

*Institute for Advancing Medical Innovation (IAMI)
The University of Kansas*

REQUEST FOR PROPOSALS

Deadline: December 14, 2009

Letter of Intent due October 30, 2009

Program Overview

Inspired by the opportunity to grow educational and entrepreneurial capacity, the Institute for Advancing Medical Innovation (IAMI) at KU was established upon the belief that: *ideas are translated to innovation to improve health*. The Institute focuses on education and research that advances medical innovations. The result will ultimately accelerate the number and quality of new drugs, medical devices, and drug–medical device combinations flowing from the investigator’s bench to the patient’s bedside. IAMI was created in December 2008 at KU through a partnership involving the Ewing Marion Kauffman Foundation and the KU Endowment Association. Combined, both organizations committed a total of \$16.1 million of seed funding to support IAMI for five years; with a long-term goal to make IAMI self-sufficient.

The Institute is led by Dr. Scott Weir; who has joint appointments at both campuses. IAMI is forming collaborative relationships with faculty and researchers involved in pharmaceutical and bioengineering research from both campuses and associated with various KU schools, academic departments, institutes, and centers. An advisory board consisting of internationally recognized leaders in medical innovation provides overall strategic leadership.

IAMI has developed a unique and novel approach for generating medical innovation by integrating entrepreneurial education with Proof-Of-Concept (POC) research projects that will be performed by KU faculty and researchers. These projects are a high priority and the Institute expects to support several of these projects on an annual basis. POC projects are intended to be applied research projects that demonstrate early-stage technical viability in terms of solving problems and/or providing significant improvements associated with known drug and medical device technology platforms. To generate these POC projects, IAMI is implementing annual Request for Proposals to develop a portfolio of funded projects that ultimately brings new medical innovation into the marketplace where they will benefit the patients who need them.

Overview of the Request For Proposals (RFP)

Description of Proof-Of-Concept (POC) Projects

The goal of the POC projects is to generate new and innovative drugs, medical devices, and drug-device combinations. These projects will take advantage of KU’s R&D expertise in pharmacy, bioengineering, and medicine. The following are examples of areas that are expected to be addressed through the POC projects:

- Novel drug targets
- Novel drug candidates
- Drug formulation
- Drug delivery platforms
- Medical devices
- Biomaterials
- Combination drug-devices
- Bioengineering tools for developing devices, materials, and combinations

POC projects will have the following characteristics:

1. Applied research that represents an extension from a base of strong, innovative, and fundamental scientific research at KU.
2. Research that can demonstrate initial or early-stage technical viability in terms of solving or diminishing significant problems or providing significant improvements associated with known technology and product platforms related to drugs, medical devices, and/or medicine.
3. The technical approach is unique and novel.
4. Defined milestones that are achievable within a specified timeframe and have the potential to evolve into subsequent phases of early-stage technology and/or product development.

Eligibility

Full-time faculty and professional research staff employed by the University of Kansas located at the Lawrence and KUMC campuses are eligible to apply as the Principal Investigator (PI). Each project must have one PI and he or she can apply as the PI for multiple projects; however, an individual can be awarded only one grant per RFP as a PI. Individuals may apply as Co-Principal Investigator on multiple projects. KU and KUMC PI's may collaborate with investigators from industry and/or other academic institutions under the framework of these projects.

Because the technical focus of the projects will be in one or more of the areas of pharmaceuticals, bioengineering and/or medicine, the Principal Investigators are expected to be associated with the schools of Pharmacy; Engineering; Medicine; Allied Health; and other departments, institutes, and centers which have strong research efforts related to drugs, medical devices, and/or medicine. Co-Principal Investigators can be associated with any school, institute, center or industry partner.

Project Duration

Because the focus is on funding proof-of-concept projects, the duration for each project will be based upon meeting project milestones. It is anticipated that many of the projects will be completed within 12 months. Each funded project may be extended and/or renewed based upon how well the project milestones are achieved. Renewal for existing projects will be evaluated on a competitive basis with new project applications.

Project Budget and Allowable Expenses

Project funding is determined by the scope of work and in meeting project milestones. It is anticipated that most projects will range between \$50,000 to \$100,000. Funds are to be used for KU expenses and these include: salary support of faculty, graduate and doctoral students, and other research staff; operating supplies; minor equipment items; prototyping expenses; imaging time; and travel directly associated with the research activity. The project budget may include non-KU expenses if it can be demonstrated that KU does not have the necessary personnel or facilities to perform the specified research tasks.

Interdisciplinary Research Approach

In many cases, medical innovation comes about through the "cross-pollination" of ideas from researchers with different backgrounds. Additionally, medical research that involves interaction with clinicians, physicians, patients, and/or medical companies has a higher probability of being commercialized and improving patient care. Therefore, interdisciplinary and collaborative research is a high priority. Principal Investigators are strongly encouraged to put together research teams that represent different but related backgrounds. Potential examples of these research teams include:

- Researchers from two or more of the following: schools of Pharmacy, Engineering, Medicine, or Allied Health; or other departments, institutes, and centers which have strong research efforts related to drugs, medical devices, and medicine.
- Researcher(s) from KU-Lawrence and/or KUMC (as stated in the first bullet) *and* a physician or clinician at KUMC.
- Researcher(s) from KU-Lawrence and/or KUMC (as stated in the first bullet) *and* a physician, clinician, patient's group, and/or drug or medical device company outside of KU.

Evaluation Criteria and Process

Proposals will be evaluated on five main criteria:

1. Potential to improve healthcare.
2. Technical merit and uniqueness of research.
3. Likelihood for commercialization.
4. Level of interdisciplinary and collaborative research.
5. Meeting the parameters of proof-of-concept research.

Proposals will be evaluated by the IAMI Advisory Board in accordance with the attached set of evaluation criteria. All Advisory Board decisions are final. Funded projects will be subject to standard KU compliance policies.

Timeline

RFP released:	October 15, 2009
Letter of Intent due:	October 30, 2009
Proposals due:	December 14, 2009
Evaluations completed:	February 8, 2010
Awards announced:	February 15, 2010

Post Award Project Management

One of the key aspects of this POC program is that each funded project will receive ongoing support and guidance from one or more project directors employed by IAMI to help advance the research towards the next steps in the overall commercialization process. The vision is that each project will have a multi-functional team that uses a broad base of resources to fully respond to the wide spectrum of topics that are typically associated with POC projects. Each team will develop project milestones and should expect to provide quarterly reports to IAMI.

Secondly, for those proposals not funded, the IAMI team will evaluate them for possible next steps. For example, some of these proposals could be revised to better meet the POC criteria and resubmitted at a later date. Or the proposal may be better positioned for a federal research grant or other funding opportunities. The goal is for IAMI to generate as much value as possible from the proposals.

Letter of Intent

A Letter of Intent (via e-mail) is required. Researchers who intend to submit proposals must send an e-mail expressing their intent to oppm@kumc.edu by October 30, 2009. This email should contain the researcher's name, proposal title, and brief project description including the commercialization opportunity. Each applicant will be contacted by an IAMI Project Director to discuss expectations related to the application process.

Application Submission

Full applications must be submitted (via e-mail) by December 14, 2009, to:

Michael Hughes
Director, Office of Project & Portfolio Management
Institute for Advancing Medical Innovation
oppm@kumc.edu

To view or download a copy of the formal application and instructions, go to <http://www2.kumc.edu/iami/>. Proposals should not exceed 10 pages in length. IAMI will provide a help desk to answer questions and provide assistance during the application process. Points of contact are Marilyn Helms and/or Michael Hughes in the Office of Project and Portfolio Management, oppm@kumc.edu (913-588-2079).

Institute for Advancing Medical Innovation
Proof of Concept Review Criteria

PI Last Name:

PI First Name:

Title	Maximum Score	Applicant Score	Comments	Definition	Low Score Definition	High Score Definition
Technology or Product Novelty and Need	25			Criteria assess the novelty of the technology and market need. Will it add marginally or significantly enhance performance and value?	(0) Adds no performance enhancement, does not address customer need	(25) Replaces current art, addresses customer need
Intellectual Property Position	15			Criteria assess the state and strength of IP protection for the technology. Is the technology novel, highly protected, and subject to securing IP rights?	(0) IPR cannot be secured because they have assigned rights to third parties, technology has been published	(15) Platform technology, multiple broad patents can be filed from the technology
Potential Market Size	13			Criteria assess the market size for the technology	(0) Niche application	(13) Billion dollar, blockbuster potential
Market Definition	10			Criteria to assess the definition of the market. Who is the customer and how will you reach them? Do clear potential licensees or corporate partners exist?	(0) Undefined market, commercialization channels	(10) Defined market, commercialization channels
Technology or Product Maturity	12			Criteria assess the maturity of the technology. Has the technology been demonstrated in the laboratory or is it still a concept?	(0) Technology is immature and could take years of R&D and significant capital investment	(12) Technology could be ready for commercialization by the end of this funding round
Utility of Proof of Concept Funding	20			Criteria assess the proposed utility of proof of concept funding. What impact would the grant have on advancing the technology or product to market?	(0) Commercial development not achievable within funding	(20) Commercial development achievable within funding
Principal Scientist Credibility	5			Criteria to assess the credibility of the Principal Scientist. Does the PS have thorough understanding and expertise in the subject technology and application? Can he or shee and the team succeed? Are there clear milestones and deliverables?	(0) Principal Scientist has insufficient expertise, does not have a track record or successful ventures	(5) Principal Scientist is leading expert in the field, has a track record of successful ventures
Total Score	100	0				