MTAF Round 3
Notice of Intent Submissions
Sector: Biotechnology

MTAF #	Project Title	Name	County	State	Amount ($)
3001	Advanced biomechanics laboratory for injury reduction and rehabilitation	University of Maine	Penobscot	ME	500,000.00
3002	Next Generation Upgrade for the University of Maine DNA Sequencing Facility	University of Maine	Penobscot	ME	500,000.00
3007	Building Capacity to Create Products and Solutions to Environmental Health Probl	University of Southern Maine	Cumberland	ME	1,700,000.00
3021	Parenteral Formulation Facility for Experimental Therapeutics	University of New England	Cumberland	ME	930,000.00
3026	Maine Center for Clinical Research	Maine Medical Center Research Institute	Cumberland	ME	800,000.00
3027	Complex Workflow Management: An Engineered Solution	The Jackson Laboratory	Hancock	ME	970,000.00

Form Data (April 29, 2010 at 04:24:03 PM)

1. Project Title. Character limitation: 80 including spaces.

Project Title	Advanced biomechanics laboratory for injury reduction and rehabilitation

2. Lead Institution

Name	University of Maine

Lead Organization Type: Choose One

Academic

Mailing Address 1	University of Maine
Mailing Address 2	5717 Corbett Hall
City	Orono
County	Penobscot
State	ME
ZIP	04469-5717

3. Authorized Institutional Representative: Primary contact for the Lead Organization, who may or may not be the same as the Project Director. If the same as the Project Director, enter Project Director in each required box.

Rep. First Name	Michael
Rep. Last Name	Hastings
Rep. Title	Director, Office of Research & Sponsored Programs
Rep. Institution	University of Maine
Rep. Telephone	207-581-1484
Rep. Email Address	umgrants@maine.edu
Rep. Mailing Address 1	5717 Corbett Hall
Rep. Mailing Address 2	None given.
Rep. City	Orono
Rep. State	ME
Rep. ZIP	None given.

4. Project Director: Scientific lead and/or project manager.

Dir. First Name	Vincent
Dir. Last Name	Caccese
Dir. Title	Dr.
Dir. Organization	University of Maine
Dir. Mailing Address 1	5711 Boardman Hall
Dir. Mailing Address 2	Dept. of Mechanical Engineering
Dir. City	Orono
Dir. State	ME
Dir. ZIP	04469
Dir. Telephone	207-581-2131
Dir. Email Address	vince.caccese@umit.maine.edu
Dir. Fax	207-581-2379

5. Collaborators, if Known: List either individual name and/or institution. If none, enter "None."

Collaborators	Tampa FL. (Dr. John Lloyd) Steven Castle, MD, Professor of Medicine at UCLA Ashish Deshpande, Assistant Professor UMaine Mehcanical Eng. Dept Mohsen Shahinpoor, Prof. and Chair, UMaine Mehcanical Eng. Dept Center for Community Inclusion and Disabilities Studies, Elizabeth DePoy

6. Approximate amount of funds requested. Please use numbers only without special characters, such as decimal point and commas. For example: 500000.

Amount ($) 500000

7. Technology Sector

Chose One Sector Biotechnology

8. Scientific Disciplines Involved. Character limitation: 125 including spaces.

Scientific Disciplines Involved

Biomechanics, Fall protection, Traumatic Brain Injury, Impact, Vibration, Finite Element Analysis, Advanced Manufacturing

9. Names of two suggested reviewers from outside Maine, who are expert in the area of work with no direct conflicts of interest. Please list names and institutional affiliation. MTI is under no obligation to use these reviewers. If none, enter "None."

Reviewer 1 None

Reviewer 2 None given.

10. Names and institutional affiliation of potential reviewers from whom to withhold application information. If none, enter "None."

Withhold from None

11. Project Overview, which includes a brief description of proposed project, including use of award funds; scientific rationale of the proposed project; potential economic impact areas; a listing of organizations participating in the project and a brief description of their roles.
Character limitation: 6,000 including spacing

Description Area

To address these issues we have assembled a team of professionals with diverse backgrounds. Alba-Technic, LLC of Arundel Maine is leading the commercialization efforts. A team of partners including Rynel, Lifeflight of Maine, the Department of Veterans Affairs and the University of Maine are proposing a different approach to solving falls and transport related problems that will address the specific nature of the impact and vibration system from input to output, while developing products that are lightweight and wearable. Alba-Technic, LLC will lead the effort to develop the functional design of the device that will be integrated into the proof-of-concept med-evac tests. Lifeflight of Maine will contribute their expertise in medical evacuation and testing time on their med-evac helicopter. Researchers at UMaine include faculty from the Mechanical Engineering Department and Center for Community Inclusion and Disability Studies and will perform advanced mechanical analysis and testing of the products. Physical activity and fitness in human life are critical to maintaining health, self-esteem, motor learning, and self-sufficiency. Yet, the opportunities for inclusion in fitness activities for disabled individuals, particularly those with severe disabilities, are extremely limited. We are in the process of developing a prototype robotic device called the Robotic Rowing Exoskeleton (RRE) that will augment movement, coordination, and strength in the activity of rowing for a range of individuals with musculoskeletal and neuromuscular disabilities that interfere with motor activity. This team has also recently embarked upon the development of impact resistant head gear using a patent pending dilatant material solution. Modern materials can often achieve superior solution with thinner products and less mass. This effort resulted in a design that more effective than any existing solution in a product that was half as thick and less massive. It is currently receiving strong support from the National Institute of health to further its development.. The effort on falls protection first began through the MTI seed grant program. The successful completion of the seed grant work lead to a NIH SBIR Phase 1 award to develop headwear to prevent fall related injuries in elderly persons. The project team recently completed the NIH Phase 1 grant. A very favorable NIH Phase 2 evaluation has the follow-on study listed as to be funded at a level of $1M+. The effort on the RRE development is currently funded by the MTI seed grant program. Simultaneously, we have embarked upon development several other tangential products that have high commercial potential including a recently submitted a proposal to the MTI seed grant program to develop a combined vibration suppression, injury stabilization device for soldiers subjected

to TBI. This current request is for equipment to be housed at the University of Maine that would accelerate development of these products. It will fill a research gap in the State of Maine and allow us to perform high level biomechanics research using advanced equipment to develop advanced products. A new laboratory facility will be equipped at the University of Maine for study of impact and vibrations biomechanics and development of new products for injury mitigation. Requested equipment includes a family of standard Hybrid III test dummies which accurately simulate the response of the human body without the need for human subjects. The Hybrid III dummy is the current standard used throughout the world. Equipment to perform vibration studies will also be requested including state of the art measuring system capable of capturing data simultaneously at very high rates. We are also requesting funding to purchase a state-of-the-art manipulator called the Whole Arm Manipulator (WAM). The WAM with the modular wrist will form the end-effector of our RRE. WAM is chosen primarily because it is a cable driven manipulator capable of being back-drivable, thereby allowing for precise and compliant interaction with the user. The use of the equipment will be available for other research from the onset. Also, requested will be state-of-the art manufacturing equipment that will allow for rapid development of aesthetic prototypes. This equipment will reside in the Advanced Manufacturing Center and will allow access to others with needs to develop textile products.

Please review your submission carefully.

The Notice of Intent must be filed electronically with MTI no later than noon, Tuesday, May 4, 2010. Late submissions will not be accepted.

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In addition, within two business days MTI will send an e-mail to the Project Director providing an application number to be included on each page of the formal application, and an acknowledgement that the Notice of Intent is complete.

Submission Metadata

IP	127.0.0.1
Browser	Mozilla/4.0 (compatible; MSIE 7.0; Windows NT 5.1; .NET CLR 1.1.4322; InfoPath.2)

Form Data (April 29, 2010 at 04:09:34 PM)

1. Project Title. Character limitation: 80 including spaces.

Project Title	Next Generation Upgrade for the University of Maine DNA Sequencing Facility

2. Lead Institution

Name	University of Maine

Lead Organization Type: Choose One

Academic

Mailing Address 1	School of Marine Sciences
Mailing Address 2	5751 Murray Hall
City	Orono
County	Penobscot
State	ME
ZIP	04469-5751

3. Authorized Institutional Representative: Primary contact for the Lead Organization, who may or may not be the same as the Project Director. If the same as the Project Director, enter Project Director in each required box.

Rep. First Name	Michael
Rep. Last Name	Hastings
Rep. Title	Director, Office of Research & Sponsored Programs
Rep. Institution	University of Maine
Rep. Telephone	207-581-1484
Rep. Email Address	umgrants@maine.edu
Rep. Mailing Address 1	5717 Corbett Hall
Rep. Mailing Address 2	None given.
Rep. City	Orono
Rep. State	ME
Rep. ZIP	04469-5717

4. Project Director: Scientific lead and/or project manager.

Dir. First Name	Rebecca
Dir. Last Name	Van Beneden
Dir. Title	Prof. of Biochemistry
Dir. Organization	University of Maine
Dir. Mailing Address 1	School of Marine Sciences
Dir. Mailing Address 2	5751 Murray Hall
Dir. City	Orono
Dir. State	ME
Dir. ZIP	04469
Dir. Telephone	207-581-2602
Dir. Email Address	rebeccav@maine.edu
Dir. Fax	207-581-2537

5. Collaborators, if Known: List either individual name and/or institution. If none, enter "None."

Collaborators	Maine Institute for Human Genetics and Health

6. Approximate amount of funds requested. Please use numbers only without special characters, such as decimal point and commas. For example: 500000.

Amount ($)	500000

7. Technology Sector

Chose One Sector Biotechnology

8. Scientific Disciplines Involved. Character limitation: 125 including spaces.

Scientific Disciplines Involved

Biotechnology

9. Names of two suggested reviewers from outside Maine, who are expert in the area of work with no direct conflicts of interest. Please list names and institutional affiliation. MTI is under no obligation to use these reviewers. If none, enter "None."

Reviewer 1 Mark E. Hahn, Ph.D. Senior Scientist Biology Department Redfield 3-38, MS#32 Woods Hole Oceanographic Institution (WHOI) Woods Hole, MA 02543-1049 email: mhahn@whoi.edu phone: 508 289 3242 Fax: 508 457 2134

Reviewer 2 Robert Tanguay, Ph.D. Associate Professor, Director, NIEHS Toxicology Training Grant Dept. of Environmental & Molecular Toxicology 423 Weniger Hall Oregon State University Corvallis, OR 97331 Phone: 541-737-6514 Fax: 541-737-7966 robert.tanguay@oregonstate.edu

10. Names and institutional affiliation of potential reviewers from whom to withhold application information. If none, enter "None."

Withhold from None

11. Project Overview, which includes a brief description of proposed project, including use of award funds; scientific rationale of the proposed project; potential economic impact areas; a listing of organizations participating in the project and a brief description of their roles.
Character limitation: 6,000 including spacing

Description Area The University of Maine DNA Sequencing Facility was established in 1994 with seed funding from an NSF EPSCoR Marine Molecular Biology grant. The Facility has been expanded and updated several times over the past 14 years. In addition to the 30 laboratories served on campus, the UMaine DNA Sequencing Facility provides services to over 130 laboratories external to the University, including other UMaine campuses, Research Institutes (for example, MMCRI) and a growing number of Maine Biotechnology companies. Gross revenues from user�s fees last year exceeded $135,000. The facility is run and maintained by Director Patty Singer, whose salary is partially (80%) supported by UMaine funds. She is assisted by a full-time technician, David Cox, who is supported by the facility user fees. The facility is supervised by R. Van Beneden, Professor of Biochemistry and Marine Sciences. These funds were used to cover 20% of the Facility Director Patty Singer�s salary, 100% of Research Technician David Cox�s salary, the $25,000 annual service contract supplies, payments on the ABI 3730 sequencer (purchased entirely with Facility funds) and all additional expenses. The Facility is non-for-profit; prices for UMaine users are set at cost. Costs to outside users are substantially higher and help to support the low fees charged in-house. In order to remain competitive and reduce user fees, the DNA Sequencing Facility needs to acquire new upgrades. Funds are requested to obtain a next generation DNA sequencer. Scientific rationale: Our goal is to provide the equipment and expertise to sequence DNA at reasonable cost to Maine investigators. The Facility excels in its service to the Maine research community by providing a rapid turnaround time and expertise in all matters concerning DNA sequencing, including DNA preparation, sequence editing and DNA primer design. Potential economic impact areas: Proposals to NSF, NIH and other external sponsors concerning molecular genetics generally require preliminary data to show both local competence and feasibility. The UMaine DNA Sequencing Facility makes analysis feasible on a cost-effective basis, thereby leveraging funds in the form of successful proposals to federal agencies. There is also the potential for investigations of individual drug response (in the human SNP studies). Participating organizations and their roles: Many of the UMaine laboratories that currently use this facility, including those in SMS, BMMB, Biology and Ecology, and Wildlife Ecology, have expressed strong interest. Other Maine campuses and institutes, such as MIHGH, have also expressed interest.

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Submission Metadata

IP	127.0.0.1
Browser	Mozilla/4.0 (compatible; MSIE 7.0; Windows NT 5.1; .NET CLR 1.1.4322; InfoPath.2)

Form Data (May 03, 2010 at 11:54:49 AM)

1. Project Title. Character limitation: 80 including spaces.

Project Title	Building Capacity to Create Products and Solutions to Environmental Health Probl

2. Lead Institution

Name	University of Southern Maine

Lead Organization Type: Choose One

Academic

Mailing Address 1	96 Falmouth St.
Mailing Address 2	None given.
City	Portland
County	Cumberland
State	ME
ZIP	04103

3. Authorized Institutional Representative: Primary contact for the Lead Organization, who may or may not be the same as the Project Director. If the same as the Project Director, enter Project Director in each required box.

Rep. First Name	Larry
Rep. Last Name	Waxler
Rep. Title	Director
Rep. Institution	University of Southern Maine
Rep. Telephone	(207) 780-4413
Rep. Email Address	larryw@usm.maine.edu
Rep. Mailing Address 1	96 Falmouth St.
Rep. Mailing Address 2	None given.
Rep. City	Portland
Rep. State	ME
Rep. ZIP	04103

4. Project Director: Scientific lead and/or project manager.

Dir. First Name	John
Dir. Last Name	Wise
Dir. Title	Professor and Director
Dir. Organization	University of Southern Maine
Dir. Mailing Address 1	96 Falmouth St.
Dir. Mailing Address 2	None given.
Dir. City	Portland
Dir. State	ME
Dir. ZIP	04103
Dir. Telephone	(207) 228-8050
Dir. Email Address	John.Wise@usm.maine.edu
Dir. Fax	None given.

5. Collaborators, if Known: List either individual name and/or institution. If none, enter "None."

Collaborators	Edie Johnston, Eldertide Amy Davidoff, University of New England John Schloss, University of New England Michael Mason, University of Maine

6. Approximate amount of funds requested. Please use numbers only without special characters, such as decimal point and commas. For example: 500000.

Amount ($)	1700000

7. Technology Sector

Chose One Sector Biotechnology

8. Scientific Disciplines Involved. Character limitation: 125 including spaces.

Scientific Disciplines Involved

Toxicology, Physiology, Marine Science, Pharmacology

9. Names of two suggested reviewers from outside Maine, who are expert in the area of work with no direct conflicts of interest. Please list names and institutional affiliation. MTI is under no obligation to use these reviewers. If none, enter "None."

Reviewer 1 Wei Zheng, Ph.D. Purdue University School of Health Sciences 550 Stadium Mall Drive, CIVL 1173B West Lafayette, IN 47907 (765) 496-6447 (office) (765) 496-1377 (fax) Email: wzheng@purdue.edu

Reviewer 2 Kent Sugden, Ph.D. The University of Montana Department of Chemistry Missoula, MT 59812 phone: (406) 243-4193 fax: (406) 243-4227 e-mail: Kent.Sugden@umontana.edu

10. Names and institutional affiliation of potential reviewers from whom to withhold application information. If none, enter "None."

Withhold from WITHELD BY MTI

11. Project Overview, which includes a brief description of proposed project, including use of award funds; scientific rationale of the proposed project; potential economic impact areas; a listing of organizations participating in the project and a brief description of their roles.
Character limitation: 6,000 including spacing

Description Area

The University of Southern Maine (USM) established the Maine Center for Toxicology and Environmental Health (MCTEH) as its signature bioscience research effort with the goal of obtaining national prominence in toxicology and environmental health. This proposal requests funds to complete nearly 2/3 of a floor in the research wing of the Science building at USM to allow MCTEH to expand its research and product development programs. The requested funds will be matched by programmatic funds that will allow MCTEH to expand its basic research and take the necessary next steps in its efforts to develop a suite of commercial products for market. The goal of MCTEH is to develop a nationally competitive research program for identifying, understanding, and preventing the health effects of environmental pollution on Maine citizens. We are building this effort on the strength of our federally funded grant research program led by the Wise Laboratory of Environmental and Genetic Toxicology. Dr. Wise and his team have substantial federal funding to investigate the genotoxic effects of metals and their potential to cause lung cancer. This project will leverage those funds and expand the effort into measures to prevent the toxic effects of these metals. In particular, we will focus on four metals of concern to Maine citizens that also are of global concern. These are chromium, arsenic, depleted uranium and silver nanoparticles. We will seek to develop projects that can offset or prevent the toxicity of these chemicals. Specifically, we will use two approaches. First, we will build on promising data in whale cells that show whales have evolved molecular measures to protect cells from metal-genotoxicity. The specific factor that provides this protection is unknown, and we will be seeking to isolate it and develop it for application to human cells. This research direction should lead to new intellectual property and patents by the Wise Laboratory. Our second approach will be to use nutraceuticals, specifically berry products to prevent the toxicity of these chemicals. We have preliminary data to suggest that berries can prevent the toxicity. As the work develops on novel products and approaches, we will develop them for their commercial potential. Promising avenues already in progress in MCTEH include nutraceuticals such as products from various types of berries that can prevent or reduce disease. Maine's position as a major producer of commercial crops of berries means that an entirely new use for large quantities of berries could be met from increasing Maine's crop production, which will allow for new markets for Maine agriculture and Maine businesses focused on nutraceutical products. Our project will also contribute to the Maine through more and better facilities. Using these facilities, we will be able to obtain more research grants, and in addition to the direct impact of these research dollars the grants will create job opportunities for skilled laboratory technicians. These workers will carry out the

day-to-day hands-on aspects of the work proposed by University scientists. Each new grant awarded is expected to add at least 1-2 full time employees. With 17 Center members at USM currently, if each one obtained 1 new grant that would equal 17-34 new technical positions. Our work also contributes to reducing the financial impact that environmental health problems cause in Maine. The presence of environmental contaminants is already causing significant health problems in Maine. These health problems impact the economy through lost work days, health care expenses and special educations costs as a consequence of environmentally related diseases. Finally, expanding MCTEH will impact the Maine economy through its education and training programs. The need for newly-discovered information, the development of new technologies, and the need for the human resources to provide the labor for these activities, will demand more, and highly trained workers in the sciences. MCTEH with its education and training programs will develop the next generation of young scientists to fill these positions. The demand for more graduates should fuel a demand for more technical training and more educators. Organizations joining in this project include Eldertide, the University of New England and the university of Maine. These partners provide resources in expertise in the focus areas of research and in developing products for commercial markets.

Please review your submission carefully.

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Submission Metadata

IP	127.0.0.1
Browser	Mozilla/4.0 (compatible; MSIE 7.0; Windows NT 5.1; GTB6.4; Tablet PC 1.7; .NET CLR 1.0.3705; .NET CLR 1.1.4322; .NET CLR 2.0.50727; InfoPath.2; .NET CLR 3.0.4506.2152; .NET CLR 3.5.30729)

Form Data (May 04, 2010 at 08:55:22 AM)

1. Project Title. Character limitation: 80 including spaces.

Project Title	Parenteral Formulation Facility for Experimental Therapeutics

2. Lead Institution

Name	University of New England

Lead Organization Type: Choose One

Non-Profit

Mailing Address 1	College of Pharmacy
Mailing Address 2	716 Stevens Avenue
City	Portland
County	Cumberland
State	ME
ZIP	04103

3. Authorized Institutional Representative: Primary contact for the Lead Organization, who may or may not be the same as the Project Director. If the same as the Project Director, enter Project Director in each required box.

Rep. First Name	Nicholas.
Rep. Last Name	Gere
Rep. Title	Director of Research Administration
Rep. Institution	University of New England
Rep. Telephone	207-602-2011
Rep. Email Address	ngere@une.edu
Rep. Mailing Address 1	11 Hills Beach Road
Rep. Mailing Address 2	None given.
Rep. City	Biddeford
Rep. State	ME
Rep. ZIP	04005

4. Project Director: Scientific lead and/or project manager.

Dir. First Name	John
Dir. Last Name	Schloss
Dir. Title	Chair, Pharmaceutical Sciences
Dir. Organization	University of New England
Dir. Mailing Address 1	College of Pharmacy
Dir. Mailing Address 2	716 Stevens Avenue
Dir. City	Portland
Dir. State	ME
Dir. ZIP	04103
Dir. Telephone	207-221-4151
Dir. Email Address	jschloss@une.edu
Dir. Fax	207-523-1926

5. Collaborators, if Known: List either individual name and/or institution. If none, enter "None."

Collaborators	None

6. Approximate amount of funds requested. Please use numbers only without special characters, such as decimal point and commas. For example: 500000.

Amount ($)	930,000

7. Technology Sector

Chose One Sector Biotechnology

8. Scientific Disciplines Involved. Character limitation: 125 including spaces.

Scientific Disciplines Involved

Pharmaceutical Sciences, Pharmaceutics, Medicinal Chemistry, Pharmaceutical Chemistry

9. Names of two suggested reviewers from outside Maine, who are expert in the area of work with no direct conflicts of interest. Please list names and institutional affiliation. MTI is under no obligation to use these reviewers. If none, enter "None."

Reviewer 1 Edward T. Maggio, Ph.D. President and Chief Executive Officer Aegis Therapeutics LLC 16870 W. Bernardo Drive, Suite 390 San Diego, CA 92127 Phone 858-618-1400 Fax 858-618-1441 Email edaegis@san.rr.com

Reviewer 2 Shelley Amster Founder & Principal ShelleyCo 44 Prairie Street Concord, MA 01742 Phone 978-371-5901 Cell 978-239-1468 Email shelley@shelleyco.com

10. Names and institutional affiliation of potential reviewers from whom to withhold application information. If none, enter "None."

Withhold from None

11. Project Overview, which includes a brief description of proposed project, including use of award funds; scientific rationale of the proposed project; potential economic impact areas; a listing of organizations participating in the project and a brief description of their roles.
Character limitation: 6,000 including spacing

Description Area To initiate a phase I clinical trial for a new drug substance, it must first be prepared in a suitable formulation. The formulated drug substance must then be subjected to various tests to assess purity, stability, and safety. Drug formulation and testing must be carried out in compliance with all federal regulations to be suitable for use in an FDA-approved study. It is frequently difficult for a small pharmaceutical startup company to identify a vendor to carry out this work in a reliable and cost-effective manner. The University of New England College of Pharmacy (UNE COP) proposes to build a facility for the parenteral formulation of experimental therapeutics. This facility will help to attract small pharmaceutical companies to Maine by providing financial incentives to Maine-based companies. UNE COP will also train students in the preparation of formulated drug products that are suitable for clinical use. Nanoparticulate drug formulations are becoming an important strategy for improving drug delivery, selective targeting, stability, and safety. There are currently very few facilities nationally that have the capability to prepare and test nanoparticulate drug formulations. By including the ability to formulate both nanoparticulate and traditional parenteral drugs the UNE COP facility will help to distinguish itself and provide an essential service in an area of increasing importance to the pharmaceutical industry.

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Form Data (May 04, 2010 at 11:39:27 AM)

1. Project Title. Character limitation: 80 including spaces.

Project Title	Maine Center for Clinical Research

2. Lead Institution

Name	Maine Medical Center Research Institute

Lead Organization Type: Choose One

Profit

Mailing Address 1	81 Research Drive
Mailing Address 2	None given.
City	Scarborough
County	Cumberland
State	ME
ZIP	04074

3. Authorized Institutional Representative: Primary contact for the Lead Organization, who may or may not be the same as the Project Director. If the same as the Project Director, enter Project Director in each required box.

Rep. First Name	Project Director
Rep. Last Name	Project Director
Rep. Title	Project Director
Rep. Institution	Project Director
Rep. Telephone	Project Director
Rep. Email Address	Project Director
Rep. Mailing Address 1	Project Director
Rep. Mailing Address 2	None given.
Rep. City	Project Director
Rep. State	ME
Rep. ZIP	Project Director

4. Project Director: Scientific lead and/or project manager.

Dir. First Name	Donald
Dir. Last Name	St. Germain
Dir. Title	Associate VP of Research, MMC
Dir. Organization	Maine Medical Center Research Institute
Dir. Mailing Address 1	81 Research Drive
Dir. Mailing Address 2	None given.
Dir. City	Scarborough
Dir. State	ME
Dir. ZIP	04074
Dir. Telephone	207-885-8121
Dir. Email Address	stgerd@mmc.org
Dir. Fax	None given.

5. Collaborators, if Known: List either individual name and/or institution. If none, enter "None."

Collaborators	Marc B. Hahn, D.O. , Dean College of Osteopathic Medicine and Senior Vice President of Health Affairs, University of New England, 11 Hills Beach Rd, Biddeford, ME, 04005 Email:deanunecom@une.edu 207-602-2340 Joel A. Wirth, M.D., Pulmonary and Critical Care Medicine, Maine Medical Center, 22 Bramhall St. Portland, ME 04101 Email: wirthj@mmc.org 207-828-1122

6. Approximate amount of funds requested. Please use numbers only without special characters, such as decimal point and commas. For example: 500000.

Amount ($) 800000

7. Technology Sector

Chose One Sector Biotechnology

8. Scientific Disciplines Involved. Character limitation: 125 including spaces.

Scientific Disciplines Involved

Biotechnology, Clinical Research, Clinical Trials

9. Names of two suggested reviewers from outside Maine, who are expert in the area of work with no direct conflicts of interest. Please list names and institutional affiliation. MTI is under no obligation to use these reviewers. If none, enter "None."

Reviewer 1 None

Reviewer 2 None

10. Names and institutional affiliation of potential reviewers from whom to withhold application information. If none, enter "None."

Withhold from None

11. Project Overview, which includes a brief description of proposed project, including use of award funds; scientific rationale of the proposed project; potential economic impact areas; a listing of organizations participating in the project and a brief description of their roles.
Character limitation: 6,000 including spacing

Description Area

Biomedical research and biotechnology are targeted areas for growth in Maine as the state seeks to add high tech-based industries to its economy. While there is a fledging biotech industry emerging in Maine, these small start-up companies lack associations and close affiliations with the medical care community who can provide them with clinical expertise and assist them in bringing their products to market. Maine Medical Center (MMC) will shortly be implementing its next research strategic plan, which will target significant investments in infrastructure and personnel with the goal of markedly enhancing its clinical and translational research activities. Key to these efforts is the establishment of a Clinical Research Office (CRO) that provides efficient and centralized research support services to investigators at MMC. Our vision is that this infrastructure can be enhanced to serve as a regional resource and thus facilitate clinical trials activities with biotech and pharmaceutical companies both within and outside of the state, and importantly with clinical and scientific collaborators at the University of New England (UNE) Colleges of Osteopathic Medicine and of Pharmacy. The need for coordinated and centralized clinical trials infrastructure is essential if medical research is to flourish within the State of Maine. Among the factors driving this imperative are the compliance risks associated with failure to meet the Center for Medicare and Medicaid Services (CMS) regulatory requirements, with specific risks related to billing. In this regard, inadequacies in organizational structures, processes, information technology and personnel lead to inefficiencies in Institutional Review Board approval, recruiting, trial management, and resource allocation which ultimately threaten the viability of clinical trials and undermine confidence from commercial partners and investors. Not only do the key components of the clinical trials infrastructure need to be centralized and coordinated, but such services are affordable only if efficiencies of scale and expertise can be accessed. Hence, a regional Clinical Research Office will bring great value to our biotech community. A unique and important component of these efforts will be the establishment of a Challenged Enrollment Organization (CEO), a multi-institutional consortium affiliated with our CRO and based at MMC, directed by Dr. Joel Wirth and designed to facilitate the enrollment of individuals with rare diseases into therapeutic trials. In addition to testing the readiness of clinical research colleagues in other New England based research centers, Dr. Wirth has explored the potential interest of possible sponsors for supporting the development of such a group. Included in this list and expressing serious interest are United Therapeutics, Pfizer, Actelium, Gilead, and Bayer. The development of such a CEO has important implications in terms of providing national recognition and

funding to our region. This proposal thus seeks funding from the Maine Technology Asset Fund to help establish a regional CRO developed in collaboration with academic partners at UNE and commercial biotech and pharmaceutical firms. Additional provisions within this application will address the need for a regional central clinical laboratory for human sample processing that will include secure storage of human samples. Funds will be used to renovate existing space to accommodate and optimize the operations of the CRO and purchase necessary equipment for sample processing, analysis, storage and transport. This CRO and associated infrastructure will facilitate the acquisition of high quality clinical data for our biotech and pharmaceutical partners at far less expense than if individual companies attempted to do this on their own. The value to the Maine economy of these efforts will be the provision of increased expertise and support to our biotech industries to aid their success, along with a significant increase in local jobs as the CRO and CEO are developed and the volume of clinical trials increases. In addition to commercial benefit, these enhanced trials operations will contribute significantly to the academic activities at MMC and UNE, thus enticing outstanding students, trainees and faculty to our region and further strengthening our biomedical community. In summary, this proposal will provide important new research capabilities within our region, foster critical collaborations between our academic health care centers and our biotech industry, and provide additional quality jobs to our citizenry.

Please review your submission carefully.

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Submission Metadata

IP	127.0.0.1
Browser	Mozilla/5.0 (Windows; U; Windows NT 5.1; en-US; rv:1.9.2.3) Gecko/20100401 Firefox/3.6.3

Form Data (May 04, 2010 at 11:54:45 AM)

1. Project Title. Character limitation: 80 including spaces.

Project Title	Complex Workflow Management: An Engineered Solution

2. Lead Institution

Name	The Jackson Laboratory

Lead Organization Type: Choose One

Non-Profit

Mailing Address 1	600 Main St.
Mailing Address 2	None given.
City	Bar Harbor
County	Hancock
State	ME
ZIP	04609

3. Authorized Institutional Representative: Primary contact for the Lead Organization, who may or may not be the same as the Project Director. If the same as the Project Director, enter Project Director in each required box.

Rep. First Name	Cookie
Rep. Last Name	Willems
Rep. Title	Senior Director, Sponsored Programs
Rep. Institution	The Jackson Laboratory
Rep. Telephone	207-288-6488
Rep. Email Address	cookie.willems@jax.org
Rep. Mailing Address 1	Box 81
Rep. Mailing Address 2	600 Main St.
Rep. City	Bar Harbor
Rep. State	ME
Rep. ZIP	04609

4. Project Director: Scientific lead and/or project manager.

Dir. First Name	Richard
Dir. Last Name	Woychik
Dir. Title	President and CEO
Dir. Organization	The Jackson Laboratory
Dir. Mailing Address 1	600 Main St.
Dir. Mailing Address 2	None given.
Dir. City	Bar Harbor
Dir. State	ME
Dir. ZIP	04609
Dir. Telephone	207-288-6041
Dir. Email Address	rick.woychik@jax.org
Dir. Fax	None given.

5. Collaborators, if Known: List either individual name and/or institution. If none, enter "None."

Collaborators	Lanco Assembly Systems, Westbrook ME; Maine Manufacturing, Sanford ME

6. Approximate amount of funds requested. Please use numbers only without special characters, such as decimal point and commas. For example: 500000.

Amount ($)	970000

7. Technology Sector

Chose One Sector Biotechnology

8. Scientific Disciplines Involved. Character limitation: 125 including spaces.

Scientific Disciplines Involved

Biomedical research, Genotyping/Molecular biology, Mouse models of human disease, Animal husbandry

9. Names of two suggested reviewers from outside Maine, who are expert in the area of work with no direct conflicts of interest. Please list names and institutional affiliation. MTI is under no obligation to use these reviewers. If none, enter "None."

Reviewer 1 Sally Camper, Ph.D., University of Michigan Dept of Human Genetics

Reviewer 2 Richard Behringer, Ph.D., Professor, Dept of Molecular Genetics, University of Texas M.D. Anderson Cancer Center, Houston, Texas

10. Names and institutional affiliation of potential reviewers from whom to withhold application information. If none, enter "None."

Withhold from **WITHELD BY MTI**

11. Project Overview, which includes a brief description of proposed project, including use of award funds; scientific rationale of the proposed project; potential economic impact areas; a listing of organizations participating in the project and a brief description of their roles.
Character limitation: 6,000 including spacing

Description Area

The Jackson Laboratory (JAX) is a private, nonprofit employer of ~1300 people in eastern Maine that focuses on mammalian genetics research to advance human health. JAX also supplies laboratory mice and state-of-the-art genetic resources and services to ~19,000 investigators in 50 countries annually. Genetically engineered mice are ideal for discovering basic biological processes, studying relationships between gene mutations and disease and modeling human disorders. They also provide a way to test therapeutic agents and evaluate precise effect with rapidly advancing analysis tools. JAX's collection of over 5000 mouse strains is one of the world's largest, and we have created specific repository resources to speed the use, understanding and maintenance of these vital research tools. Scientists labored for years to engineer a mouse with the deletion of a single gene. Now, genetic engineering advances allow JAX to manipulate the mouse genome and rapidly create genetically engineered models with multiple gene deletions or alterations, and whose gene expression can be tracked through a growing variety of techniques. In addition, models developed worldwide are donated to JAX because of the research community's confidence in our ability to securely and reliably archive, maintain and distribute these models. In 5 years, JAX strain importation has increased from 50 to 600 new genetically engineered models/year. There is an immediate and growing need for JAX to expand mouse room capacity, management techniques and trained personnel to accommodate increasing demand for genetically engineered mice and to allow full use of these models by the scientific community. This rapid increase in pace and volume of targeted new model creation means production must shift from a limited number of popular strains easily produced in large numbers, to thousands of smaller colonies that each requires its own accurate system for identification, maintenance, tracking and distribution. Requested funding would equip newly constructed space where specialized colonies of mice will be maintained for research in a wide variety of human diseases, including diabetes, ALS, Parkinson's and autism. This creates the urgent need for 1) more specialized employees with higher levels of training and 2) development of innovative production methods and workflow systems to manage the volume and variety of animals. We anticipate adding 14 jobs to the current pool of 40 colonists over the next 5 years as a project result. Also, the need to create new workflow systems provides opportunity for collaboration and commercialization with Maine partners. To do this, we need dedicated space equipped for developing these systems. One area most affected by the increasing variety of mouse strains is the JAX Transgenic Genotyping Service (TGS). TGS provides strain-specific genotyping, determining the expression of a specific gene through the use of biological assays. Strains requiring genotyping may be located in a host of campus locations, including importation, cryopreservation, research colonies and production or custom

breeding rooms. Each area must collect, record and send a tissue sample from their mice to TGS for genetic analysis. This collection, transport and tracking of thousands of samples a day is complex and intricate. Designed internally, our system provides unique sample identification and accurately receives, processes and reports genotyping results. It has supported a work volume increase of 150% over 4 years. With rapid proliferation of new strains, this system cannot keep up. JAX must devise new ways to meet steadily increasing demand. Fast and accurate workload systems are required if JAX is to remain the global research community's primary source of unique mouse models and services. Without improved processes and advanced systems for this high volume of specialized work, this critical path unit will lose its momentum, increase turnaround times and slow delivery of strains and services to an unacceptable degree. Process improvements and workflow systems targeted for design and implementation using MTAF funds offer possible development and commercialization opportunities. In addition to increasing internal capacity, MTAF investment will allow JAX to develop external genotyping services for laboratories worldwide. The critical steps for ramping up JAX capacity are 1) identifying more accurate and efficient processes for handling protocols and reagents needed for genotyping, and 2) enhancing methods of sample collection, handling, documenting and reporting. The first can be done by working with identified firms that specialize in process analysis and efficiencies, including Maine companies (Lanco Assembly Systems in Westbrook and Maine Manufacturing in Sanford). The second step requires the continued ingenuity of JAX and external collaborators to develop products and methods to streamline the workflow of individual identification and tissue sample collection within the mouse room, transport and tracking to TGS, sample processing and subsequent reporting and processing of genotyping results. Specialized space to develop efficiency and throughput capacity will enable JAX to meet product and service demands and work toward external service offerings that we do not have capacity to offer now. This space complements previous MTAF projects that will generate more mouse strains that must be maintained, genotyped and distributed. This proposal seeks funding that will allow JAX to 1) equip advanced, high health status mouse room space to enable precision handling of rapidly growing numbers of colonies of customized research models; 2) develop high throughput processes for genotyping rapidly increasing numbers of new strains; and 3) develop commercialization opportunities through workflow innovations that could result in new product management systems and methods with IP potential.

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