner companies which, in turn, is predicted to stimulate corporate growth, promote the creation of 40-80 new jobs, increase biotechnology activities in the state and thus lead to further economic development in North Dakota.

Such collaborations with multiple private sector partners will allow assembly of a top-notch research talent pool at the Center, further enabling collaborative research programs with additional companies. Creating a biotech corridor in N.D. will require the participation of several such biotechnology companies, as achieving a critical mass of talent and businesses is necessary to achieving self-sustenance and interdependence of a regional biotech community. The Center will be the catalyst in achieving this end result.

The following are the essential qualifying factors:

- The Center is part of NDSU College of Pharmacy, Nursing, and Allied Sciences, which is an institution of higher education under the control of the State Board of Higher Education.
- The Center is working in partnership with private sectors companies and will create high-value private sector employment opportunities as projected in the letter of support.
- The Center requests \$3,065,000 from the state with \$6,630,000 match. Thus, the Center provides two dollars of matching funds for each dollar of state funds. The matching funds are not state funds. These funds are a combination of private sector partners, funds from Federal grant subcontracts, public funds and intellectual property.
- The funds will not be used to supplant funding for current operations, academic instruction, or to

pay indirect costs.

- The center will focus on development of vaccines and biopharmaceutical products. The state funds requested would help set up the Center with adequate personnel, equipment, supplies, and operating costs for collaborative private-public projects.

- What makes the project or program a center of excellence?

CBRP was established with strong ties to the Department of Pharmaceutical Sciences. The Director of the Center is a Professor of this Department and the Department has a strong focus and expertise in biopharmaceutical drug development and biopharmaceutical drug delivery. The Department of Pharmaceutical Sciences, one of the four units of NDSU's College of Pharmacy, Nursing and Allied Sciences, is well known nationally and internationally for high-quality research and development of biopharmaceuticals. Currently, several of the tenured and tenure-track faculty within the department have grants from federal and/or national research foundation sources; over \$10.5M in Federal grants (NIH) in collaboration with Department of Chemistry to establish a Center for Biomedical Research Excellence (COBRE) at NDSU and also as part of \$16.3 million NIH INBRE grant. In addition, the Department manages three NIH "R-01" grants and a major grant from NSF. The department's faculty routinely engages in multi-department, multi-investigator grants and contracts with other departments within and outside NDSU. The Department of Pharmaceutical Sciences has an excellent national and international reputation amongst peers around the world in academia and biopharmaceutical companies. In concert with active and strong life science sector private partners, the CBRP is well poised to expand its horizons in developing medical devices, biopharmaceutical drug products and vaccines, and in creating the biotechnology cluster in N.D.

- Brief section on history of the center including stage of development: already well established; in the early stages of being developed; in planning stage.

CBRP was founded at NDSU's College of Pharmacy and seeded by the N.D. ED-CoE and several corporate partners over two years ago. The Center was originally envisioned by researchers at the

Pharmaceutical Sciences Department at NDSU to focus on vaccines based on the research focus of the department. The Center has since recruited a Director with significant experience in developing Biopharmaceutical products and vaccines. The initial focus was in DNA-based vaccines, primarily due to expertise in DNA delivery at NDSU and based on the expertise of its corporate partners, such as, Aldevron. However, in order to seize the opportunities afforded by very recent discoveries in transplant medicine, RNA interference and drug delivery, the Center has expanded its scope to extend its capabilities to non-vaccine biopharmaceuticals and devices.

- The Centers of Excellence Commission is required to determine whether the applicant has conducted the due diligence necessary to put together a viable proposal. Please explain the process that was undertaken to determine that this is a viable proposal.

The Director of the Center, Dr. Satishchandran Chandrasekhar (Satish), has extensive background in the biopharmaceutical industry. He founded several companies in cutting-edge biotechnology space, such as DNA vaccines and RNA interference, and has held positions as senior executive in multiple biotechnology companies, where he directed programs in discovery and development. Immediately prior to joining the Center he was the Chief Technology Officer in the Biotherapeutic Division (OTU) of Pfizer. His role at Pfizer was also similar; to identify unmet need, to address commercial viability of products, to identify gaps, bring technologies to bear on the gaps and to coordinate with disease program divisions and business units of the Company. He has published extensively and has several patents that have been commercialized. He is on the board of directors and the scientific advisory board of several biotechnology companies. During his 20+ years of tenure in the biopharmaceutical space, Satish has developed multiple products from discovery through product development and into the clinic. The expertise that Satish brings to the Center in evaluating technologies, programs and gaps in bringing product candidates to the marketplace and committed collaboration from venture-funded companies gives a degree of assurance that the proposal is highly viable.

The programs that are planned in collaboration with the private sector partners are in technologies

and product candidates that have the multibillion-dollar revenue potential, and therefore were able to raise significant venture capital. Venture capital firms that funded these companies completed significant due-diligence on their investments that assessed technology risks, business risks and marketing risks. The programs in transplant medicine, vaccines and immunotherapeutics address unmet needs and have significant economic impact.

While some of the research activities at the Center address gaps in assisting the private sector partners to move their products into the market place through product development, regulatory and clinical strategy development, the other research activities at the Center will address the gaps that are general to biotherapeutic drug development. These include research activities in drug delivery, adjuvants for vaccines and RNA interference. Developing a comprehensive set of interconnected modules and capabilities will allow the Center to be poised to take its own drug development from discovery all the way to the market place.

Aside from assisting private sector partners with their products, the Center will focus its internal discovery and product development efforts on unmet and high economic impact areas.

VI. Funding Request – Required Information:

1. Amount of center of excellence funding being requested?

\$3,015,000 for a three-year period.

2. Amount of matching funds by source and type?

a. Private Sector Business Match

i. Cash to be given to the Center

\$1,130,000

ii. Cash reserved by the private sector partner to be expended on behalf of the project

\$500,000

iii. In-Kind Assets allocated for the benefit of the project

\$3,000,000

b. Other Funds Facilitated Through the Collaboration of the Private Sector Participants

i. Local Economic Development Funds

1. Cash to be given to the Center

\$2,000,000

2. Cash reserved to be expended on behalf of the project

3. In-Kind Assets allocated for the benefit of the project

ii. Community Funds

1. Cash to be given to the Center

2. Cash reserved to be expended on behalf of the project

3. In-Kind Assets allocated for the benefit of the project

iii. Other Private Organizations

1. Cash to be given to the Center

2. Cash reserved to be expended on behalf of the project

3. In-Kind Assets allocated for the benefit of the project

iv. Federal Funds

1. Cash to be given to the Center

2. Cash reserved to be expended on behalf of the project

3. In-Kind Assets allocated for the benefit of the project

c. Total Matching Funds:

\$6,630,000

3. Degree of certainty and time-line of when matching funds will be available?

- 100% certainty that the funds will be made available to the Center.
- SomahLution, Inc. is fully capitalized to take transplant related products into market

in 3 years, they are adequately funded for 3+ years, \$18.4M has been raised in the last Series A round.

- Avianax, LLC is well funded through Department of Energy grant of about \$4.5M. Avianax will subcontract product development efforts to the Center.
- The funds from all of the private sector partners would be advanced to the Center on a quarterly basis. The private sector partners are well capitalized and have operational funds to cover the three year period of the collaboration and beyond

4. Amount of other funds already invested, or which will be invested, but not eligible for match?

a. State Funds

\$2,000,000 awarded in July 2008

b. Other Funds Secured (but not in collaboration with private sector participants)

c. Total Funds Not Eligible for Match

5. Please attach a one-page budget, and a budget narrative, detailing how the funds would be expended and a tentative timeline for the expenditures.

6. For any in-kind match, please attach documentation detailing the valuation.

VII. Criteria for Funding:

Provide the following information:

A. Legislatively determined factors:

In considering whether to approve or disapprove an application, the Commission shall consider whether the center will:

1. Use university or college research to promote private sector job growth and expansion of knowledge-based industries or use university or college research to promote the development of new products, high-tech companies, or skilled jobs in this state.

The Center would continue to strengthen education and training in biopharmaceuticals and development of biopharmaceuticals and vaccines. The term vaccinology is used to describe the full gamut of vaccine development and application activities, including research to discover protective antigens, construction

of vaccine candidates (attenuated strains, purified antigens and DNA vaccine plasmids) and identification of novel adjuvants, to evaluate the safety and immunogenicity of vaccines in humans, detailed studies of human immune responses to vaccine antigens, and epidemiologic studies to identify target population for immunization. Similarly, although biopharmaceuticals are classed together, they are unique in their molecular nature. While >95% of available and accessible expertise in pharmaceuticals is based on small molecule drug development, it has little relevance to biopharmaceutical drug development; biopharmaceutical drug product development is uniquely different and is often tailored to each type of biopharmaceutical drug substance. The expertise and skills required for manufacturing and scale-up of biopharmaceuticals and vaccines are also not obtained easily through current academic disciplines. To enable the development of a functional cluster, the Center would: (a) Appoint senior level talents in the multidisciplinary and multifaceted fields of biopharmaceutics, (b) Develop programs in strategic areas of biopharmaceutical development, (c) Train the next generation of highly skilled and valued vaccinologists, which would include training in academic and industrial vaccinology, (d) Develop, support and create incentives for post-doctoral fellowships in both basic and clinical vaccinology, (e) Develop co-op programs to enable undergraduates and graduate students to participate in drug development with industry, (f) Develop scholar exchange programs with biotechnology companies and biotechnology institutions around the world, (g) Create biotech entrepreneurship in the area by working with the School of Business and through co-op programs and encouraging inventors, and (h) Provide an opportunity to expand the life sciences sector in the state and enhance the growth of the vaccine industry cluster in the region and state.

Following the trail blazed by Aldevron, Avianax, Altravax and SomahLution, and other private sector partners, the Center would promote private sector job growth in a knowledge-based industry while generating new, high-tech products that address commercially viable unmet medical needs.

The Center will continue to foster collaborations among academia, industry and government, which would have positive impact in expediting the development of several biopharmaceuticals, including vaccines. In order to ensure the above collaborations are strengthened, the Center would explore the feasibility of novel incentives through collaborative research/development partnerships for biopharmaceutical development that would particularly be relevant to small companies that rely on early-stage investments before product sales.

The Center would also strengthen international collaborations for biopharmaceuticals research, development and evaluation, by developing opportunities for participation by North Dakota scientists in biopharmaceutical research globally; through technology transfer and by facilitating North Dakota's participation in these projects; work with Centers for Disease Control (CDC) to ensure availability of critical data for priority setting, site selection for clinical trials, and appropriate introduction of novel products. Establishing an international presence and reputation could facilitate attraction of key industry players in biotechnology and biopharmaceuticals to the region and state.

The Center would help the process of moving the most innovative research from NDSU and local area institutions into the business sector, which in turn would promote the creation of higher-paying jobs for North Dakotans. The Center would develop relationships with seasoned businesses as well as potential licensees interested in the market potential of specific products and/or technologies in life sciences (e.g., vaccine, biopharmaceuticals and biotechnology).

The Center would draw its expertise from NDSU Pharmaceutical Sciences, partnering companies, and GFMEDC to accomplish the following: (a) Develop new biopharmaceuticals, vaccines and diagnostics; (b) Train and generate a high-skilled biopharmaceutical/pharmaceutical biotechnology workforce; (c) Produce a sustainable biopharmaceutical research and development facility blending the best practices of industry and academia; and (d) Stimulate growth of a stronger and larger biopharmaceutical industry in North Dakota.

2. Create high-value private sector employment opportunities in this state.

The CBRP would lead to near-term creation of over 40 high value private sector jobs, including about 10 new jobs by direct hires in CBRP. Major hiring is expected from private sector partners and collaborators through contracted or sponsored research and development. Additional jobs will be created through new start-ups in the biopharmaceutical space and by attracting biotechnology company activities to the area. Thus, the Center will: enhance and aid current life science businesses, attract new businesses, stimulate private investment, promote the creation of jobs, and encourage the expansion and retention of existing companies, and provide businesses in North Dakota with workforce development in a growing and valuable business sector.

3. Provide for public-private sector involvement and partnerships.

Public-private sector involvement and partnerships with existing North Dakota biopharmaceutical companies and healthcare systems are strategic cornerstones of Center's mission. Partnerships with Aldevron, CSM, Avianax, Altravax, Cetero and Sanford Health have been initiated or planned; these will further facilitate the procurement of new life science companies to make products or product components in North Dakota.

4. Leverage other funding, including cash from the private sector.

The Center has leveraged \$3,130,000 in cash, \$500,000 in reserved cash and \$3,000,000 in-kind.

5. Increase research and development activities that may involve federal funding from the national science foundation experimental program to stimulate competitive research.

The Center will use equipment, materials, salary and travel as match from the Experimental Program to Stimulate Competitive Research (EPSCoR), Defense EPSCoR, U.S. NIH CoBRE, NIH BRIN and NASA EPSCoR competitive grants and contracts. At maturation, CBRP will also submit competitive research proposals to the agencies listed above. Such research will also be helpful in solving other commercial problems, e.g., biologic products for catalysis and processing high-value protein products.

6. Foster and practice entrepreneurship.

The Center's core business model will enable and foster entrepreneurship. The Center will help develop new start-up companies that would utilize intellectual property developed by the Center or through the use of licensed intellectual property as the foundation for their business models. The Center will also assist start-ups to obtain funding through venture and angel investors. Entrepreneurship is also highly promoted and encouraged by the NDSU Research and Technology Park.

7. Promote the commercialization of new products and services in industry clusters (advanced manufacturing, energy, information and technology, tourism, value-added agriculture, or an industry, including the aerospace industry, specifically identified by the Department of Commerce as an industry that will contribute to the gross state product).

The Center will help generate or attract new businesses in biotechnology and biopharmaceuticals, stimulate private investment and create jobs, encourage the expansion and retention of existing companies, and provide businesses in North Dakota with workforce training and product development. Through its activities significant commercialization in the biopharmaceutical services sector is anticipated. All these activities will contribute to growing North Dakota's gross state product.

8. Become financially self-sustaining.

Presently, the Center is funded by ND-COE, research grants and contracts from state, regional and federal grant agencies as well as sponsored research funding by private sector partners. The Center should be self-funding within five years through a combination of grants and contracts. In the future, self-sustaining revenues will be generated through licensure of patented technologies. It is also hoped that personnel associated with the Center will "spin off" their own regional biopharmaceutical companies based around product development or pure fee-for-service research and development. In this way, the desired critical mass of expertise and experience can build on itself and reach the point where North Dakota life sciences and biopharmaceutical industries are of such a size that they can attract significant investment capital from major investors and companies.

9. Establish and meet a deadline for acquiring and expending all public and private funds specified in the application.

The deadline for acquiring and expending all public and private funds will be handled according to NDSU policies and procedures. Reports will be submitted annually and will include data on acquiring and expending public and private funds. The major challenge would be hiring senior biopharmaceutical talents to seed various programs. However, we strongly believe that we would attain the stated goals for the Center.

B. Centers of Excellence Commission determined factors:

10. Community support.

There is significant community support as evidenced by GIF's willingness to consider funding the Center. The goals of the Center are well-aligned with the mission and vision of the GFMEDC, the administrating entity of the GIF.

11. Collaboration among institutions.

The Center will collaborate with area institutions, such as UND, UNDRF, Minnesota State University Moorhead, Concordia College and amongst the various departments at NDSU. The Center is poised to initiate collaboration with the Center of Excellence for Passive Immunotherapy at UNDRF.

VIII. Accountability and Reporting:

Proposals shall include:

1. A description or listing of the sources and/or metrics to be used to measure the extent to which the criteria listed in Section VII will be achieved.

The Center will solicit feedback from private sector partners in order to evaluate the success of the project. The participating partners will provide reports annually with information pertinent to commercialization activities. Such information will be compiled by CBRP and provided to the ED-COE for further evaluation. The requested information will include new jobs created, increase in revenue, etc.

2. The major results expected and a time-line for the expected results.

The Center is anticipated to be fully staffed and operational by July 2011. The overall results anticipated

by the end of the project are to set up the facilities, satisfy private sector partners' goals, and progress towards self-sustenance. The Center will initiate its internal efforts on discovery research in drug delivery, RNAi and adjuvants, and thus be able to secure significant grant funding and/or sponsored research by 2013. Future goals include developing patents and products, limited only by the process of "Science" and "Research".

3. Measurable goals and objectives for the Center's first year in operation. Each approved Center will be required to submit annually measurable goals and objectives for the upcoming year and an update on the previous measurable goals and objectives.

1. Meet private sector partners' timelines, 2. Hire senior level talents, 3. Complete hiring of post-doctoral fellows and researchers, 4. Initiate discovery programs and 5. Initiate teaching programs to enable workforce development

4. Provisions to comply with the monitoring policies of the Commission including submission of annual progress reports.

We will submit a preliminary report after project start-up in order to document initial activities, and to allow the Commission to review CBRP initial start-up and plans. The Center director will submit annual reports detailing the status of this proposal, summary of projects and their accomplishments, and financial/workforce/contracts status review. Annual review meetings will be scheduled as requested by the Commission.

5. The Commission is required by statute to monitor each Center's activities for a period of six to ten years in order to determine whether the Center is having the desired economic impact. As a condition for receipt of funds, each Center shall agree to provide the Commission with the information necessary to monitor the post award activities of the Center.

The Center will provide the Commission with any required information necessary to monitor six to ten years post award activities in order to determine the desired economic impact of the Center.

IX. Proposal Submission:

1. Proposals shall be no more than 20 pages in length, double-spaced and with no less than 12-point type, plus any attachments, with the first attachment being the one-page budget.
2. Applicants are encouraged to submit proposals electronically.
3. Two copies of the proposal shall be submitted initially for review regarding completeness and compliance with legislative requirements.

Electronic copies are to be sent to Justin Dever (jdever@nd.gov) at the North Dakota Department of Commerce.

If submitting applications by hard copy, send to:

Justin Dever
North Dakota Department of Commerce
P.O. Box 2057
Bismarck, North Dakota 58502-5300
701.328.7258

5. Ten copies of the final proposal (as opposed to the initial proposal referred to in paragraph four above) shall be sent to the Department of Commerce to be forwarded to the Centers of Excellence Commission. If the proposal is being submitted electronically, send single electronic copies to Justin Dever at the email addresses listed above.

X. Process/Time-line:

See last page of application for the time-line for the spring 2010 round of Centers of Excellence funding.

XI. Evaluation:

The Commission will evaluate each application using the criteria contained in Section VII. Special emphasis will be placed on creating high-value employment opportunities in the state and less emphasis will be placed on community support, collaboration among institutions, and establishing and meeting a deadline for acquiring and expending all public and private funds specified in the application. All other criteria will be judged with equal emphasis. The legislation allows flexibility for the commission to evaluate based on the above criteria as well as any other factors deemed necessary.

The Commission may also call for an independent, expert review of the application to determine whether the proposed center is viable and whether the proposed center is likely to have the desired economic impact.

XII. Grant Agreements:

Any successful proposals will be required to enter into a grant agreement prior to receiving any funds. This grant agreement will include a statement of the recipient's responsibilities and actions the Commission may take if the recipient does not comply with state law or their responsibilities outlined in the agreement.

XIII. Previously Funded Centers:

Additional information may be requested by the Commission if a previously funded Center of Excellence is applying for additional funds.

ATTACHMENTS

- Budget
- Budget Narrative
- Appendices
 - C. Satishchandran, Principal Investigator
 - Biographical Sketch/Resume
 - Growth Initiative Fund, Inc.
 - Letter of Support
 - Mary Batcheller – Biography
 - SomahLution
 - Letter of Support
 - Business Plan
 - Commitment of Funding
 - Verification of Private Sector Participation
 - Arkesh Mehta – Resume
 - Mutual Nondisclosure Agreement
 - Altravax
 - Letter of Support
 - Company Profile
 - Verification of Private Sector Participation
 - Robert Whalen – Resume
 - Mutual Nondisclosure Agreement
 - Avianax
 - Letter of Support
 - Verification of Private Sector Participation
 - James Schiltz – Resume
 - Avianax/NDSU Collaboration Agreement
 - University of North Dakota
 - Letter of Support
 - David Bradley – Biographical Sketch/Resume

CRBP(2) Proposed Budget- Complete Breakdown

ND - COE Funds Request	Year 1	Year 2	Year 3	Total
Associate Research Professor (1)	125,000	131,250	137,813	394,063
Assistant Research Professor (1)	104,000	109,200	114,660	327,860
Post Doctoral Researchers(2)	80,000	84,000	88,200	252,200
Laboratory Technicians (2)	72,000	75,600	79,380	226,980
Administrative Assistant (1)	41,000	43,050	45,203	129,253
Regulatory Administrator (1)	80,000	84,000	88,200	252,200
Business Development Co-Opts (2)	80,000	84,000	88,200	252,200
Clinical Researcher (1)	80,000	84,000	88,200	252,200
Graduate Research Assistants (3)	48,000	50,400	52,920	151,320
Fringe Benefits	198,600	208,530	218,957	626,087
Personnel (Salary & FB)	908,600	954,030	1,001,732	2,864,362
Equipment	159,238	41,400		200,638
Total Budget - COE Funds	1,067,838	995,430	1,001,732	3,065,000
Matching Funds Pledged	Year 1	Year 2	Year 3	Total
Post Doctoral Researcher (1)	40,000	42,000	44,100	126,100
Fringe Benefits	12,000	12,600	13,230	37,830
Personnel (Salary & FB)	52,000	54,600	57,330	163,930
Operating	92,000	45,000	45,000	182,000
Research Supplies	110,000	125,000	125,000	360,000
Product Development	150,000	250,000	250,000	650,000
Preclinical Development	150,000	250,000	250,000	650,000
Equipment	400,000	200,000	74,070	674,070
Lease	150,000	150,000	150,000	450,000
Cash Match Budget	1,104,000	1,074,600	951,400	3,130,000
Cash Reserved Match	166,666	166,667	166,667	500,000
In-Kind Match	3,000,000			3,000,000
TOTAL MATCH	4,270,666	1,241,267	1,118,067	6,630,000

CBRP Budget Narrative

Overview: The budget is broken up and elaborated to show that the CoE funds will primarily be utilized for hiring of personnel, while the matching funds will be used for operational, contractual and other needs of the Center.

Personnel: Over 10 personnel will be hired into the CBRP with the funds requested in this application. These will include senior staff researchers, post-doctoral researchers, graduate students, Undergraduate co-op students from the business schools and science students in the region, and individuals with product development, clinical and regulatory experience. The goal is to assemble a comprehensive group/structure at the Center to enable discovery research through to clinical development of its private sector partners and to enable the Center to develop its internal research and development of products derived from the research. The goal and the mission of the Center is to create many opportunities through development of its private sector partners and through its internal programs to create high value biotech jobs in the region (Red River Valley Research Corridor and in the State of North Dakota). The predicted results of these activities also include initiating biotech startups and licensing of intellectual properties and products. Through these multiple ways the Center will also become self sufficient in 5 years and to be able to take on additional grants and contracts from federal agencies and private foundations/companies. The goal is to create entrepreneurship in the region and to increase the biotech intensity, diversity and the critical mass needed to achieve these. In addition to generating jobs to attract biotech professionals from around the country, the Center will also be able to undertake teaching and training of undergraduates, graduate students and postdoctoral researchers to generate the needed workforce to attract biotechnology businesses to the area.

Operational: Budget is allocated to cover routine operational needs and office equipment. The Center plans to be housed in a separate facility with adequate room to accommodate the hires planned here and with room for expansion. Significant travel is anticipated to meet with private sector partners, FDA, manufacturing, clinical and preclinical sites around the country. Some of it will be borne by the private sector partners. Additional travel is envisaged to meet and attract new private sector partners and for business development of Center's products, services and intellectual properties.

Product Development: This includes manufacture of the product, consults in GLP, GMP and GCP, and for method validations for QC and release of products for regulated preclinical and clinical studies.

Research Supplies: This is calculated based on ~15,000 per year per product development hire.

Preclinical Development: Biopharmaceutical research is only possible with access to animal studies and in many instances will require specially genotyped or bred animals, both small and large animal studies may be required.

Equipment: The Center will be moving to a new facility to accommodate the new hires and for future expansion. This will require leasing or buying equipments that are needed for carrying out the work, internal research and development and those in collaboration with private sector partners.

Lease: In order to accommodate the growth needs of the Center, the Center anticipates moving out of its humble and smaller temporary facilities at the College of Pharmacy to approximately 6000-8000 square feet of space. No leasehold improvements are planned, only modifications to adapt the facility to the immediate needs of the Center are planned, and this will use not the CoE funds, but will utilize the matching funds from private sector. The budget is based on what is currently offered for such space such at the NDSU Incubator. The Alien Technologies building adjacent to the NDSU Campus is a distinct possibility as the future home of the Center. Proximity to the University is relevant and crucial to attract students and post-docs and to create the vibrant biotech culture. Also, access to equipment and pursuit of scholarly activities amongst researchers is also favored by proximity.