

Contact: Rachel Boon

**REQUEST FOR A NEW INSTITUTE AT IOWA STATE UNIVERSITY:
NANOVACCINE INSTITUTE**

Action Requested: Approval of the request by Iowa State University to create a Nanovaccine Institute (NI) reporting to the Office of the Vice President for Research.

Executive Summary: The goal of the proposed NI will be to foster and coordinate focused research programs that will result in life-saving medical and veterinary research with global impact, provide unique educational opportunities to ISU students, and attract national and international recognition to ISU and the region. The NI will be funded entirely by extramural grants and contracts. The Board Office reviewed this request and recommends approval.

Background:

- ◇ Description of proposed new institute. The proposed NI will formalize an interdisciplinary, multi-institutional research venture established in 2013 via the ISU Presidential Interdisciplinary Research Initiative.

The goal of the proposed NI will be to foster and coordinate focused research programs that will result in life-saving medical and veterinary research with global impact, provide unique educational opportunities to ISU students, and attract national and international recognition to ISU and the region. The proposed NI will establish:

- An interdisciplinary, multi-institutional scientific research consortium with its anchor at ISU and affiliates at University of Iowa and University of Nebraska Medical Center (UNMC) in Omaha.
- A scientific platform for collaborative interdisciplinary research aimed at producing efficacious, safe, and readily deployable therapies for existing and emerging diseases through novel nanovaccines and nanotherapeutics for respiratory infections, tropical diseases, neural disorders, cancer, and veterinary diseases.
- A focus on deploying promising therapies to the market using public-private partnerships that translate promising approaches from laboratory-scale research studies to clinical trials via collaborations with industry and medical schools to commercialize emerging technologies.
- A supporting infrastructure to aggressively pursue a diversified portfolio of external funding, supported by expert grant writing and grant administration support to faculty teams for large-scale, multi-investigator research proposals.

The current venture includes 65 researchers from 19 organizations, including collaborators in universities, research institutes, national laboratories, companies, and healthcare coalitions. Consortium leaders and many team members have national prominence and patents in the areas of nanotechnology and vaccines, and the team includes expertise in immunology, microbiology, nanotechnology, materials sciences, clinical sciences, and social science. The NI will expand on the strengths and potential of the current venture to establish it as a premier research and translational center aimed at addressing emerging health issues in developing and developed countries through novel nanovaccine technologies.

- ◇ Need for the proposed institute. Vaccines have been beneficial in protecting humans and animals from disease, with existing vaccines preventing over 10 million deaths every year across the world. Yet there is a need for new vaccines and improved formulations of existing

vaccines that are safer, more efficacious, and more readily deployable. The increased pace of global travel, livestock production methods, global trade in meat, and displaced wildlife pose threats that are surpassing control measures. There is also concern that diseases caused by new or drug-resistant pathogens could reach pandemic levels in susceptible populations. The proposed NI will meet these societal needs by developing nanovaccines and nanotherapies for respiratory infections, tropical diseases, neural disorders, cancer, and veterinary diseases. Research will translate from laboratory-scale studies to clinical trials by building partnerships with industry and medical schools to commercialize technologies, including two existing relationships developed with FDA-approved pharmaceutical manufacturing facilities for scale-up and production of nanovaccines and nanotherapeutics for human clinical trials.

An interdisciplinary systems approach will work simultaneously on both ends of the product development pipeline to accelerate invention, testing, regulatory approval, and commercialization. A systems approach to vaccine and therapeutics development is based on five tightly integrated research thrusts:

- Antigen design and production
- Nanoscale adjuvants and delivery systems
- Evaluation of vaccine efficacy and immunological mechanisms
- FDA-approved manufacturing scale-up and human clinical testing
- Analysis of public policy, deployment logistics, and economics of human vaccines

- ◇ Relationship to mission. ISU's mission is to "create, share and apply knowledge to make Iowa and the world a better place," with a focus on "conducting high impact research that addresses the grand challenges of the 21st Century."

The NI aligns with this mission by expanding on ISU's research strengths in bioscience and bioengineering, including researchers from five of ISU's seven colleges. The NI contributes to education and engagement missions by involving graduate students in research projects, and partnering with industry and nonprofits to bring nanovaccine therapies to market.

- ◇ Relationship to other centers at the university. At ISU, other related centers include the Iowa Center for Advanced Neurotoxicology (ICAN), primarily aligned with faculty in the College of Veterinary Medicine. ICAN research projects focus on environmental neurotoxicant exposures and their links to neurodegenerative disorders, prion diseases such as Mad Cow Diseases, and neurotoxins of parasitic worms as parasiticides. ICAN's research does not include nanotechnology or immunology, which are both focal areas for the NI. However, some of its researchers are experts in the disease targets for the NI and will be involved in NI-led research projects, thereby extending the fundamental research pursued by ICAN to therapeutic approaches to mitigate the impacts of these diseases.

The ISU College of Veterinary Medicine also houses the Institute for International Cooperation in Animal Biologics (IICAB), which has a focus on improving the availability, safety, efficacy, and use of veterinary biologics throughout the world. However, IICAB's activities relate to education and outreach related to veterinary projects, rather than vaccine research and development.

The NI will include other institutions as affiliate members. Current efforts include research groups at the University of Iowa and UNMC, and both research groups will become NI affiliate locations. The leads for these locations will be Associate Directors of the NI.

The NI will have an advisory group comprised of associate directors of the affiliated locations and the NI's disease sub-group research leads. The group will hold a monthly meeting to review progress and provide advice on funding opportunities and planning to the NI director.

- ◆ Unique features. There are nanomedicine centers or institutes at universities in more than a dozen states, but this will be the first nanovaccine institute in the country.

The ability to evaluate nanovaccines in animal models at ISU's College of Veterinary Medicine is a significant competitive advantage. The U.S. Food and Drug Administration generally requires investigational new drugs be tested in two species (one rodent, one non-rodent) before progressing to human clinical trials. ISU has Biological Safety Level 3 laboratory facilities for evaluating vaccines against potentially lethal pathogens such as anthrax, plague, and avian influenza.

Other significant resources are ISU's 31 core instrumentation facilities managed by the Office of Biotechnology. Shared equipment eliminates the need to pursue funding for specialized research equipment, and the ISU Research Foundation and Office of Intellectual Property & Technology Transfer will support technology transfer from NI research.

- ◆ Evaluation plan. Each spring the NI's activities, metrics, progress and goals will be jointly reviewed by the VPR and the co-sponsoring ISU colleges. The Director will receive a written performance assessment based on that review. In addition, the Institute will be reviewed in its fifth year and every seven years thereafter.
- ◆ Resources. Sufficient administrative staffing for the NI is already in place as part of the existing research activity. Affiliated faculty will continue to use their existing office and laboratory spaces. No additional facilities or equipment are needed.
- ◆ Funding Sources. The NI will be funded entirely by extramural grants and contracts. No state appropriations or tuition revenue will be used to support the NI. The NI's ISU researchers have a stable funding portfolio of \$2 million per year. Major sponsors for ISU funding are currently NIH, DOD, and USDA. Non-profit organizations like the Crohn's and Colitis Foundation also provide funding. To support NI administrative functions that are not allowable by external grants, ISU will reallocate a portion of indirect cost recovery that flows directly from the NI's external research funding expenditures (\$190k initially).

In the absence of external funds, the NI will be closed.

- ◆ Cost.

Total Costs	Source(s)	New Costs
Year 1: \$190,000	Indirect Cost Recovery	
Year 2: \$195,000	Indirect Cost Recovery	\$5,000
Year 3: \$200,000	Indirect Cost Recovery	\$5,000
Year 4: \$205,000	Indirect Cost Recovery	\$5,000
Year 5: \$210,000	Indirect Cost Recovery	\$5,000
Year 6: \$215,000	Indirect Cost Recovery	\$5,000
Year 7: \$220,000	Indirect Cost Recovery	\$5,000

- ◆ Date of implementation. Upon approval, the NI will be established in May 2017.

Letters of Support



OFFICE OF THE VICE PRESIDENT FOR
RESEARCH AND ECONOMIC DEVELOPMENT

2660 University Capitol Centre
Iowa City, Iowa 52242-5500
319-335-2119

31 January 2017

Board of Regents, State of Iowa
11260 Aurora Avenue
Urbandale, IA 50322-7905

Attention: Bruce Rastetter, President

Dear Members of the Board:

The University of Iowa supports the creation of the proposed Nanovaccine Institute, headquartered at Iowa State University, and intends to participate in the proposed Institute as an affiliate location.

Researchers from three University of Iowa Colleges, including the Carver College of Medicine, the College of Pharmacy, and the College of Public Health, as well as four academic departments (Microbiology, Pathology, Pharmaceutics and Translational Therapeutics, and Epidemiology) have been active participants in the Nanovaccine Initiative for the past three and a half years. Over this period, the consortium has facilitated inter-institutional collaboration between team members, which has led to the submission of collaborative research proposals to various funding agencies (e.g., NIH, DOD) and jointly authored publications. We see great value in these collaborative and interdisciplinary efforts both to our faculty as well as to the State of Iowa because of the research advances made by the consortium members.

If approved by the Iowa Board of Regents, the proposed Nanovaccine Institute will have an affiliate location in Iowa City led by Professor Thomas Waldschmidt in the Department of Pathology. We will fully support the collaborative activities of the proposed Institute by actively participating in multi-institutional and interdisciplinary research proposals and activities.

In closing, the proposed Nanovaccine Institute will benefit the people of Iowa by carrying out research activities that will result in life-saving medical and veterinary products with global impact, provide unique educational opportunities to students, attract national and international recognition to Iowa, and create new biotech companies, thereby having a positive economic impact on the State. The University of Iowa supports the creation of this Institute and plans to be an active participant in its research activities.

Sincerely,

Dan Reed
Vice President for Research and
Economic Development

P. Barry Butler
Executive Vice President and Provost



OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

February 3, 2017

Board of Regents, State of Iowa
11260 Aurora Avenue
Urbandale, IA 50322-7905

Attention: Bruce Rastetter, President

Dear Members of the Board,

As Vice Chancellor for Research, I enthusiastically support the involvement of the University of Nebraska Medical Center (UNMC) in the creation of the proposed Nanovaccine Institute, headquartered at Iowa State University, and participation in the proposed Institute as an affiliate location.

Multiple researchers from UNMC Colleges of Pharmacy and Medicines, particularly the departments of Biochemistry and Pharmacology & Experimental Neuroscience, as well as the Center for Drug Delivery and Nanomedicine have been active participants in the Nanovaccine Initiative for the past three and a half years. Over this time period, the consortium has facilitated multiple inter-institutional collaborations and submitted collaborative research proposals to various funding agencies (e.g., NIH, DOD) as well as jointly authored publications. We see great value in these collaborative and interdisciplinary efforts both to our faculty and also to the States of Iowa and Nebraska because of the research advances made by the consortium members. Our own investments in nanomedicine research in the form of the Nebraska Nanomedicine Production Plant and the Center for Nanomedicine underscore our commitments to this important area.

If approved by the Iowa Board of Regents, the proposed Nanovaccine Institute will have an affiliate location at UNMC in Omaha, led by Dr. Surinder Batra, Department of Biochemistry and Dr. Howard Gendelman, Department of Pharmacology & Experimental Neuroscience.

The proposed Nanovaccine Institute will directly benefit the people of Iowa and Nebraska by carrying out research activities that will result in life-saving medical and veterinary products with global impact, provide unique educational opportunities to students, attract national and international recognition to both States, and help develop new biotech companies for a positive economic impact on both States. Again, I confirm UNMC's support of multi-institutional and interdisciplinary research proposals and activities with this institute.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jennifer L. Larsen".

Jennifer L. Larsen, MD
Vice Chancellor for Research
Louise and Morton Degen Professor of Internal Medicine
University of Nebraska Medical Center