

MICHIGAN LIFE SCIENCES CORRIDOR FUND

REQUEST FOR PROPOSALS

FISCAL YEAR 2002 COMPETITION

MLSC 2001

AUGUST 17, 2001

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Acronyms

CEO	Chief Executive Officer
CTA	Core Technology Alliance, five-center, four-institution technology infrastructure program funded by MLSC 2000 awards
GMP	Good Manufacturing Practice
IACUC	Institutional Animal Care and Use Committee
IPDP	Intellectual Property Disposition Plan
IRB	Institutional Review Board (for studies involving human subjects)
MEDC	Michigan Economic Development Corporation
MLSC	Michigan Life Sciences Corridor
MLSC Fund	The Michigan Life Sciences Corridor Fund
OHRP	Office for Human Research Protections (NIH)
OLAW	Office of Laboratory Animal Welfare
R&D	Research and Development
RFP	Request for Proposals

MICHIGAN LIFE SCIENCES CORRIDOR FUND

REQUEST FOR PROPOSALS

MLSC 2001

FISCAL YEAR 2002 COMPETITION

1. ABSTRACT

The Michigan Life Sciences Corridor Fund (MLSC Fund) requests proposals for projects that will contribute to research in the life sciences and to enhancing the development of related technologies and technology-based business activities in Michigan. Three categories of funding have been established by the State of Michigan (Public Act 120 of 1999, 292 of 2000, and 80 of 2001):

- Category I—basic research in health-related disciplines to Michigan universities or Michigan non-profit institutions
- Category II—collaborative applied research and development projects with an emphasis on testing or developing emerging discoveries with a potential to contribute to health and to the life sciences industry in Michigan
- Category III—commercial projects to establish or enhance enterprises in Michigan to commercialize the results of life sciences research.

Proposals for MLSC 2001 awards will be accepted, reviewed, and ranked in three groups corresponding to the three categories of funding. Each proposal category has specific qualifying requirements and evaluation criteria for competitive ranking of qualified pre-proposals and full proposals. All requirements, forms, evaluation criteria, and instructions for completing applications are contained in this Request for Proposals (RFP).

The MLSC 2001 program design is substantially different from the MLSC 2000 program design. To be eligible for the MLSC 2001 round of awards, **all applicants must submit a pre-proposal. Submission of full proposals is by invitation only.**

Section 3.3.14 specifies the due dates and delivery address for pre-proposals and full proposals. The overall structure of the program is summarized in Section 3.2. Examples of programs consistent with the MLSC program design are provided. (Section 3.4)

The RFP and the forms are provided on the Internet at the following location: <http://medc.michigan.org/>. Submission of preproposal applications will occur via a web-based application system which will be made available to applicants in September 2001.

2. INTRODUCTION

2.1. Mission of the Michigan Life Sciences Corridor Fund

The growth of the life sciences industry in the United States to the highest level in the world stems from a confluence of factors. Among these factors, three have been especially important. Federal agencies such as the National Institutes of Health have supported basic scientific research and training in universities. Large pharmaceutical firms have conducted proprietary research and development (R&D). And the venture capital community has been willing to invest in the high risk but high-return potential of scientific discoveries and technological innovations. The most successful developments in the biotechnology industry have occurred in proximity to leading university research centers, where forefront science and advanced training could interact with an entrepreneurial spirit fostered by both investors and researchers. The Legislature and the Governor of Michigan have recognized the importance of this vital nexus of factors and seek to promote it in the State for the benefit of the people of Michigan and the nation.

As a party to the November 1998 settlement of 46 states with the four largest U.S. manufacturers of tobacco products, Michigan is expected to receive periodic payments totaling more than \$8.5 billion over the next 25 years. In 1999 Michigan Legislature created the Health and Aging Research and Development Initiative and committed \$1 billion in annual appropriations of \$50 million from the tobacco settlement revenues to support development of a technology corridor in Michigan for research and commercial development focusing on the life sciences. This Michigan Life Sciences Corridor (MLSC) extends from Detroit to West Michigan.

A Michigan Life Sciences Corridor Fund (MLSC Fund) has been established to attract and nurture a growth industry in the life sciences and related technologies, in collaboration with the major Michigan research universities and private research organizations within this corridor and around the State. The Health and Aging Research and Development Initiative and the MLSC Fund have adopted the following mission:

To create, over the next two decades, a Michigan Life Sciences Corridor encompassing the best of academic science along with a robust, entrepreneurial private sector of new and established firms, thereby enhancing economic opportunities and health and well-being for the citizens of Michigan.

(Michigan Life Sciences Corridor Guidelines, February 24, 2000, p. 2)

In addition, the MLSC has targeted a goal of advancing Michigan from a top ten to a top five ranked state in life sciences research and employment by the year 2020.

To pursue this mission, the MLSC Fund, under the guidance of the Health and Aging Steering Committee established by Public Act 120 of 1999, 292 of 2000, and 80 of 2001, will fund projects in three categories, in accordance with the appropriating legislation, as described in Section 3.1.

2.2. Program Administration

The Health and Aging Steering Committee is chartered under Section 418, Michigan Public Act 120 of 1999, 292 of 2000, and 80 of 2001, to: (1) provide advice and oversight of the Health and Aging Research and Development Initiative; (2) develop criteria for the award of contracts or grants to qualifying universities, institutions, or individuals; and (3) make decisions regarding distribution of these grant funds in accordance with the allocations and conditions prescribed in the Act. The Steering Committee (also known as the Life Sciences Steering Committee) consists of the following members, appointed by the Governor:

- Doug Rothwell, Committee Chairman, President and CEO, Michigan Economic Development Corporation
- Donna Banks, Senior Vice President for Global Innovations, Kellogg Company
- Lee Bollinger, President, University of Michigan
- John Brown, President and CEO, Stryker Corporation
- Mary Campbell, General Partner, Enterprise Development Fund
- David Canter, Senior Vice President, Global Research and Development, Pfizer Inc.
- Phillip Carra, Vice President of Government Affairs and Public Policy, Pharmacia Corporation
- Richard M. Gross, Vice President and Director of Research and Development, The Dow Chemical Company
- Michael Jandernoa, Chairman of the Board, Perrigo Company
- Peter McPherson, President, Michigan State University
- Roger Newton, President and CEO, Esperion Therapeutics, Inc.
- Irvin D. Reid, President, Wayne State University
- David Van Andel, Chairman and CEO, Van Andel Institute.

The Michigan Economic Development Corporation (MEDC) provides staff support to the MLSC Fund and the Steering Committee. MEDC was formed in 1999 as a public corporation under the Intergovernmental Cooperation Act of 1967 and has been granted the ability, authority, and reach to serve as a one-stop resource for business retention, expansion, and relocation projects in the State. MEDC is governed by a board of directors composed of business leaders, local economic developers, and educators. For more information on MEDC and the history behind the MLSC Fund, visit the MEDC website at <http://medc.michigan.org/>.

3. MLSC 2001 GENERAL PROGRAM DESCRIPTION

3.1. Overall MLSC 2001 Program and Funding Levels for Categories I, II and III

Appropriation for the MSLC 2001 program (FY2002 Michigan budget) is pending at the time of the release of this RFP. It is estimated that approximately \$40 million will be available in FY 2002. Of this amount, the pending legislation indicates that forty percent will be allocated for Category I, and fifty percent for Category II, and ten percent to Category III.¹

- Forty percent of the fund (**Category I**) is allocated for basic research, to be distributed on a competitive basis to Michigan universities or Michigan non-profit research institutes for basic research in health-related areas with not less than \$5 million allocated to research related to aging diseases and health problems.
- Fifty percent of the fund (**Category II**) is allocated for collaborative applied research, specifically, peer reviewed collaborative awards among Michigan universities, Michigan companies, and/or private and non-profit research facilities, with emphasis on testing or developing emerging discoveries.
- Ten percent of the fund (**Category III**) is allocated to support commercialization opportunities for life science research in Michigan for Michigan for-profit and non-profit entities.

3.2. Principles, Strategies and Structure of the MLSC 2001 Program

The MLSC 2001 program design takes into account the experience of the MLSC 2000 application and awards process, including feedback from representative applicants and awardees; the scientific infrastructure of Michigan; and the goals of the MLSC, the legislative mandates for it, and the funds available for the MLSC 2001 competition. It also considers the increasing recognition by researchers and by funding agencies that collaborative research is needed to effectively tackle complex biological problems.

¹ When the FY2002 budget is finalized, the MEDC Web site, <http://medc.michigan.org>, will be updated to indicate the projected funds available for each category.

The MLSC 2001 program is designed around the following **principles**:

- As world-class science and graduate education is a necessary (but not sufficient) condition for regional economic development, **build Michigan's life sciences university-based (including Van Andel Research Institute and similar institutions) research enterprise.**
- As the whole can be greater than the sum of the parts, **increase the degree of collaboration among Michigan life science research performers.**
- As first rank entrepreneurial faculty and students are the engines that drive much research-derived economic growth, **provide opportunity and incentives for faculty to collaborate with, and get experience in, both science-based start-ups and R&D-driven companies.**
- As many successful science-based or high-tech firms have close relationships with first-rank university researchers, **provide opportunity and incentives for Michigan companies to work with researchers, undergraduates and graduate students in Michigan universities and non-profit research institutes.**
- As there is economic synergy within industries, **create "critical mass" in Michigan in a particular science, technology or industry rather than spreading the funding across too broad a range of projects. MLSC-funded projects should be of sufficient scale and scope (and provide or promise to leverage significant other funds) to have a material impact on Michigan's research capacity and/or economic development.**

The following **strategies** apply to the MLSC 2001 program:

- MLSC 2001, in all categories, will focus on: a) scientifically meritorious activities which build, or build on, the State's research and development capabilities; and b) activities that have potential to attract additional resources (research funding, private equity funding, quality researchers, the best graduate students or experienced entrepreneurs) to Michigan universities, research institutions, and companies.
- With the aim of improving the quality of human life and the environment, funded activity under MLSC 2001 may employ various biological models and organisms – including microbes, plants, and animals other than humans – using unifying genomic, energetic, and other life science concepts to address fundamental research problems or develop, test, and commercialize useful products and techniques.
- MLSC 2001 has set high standards for collaboration and requires, in the pre-proposal and full proposal, evidence of genuine, productive collaboration.
- Contribution of resources by the applicant and collaborating organizations will be considered in the evaluation of proposals.

- Full proposals will be by invitation only. A pre-proposal process, binding with respect to content, is designed to provide feedback to applicants on their responsiveness to program goals, and deselecting those not meeting the triage criteria.²
- Groups and companies that received awards in MLSC 2000 are eligible to apply for MLSC 2001 funding, and will compete on the basis of quality and program contribution with other applications. MLSC 2000 round awardees who are applying for continuation or addition to their award need to provide description of the program accomplishments to date in the new application. Renewal funding will be provided to all Core Technology Alliance (CTA) components making satisfactory progress towards their established goals and milestones, as approved by the Steering Committee in conjunction with the MLSC 2000 award cycle decisions.
- Review and award criteria are designed to focus MLSC's funds so as to have maximum potential to impact on increasing the Michigan life-sciences research base and/or the development of a life sciences industry in Michigan.

3.3. Proposal Information Common to All Categories

The Michigan Public Act that appropriated funds for the Health and Aging Research and Development Initiative (Public Act 120 of 1999, 292 of 2000, and 80 of 2001) defined three categories of funding. Proposals for fiscal year 2001 awards will be accepted, reviewed, and ranked in those three categories:

- Category I: (Basic Research Fund): basic research in health-related areas to Michigan universities or Michigan non-profit research institutions.
- Category II: (Collaborative Research and Development Fund): collaborative applied research and development projects with an emphasis on testing or developing emerging discoveries with a potential to contribute to health and to the life sciences and technology industries in Michigan by Michigan universities, Michigan companies and/or private or not-for-profit research facilities.
- Category III: (Commercial Development Fund): commercial development projects to establish or enhance enterprises in Michigan to commercialize the results of life sciences research.

The MLSC 2001 program design is substantially different from the MLSC 2000 program design and is summarized in the table below. To be eligible for MLSC 2001 round of awards, **all applicants must submit a pre-proposal. Submission of full proposals is by invitation only.** Each category has specific requirements for qualified proposals and evaluation

² Depending on funds available and funds estimated by the pre-proposals, it may be necessary to further limit the number of full proposals requested.

criteria for ranking the qualified proposals. All requirements, evaluation criteria, and instructions for completing an application are contained in this Request for Proposals (RFP). The subsections of Section 3 describe general features of the proposal and award process, including the general requirements for all proposal groups. Detailed requirements and instructions for Categories I, II, and III are provided in Sections 6, 7, and 8, respectively. To qualify for selection, an applicant must meet the general requirements stated in Sections 3, as well as the requirements specific to the MLSC category to which the proposed project belongs.

The legislation notes that appropriated funds must be matched with other university, private or federal funding. See Section 3.3.5.

Summary of the MLSC-2001 Structure

	Category I	Category II	Category III
Legislative Direction	Basic research Health-related areas ≥\$5 million for diseases related to aging	Collaborative Applied Testing new or emerging technologies	Commercialization
Legislative Percent Allocation	40 %	50%	10%
Eligible Applicant Organizations	Michigan universities Michigan non-profit research institutions	Michigan universities Michigan companies Private and/or non- profit research facilities	Private and/or non- profit Michigan entities
Submission Requirements	Pre-proposal required Full proposals by invitation	Pre-proposal required Full proposals by invitation	Pre-proposal required Full proposals by invitation
Program Characteristics	Scale Scope Collaboration Platform Investments Leveraging potential	Scale Scope Leveraging potential Defined path to market/use Collaboration Organizational commitment	Programs that address needs in life science commercialization
Proposal Evaluation Criteria	<ul style="list-style-type: none"> ▪ Scientific quality ▪ Expertise ▪ Facilities/Resources ▪ Collaboration encouraged ▪ Leverage ▪ Potential to increase Michigan's research capacity ▪ Michigan Economic Impact 	<ul style="list-style-type: none"> ▪ Scientific quality ▪ Feasibility ▪ Facilities/Resources ▪ Defined path to market/use ▪ Collaboration ▪ Organizational commitment ▪ Leverage ▪ Intellectual property plan ▪ Michigan Economic Impact 	<ul style="list-style-type: none"> ▪ Quality of proposed project ▪ Organizational expertise ▪ Justification for proposed project ▪ Organizational resources ▪ Leverage ▪ Usage/fee structure ▪ Michigan Economic Impact
Proposal Award Criteria	<ul style="list-style-type: none"> ▪ Portfolio Balance ▪ Available Funds ▪ Relevance to Aging³ ▪ Matching Compliance 	<ul style="list-style-type: none"> ▪ Portfolio Balance ▪ Available Funds ▪ Matching Compliance 	<ul style="list-style-type: none"> ▪ Portfolio Balance ▪ Available Funds ▪ Matching Compliance
Estimated Funds Available⁴	\$16 million	\$20 million	\$4 million

³ The legislative language instructs that not less than \$5 million from Category I must be awarded to applications related to aging diseases and health problems .

⁴ The number of grants that can be awarded is contingent on the MLSC program appropriation and dependent on the amounts approved for the successful proposals .

3.3.1. Eligibility

The eligibility requirements for awards as an applicant organization from the MLSC Fund differ by funding category. The following definitions apply to the eligibility requirements:

- To be eligible as a “Michigan university,” the Program Director for the project must be a faculty member or administration official at an accredited institution of higher education in Michigan. The principal site for the project must also be at an accredited institution of higher education in Michigan or a facility closely associated with such institution.
- To be eligible as a “non-profit research institution in Michigan,” or "private research facility in Michigan" the Program Director for the project must be an employee of an organization whose business lines include research and/or development. The principal site for the project must be at a facility located in Michigan and either (1) owned by the research organization or (2) owned by an organization collaborating on this project. If the principal site is owned by a collaborating organization, that organization must meet the “principal site of the project” requirement for a Michigan university, public or private research organization in Michigan, or Michigan-based for-profit firm, as defined in this section.
- To be eligible as a “Michigan-based for-profit firm,” the Program Director for the project must be an employee of a for-profit business who will be located for the duration of the project primarily at the principal site at which or from which the project will be conducted. The for-profit firm must either (1) be incorporated in Michigan and be conducting at least some of its business in Michigan; (2) be conducting a major share of its business activity in Michigan; or (3) for firms with the major share of their business activity outside Michigan, have existing business activity in Michigan that is economically significant within the State or a region of the State and be intending to locate a significant portion of any commercial activity resulting from this project within the State.

Section 3.3.4 discusses the criteria for participation of non-Michigan organizations as collaborating entities.

3.3.2. Scientific or Commercial Theme/Direction

Each proposal should have a specific scientific and/or commercial theme/direction. The Category I and II MLSC proposals should present plans for collaborative efforts to study health and life science-related research areas with approaches designed to lead to enhancement of Michigan’s research capacity (Category I) or to the development of commercially viable products such as diagnostics, pharmaceuticals, and medical devices (Category II). Category I and II proposals may also include projects that seek to create facilities that support or enhance basic or applied research capabilities, respectively, in Michigan. Such proposals should provide examples of the kinds of collaborative research and commercialization that the award will foster and facilitate. They should also detail how the success of the program would attain the MLSC goals and leverage funds from Michigan, federal or private sources. Category III proposals should focus on projects that enhance Michigan life sciences commercialization, specifically to

address critical commercialization needs in Michigan life sciences business environment (See Section 8 for full discussion).

Each proposal should tailor its requests for personnel, supplies, facilities, instrumentation, core services, career development, etc., to the specific resources needed to expand the research base and/or commercialization potential in the chosen area of life sciences. For example, proposals could request infrastructure components such as major pieces of equipment or facilities to house such equipment, as well as specialized staff to operate the infrastructure. MLSC Funds can be used for the enhancement of technology transfer activities in terms of personnel (e.g., consultants in patent law) or facilities (e.g., incubator laboratories) or pre-seed support or other commercialization services.

Section 3.4 provides several illustrative examples of the kinds of programs that might be proposed. Investigators are encouraged to develop programs that meet their specific needs and the MLSC goals.

3.3.3. Qualifying Research Fields

Promising areas of life sciences research, application development, and commercialization are likely to change over time, reflecting the evolution of the underlying scientific disciplines and the dynamics of emerging and changing markets for biomedical and life-science technologies. Given this dynamic evolution, the MSLC Fund has initially refrained from defining highly specific R&D areas in the life sciences and related technologies for funding emphasis.

Applicants are welcome to submit proposals in a range of areas of life sciences and related technologies that are consistent with the purposes and enabling legislation of the MLSC Fund (Sections 2.1 and 2.2). The legislation requires that for Category I “not less than \$5 million” be “allocated to research related to aging diseases and health problems.” (See Section 3.3.17 for the MLSC definition of aging diseases and health problems.) The MLSC Guidelines speak to the overall program “enhancing...the health and well being for the citizens of Michigan.” **For each of the three categories of funding, the applicants are instructed to clearly delineate how the proposed program is responsive to this aspect of the legislative language and MLSC Guidelines.**

Life sciences for the purposes of the MLSC-2001 program will not include projects that address healthcare delivery, public health, epidemiology, natural resources management, agriculture, and ecology. The MLSC-2001 program does not seek proposals for scientific education or curriculum development.

3.3.4. Collaboration

For proposals in Category I, collaborations are encouraged. Proposals in Category II must include collaboration between two or more institutions or organizations. While Category III does not explicitly require collaboration, the concepts of commercialization services and incubators will by their nature involve interactions between multiple organizational entities. Each proposal must designate a lead organization (the applicant organization) that will be responsible for the administration of the proposal, should it be awarded. Individual organizations are encouraged to concentrate in areas of strength.

Examples of genuine collaboration include the following:

- The history of and long-term plan for the proposed collaboration and an indication of its extension beyond the proposed project demonstrate joint commitment to the project.
- An indication of longer-term shared or reinforcing plans and incentives among collaborating organizations demonstrate joint commitment to the goals of the project.
- Evidence from the content of the written proposal that each collaborative partner has authored or developed a specific aspect of the proposal or will perform specific aims of the project.
- Plans for commitment of resources (time, money, facilities, equipment, intellectual property or other resources) demonstrate the commitment of collaborating organizations to the goals of the collaboration and the proposed project.
- Indication that each collaborative partner will provide specific technological or methodological expertise, specific materials, or specific experimental data/resources relevant to the problem under investigation is evidence of joint commitment to the project.

In general, collaborating entities should be Michigan-based as defined in **Section 3.3.1**, as the goal of the MLSC is to increase collaboration between Michigan Universities, Michigan research institutions, and Michigan companies. However, collaboration with non-Michigan based entities may be proposed. The applicant must specifically address the reasons for such collaborations, such as accessing specialized resources, scientific, technical and commercial expertise, and must indicate the potential benefits to Michigan of the proposed collaboration.

3.3.5. Organizational Contributions/Match

The legislation that created the MLSC requires that appropriated funds must be matched with university, private, or federal funding. The legislation is silent on the proportion and form of match. Review criteria for each category include collaboration and leverage. The award criteria include the level of matching contribution.

Each of the participating organizations must provide a specific contribution to the program. This can be provided in varying forms and could include matching funds, instrumentation support,

salary support, in-kind services, indirect cost charges foregone, or other contributions. While these contributions will be used in the evaluation of proposals, cognizance will be made of the nature and amounts of resources available for these purposes at different institutions and organizations.

For proposals of equal quality, organizational contributions/match may be considered in selecting the proposal to be awarded.

3.3.6. Designated Administrative Entity

Each proposal must designate a Michigan-based organization responsible for administration of the project; in general, this organization will play a major role in the project. An investigator from that same organization should be designated as the overall Program Director, be responsible for coordinating the inter-organizational functions, and serve as the contact point for administrative functions. In general, this person will also be playing a major role in the project.

3.3.7. Award Type and Duration

MLSC 2001 awards will be made for up to three years. MLSC staff will contact awardees post-award to negotiate grant and contract terms for the award and to structure an award monitoring program for the awardees. Successful applicants will be informed of the requirements for progress reports.

Applications from Michigan universities and Michigan not-for-profit research institutes will be considered for grant awards.

Awards given to for-profit organizations may be in the form of a cooperative agreement, service contract, loan, equity, other financing arrangement or combinations thereof. A grant may be a component of an award only if proper justification for such treatment is provided. The proposed award type and/or financing structure in applications by for-profit organizations will not be a review criterion for granting the award. The award structure and terms will be negotiated post-award after appropriate due diligence by MLSC staff.

3.3.8. Indirect Cost Rates

The indirect cost rates used in proposal budget plans should be no greater than 20 percent of total direct costs. The applicant organization shown on the face page may request funds in the direct cost category to cover administrative costs for oversight of the program (e.g., salary support for the Program Director, secretarial support and supplies).

3.3.9. Intellectual Property

Given the complexity and importance of intellectual property related to life sciences research and development and commercialization, it is critical that all MLSC proposals contain a plan for legal and administrative management of research discoveries. Therefore, applicants should include in the full proposal application an intellectual property disposition plan (IPDP) that clearly delineates the broad structure for managing intellectual property issues encompassed by the proposed program. Given the complexities of collaborative research programs, and the varying collaborative requirements for each MLSC Category (see Section 3.4.4), each plan needs to be developed on a case-by-case basis incorporating the following basic components, as applicable:

- Treatment of confidential information and proprietary materials within the context of the project.
- Summary description of background technology contributed by each collaborative party and its treatment within the context of the proposed project, including any significant third party licenses required to proceed with the program.
- Plan for protecting intellectual property anticipated to be generated by the proposed program including how the cost of the protection will be covered.
- Ownership rights and management responsibility for intellectual property generated by the program.
- Summary plan and responsibility for commercializing the intellectual property from the program.

Each proposal's intellectual property disposition plan (IPDP) should briefly describe:

- Which anticipated agreements, such as material transfer agreements, nondisclosure agreements, licenses, etc., have been or will be agreed upon either in template or final form.

- What has been agreed to prior to the commencement of research, as well as a plan for how any remaining issues will be negotiated (time line, participants, ground rules, etc.).

The IPDP should indicate how resources required for legal and administrative costs related to intellectual property management and commercialization will be obtained, whether or not requests for such funds are contained in the proposal. If current intellectual property management or technology transfer resources are insufficient in quality or quantity, the plan should explain how these deficiencies would be addressed in order to assure optimum management of intellectual property generated within the MLSC -supported program.

Once a year, MLSC award recipients will be required to submit a brief Intellectual Property Report. This report must include any significant changes to the IPDP and the following specific information:

- Any new inventions, patent applications, or patents issued related to the project
- License fees paid or received, and any new licenses
- Patent costs paid (and recovered, where applicable)
- Commercialization and technology transfer results achieved.

All invited full proposals to the MLSC Fund must include an intellectual property disposition plan (IPDP) meeting the above requirements as a condition of qualifying for evaluation and award.

3.3.10. Financial Conflicts of Interest

For all invited full proposals, the signature of the official signing for the applicant organization on the face page serves as certification that there is in effect an administrative process to identify and resolve financial conflicts of interest that may affect the objectivity of the research and/or development being proposed. The organization agrees to inform the MLSC Fund of all conflicting financial interests that have been identified and to describe how they have been resolved to protect the project from bias.

3.3.11. Completion of All Relevant Items for Proposals

Applicants submitting either pre-proposals or proposals are expected to complete all sections of the application as indicated on the Checklist (MLSC Form-01). Receipt dates for the Pre-proposals and Proposals are specified in **Section 3.3.14.**

Assurance that application submissions contain all required items is the sole responsibility of the applicant. Proposals that do not include all of the required components will not be reviewed. No supplementary or revised materials will be accepted after the scheduled date for submission. Decisions by the Steering Committee about the disposition of the pre-proposals and proposals will be final and not subject to appeal.

3.3.12. Format Specifications and Submission of Applications

MLSC 2001 round preproposal applications are to be submitted electronically using a web-based application. **No applications will be accepted via mail or any other delivery method.**

The web-based application forms are similar to MLSC forms included in this request for proposals. The website to submit these forms will be announced in September 2001. The web-based MLSC application forms should be used for entering the information required by the detailed instructions. In particular, the appropriate face cover page (Form MLSC-02 for pre-proposals and MLSC-03 for full proposals) must be completed in full. Specific instructions regarding the submission format will be given on the website where applications are to be submitted.

English should be used in preparing proposals and the use of jargon should be avoided. When abbreviations or acronyms not universally known are used, the term should be spelled out the first time it is used, with the appropriate abbreviation or acronym in parentheses. The abbreviation or acronym may be used thereafter.

3.3.13. Notice of Proprietary Information

If the pre-proposal or proposal contains information that constitutes trade secrets, information that is commercial or financial, or information that is confidential or privileged, the information must be identified by asterisks (*) on the page on which it appears. List the page numbers of all pages marked in this way on the face page of the pre-proposal or proposal (Forms, MLSC-02, line 2; MLSC-03, line 2).

Proposal information is furnished to the MLSC Fund in confidence, with the understanding that it will be used or disclosed only for evaluation of this proposal; provided that, if a grant is awarded as a result of, or in connection with, the submission of this proposal, the MLSC Fund shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the MLSC Fund's right to use the information, if it is obtained without restriction from another source.

When a proposal contains information that constitutes trade secrets, information that is commercial or financial, or information that is confidential or privileged, the MLSC Fund accepts that the information is furnished in confidence, with the understanding that it will be used or disclosed only for evaluation of this proposal. Nondisclosure agreements with the MLSC Fund are required of all persons who may have access to proposals containing proprietary information.

As indicated in Sections 4.1 and 5.2, the Abstract should not contain any proprietary information.

3.3.14. Proposal Deadlines

Pre-proposals must be received by November 5, 2001.

It is anticipated that decisions to solicit full proposals will be made by December 14, 2001.

It is anticipated that invited full proposal due date will be March 1, 2002; the final due date will be communicated to the applicants in the invitation letter.

It is anticipated that decisions regarding final awards will be made by June 2002.

Acknowledgment of Receipt of Submission. Applicants will receive an e-mail acknowledgment of the receipt of a proposal upon successful web-based application submission. Applicants are requested not to contact MLSC staff for acknowledgement of receipt.

3.3.15. Proposal Review and Decision Process

Pre-proposals and proposals will undergo peer review similar to those used by federal funding agencies and numerous philanthropic organizations. Review will be completed by an independent peer review agency contracted for the assignment by the MLSC staff. At each stage, reviewers with expertise appropriate to the scientific and commercial content of the proposal will evaluate and rank the submitted written materials according to the criteria specified in this RFP.

The recommended rankings will be presented to the MLSC Steering Committee, which will add its assessment of the project's value to the State of Michigan and the development of the MLSC Corridor using Award Criteria appropriate for each category. Full proposal invitations and awards will be made by the Steering Committee.

At each stage, both successful and unsuccessful applicants will receive evaluative feedback. In the pre-proposal stage, reviewers will address the category-specific eligibility and ranking criteria principally with numerical ratings. At the proposal stage, it is anticipated that an edited summary of the reviewer comments and numerical ratings will be prepared, indicating the proposal's degree of success in meeting the MLSC-2001 category-specific evaluation criteria.

3.3.16. Future Rounds of the MLSC Program

At this time, it is anticipated that a third round of the MLSC Program (MLSC 2002) will be issued in calendar year 2002 for award in calendar year 2003. The content of that RFP will be determined subsequent to the receipt of the 2001 proposals and evaluation of this year's program.

3.3.17. Definition of Aging Diseases and Health Problems

For the purpose of Category I of MLSC-2001 program, research in 'aging diseases and health problems' is defined to include studies to elucidate the biochemical, genetic and physiological mechanisms of aging in humans. This includes investigations of the gradual or

programmed alterations of structure and function that characterize normal aging, as well as investigations of the abnormal changes that are risk factors for or accompany age-related disease states. Examples of specific diseases include: Alzheimer's disease and other degenerative disease of the nervous system; cardiovascular disease, cancer, diabetes; bone, muscle, skin, joint and movement disorders; vision, hearing and other sensory disorders; benign prostatic hyperplasia; and infectious diseases. The use and choice of model systems for these purposes must be clearly justified and rationalized in the proposals.⁵

3.4. Examples of Innovative Program Proposals that Meet the MLSC 2001 Guidelines

The MLSC 2001 program design differs significantly from the MLSC 2000. Applicants should carefully read the general instructions in all parts of Section 3, and the specific category instructions in Sections 6, 7, and 8. The MLSC 2001 program allows for significant applicant creativity in order to achieve the goals of the MLSC and the authorizing legislation while allowing applicants to meet the scientific, technical, and commercialization needs of their research areas and organizational entities. The following five examples of conforming proposal ideas illustrate the potential of the proposed program design criteria. **They are meant as illustrative examples of the kinds of programs that might be proposed. Investigators are encouraged to develop program designs that meet their specific needs and the MLSC goals.**

Example 1: Collaborative Applications Grant Fund. Category II proposals could build on scientific infrastructure investments by MLSC by supporting biotechnology researchers to use or extend these resources towards commercialization goals. For example, collaborative academic/industry projects may seek to use the CTA resources and request funds to cover the CTA fees, as long as there is an adequate demonstration of significant private sector contribution of resources. Further, in order to facilitate usage of the infrastructure sites for commercial feasibility studies or pilot projects, current CTA sites (funded in MLSC 2000) and infrastructure projects proposed for MLSC 2001 could apply under Category II to create an Applications Grant Fund. A major facility or site could apply for a fund (up to \$300,000 total per year per site, for example) to cover the cost of usage of the infrastructure or equipment—in clearly defined applications-oriented research—by industrial scientists or by academic scientists working in collaboration with a company. Applications for use of these feasibility/pilot funds would then be made directly to the infrastructure/CTA site with rapid review, evaluation, and administration made by the infrastructure/CTA site. Peer review would be the responsibility of the infrastructure/CTA site receiving the MSLC 2001 award. Individual projects could request up to \$20,000 per pilot/feasibility study, with the administrator of the fund (infrastructure/CTA site) taking the responsibility for assuring private investment or match.

Example 2: Create a Critical Mass of Research on a Disease Associated with Aging. Category I grants are intended to create an improved basic research enterprise in Michigan and the focus of Category I program design is on platform investments that enable a wide range of biomedical research. This does not rule out, however, disease or organ focused research programs that are of sufficient scale and scope, that they can arguably create a center of excellence in the State of Michigan. A multi-institutional research program focused on a specific

⁵ The definition was formulated by using part of the definition of the Biology of Aging Program of the NIH, National Institute of Aging and a listing of a number of recent initiatives by the National Institute of Aging.

disease (especially a disease associated with aging such as diabetes, heart disease, or cancer), particularly one designed to leverage current or future funding, would be appropriate for Category I. The logic is that this type of activity would have the potential to create a research cluster with critical mass in the State. Such clusters of activity could have considerable economic development potential for the State and could allow it to become one of a handful of centers of excellence in a particular, high-potential research area.

Example 3: Pre-Seed or Entrepreneur Grant Fund. Category III grants could provide pre-seed funding for life science start-ups through an intermediary university-based, private or non-profit entity. For example, an incubator, university, or consortium of universities, private entities and non-profits or a combination of the above could apply, under Category III, to create and administer a Pre-Seed Grant Fund. The allocations from such a fund—probably in the range of \$50,000-\$200,000 per award per year—could be made quarterly to individuals or companies on the basis of a review of commercialization potential. Since applications to the Pre-Seed Grant Fund would be reviewed and administered by the incubator or consortium, a key aspect of this type of proposal to the MLSC would be the detailed description of plans for all aspects of such a program, including review mechanisms and matching investment requirements. The same type of application focused on research-based start-ups—an Entrepreneur’s Grant Fund—could be put forward by a university, non-profit or private entity, if the proposal demonstrated how MLSC funds would be matched by university or private resources to support faculty members starting companies.

Example 4: Faculty and Departmental Development and Support. Applications for combined support from Category I and II could propose a program to recruit and retain outstanding faculty members in special focus areas, especially for specific areas on the cutting edge of the life sciences commercialization. Such an application might be submitted by a group of faculty investigators from several inter-related departments (or institutions) whose research interests were allied toward the development of commercially useful products (e.g., a specific class of pharmaceuticals, development of a specific type of nanotechnology) and who had identified one or several commercial partners. The requested budget would have two components. Category I funds would be requested for academia-related activities such as for an investigators’ salaries; laboratory set-up (including equipment, supplies, and renovation of space); salaries for technical and secretarial help; and stipends for postdoctoral fellows, graduate students, and summer student assistance. Category II funds could be requested, for example, to support a special sabbatical program for faculty for those times when their activities would be focused on testing and developing an emerging research result in the biotechnical or industrial environment as a program of mutual interest. The evaluation of such a proposal would involve consideration of both Category I and II criteria.

Example 5: Supporting Private Research Programs. An individual company should be able to successfully lead an application for support from Category II as long as the application conformed to the various “public” goals of the program: genuine collaboration with a Michigan university, research institution, or company; high-market-potential applications-focused research; and potential to leverage funding. For example, a company could propose to build and operate an applied research capacity that did not exist presently in the State. Under the proposed program design for Category II in MLSC 2001, such proposals would be rated not only on

scientific quality, but also, on the basis of the quality and strength of the collaboration, the market potential and economic value to Michigan, and the degree to which MLSC funds would leverage other funds or resources.

Example 6: Support for Commercialization Services. Applicants providing services to support and enhance the life science business environment in Michigan could apply for Category III funds that specifically address needs in Michigan's commercialization infrastructure. For example, such an application may be submitted by an executive recruitment organization with extensive experience in recruiting life science management professionals. Such an applicant could establish an office and provide recruitment services to Michigan based start-ups. Category III funds could be requested, for example, to provide leasing expenses, establish a recruitment fund (for moving expenses, salary enhancement, etc), subsidize the expenses for small start-ups.

Example 7: Technology Infrastructure and Services Support. Applications for combined support from Category II and III could propose a program that builds on the life science related technology infrastructure (i.e. facility, equipment, etc) and enhances life science business operations (i.e. management support, market analysis, etc.). Such an application may be submitted by a team of professionals developing an incubator facility focused on addressing business concerns pertaining to life science companies and/or technology. The requested budget would contain a component specific to both Category II and Category III respectively. Category II funds could be requested to help support technology infrastructure such as facility enhancement/development, equipment, supplies for technology development. Category III funds could be requested to help support business services that will maximize the opportunities to enhance core technology, for example, to provide patent costs, management costs, market assessment services, or other related business services to companies housed within the incubator facility.

3.5. Programs Addressing more than one Funding Category

Applicants whose programs address more than one funding category, should indicate this on the face page (Item 1b on both MLSC-Form 02 (pre-proposal), MLSC-Form 03 (full proposal) by checking the appropriate boxes. The overall structure of the pre-proposal statements (Sections 6.3, 7.3, 8.4) and the full proposal program plans (Sections 6.5, 7.5, 8.6) for the funding categories are parallel in format. Applicants should consider the issues, for example, in the individual items of the relevant funding categories, and combine and address them under one bold face heading. Applications seeking funding from two or more categories have to conform to the eligibility and review criteria for each category.

4. GENERAL INSTRUCTIONS FOR ALL CATEGORIES OF PRE-PROPOSALS

These instructions pertain to pre-proposal submissions for all MLSC Fund categories. Note that while these forms are very similar to the MLSC 2000 forms, some changes have been made.

Pre-proposals consist of three parts, the face page, the Pre-Proposal Statement, and a listing of and the individual Biographical Sketches for the Program Director and co-investigators (Form MLSC-04). Pre-proposals must use the face page provided in the appendix (Form MLSC-01),

the Continuation Page Format for the Pre-proposal Statement and for the listing of program participants; and Form MLSC-04 for the individual Biographical Sketches. **No more than 4 pages can be used for the required Pre-proposal Statement. The Face Page and Biographical Sketches do not count in this page limit. All of these forms will be part of the web-based application submission. No paper submissions will be accepted.**

4.1. Pre-Proposal Face Page

This section contains instructions for the Pre-Proposal Face Page (Form MLSC- 02/1). Entries in the proposal forms must be clear, readily legible, and conform to the following two requirements: (1) The height of the uppercase letters must not be smaller than 10 points, and (2) No more than 6 lines of type must be within a vertical inch.

Note: Modification of the form format will invalidate the submission, which will be returned without evaluation.

Item 1a. Project Title. Choose a title that is specifically descriptive, rather than general. Do not exceed 56 characters, including the spaces between words and punctuation.

Item 1b. Project Category. Indicate to which MLSC Category(ies) the proposal is responding.

Item 2. Proprietary Information. Indicate pages of the pre-proposal containing proprietary information. If no proprietary information is in the pre-proposal, enter "None".

Item 3. Program Director. Items 3a through 3h pertain to the one person responsible to the applicant organization for the scientific and technical direction of the project. MLSC Fund staff conducts official business only with Program Directors and institutional officials. Do not enter multiple names or data for different individuals in these blocks.

Item 3a. Name. Enter the last name, first name, and middle name or initial of the Program Director. Do not exceed 30 characters, including the spaces between words and punctuation.

Item 3b. Position Title. Enter the academic or professional title of the Program Director. If more than one title, enter the one most relevant to the proposed project. Do not exceed 30 characters, including the spaces between words and punctuation.

Item 3c. Telephone and Fax Numbers. Provide a daytime telephone number and, if available, a fax number, for the Program Director. Do not exceed 25 characters for each number, including spaces.

Item 3d. Email Address. Provide the email address for the Program Director. Do not exceed 40 characters. **Note that all notices regarding the application will be sent to this e-mail address. Therefore, please verify that you have entered it correctly.**

Item 3e. Applicant Organization and Applicant Organization Address. Name the one organization that will be legally and financially responsible for the conduct of activities

supported by the award. (Use the organizational name consistent with that of the EIN or DUNS number.) Provide a complete address including information pertinent for express delivery.

Item 4. Type of Organization. Check the appropriate organization type. See **Section 3.3.1** for the definition of a Michigan-based for-profit firm.

Item 5. Collaborating Organizations. Provide the names of all collaborating organizations for this proposal. Indicate in parenthesis the type of organization, using “MU” for Michigan University, “MN” for Michigan-based Non-profit organization, and “MFP” for Michigan-base For-Profit organization. Use an asterisk (*) to indicate any non-Michigan entities.

Item 6. Point of Contact for Proposal-Related Matters. Provide the name, title, telephone, fax and e-mail address for this person.

Item 7. Official Signing for Applicant Organization. Name an individual authorized to act for the applicant organization and to assume the obligations imposed by relevant laws, requirements, and conditions for a grant or grant application. Provide a voice telephone number, a fax number, and, if available, an electronic mail address.

Item 8. Duration of Support. Indicate the number of years of funding anticipated to be requested (1-3).

Item 9. First Year Costs. Provide an estimate of the total first year costs anticipated to be requested (Direct plus indirect costs).

Item 10. Full Period Costs. Provide an estimate of the total costs anticipated to be requested for the entire project period. This figure will be used in assessing the scale of the proposal.

Item 11. Abstract. State the program’s broad, long-term objectives including the life science theme, health-related goals, and, if applicable, for Category I, relationship to aging diseases research. Indicate how the program will build Michigan’s research capacity and/or economic development. Indicate the strengths and resources the program will build upon and enhance. The abstract is meant to serve as a succinct and accurate description of the proposed project and must be releasable to the public. Therefore, **do not include any proprietary/confidential information in it. Do not exceed** the space provided. Follow the font size restrictions in section 3.3.12.

Item 12. Content Areas of the Proposal List the technical and scientific disciplines and commercialization services (if applicable), involved in the program. For example, nanotechnology, micropumps, incubator development, genetic aspects of diabetes, development of immunotoxins for cancer therapy, patent law curriculum. This information will assist in planning for the review.

4.2. Pre-Proposal Statement

The Pre-Proposal Statement for each category of application is structured to address the MLSC Mission (Section 2.1) and legislative guidelines for that category. The content of the Pre-Proposal Statements and the evaluation criteria for the individual categories are detailed in Sections 6, 7, and 8. The required information should be provided using the Continuation Page format with adherence to the character size, type density, and margins of that format specified in section 3.3.12. **Boldface** headings should be used to indicate each section.

A maximum of four (4) Continuation Pages can be submitted for the Pre-Proposal Statement.

The content of the pre-proposal is binding. Subsequent invited proposals that differ materially in content from the pre-proposal will be deemed non-compliant and will not be reviewed.

Pre-proposals not following the format and page limitations will not be accepted by the web-based application system.

Separate appendix material, such as reprints, organization brochures, etc., should not be submitted. Such materials will not be accepted by the web-based application.

Decisions by the Steering Committee are binding and not subject to appeal. Applicants for preproposals approved by the Steering Committee will receive an invitation letter to submit a full proposal application. All preproposal submissions will receive feedback as noted in Section 3.3.15.

4.3. Biographical Sketches

Use a Continuation Page to provide a list of the each person who will play a key role and his/her employing organization (Section 5.2 provides guidance on Key Personnel.) in the program. List the Program Director first, followed by the other participants in alphabetical order. For each listed individual provide in the same order a biographical sketch using photocopies or downloaded files of the Biographical Sketch Form provided with this RFP (Form MLSC-04). Each biographical sketch must be no more than two pages. When a second (continuation) page is used, enter the individual's name followed by "Continued" at the top of the page. Emphasis should be on recent publications and activities relevant to the proposal. Biographical Sketches should be up to date.

Use a portion of the second page of the Biographical Sketch to briefly summarize the research and commercialization experience of each participant as relevant to his or her role in the proposed program (approximately 150-250 words or 10-12 lines).

Also use the Biographical Sketch Form to indicate patents and licenses, relevant to the proposed effort, attained in the past five years by program participants.

5. GENERAL INSTRUCTIONS FOR ALL CATEGORIES OF PROPOSALS

These instructions pertain to full proposals invited for any MLSC Fund category. Note that while these forms are very similar to the MLSC 2000, some changes have been made. Please use the Checklist (Form MLSC-01) to verify that the proposal contains all necessary forms in the appropriate order.

Note: Modifications of the layout or format of the proposal Face Page or Proposal Form Page will disqualify the proposal, which will be returned without evaluation.

Note: **Full proposals are by invitation only.** Applicants who are invited to submit a full proposal will be provided with additional instructions regarding the submission of their applications in conjunction with the invitation letter.

5.1. Proposal Face Page

This section contains instructions for the Proposal Form Face Page (Form MLSC-03, page 1). Entries in the proposal forms must be clear, readily legible, and conform to the following two requirements: (1) The height of the uppercase letters must not be smaller than 10 points, and (2) no more than 6 lines of type must be within a vertical inch.

Follow the character length restrictions noted in the instructions below and summarized in the checklist, Form MLSC-01.

Item 1a. Project Title. Choose a title that specifically describes the proposed effort, rather than a generality. Do not exceed 56 characters, including the spaces between words and punctuation. **This item must be the same as the corresponding pre-proposal.**

Item 1b. Project Category. Indicate which of the MLSC Category(ies) the proposal is responsive to. **This item must be the same as the corresponding pre-proposal.**

Item 2. Proprietary Information. Use this line to indicate proposal pages that contain proprietary information. (See Section 3.3.13).

Item 3. Program Director. Items 3a through 3h pertain to the one person responsible to the applicant organization for the administrative oversight of the project. MEDC staff and contractors will conduct official business only with Program Directors and organizational officials. Do not enter multiple names or data for different individuals in these blocks. Co-investigators should be identified as Key Personnel on Page 2 of Form MLSC-03.

Item 3a. Name. Enter the last name, first name, and middle name or initial of the Program Director. Do not exceed 30 characters, including the spaces between words and punctuation. **This item must be the same as the corresponding pre-proposal.**

Item 3b. Degree(s). Enter up to three academic and professional degrees, e.g., M.D., or other credentials, such as licenses. Do not exceed 30 characters, including the spaces between words and punctuation.

Item 3c. Position Title. Enter the academic or professional title of the Program Director. If this individual has more than one title, enter the one most relevant to the proposed project. Do not exceed 30 characters, including the spaces between words and punctuation.

Item 3d. Delivery Address. Provide complete information (including room number, building, and street address) necessary for postal and/or express delivery to the individual named in Item 3a. All written communications with the Program Director will use this address. Enter up to five lines, with no more than 32 characters per line. Do not repeat the name entered in Item 3a.

Item 3e. Company, Department, Laboratory, or Equivalent. Enter the organizational affiliation of the Program Director, such as the university, public or private research organization or for-profit firm by which the Program Director is employed. Do not exceed 30 characters, including the spaces between words and punctuation. **The applicant organization must be the same as the corresponding pre-proposal.**

Item 3f. Major Subdivision. For a university, enter the name of the major subdivision, such as School of Medicine, School of Public Health, College of Arts and Sciences, etc. For a research organization or commercial entity, a major department or division may be entered. If there is not an appropriate major subdivision to name, enter, "none." Do not exceed 30 characters, including the spaces between words and punctuation.

Item 3g. Telephone and Fax Numbers. Provide a daytime telephone number and, if available, a fax number, for the Program Director. Do not exceed 25 characters for each number, including spaces.

Item 3h. Email Address. Provide the email address for the Program Director. Do not exceed 40 characters. **Note that all notices regarding the application will be sent to this e-mail address. Therefore, please verify that you have entered it correctly.**

Item 4. Human Subjects. If activities involving human subjects are not planned at any time during the proposed project period, check "No." The remaining parts of Item 4 are then not applicable. If activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, check "Yes."

In all cases in which activities involving human subjects are planned, the applicants must abide by the federal and State of Michigan rules and regulations governing studies of human subjects at the participating organizations. If the applicant organization has an approved Multiple Project Assurance of Compliance on file with the National Institutes of Health Office for Human Research Protections (OHRP), enter the Assurance number in Item 4b. Enter the latest date of approval of the Institutional Review Board (IRB) in Item 4a. If the IRB review is delayed

beyond the submission of the MLSC Fund proposal, enter "Pending" in Item 4a. In this case, the applicant must submit verification of IRB approval to the MLSC Fund [within 60 days of submitting the proposal]. Any modifications in the Program Plan section of the proposal required by the IRB must be submitted with this follow-up verification.

Item 5. Vertebrate Animals. If activities involving vertebrate animals are not planned at any time during the proposed project period, check "No." The remaining parts of Item 5 are then not applicable.

If activities involving vertebrate animals are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating organization, check "Yes." If the applicant organization has an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), enter the Assurance number in Item 5b. In addition, provide the date of approval by the Institutional Animal Care and Use Committee (IACUC). If the IACUC review is delayed beyond the submission of the proposal, enter "Pending" in Item 5a. A follow-up verification of IACUC approval from an official signing for the applicant organization must then be sent to the MLSC Fund [within 60 days after submission of the proposal]. Any modifications of the Program Plan section of the proposal required by the IACUC must be submitted with this follow-up verification.

If the applicant organization does not have an approved Animal Welfare Assurance on file with OLAW, insert "None" in Item 5b. In this case, the applicant organization, by the signature on the face page, is declaring that it will comply with U.S. Public Health Service policy regarding the care and use of animals.

Item 6a. Dates of First Budget Year. Enter the proposed beginning date and end date of the period for which support is being requested. Enter the month, day, and year with two digits each (MM/DD/YY format).

Item 6b. Direct Costs (first year). Enter the direct costs from column 1, Item 11 on the Composite Budget for Program for Entire Proposed Period of Support Form (Form MLSC-07).

Item 6c. Indirect Costs (first year). Enter the total of all indirect costs for the first year of the project column 1, Item 12 on the Composite Budget for Program for Entire Proposed Period of Support Form (Form MLSC-07). See **Section 3.3.8** for the MLSC Fund policy on indirect cost rates.

Item 7a. Dates of Second Budget Year. If a second year of support is requested, enter the proposed beginning date and end date of that period. Enter the month, day, and year with two digits each (MM/DD/YY format). If only one year of support is being requested, indicate N/A.

Item 7b. Direct Costs (second year). Enter the direct costs from column 2, Item 11 on the Composite Budget for Program for Entire Proposed Period of Support Form (Form MLSC-07).

Item 7c. Indirect Costs (second year). Enter the total of all indirect costs for the second year of the project from column 2, Item 12 on the Composite Budget for Program for Entire Proposed

Period of Support Form (Form MLSC-07). See **Section 3.3.8** for the MLSC Fund policy on indirect cost rates.

Item 8a. Dates of Third Budget Year. If a third year of support is requested, enter the proposed beginning date and end date of that period. Enter the month, day, and year with two digits each (MM/DD/YY format). If only two years of support is being requested, indicate N/A.

Item 8b. Direct Costs (third year). Enter the direct costs from column 3, Item 11 on the Composite Budget for Program for Entire Proposed Period of Support Form (Form MLSC-07).

Item 8c. Indirect Costs third year). Enter the total of all indirect costs for the third year of the project column 3, Item 12 on the Composite Budget for Program for Entire Proposed Period of Support Form (Form MLSC-07). See **Section 3.3.8** for the MLSC Fund policy on indirect cost rates.

Item 9. Total Costs (full period). Enter the total costs (direct and indirect) for all years of the project. This should equal the sum of Items 6b, 6c, 7b, 7c, 8b and 8c, which is also equal to Item 16 on MLSC-07.

Item 10. Applicant Organization. Name the one organization that will be legally and financially responsible for the conduct of activities supported by the award. (Use the organizational name consistent with that of the EIN or DUNS number.) Include a complete address. Enter up to six lines, with no more than 32 characters per line.

Item 11. Type of Organization. Check the appropriate organization type. See **Section 3.3.1** for definition of a Michigan-based for-profit firm. **This item must be the same as the corresponding pre-proposal.**

Item 12. Entity Identification Number, DUNS Number. Enter the number assigned to the applicant organization by the Michigan Department of Development or Board of Regents for payment and accounting purposes. If a number has not yet been assigned, enter the organization's Internal Revenue Service employer identification number (nine digit EIN). If a Dun & Bradstreet (DUNS) number is available, it should also be entered. (The DUNS number is a nine-digit identification code assigned by Dun & Bradstreet.) Do not exceed 20 characters per number entered.

Item 13. Administrative Official to be Notified If Award Is Made. Name the applicant organization administrative official to be notified if an award is made. Provide a complete address for postal and/or express delivery, a voice telephone number, a fax number, and an electronic mail address, if available. Enter up to 10 lines, with no more than 32 characters per line.

Item 14. Official Signing for Applicant Organization. Name an individual authorized to act for the applicant organization and to assume the obligations imposed by relevant laws, requirements, and conditions for a grant or grant application. Provide a complete address for postal and/or

express delivery, a voice telephone number, a fax number, and an electronic mail address, if available. Enter up to 10 lines, with no more than 32 characters per line.

Item 15. Program Director Assurance. An original signature, in ink, is required from the person named in Item 3a. “Per” signatures are not acceptable. Date of signature must be included.

Item 16. Applicant Organization Certification and Acceptance. An original signature, in ink, is required, from the person named in Item 13. “Per” signatures are not acceptable. Date of signature must be included. In signing the proposal face page, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the proposal. The applicant organization is responsible for verifying the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the proposal, including the indirect cost rates used to calculate Items 7b and 8b. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of a proposal, suspension and/or termination of an award; or debarment of individuals, or possible legal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the award-supported project or activities resulting from this proposal. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

5.2. Abstract, Performance Sites and Key Personnel

Include the completed Proposal Form Page 2 (Form MLSC-03, page 2) as the second page in all proposals.

Item 17. Abstract. State the program’s broad, long-term objectives, including the life science theme, health-related goals, and, for Category I if applicable, the relationship to aging diseases research. Indicate how the program will build Michigan’s research capacity and/or economic development. Indicate the strengths and resources the program will build upon and enhance. The abstract is meant to serve as a succinct and accurate description of the proposed project, and if the application is funded, it will become public information. Therefore, **do not include any proprietary/confidential information in the abstract. Do not exceed** the space provided. Follow the character size restrictions stated in section 3.3.12. Use a font size that is legible.

Although the text can be modified, the overall content of this item and the program must be the same as that of the corresponding pre-proposal.

Item 18. Performance Site(s). Indicate where the work described in the Program Plan will be conducted. List all the collaborating sites, including all sites inside Michigan and any sites outside Michigan. Indicate in parentheses next to the name of the organization the type of organization, using “MU” for Michigan University, “MN” for Michigan-based Non-profit organization, and “MFP” for Michigan-base For-Profit organization. Use an asterisk (*) to indicate any non-Michigan entities.

Item 19. Key Personnel. List the Program Director, followed by any co-investigators, and other key personnel. Key personnel are defined as, and should be limited to, individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be listed as key personnel only when their level of involvement meets this definition. Individuals providing key technical services should be included. Individuals providing routine technical services are not considered key personnel. For each individual, provide name, organization, and role on the project. Under role on the project, indicate how the individual will function with regard to the proposed project, for example, co-investigator, graduate research assistant, etc. If the space provided on Page 2 is insufficient, enter all of the information for this item as a section of a Continuation Page, under the heading “Key Personnel” and enter “see Continuation Page” in the last Name space in Item 18.

5.3. Table of Contents

Page 3 of every proposal must be a Table of Contents. Provide the page number for each section of the proposal, according to the order of sections listed in on the Checklist, Form MLSC-01 of this RFP. Also use the checklist to ensure that all the required pages and sections are included and that they are in the correct order.

In the Table of Contents, include the Face Page (Form MLSC-03, page1) as page 1, the Abstract, Performance Sites, and Key Personnel page (Form MLSC-03, page 2) as page 2, and the Table of Contents page as page 3. Number subsequent pages consecutively throughout the proposal. Do not include unnumbered pages and do not use suffixes, such as 5a, 5b.

5.4. Biographical Sketches

Include Biographical Sketches for the Program Director, the co-investigators, and research scientists. Biographical Sketches of technical staff who provide unique services or specialized expertise should also be included. Do not include biographical sketches for technical staff that provide routine services. Biographical Sketches should be provided for all, and not only Key Personnel listed under item 19 on Proposal page 2.

Use photocopies or downloaded files of the Biographical Sketch form provided with this RFP (Form MLSC-04) to submit a biographical sketch for each person listed as key personnel. Each biographical sketch must be no more than two pages. When a second (continuation) page is used, enter the individual’s name followed by “Continued” at the top of the page. In the submitted proposal, order the biographical sketches in the same order as the listing of Key Personnel (on MLSC-03 Page 2 or on its Continuation Page). Emphasis should be on recent publications and activities relevant to this program. Biographical Sketches should be up to date. Reviewers may interpret a lack of recent publications may be assumed by reviewers to represent a lack of recent productivity.

Use a portion of the second page of the Biographical Sketch to briefly summarize the participant's research and commercialization experience that is relevant to his or her role in the proposed program. (Approximately 150-250 words or 10-12 lines).

Also use the Biographical Sketch to indicate patents and licenses attained in the past five years by program participants.

5.5. Letters of Commitment /Consultation

If key resources/reagents are to be provided by persons not participating in the program, letters indicating the specific availability of these resources must be included in the proposal.

Letters from key consultants indicating their availability and detailing their specific involvement must also be included. Consultantship will not be considered as collaboration in the evaluation of the program.

5.6. Intellectual Property Distribution Plan

Every proposal must include an Intellectual Property Disposition Plan, in accordance with **Section 3.3.9.**

5.7. Detailed Budget for the First Year

Three forms, MLSC-05, -06 and -07, are required to present the budget for the program. **Each** applicant organization and collaborating organization should prepare form MLSC-05 to show the itemized costs for that organization for the first year. Indicate the name of the organization on the space provided on the top line of the form. **The Applicant Organization and each** collaborating organization should also prepare form MLSC-06 to provide a summary of the costs for that organization for all years of the program. Indicate the name of the organization in the space provided at the top of the form.

A single copy of Form MLSC-07 should be used to present **a composite budget**, including the applicant organization and any collaborating organizations, for the entire program and entire project period. The amounts shown in MLSC-07 must be the sums of the respective amounts of the organizational forms.

All amounts must be in U.S. dollars.

Follow the instructions below to provide explanatory details using the Continuation Page Format for pages with the heading "Justification for Detailed Budget for First Year." Use a separate page headed "Justification for Detailed Budget for First Year" for each collaborating organization. For proposals with collaborating organizations, include the organization name in the heading.

For special or large requests, separate Forms MLSC-05 and MLSC-06 may be useful. For example, for a large piece of infrastructure equipment that will require specialized personnel, supplies, and renovation costs; a separate MLSC-05 form listing all of the associated costs may facilitate review and administration. Likewise, if a Career Development Plan or CTA Application Grants Fund (See examples in Section 3.4.) is proposed that will involve costs in

multiple budget categories, separate Forms MLSC-05 may be used and appropriately documented with separate “Justification for Detailed Budget for First Year” pages. Simple requests, e.g., for a Career Development Plan involving only salary, can be listed on the Form MLSC-05 for the appropriate organization.

Item 1. Personnel Enter the following information for Item 1 in the Detailed Budget for First Year form (MLSC-05) in the spaces provided, starting with the Program Director or co-Principal Investigator. Include a separate entry for all individuals listed as Key Personnel (see **Section 5.2**). For other project personnel, job categories may be listed rather than individual names. Include the names or a job category for all organizational employees who will work on the project during the first year, regardless of whether a salary is requested. Include all collaborating investigators, individuals in training, and support staff.

If the project has more than eight individuals or job categories, list the first seven in the space provided on Form MLSC-04 and enter the additional individuals on a second copy of Form MLSC-05. In the eighth line of the first Form MLSC-05, enter “Additional Personnel” in the Name space and the subtotals for Items 2a, 2b, and 2c from the additional copies of Form MLSC-05.

1a. Name. Starting with the Program Director, list the employees’ names or (for non-key personnel) job categories.

1b. Role on Project. Identify the role of the individual or job category listed in the Name column; describe their specific functions.

1c. Percent of Effort on Project. For each individual or job category, list the percentage of each appointment (or total FTEs, for a job category) to be spent on this project.

Item 2. Dollar Amount Requested. Use the following instructions to complete Item 2 in the Detailed Budget for First Year form and provide supporting detail in the “Justification for Detailed Budget for First Year.” For projects with more than eight individuals and job categories to be listed, see the instructions under Item 1, above, on use of additional copies of Form MLSC-05.

2a. Salary Requested. Enter the dollar amounts for each individual or job category for which funds are requested. The salary requested is calculated by multiplying the individual’s base salary by the percent of effort on this project. If a lesser amount is requested, e.g., endowed position or institutional sources will provide part of the salary, explain in the “Justification for Detailed Budget for First Year.”

2b. Fringe Benefits. Fringe benefits may be requested, in accordance with organizational guidelines for each position.

2c. Total. Enter the sum of Items 2a and 2b for the individual or job category in the space for Item 2c.

Item 3. Subtotals. Add entries for Items 2a, 2b, and 2c by column and enter the respective subtotal in the spaces provided beneath each column.

Item 4. Consultant Costs. Whether or not costs are involved, list in the space provided the names and organizational affiliations of all consultants. Consultants should be listed on the budget page of the organization for which their activity is most appropriate. If they will be involved with the program as a whole, they should be listed on the page of the applicant organization. Include consultant physicians in connection with patient care and persons who serve on external monitoring boards or advisory committees to the project. Describe the services to be performed and include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs in the “Justification for Detailed Budget for First Year.” Include consultant travel in Item 4, as a “consultant cost,” not in Item 7, which is travel for program personnel listed in item 1.

Item 5. Equipment. In the “Justification for Detailed Budget for First Year”, list each item of equipment separately and justify each purchase in terms of its role in the project. Enter the total for all equipment in the space provided on Form MLSC-05. Equipment should be listed on the budget page for the organization where it will be located. For infrastructure requests, the contribution to the program of major pieces of capital equipment should be discussed in the Program Plan as well.

Item 6. Supplies. In the “Justification for Detailed Budget for First Year” itemize supplies in separate broad categories, such as glassware, chemicals, radioisotopes, etc. Categories with amounts less than \$5,000 need not be itemized. If animals are to be purchased, state the species and the number to be used. Enter the total for all supplies in the space provided on Form MLSC-05. Supplies should be listed on the budget page for the organization where they will be used.

Item 7. Travel. Itemize travel trips in the “Justification for Detailed Budget for First Year.” Include the purpose and destination of each trip and the number of individuals for whom funds are requested. If named individuals are supported by multiple other funding sources, justify the use of MLSC funds for this travel.

Item 8. Patient Care Costs. If inpatient or outpatient costs are requested, provide the names of any hospitals or clinics in the “Justification for Detailed Budget for First Year” and the amounts requested for each. Specify the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment. If both inpatient and outpatient costs are requested, provide information for each under separate subheadings in the “Justification for Detailed Budget for First Year.”

- If multiple sites are to be used, provide detailed information by site.
- Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly.
- Provide specific information regarding anticipated sources of other support for patient care costs, e.g., third party recovery or pharmaceutical companies.

Include any potential or expected utilization of General Clinical Research Centers. Enter the totals for inpatient and outpatient costs from the “Justification for Detailed Budget for First Year” in the spaces provided on Form MLSC-05 (Items 8a and 8b, respectively).

Item 9. Alterations and Renovations Itemize by category and explain in the “Justification for Detailed Budget for First Year” the costs of essential alterations and renovations. Include repairs, painting, removal or installation of partitions, shielding, and air conditioning. Where applicable, provide the square footage and costs. Alterations and renovations should be listed on the budget page for the organization where they will be made. If these costs are part of the infrastructure development, enter the total cost for alterations and renovations in Item 9 on Form MLSC-05. Their contribution to the program should also be addressed in the Program Plan.

Item 10. Other Expenses Itemize in the “Justification for Detailed Budget for First Year” any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of care days), patient travel, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, and service contracts. This category may be used for the line item for costs associated with patenting or other expenditures related to intellectual property. Enter the total for Other Expenses from the “Justification for Detailed Budget for First Year” in the space provided on Form MLSC-05.

Item 11. Total of Direct Costs for First Year Enter the sum of Items 3 through 10 in the space provided on Form MLSC-05.

Item 12. Indirect Costs for the First Year. Enter the amount requested and indicate on Budget Justification page the base for the calculation (i.e. against total direct costs or subcategories of specific costs). **See Section 3.3.8** for the allowable costs.

Item 13. Total Costs for First Year. Enter the sum of Items 11 and 12.

5.8. Budgets for Entire Proposed Period of Support

The applicant organization and each participating organization should use a separate Organizational Summary Budget for Entire Proposed Period of Support Form (Form MLSC-06). Use the first column to enter the first-year totals for each budget category (Items 3 through 13) from Form MLSC-05. If additional years are requested, use the second and third columns to enter the corresponding totals, by category. Identify with a double asterisk (**), and explain on the page entitled “Justification for Detailed Budget for First Year” (under the heading “Budget for Entire Proposed Period of Support”) any significant increases or decreases in the second or third year from the first-year budget. A significant increase is defined as anything more than a standard escalation, e.g., salaries or inflation, from the initial to the future year(s) of support.

Item 14. Organization’s Total Costs for Entire Proposed Period of Support. Enter the sum of the annual totals from Item 13.

5.9. Composite Budget for the Program

In addition to MLSC-06 forms for each collaborating organization, use Form MLSC-07 to present a composite budget for the entire program. This should represent the totals for the individual items in all the organizational MLSC-06 forms. Items 14, 15, 16 should be calculated as indicated below.

Item 14. Program's Total of Direct Costs for Entire Proposed Project Period. Enter the sum of the annual totals from Item 11.

Item 15. Program's Total of Indirect Costs for Entire Proposed Project Period. Enter the sum of the annual totals from Item 12.

Item 16. Program's Total Costs for Entire Proposed Project Period. Enter the sum of the annual totals from Item 13.

5.10. Other Support

Information on active and pending other sources of support relevant to this proposal is required for each individual listed as key personnel (see instructions in **Section 5.2** for Form MLSC-03, page 2), excluding consultants. Provide the information itemized below using the Continuation Page Format and providing the heading "Other Support" for each page. Other support is defined as all financial resources relevant to activities in this proposal, whether federal, non-federal, commercial or institutional, available in direct support of an individual's research endeavors, such as research grants, cooperative agreements, contracts, or institutional awards. Training awards, prizes, or gifts are not included.

For each individual, include a subheading under the heading "Other Support." Follow the item-by-item instructions below for the information to be included for each project that supplies (or will supply, if award is pending) support to the individual. You may use the format specified by the National Institutes of Health for this information or any other reasonable way of organizing the information items for easy review.

- For key personnel with no active or pending other support, enter "None" on the line below the subheading for the person's name.
- List all active projects under which the individual is supported first, then list any pending projects for the individual.
- If the project support is provided under a subproject of a consortium as a subcontract arrangement, or as part of a multi-project award, use the project number, principal investigator, and source for the overall project, but provide all other information for the subproject only.

Project Number. If applicable, include a code or identifier for the project used by the organization for which the individual performs the work.

Source. Identify the agency, institute, foundation, or other organization that is providing (or will supply, if support is pending) the support.

Title of Project. Include the title of the project.

Major Goals. Provide a brief statement of the overall objectives of the project, subproject, or subcontract.

Dates of Approved or Proposed Project. Indicate the inclusive dates of the project as approved or proposed. For example, in the case of support from the National Institutes of Health, provide the dates of the approved or proposed competitive segment.

Annual Direct Cost. In the case of an active project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial year.

Percent Effort. For an active project, provide the supported individual's level of effort (even if unsalaried) as approved for the current budget period. For a pending project, indicate the level of effort as proposed for the initial budget period. In cases where an individual's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

Overlap. After listing all the active and pending projects for an individual, with the information specified above, summarize for each individual any potential overlap between the active or pending projects and this proposal in terms of the science, budget, or an individual's committed effort. Any necessary resolution of overlap due to this proposal being funded will occur through consultation between MLSC staff and the staff of the applicant organization at the time of award.

5.11. Resources/Facilities

Using the Continuation Page Format, for each collaborating organization provide a separate page with the heading "Resources/Facilities" to provide details on each of the following types of resources that will be used in the proposed program.

Facilities. Specify the facilities to be used for the proposed program. Indicate the performance sites and describe pertinent capabilities, relative proximity, and extent of availability to the project. Organize the facilities under the following subheadings, as applicable: Laboratories, Clinical Facilities, Animal Facilities, Computer Facilities, Office Facilities, and Other. In the "Other" category, identify support services such as machine shops or electronic shops, and specify the extent to which they will be available to the project.

Major Equipment. List the most important equipment items already available for this project. Include the location and pertinent capabilities of each item.

5.12. Program Plan

The program plan for each category of application is structured to address the MLSC Mission (Section 2.1) and legislative guidelines for that category. The content of the program plan and the evaluation criteria for the individual categories are detailed in Sections 6, 7, and 8. The required information should be provided using the Continuation Page format (Section 3.3.12) with adherence to the character size, type density, and margins of that format. **Boldface** headings should be used to indicate each section.

A maximum of 20 Continuation Pages can be submitted for the program plan.

Proposals not following the format and page limitations will not be reviewed.

Separate appendix material such as reprints, organization brochures, etc. will not be accepted in support of the application.

Decisions by the Steering Committee on invitations for full proposals and awards will be binding and not subject to appeal. Unsuccessful applicants are encouraged to reapply in the next MLSC round. All full proposal submissions will receive feedback as noted in Section 3.3.15.

6. CATEGORY I PROGRAM INSTRUCTIONS

6.1. Category I Program Goals

Category I is focused on platform investments in research tools and programs that have the scale, scope, and quality to move Michigan toward a position of national leadership. Proposals should build the research capacity and activity of the State in a way that increases the ability of the State to attract or develop companies, researchers, or students to Michigan or attract them to the state.

Grants that contribute to this goal are likely to have one or more of the following objectives:

- Enable a broad range of research (e.g. multi-user facilities, infrastructure, tools);
- Develop and refine a path-breaking approach at a scale sufficient to make a material difference to Michigan's research enterprise;
- Create a critical mass--often multi-institutional--of research excellence in a field of large potential commercial importance (e.g., diabetes, cancer, medical devices for cardiac intervention)

Such investment objectives—in facilities and equipment, collaborative centers, or broad-based coordinated basic research programs—are rarely systematically or fully supported by federal research agencies. The major infrastructure proposal funded during MLSC 2000 (the CTA) is an example of a platform investment.⁶ The five areas – genomics, proteomics, bioinformatics, animal models, and structural biology – are cornerstone investments of importance to life sciences researchers in many Michigan companies and universities.

Other platform investments that are arguably directly relevant to the future of Michigan's life science industries would be grants of significant scale and scope aimed at nanotechnology, imaging, and medicinal chemistry. For some of these areas of science and technology, for

⁶ Proposals that indicate the use of non-CTA entities to provide the types of services and resources available and operational at the CTA, but not available at any of the applicant organizations, may be required by the MEDC to use the CTA as the provider of those services.

example, in nanotechnology or imaging, capacity building in Michigan may require the purchase of facilities or equipment. In others the development of core capacity in the State may not depend on large new facilities and equipment investments, but may be furthered by funding a substantial, multi-institutional research center and program.

6.2. Category I Program Characteristics

Category I proposals for the MLSC 2001 program should be based on the following principles. Applicants are referred to Section 3.4 for examples of possible program designs.

- **Scale, scope, collaboration, and quality are critical:** Each grant award from Category I should support a program of sufficient scale, scope, and quality to move Michigan toward a position of national leadership in some aspect of biomedical research. While a single investigator or single institution may propose a substantial program, preference will be given to multi-institution, multi-disciplinary collaborative research centers and projects.
- **Contribution to Michigan research capacity or performance:** The applicant needs to demonstrate that the grant would build or extend an important research capability in the State. This can be done either by building on the Core Technology Alliance (CTA) with new tools, by building an independent new research infrastructure, or by a substantial, coordinated broad-based research program. This can also be accomplished through a research program that, while aimed at a specific research question, will arguably develop important, fundamental tools and techniques that will help develop Michigan's research enterprise. The burden is on the applicant to demonstrate that the grant would contribute to the creation of a significant research "asset" in Michigan (e.g., a critical mass of research work in an important area).
- **MLSC Funding should be used as a leverage for other funding:** The use of Category I funds to match or leverage other funding is encouraged. The burden is on the applicant to demonstrate how the requested MLSC funds will build on the current resources/funding in ways not possible with that current funding or that MLSC funds will be used to create new collaborative efforts, research infrastructure, or scientific enterprises that will serve as a base for attracting additional or future federal, private, or commercialization funds to Michigan.
- **Portfolio focus on diseases associated with aging.** The legislative language that established the MLSC Fund earmarked \$5 million per year for diseases and health problems associated with aging. Thus MLSC-2001 actively seeks proposals explicitly creates a preference at the award stage for those proposals - of appropriate scale and scope - that build Michigan's research capability and performance in diseases such as diabetes, cancer, and Alzheimer's disease. See Section 3.3.17 for the definition of diseases associated with aging.

6.3. Category I Pre-Proposal Statement

In developing the Pre-Proposal Statement, applicants should consider the MLSC Goals and Objectives (Section 2.2), the MLSC 2001 Program Principles (Section 3.2) and the Category I Goals and Program Characteristics (Sections 6.1 and 6.2). The Pre-Proposal Statement must be presented in no more than four (4) pages using the Continuation Page Format and **boldface headings** to indicate sections A-C.

A. Goals, Scale, and Scope/Platform of the Proposed Program

Indicate the program goals, scope, structure and scale. Indicate whether any special features are planned (See Section 6.5, Item G)

Indicate the rationale for the choice of this goal and structure and its potential to increase Michigan's research capacity.

B. Participating Investigators and Organizational Resources

Indicate the participating co-investigators, their scientific and administrative roles in the program, and how their participation will result in achieving the program goals.

Indicate the resources, physical, scientific, and technological available in the collaborating institutions and organizations.

C. Collaborative Plans and Leveraging Potential

Indicate how the proposed collaboration will allow for the achievement of more rapid and higher quality progress toward the program goals.

Indicate the aspects/characteristics of this program that leverage current funding or give it the potential to leverage future funding.

6.4. Category I Pre-proposal Review Criteria (*Project Eligibility and Program Contribution*)

Eligibility Criteria

- Scale and Scope Of Project/Platform Investment
- Program Characteristics Indicative of Leveraging Potential

Ranking Criteria

- Scientific Credibility and Availability of Key Facilities and Resources
- Qualifications of Principal Investigator and Collaborators for Proposed Project

(Any proposals not meeting minimum standards on the above two criteria will not be considered further in the evaluation process)

- Potential Contribution to Michigan Research Capacity or Performance and/or Leverage of MLSC Funds
- Potential for Inter-institutional Collaboration

6.5. Category I Program Plan Instructions

In developing the proposal statement, applicants should consider the MLSC Mission (Section 2.1), the MLSC 2001 Program Principles (Section 3.2), and the Category I Goals and Program Characteristics (Sections 6.1 and 6.2). The proposal statement must be presented in no more than twenty (20) pages using the Continuation Page Format and boldface to indicate items A-G.

A. Problem Area Goals, Scale, and Scope of the Proposed Program/Platform

Describe the problem area to be addressed, the current state of knowledge in that area, contributions to that state of knowledge by program participants, and the novelty and cogency of proposed methodologies, models, and hypotheses to be utilized or explored in the proposed program. Describe the program goals, structure, and scale and their potential to enhance Michigan's research capacity.

Describe the rationale for the choice of this theme, its relevance to life sciences, human health, or aging.

B. Participating Investigators and Institutional/Organizational Resources

Describe the rationale for the choice of participating investigators (Program Director, co-investigators, research scientists); their scientific, technological, and administrative roles in the program; how their expertise makes them appropriate for their roles; and how their participation will result in achieving the program goals.

Describe the resources, physical, scientific, and technological, available at the collaborating institutions and organizations and how their availability will result in achieving the program goals.

C. Collaborative Plans and Program Synergy

Describe the plans for collaboration and interaction among the program participants and how this will be implemented on a daily basis, as well as over the course of the program.

Describe how the collaborative plan will foster more rapid and higher quality progress toward the program goals.

Describe how the collaborative plan will enhance Michigan's life science research capacity.

D. Organizational Structure

Describe the organizational and administrative structure of the program. Indicate the specific individuals responsible for various activities and their organizational relationship to one another and to the Program Director.

Describe the communication and interaction structure of the program (e.g., website, e-mail, seminars, weekly meetings, retreats, and annual meetings).

Describe any proposed program oversight. If advisory groups are proposed, indicate the criteria for the selection of advisors.)

Describe the plans to address and facilitate Intellectual Property issues. Do not duplicate the material presented in IPDP (See **Section 3.3.9**), but rather indicate how the IPDP plan will facilitate and expedite the development and commercialization of discoveries from this program.

E. Leveraging and Matching of Michigan Funding Resources

Indicate how this program differs from similar state, regional, national, or international programs using similar methodological approaches or studying similar research issues.

Describe how the proposed program builds on the current funding of program participants from Michigan, federal (such as NSF, NIH), or private funding sources. Do not duplicate the information presented in **Section 5.10**, Other Support, but rather discuss the relationship of the requested MLSC funding to current funding.

Describe how the proposed program will provide leverage for future funding of program participants from state, federal, or private funding sources.

Describe what funds and other resources are applied to meet program matching requirements.

Describe how the work of this project is anticipated to continue beyond the requested MLSC Fund support.

F. Institutional/Organizational Commitments

For each entity participating in the program, describe the specific new resources that will be committed to this program and how these resources will facilitate achieving the goals of the program.

G. Program Special Features

Programs are **not** required to have special features such as career development programs, technology enhancement plans or infrastructure/capital equipment plans. **If such plans are proposed**, they must be described in sufficient detail to allow for the evaluation of their feasibility and potential to attain the overall program goals. Thus, the goals, structure, policies, operations, administration of the special feature should be presented, and if necessary, a separate budget page and budget justification used. (See Section 5.7.)

Several examples of Special Features are presented below, **solely as examples, not as requirements or indications of award preference.**

1. Infrastructure/Capital Equipment Plan

Describe any infrastructure elements/capital equipment to be created, renovated, or expanded with the requested MLSC funding. Describe any other resources currently available or being sought for this same purpose. The location of the requested infrastructure/equipment should be described and the advantages of that site indicated.

Describe how the requested resources are key to the collaborative effort in enabling both high priority research and research collaboration. Describe how they will constitute a major improvement in capacities within Michigan.

Describe the access requirements, particularly with respect to access by other organizations (Michigan universities, private or public nonprofit research organizations) and for-profit firms. If user fees or other charges will be used to support the operation or regulate access, detail the anticipated fees and explain the basis for them.

Discuss the cost of all purchases and leases, as well as ongoing (annual) operating and maintenance costs. If annual costs are expected to vary significantly over time, explain the variation.

Provide a schedule for purchase, installation, trial period, and ramp-up to full operation, as appropriate.

Explain how the infrastructure will be maintained and operated after the conclusion of the MLSC project period.

2. Career Development Plan

If a career development plan is proposed, describe a clear policy and plan for the recruitment of career development candidates. Indicate the number and kinds (postdoctoral, early career faculty, transitional investigators, etc.) of positions that would be available during the project period and the criteria for eligibility and selection. Describe selection process. Describe the kind of resources that would be made available

to successful candidates as part of the program (salary, technician, supplies, reduction of administrative duties, etc.).

3. Technology Transfer Plan

Describe the current technology transfer resources available at the collaborating institutions.

4. Other Special Features

Applicants can design special features for their programs that will enhance research progress, increase the Michigan research base, or in other ways address MLSC goals. The proposal should clearly delineate the goals, structures, policies, operations and administration of these special features in sufficient detail to allow the evaluation of them in the context of the proposal.

6.6. Category I Full Proposal Review Criteria (Rating and Ranking)

- Scientific and Technical Quality of Proposed Research
- Expertise of Investigators/Collaborators in Relation to Proposed Research
- Quality of Collaboration(s) and Administrative Structure and Organizational Commitments
- Sufficiency of Plans to Leverage Current Funding or Enhance Future Funding Potential
- Potential to Expand or Develop Michigan Research Capacity or Performance
- Availability of Facilities/Resources Needed for Proposed Research

6.7. Category I Full Proposal Award Criteria (Award Decisions)

- Review Rating and Ranking
- Program Portfolio Balance (minimum of \$5million will be dedicated to projects involving research related to aging diseases and health problems)
- Funds Available in Category
- Compliance with Matching Requirements

7. CATEGORY II PROGRAM INSTRUCTIONS

7.1. Category II Program Goals

Category II supports projects of high-quality research aimed at biomedical or bioengineering commercial applications or enhancing Michigan life science applied research capacity through infrastructure or capability development. The quality of collaboration and market/economic potential are among the main evaluation criteria for selection among applicants.

Category II awards will support substantive, application-focused research collaborations among Michigan institutions (non-profit and private) as a way to develop more robust long-term

economic development returns from life sciences research. Non-Michigan organizations may be involved as collaborators as described in Section 3.3.4, but they cannot be the applicant organization.

7.2. Category II Program Characteristics

Category II proposals for the MLSC 2001 program should be based on the following principles. Applicants are referred to Section 3.4 for examples of possible program designs.

- **Proposal thematic focus required:** Category II funds are intended to support proof-of-concept studies, early clinical investigations of an emerging discovery, and early clinical use. Among high potential, research- or engineering-based applications areas are drug discovery and development, diagnostics, therapeutics, devices, processes and synthesis, and instrumentation. Relevant areas include, but are not limited to:
 - Rational Drug Design or Drug Discovery Services or Technologies
 - Bioinformatics Services or Technologies
 - Medical Diagnostics
 - Drug-Delivery Systems
 - Analytical Disposables (e.g. biochips and devices for research and applications)
 - Analytical Equipment (research and applications)
 - Specialty Chemicals, Biochemicals, or Biomaterials
 - Chemical or Biochemical Synthesis Services
 - Clinical Products/Kits (used by health care professionals)
 - Consumer Products and Services Utilizing Life Science Applications
 - Clinical Decision Support Systems
 - Computer-Enabled Surgery/Procedure Equipment
 - External Medical Devices
 - Bioscience Manufacturing Technology and Services
 - Implantable Devices
 - Technology and Tools for Life Sciences Research
 - Implantable Micro Devices
 - Non-Invasive/Remote Sensing Devices
 - Bio-process Equipment and Services
 - Therapeutics including Gene and Cell Therapy
 - Therapeutic Target Discovery and Validation

Later stage clinical trials/studies will not be part of this program because of cost limitations and because corporate interest should have evolved to support discoveries close to commercialization or recognized to have significant commercialization potential. The burden is on the applicant to establish that the proposed research has a high probability of contributing directly to a viable commercial application.

- **Preference for scale, scope, and leverage:** Each award from Category II will support an activity of sufficient scale, scope and commercial potential to help move Michigan toward a position of national leadership in some aspect of biomedical applications or life science industry. Further, each MLSC investment should “leverage” considerable investment from other sources—company funds or resources, foundation funds, etc.⁷ While no fixed match or leverage ratio is required, it is anticipated that, other factors being equal, preference will be given at the award stage to proposals that maximize matching contributions to leverage MLSC funds.
- **Preference for high market potential and contribution to Michigan economy:** Preference will be given to proposals that show that the research work can directly contribute to applications with significant market potential. Further, preference will be given to proposals that show how the proposed work can contribute directly, if not immediately, to the development of high-wage, high-skill employment opportunities in the State of Michigan.
- **High standards for collaboration:** The applicant must establish that the proposal involves substantive collaboration between two or more institutions or organizations. Preference is given to collaborative endeavors that involve academic and commercial partners. The intent of the collaborative requirement is to have substantive collaboration, not consultation. Thus, collaboration should be demonstrated as an activity leading to co-authorship of published papers or co-development of intellectual property or products. Such activities are accomplished primarily by commitment of significant time to laboratory research or by clear demonstration of intellectual contribution by the collaborator to the content and development of the written proposal. Section 3.3.4 lists examples of such types of collaboration.
- **Organizational contribution:** Each of the participating organizations must provide a specific contribution to the program. These can be provided in varying forms and could include matching funds, instrumentation support, salary support, or in-kind services. While these contributions will be used in the evaluation of proposals, cognizance will be made of the nature and amounts of resources available for these purposes at different institutions and organizations. Contributions should not reiterate currently provided institutional resources, such as currently used space or equipment, but must represent a specific new commitment to this program; reassigning currently used space or equipment for new purposes is permitted. To the extent that non-Michigan partners are proposed, the scientific and commercial advantage to Michigan must be clearly delineated and justified in the proposal.
- **MLSC Funding should be used as leverage for other available funding:** The use of Category II funds to match or leverage other funding is encouraged. The MLSC preference is that Category II funds should not replace or duplicate funding available

⁷ Proposals that indicate the use of non-CTA entities to provide the types of services and resources available and operational at the CTA, but not available at any of the applicant organizations, may be required by the MEDC to use the CTA as the provider of those services.

from federal agencies. The burden is on the applicant to demonstrate how the requested MLSC funds will build on the current resources/funding to advance project development in ways not possible with current funding or will be used to create new collaborative efforts, research infrastructure, or commercial or scientific enterprises that will serve as a base for attracting additional or future federal, private foundation, bank, finance company, or venture funds to Michigan.

7.3. Category II Pre-Proposal Statement

In developing the Pre-Proposal Statement, applicants should consider the MLSC Mission (Section 2.1), the MLSC 2001 Program Principles (Section 3.2), and the Category II Goals and Program Characteristics (Sections 7.1 and 7.2). The Pre-Proposal Statement must be presented in no more than four (4) pages using the Continuation Page Format and **boldface headings** to indicate Items A-D.

A. Research/Commercialization Goals, Scale/Scope of the Proposed Program

Indicate the program goals, research and commercialization concepts, structure, scope, and scale.

Indicate the rationale for the choice of this theme, its relevance to life sciences research, and its potential to lead to the development of commercializable products in Michigan.

B. Participating Investigators and Institutional/Organizational Resources

Indicate the participating investigators, their scientific, technical, commercialization, and administrative roles in the program, and how their participation will result in achieving the program goals.

Indicate the technical and commercialization records and/or experience of the program participants.

Indicate the resources, physical and scientific available in the collaborating institutions and organizations.

C. Collaborative Plans/Leveraging Potential

Indicate how the proposed collaboration will allow for the achievement of more rapid and higher quality progress toward the program goals.

Indicate the aspects/characteristics of this program that create leverage for other funding sources.

D. Market Potential/Path to Market/Use

Indicate how the proposed program will enhance the life sciences industry in Michigan. (If appropriate, indicate how the involvement of any non-Michigan entities or the development of part of the project outside of Michigan will **still** bring economic benefit to Michigan.)

Indicate the market or economic development potential for the proposed program area including market need addressed and the value proposition for the proposed approach.

Indicate the competitive advantage the proposed application (product or service) is expected to have over other applications, existing or anticipated, that address the same market need.

7.4. Category II Pre-proposal Review Criteria (*Project Eligibility and Program Contribution*)

Eligibility Criteria

- Application Demonstrates Focus
- Articulation of Path to Market/Use
- Adequate Strength and Workable Structure for Proposed Collaborations

Ranking Criteria

- Research Concept Quality/Feasibility of Commercial Contribution
- Qualifications of the Principal Investigator and Collaborators for Proposed Project
- Availability of Key Facilities Resources
(Any applications that do not meet minimum standard on the scientific and technical merit of the proposal as assessed by the above three criteria will be eliminated from further consideration)
- Quality of the Collaborative Structure and Leverage of MLSC funds
- Market Potential/Economic Development Potential
- Scale and Scope of Project (Material Impact on Michigan)

7.5. Category II Program Plan Instructions

In developing the proposal statement, applicants should consider the MLSC Mission (Section 2.2), the MLSC 2001 Program Principles (Section 3.2) and the Category II Goals and Program Characteristics (Sections 7.1 and 7.2). The proposal statement must be presented in no more than twenty (20) pages using the Continuation Page Format and boldface to indicate items A-H.

A. Research /Commercialization Theme and Program Scale and Scope

Describe the program goals, research and commercialization concepts, structure and scale.

Describe the rationale for the choice of this theme, its relevance to life sciences research and human health, and its potential to lead to the development of commercializable products and to economic development in Michigan.

B. Participating Investigators and Institutional/Organizational Resources

Describe the rationale for the choice of participating investigators (Program Director, co-investigators, research scientists); their commercialization, scientific, technological, and administrative roles in the program; how their expertise makes them appropriate for their roles; and how their participation will result in achieving the program goals.

Describe the resources, physical, scientific, technological and commercial available at the collaborating institutions and organizations and how their availability will result in achieving the program goals.

Summarize briefly the technical and commercialization records and/or experience of the program participants and organizations. Describe how additional entrepreneurial experience will be gained or developed.

C. Collaborative Plans and Program Synergy

Describe the plans for collaboration and interaction among the program participants and how this will be implemented on a daily basis as well as over the course of the program.

Describe how the collaborative plan will foster more rapid and higher quality progress toward the program goals, particularly toward product development.

D. Organizational Structure

Describe the organizational and administrative structure of the program. Describe the specific individuals responsible for various activities and their organizational relationship to one another and to the Program Director.

Describe the communication and interaction structure of the program.

Describe program oversight. If advisory groups are proposed, describe the criteria for the selection of advisors.

Describe the current technology transfer resources available at the collaborating organizations.

E. Market Development Potential/Commercialization Path

Describe the plans to develop and enhance the commercialization potential of the program.

Describe the market potential of the proposed program area. For example, market size (demand estimates), projected time to market and total costs of product development, production costs and sales price estimates (R&D cost recovery rate), comparison with competitive technologies and

products, and like sales and use profile (business model), e.g. licensing for single use vs. repetitive use.

Describe how the program will enhance the life sciences industry in Michigan. If applicable, describe how the involvement of any non-Michigan entities or the development of part of the project outside of Michigan will **still** bring economic benefits to Michigan.

Articulate the commercialization pathways and approaches. Indicate proposed time frames, funding sources and target deadline. Provide economic and developmental milestones.

Describe the competitive advantage the proposed application (product or service) is expected to have over other applications, existing or anticipated, that address the same market need.

Describe the plans to address and facilitate Intellectual Property issues. Do not duplicate the material presented in IPDP (See **Section 3.3.9**), but rather describe how the IPDP will facilitate and expedite the development and commercialization of discoveries from this program.

F. Organizational Contributions

For each entity participating in the program, describe the specific new resources that will be committed to this program and how these resources will facilitate achieving the goals of the program.

G. Leveraging and Matching of Michigan Funding Resources

Describe how the proposed program builds on the current funding of program participants from Michigan, federal (such as NSF, NIH) or private funding sources. Do not duplicate the information presented in **Section 5.10**, Other Support, but rather discuss the relationship of the requested funding to current funding.

Describe the plans to leverage funds from other sources for the current program.

Describe how the proposed program will provide leverage for future funding of program participants from the Michigan, federal, or private funding sources.

Describe what funds and other resources are applied to meet program matching requirements.

Describe how the work of this project is anticipated to continue beyond the requested MLSC Fund support.

H. Program Special Features

Programs are **not** required to have Special Features such as Career Development Programs, Technology Enhancement Plans, Infrastructure/Capital Equipment Plans, or Pilot/Seed Developmental Plan. **If such plans are proposed**, they must be described in sufficient detail to allow for the evaluation of their feasibility and potential to attain the overall program goals. Thus, the goals, structure, policies, operations, administration of the special feature should be presented, and if necessary, a separate budget page and budget justification used. (**See Section 5.7.**)

Several examples of Special Features are presented below, **solely as examples, not as requirements or indications of award preference.**

1. Infrastructure/Capital Equipment Plan

Describe any infrastructure elements/capital equipment to be created, renovated, or expanded with the requested MLSC funding. Describe any other resources currently available or being sought for this same purpose. The location of the requested infrastructure/equipment should be described and the advantages of that site indicated.

Describe how the requested resources are key to the collaborative effort in enabling both high priority research and research collaboration. Describe how they will constitute a major improvement in capacities within Michigan.

Describe the access requirements, particularly with respect to access by other organizations (Michigan universities, private or public nonprofit research organizations) and for-profit firms. If user fees or other charges will be used to support the operation or regulate access, detail the anticipated fees and explain the basis for them.

Discuss the cost of all purchases and leases, as well as ongoing (annual) operating and maintenance costs. If annual costs are expected to vary significantly over time, explain the variation.

Provide a schedule for purchase, installation, trial period, and ramp-up to full operation, as appropriate.

Explain how the infrastructure will be maintained and operated after the conclusion of the MLSC project period.

2. Career Development Plan

If a career development plan is proposed, describe a clear policy and plan for the recruitment of career development candidates. Indicate the number and kinds (postdoctoral, early career faculty, transitional investigators, etc.) of positions that would be available during the project period, the criteria for eligibility and selection and a description of the selection process. Describe the kind of resources that would be made

available to successful candidates as part of the program (salary, technician, supplies, reduction of administrative duties, etc.)

3. Technology Transfer Plan

Describe current technology transfer resources available at the collaborating organizations. Describe any enhancements needed to commercialize program's technology.

If personnel are to be recruited, describe the types of expertise that will be sought and the institution(s)/organization(s) that would employ these individuals. Describe how these services will be supported at the end of the MLSC project period.

If commercial services will be purchased, describe the types and nature of these services and the evaluation criteria that will be used in selecting the provider. If a specific provider has been identified, describe the organizational expertise and resources of the provider. Describe how these services will be supported at the end of the MLSC project period.

4. Other Special Features

Applicants can design special features for their programs that will enhance research progress, increase the Michigan research base, or in other ways address MLSC goals. The proposal should clearly delineate the goals, structures, policies, operations and administration of these special features in sufficient detail to allow the evaluation of them in the context of the proposal.

7.6. Category II Full Proposal Review Criteria (Rating and Ranking)

- Scientific and Technical Quality of the Proposed Research
- Feasibility of Proposed Work with Time/Funds Available
- Articulation of Path to Market/Use and Market Potential
- Potential of the Proposed Work to Impact on the Economic Development of Michigan
- Quality of the Collaborative Effort and Expertise of the Collaborative Team
- Quality of the Organizational Commitments to the Project
- Potential of the Project to Leverage Resources
- Quality of the Intellectual Property Plan
- Availability of Facilities/Resources Needed for the Proposed Research

7.7. Category II Full Proposal Award Criteria (Award Decisions)

- Review Rating and Ranking
- Portfolio Balance
- Availability of Category Funds
- Compliance with Matching Requirement

8. CATEGORY III: PROGRAM INSTRUCTIONS

8.1. Category III Program Goals

The objective of Category III program in this award cycle is to address the high priority needs in Michigan's life sciences commercialization environment. The funds in this category are targeted towards supporting business activities that improve the conversion of scientific knowledge and intellectual property in the State into commercial opportunities.

MLSC Steering Committee has sponsored studies by Battelle Memorial Institute and Innovation Associates to identify highest priority needs in building a robust life sciences industry in Michigan. The studies have identified the following five needs as the most significant to address:

1. Sufficient capital in all stages of life science venture development, with a specific emphasis in the early stage.
2. Access to specialized infrastructure for life sciences industrial research and development, specifically wet labs and incubator space.
3. Availability of experienced talent, specifically senior management for startup companies.
4. Efficient and effective technology transfer.
5. Improved entrepreneurial environment with an emphasis on opportunities for developing life sciences management skills.

Category III proposals should address the needs listed above. Emphasis is going to be given to projects that demonstrate potential for impact in their scale and scope and represent new innovative approaches to accelerating life sciences technology commercialization in Michigan. Proposals that deliver benefits to a significant segment of the targeted entrepreneurs are preferred over projects with narrow benefit. Commercial service offerings should be geographically proximal to Corridor's research and commercialization centers.

Given the limited amount of funding in this Category (10% of the total), it is highly encouraged that any funds sought from the MLSC program be leveraged with funds and resources from other sources. Combination of MLSC funding with other Michigan economic development programs, such as SmartZones or local economic development initiatives is encouraged. While collaboration is not specifically required for Category III applications, it is likely that collaborative programs will be more successful in creating leverage opportunities.

Category III funding is intended to support business activities as opposed to scientific and technical work supported by Categories I and II. Therefore, proposals that seek funding for both types of activities, such as incubator facilities that offer research facilities and business support services, should indicate the funding they seek from Category II and III, respectively.

8.2. Category III Program Characteristics

Category III proposals for the MLSC 2001 program should be based on the following principles. Applicants are also referred to Section 3.4 for examples of possible program designs.

Category III funds support commercialization services, the development and construction of facilities and capabilities required for commercialization, including funds that support business foundation in Michigan. The applicants need to demonstrate that a) the proposed commercialization program fills a critical need in Michigan; and b) the proposed program is focused on a reasonable set of applications of biomedical science or bioengineering, and c) the proposed program offers high quality, innovative services with ready access by Michigan entrepreneurs.

8.3. Description of Needs and Funding Examples

The following gives further definition for the high priority needs for Michigan life sciences commercialization and examples in addition to the ones described in Section 3.4 of the types of projects that could be considered for funding in Category III.

A. Need 1: Sufficient Capital:

Michigan life sciences industry needs more seed and later stage investors. Entrepreneurs are unable to identify angel investors familiar with the life sciences, they fail to understand plans in the early formative stages often do not meet venture capital investment criteria, and they present business plans with weak finance and marketing sections. To help enhance the level of seed funding available for life science companies in the State to improve in these areas, the MLSC is seeking proposals that help alleviate seed funding concerns for life science companies. The example describes a type of proposal that would meet this need:

1. Pre-seed or seed capital funding proposals

A venture capital company or private equity group with a track record might submit a proposal for managing an early stage fund. Category II funds could be applied for to support technology feasibility studies, prototype development and other projects to mitigate technology risk inherent in early stage investments. Category III funds would be used to support nontechnical business formation and development activities. The MLSC funds should be matched with monies raised from private sources. Given the source of MLSC funding, companies receiving financing through this program would need to continue to operate in Michigan for a specified period post-funding.

B. Need 2: Access to Specialized Infrastructure:

Access to cost efficient physical capital is an important issue facing life science companies in the State of Michigan. Often the ability to pay rent, or buy necessary equipment for product development and proof of concept are rate-limiting factors in growing life science companies. To help minimize these concerns, the MLSC is seeking proposals that will address this issue and

enhance the life science business environment in the State. The following are some examples of the types of application proposals that address this need:

1. Development of incubators and wet lab facilities

The past experiences with incubator facilities show that successful programs offer both facilities and business services in modular, customizable fashion. Company or developer converting space into a wet lab facility could apply for funds to offset the costs associated with the construction and equipment purchases (Category II). Business activities could be funded through Category III. MLSC funding could be leveraged through the SmartZone™ program. Matches through local development groups would be highly desirable. Applications should create plan for long-term sustainability for the facility.

2. Development of specialized manufacturing space

There is a worldwide shortage of manufacturing for biologicals and in Michigan companies emerging from academia need facilities to manufacture scale-up quantities or clinical supplies under GMP conditions. Applicants targeting this need should develop proposals that address the technology and management issues around developing such a facility. Access by multiple users with modularity to allow flexible product mixes would be attractive features in such proposals. Market research should demonstrate market need and fee structures that ensure long-term sustainability.

C. Need 3: Availability of Experienced Talent

Access to an adequately trained and specialized life science workforce is integral to building a high caliber life science industry within the State. To address this issue, the MLSC is requesting applications that develop initiatives for attracting, retaining, and developing qualified personnel in the life science industry. Currently one of the most significant needs in Michigan is availability of senior management for early stage ventures. The following are some examples of the types of application proposals that address this need:

1. Management recruitment services

Executive search firm specializing in Life Science management recruitment and with national reach for talent could seek a service contract to establish a presence in Michigan. Proposed service offering would be to assist life science companies and business formation assistants such as those found at universities and service organizations in identifying management talent. The award could help offset the retainer fees or lower the overall fee structure in order to expand access to these types of services for early stage companies. Consulting early stage companies in designing their management teams and compensation plans could also be a feature in such service offerings.

2. Fund for expenses for executive recruitment

As a group or individually, interested parties such as executive recruitment firms, venture capitalists, angel groups, company formation assistants, etc. could apply for funds to be used to offset the cost for executive recruitment. Examples may include payment of search costs, recruitment costs, salaries, relocation costs, travel funds, car payments, and professional

executive recruitment fees. Such proposal would need to delineate the application process, qualifications for applicants, and decision-making process to use this pool of funds.

3. Contracts for interim management and consulting services

Service contracts or funds that would help alleviate the cost of retaining interim management and specialized consultants for marketing, public relations, regulatory, human resources, business development and other management areas could form a basis for proposals in Category III.

4. Recruitment services for temporary and full time scientific and technical staffing

Similar in concept to Example 1, proposals focusing on recruitment of staff for life sciences companies. Development of talent management programs for life sciences to build on services offered by Department of Career Development may also feature in such proposals.

D. Need 4: Efficient and effective technology transfer

New company foundation and rejuvenation of existing companies in life sciences is dependent on access to technology that has adequate intellectual property protection coupled with detailed market information and strategic planning. Michigan new ventures require an enhanced access to services and resources that facilitate the process of converting technology assets into commercial opportunities through skilled business formation management.

1. Development of MLSC Center for Intellectual Property and Market Information

This center would provide both access to information databases and skilled professional services in the field of intellectual property and market information retrieval and management. The center would be able to purchase access to commercial databases and research reports that individual entities within the corridor could not justify economically. It could retain the services of consultants and experts specializing in life science intellectual property management and market research. Key success factor for such a center would be experienced staff professionals who would be able to carry out searches on issues such as patentability, freedom to operate, competitive landscape, market needs, etc. Key aspect for such a proposal would be development of fee structures that permit access to early stage companies but create a realistic long-term sustainability plan. Collaborations with law and business schools and schools of information sciences for database and technology access and internship programs might be elements of such proposals.

2. Fund for protection of Michigan intellectual property

Maintaining patent protection for early ventures is challenging, given the costs involved in particularly international stage patent prosecution. A fund that would provide assistance to prevent the loss of valuable patent rights managed by professional intellectual property experts would protect the value created by Michigan research enterprise.

E. Need 5: Improved entrepreneurial environment

Successful life sciences communities offer individuals within it opportunities to enhance their skills, build networks of contacts to support the activities of their organizations, and to participate in community-building activities in their professional areas. To help establish an

image for Michigan as a leading life sciences business environment and actively promote the State's life sciences potential within and outside the State, the MLSC is seeking proposals that would help expand on an existing social network to provide the above-mentioned benefits to Corridor participants. Examples of the types of applications that would be suitable for funding are described below:

1. Training and professional opportunities in life sciences management

Institutions skilled in organizing educational activities (seminars, courses, and training) to members of life science organizations could propose to develop curriculum, provide faculty stipends, establish student scholarships, etc. Such proposal could establish an entrepreneurial academy that focuses on management issues related to the life sciences, including specialized topics, such as financing (both from investor and company standpoints), intellectual property management, regulatory issues, business development, and human resource management.

2. Organize life sciences forums or workshops on technical and management topics

Institutions seeking sponsorship to host life science technology forums comprised of industry and University scientists with common interests. Investor forums in Michigan could create opportunities for technology entrepreneurs to present their innovations to an audience of investors, management talent, academics, scientists and corporate representatives. Forums on specialized topics on life sciences business management could be yet another platform for this concept.

****These are only a few descriptive examples of the types of proposals the MLSC is seeking that provide solutions to enhancing the life science business environment in the State of Michigan. Alternative solutions are encouraged and will be evaluated in an identical manner as those described above.**

8.4. Category III Pre-Proposal Statement

In developing the Pre-Proposal Statement, applicants should consider the MLSC Mission (Section 2.1), the MLSC 2001 Program Principles (Section 3.2), and the Category III Goals and Program Characteristics (Sections 8.1 and 8.2). The Pre-Proposal Statement must be presented in no more than four (4) pages using the Continuation Page Format and **boldface headings** to indicate items A-B.

A. Goals, Scale, and Structure of the Proposed Program

Indicate the commercialization need to be addressed or the commercialization services to be developed and the rationale for this choice.

Indicate how this program will increase Michigan's commercial capacity or performance.

Indicate how the proposed program will provide leverage for future funding of program participants from Michigan, federal, or private funding sources.

B. Program Participants and Organizational Resources

Indicate the program participants; their commercialization, technological, and administrative roles in the program; and how their participation will result in achieving the program goals.

Summarize briefly the commercialization records and/or experience of the program participants.

Indicate the resources, physical and intellectual available in the collaborating institutions and organizations.

8.5. Category III Pre-Proposal Review Criteria (Project Eligibility/Program Contribution)

Eligibility Criteria

- Importance of Commercialization Need Addressed
- Organizational Expertise for Proposed Project

Ranking Criteria

- Potential for Enhancing Michigan Life Sciences Commercial Capacity or Performance
- Organization Expertise
- Organizational Resources
- Leverage of MLSC Funds

8.6. Category III Program Plan Instructions

In developing the proposal statement, applicants should consider the MLSC Mission (Section 2.1), the MLSC 2001 Program Principles (Section 3.2), and the Category III Goals and Program Characteristics (Sections 8.1 and 8.2). The proposal statement must be presented in no more than twenty (20) pages using the Continuation Page Format and boldface to indicate items A-I. Note that item G applies only to commercialization services and item H applies only to facilities development. Item I only applies to entrepreneurial enhancement services, and item J only applies to other specialized services. Address these items only if they are relevant to the proposal. As indicated in Section 5.7, it may be appropriate to provide separate budget sheets for items G-J.

A. Program Goals

Describe the program goals, that is, the service to be provided or the facility or capability to be developed and the targeted use/users thereof. Provide evidence that the program goals meet the needs of the target use/users.

Describe the rationale for the choice of these goals and the proposal's potential to enhance Michigan's commercialization infrastructure, entrepreneurial culture, and biotechnology industry.

Describe how this program fills a commercialization need in Michigan. Describe unique aspects of this program and how it differs from similar state, regional, national, or international programs.

B. Participant and Organizational Expertise

Describe the rationale for the choice of the program participants; their business, technological, and administrative roles in the program; how their expertise makes them appropriate for their roles; and how their participation will result in achieving the program goals.

Summarize briefly the commercialization records and/or experience of the program participants and organizations and describe how additional entrepreneurial experience will be gained or developed.

Describe the resources, commercial, technological, physical, and technical, available at the participating organizations. Describe how their availability will result in achieving the program goals.

C. Organizational Structure

Describe the organizational and administrative structure of the program. Describe the specific individuals responsible for various activities and their organizational relationship to one another and to the Program Director.

Describe program oversight. If advisory groups are proposed, describe the criteria for the selection of advisors.

Describe the plans to address and facilitate Intellectual Property issues. Do not duplicate the material presented in IPDP (See **Section 3.3.9**), but rather describe how the IPDP will facilitate and expedite the development and commercialization of discoveries from this program. Intellectual property issues may not be a factor in programs appropriate for Category III funding. If this the case, it should be noted in the proposal that intellectual property issues are not present in the program with rationale as to why that conclusion was drawn.

If personnel are to be recruited, describe the types of expertise that will be sought and the institution(s)/organization(s) that would employ these individuals. Describe how these services will be supported at the end of the MLSC project period.

If some commercial services will be purchased or subcontracted, describe the types and nature of these services and the evaluation criteria that will be used in selecting the provider. If a specific provider has been identified, describe the organizational expertise and resources of the provider. Describe how these services will be supported at the end of the MLSC project period.

D. Implementation Plan

Provide a time line and implementation plan for the proposed program.

Provide a fee structure for proposed services and document the potential user pool and anticipated usage.

E. Organizational Contributions

For each entity participating in the program, describe the specific new resources that will be committed to this program and how these resources will facilitate achieving the goals of the program.

F. Leveraging and Matching of Michigan Funding Resources

Describe how the proposed program builds on the current funding of program participants from Michigan sources, federal funding sources (such as NSF, NIH), or private funding sources. Do not duplicate the information presented in **Section 5.10**, Other Support, but rather discuss the relationship of the requested funding to current resources.

Describe how the proposed program will provide leverage for future funding of program participants from Michigan, federal, or private funding sources.

Describe what funds and other resources are applied to meet program matching requirements.

Describe how the work of this project is anticipated to continue beyond the requested MLSC support.

G. Commercialization Services

(Submit this section only if the proposal will involve commercialization.)

If a **Commercialization Needs** Support Plan is proposed, describe a clear policy and strategy for the use of such funds. Describe the number of awards, the amount of funds that could be requested for a project, and the types of costs that would be supported. Describe how proposals requesting such funds would be solicited, evaluated for award, and monitored for progress. Describe the criteria by which the success of the fund would be assessed.

H. Facilities Development

(Submit this section only if the proposal will involve facilities development. Note that facility improvements and equipment purchases should be budgeted to be funded from Category II funds.)

Describe any infrastructure elements/capital equipment to be created, renovated, or expanded with the requested MLSC funding. Describe any other resources currently available or being sought for this same purpose. The location of the requested infrastructure/equipment should be described and the advantages of that site indicated.

Describe how they will constitute a major improvement in capacities within Michigan to foster life sciences commercialization and collaboration.

Describe the access requirements, particularly with respect to access by other organizations (Michigan universities, private or public nonprofit research organizations) and for-profit firms. If user fees or other charges will be used to support the operation or regulate access, detail the anticipated fees and explain the basis for them.

Discuss the cost of all purchases and leases, as well as ongoing (annual) operating and maintenance costs. If annual costs are expected to vary significantly over time, explain the variation.

Provide a schedule for purchase, installation, trial period, and ramp-up to full operation, as appropriate.

Explain how the infrastructure will be maintained and operated after the conclusion of the MLSC project period.

I. Entrepreneurial Enhancement Services

(Submit this section only if the proposal will involve entrepreneurial enhancement services. Address only those services that are proposed)

If a **Career Development Plan** is proposed, describe a clear policy and plan for the selection of career development candidates. Indicate the number and kinds (postdoctoral, early career faculty, transitional investigators, attorneys, MBAs, etc.) of positions that would be available during the project period, the criteria for eligibility and selection and a description of the selection process. Describe the kind of resources that would be made available to successful candidates as part of the program (salary, technician, supplies, reduction of administrative duties, payment of course fees, etc.)

If a **Technology Transfer Enhancement Plan** is proposed, indicate the needs in the current technology transfer resources available at the collaborating organizations. Describe how enhancement will be achieved. If personnel are to be recruited, describe the types of expertise that will be sought and the institution(s)/organization(s) that would employ these individuals. Describe how these services will be supported at the end of the MLSC project period.

If a **Pre-seed or Pilot Project** support plan is proposed, describe a clear policy and strategy for the use of such funds. Describe the number of awards, the amount of funds that could be requested for a project, and the types of costs that would be supported. Describe how proposals requesting such funds would be solicited, evaluated for award, and monitored for progress. Describe the criteria by which the success of the fund would be assessed.

J. Other Specialized Services

(Submit this section only if the proposal will involve other special services.)

Applicants may wish to propose other specialized services related to the enhancement of the Michigan's commercialization enterprise. If such plans or services are proposed, they must be described in sufficient detail to allow for the evaluation of their feasibility and potential to attain the program goals. Thus, the goals, structure, policies, operations, administration of the special feature should be presented. If necessary, prepare a separate budget page and budget justification. (See Section 5.7.).

8.7. Category III Full Proposal Review Criteria (*Rating and Ranking*)

- Quality, Quantity and Importance to Michigan of the Capacity to be Developed
- Organizational Expertise
- Justification for Proposed Project
- Adequacy of Implementation, Administrative, and Facilities Plans
- Organizational Resources
- Adequacy of Plans for Leveraging Funds/Matching Funds
- Documentation of Future Uses/Users/Fee Structure
- Intellectual Property Plans

8.8. Category III Full Proposal Award Criteria (*Award Decisions*)

- Portfolio Balance
- Availability of Category Funds
- Special MLSC Program Needs
- Matching Funds Committed

9. INQUIRIES

Inquiries about the MLSC Fund Proposals can be made by e-mail to:

MLSCinfo@michigan.org

Inquiries will be responded to by e-mail within the next business day.

10. LIST OF MLSC FORMS

- MLSC-01: Checklist
- MLSC-02: Pre-proposal Face Page
- MLSC-03: Proposal Face Page
- MLSC-03: Proposal Page 2
- MLSC-04: Biographical Sketch
- MLSC-05: First Year Budget

MLSC-06: Budget for the Entire Proposed Period of Support
MLSC-07: Composite Budget for the Program