Building the Michigan Life Sciences Corridor

Michigan Health and Aging Research and Development Initiative

Background, Principles, and General Program Guidelines For Investigators and Stakeholders

As revised by the Michigan Life Sciences Corridor Steering Committee in its February 6, 2002 meeting

1. Introduction

The Michigan Life Sciences Corridor program has been operating successfully for the past two years. During this time the program has evolved to reflect lessons learned from applying these Guidelines in practice as well as from the rapidly evolving life sciences research and development landscape, both in Michigan and elsewhere. These updated guidelines incorporate the changes that have been adopted by the Steering Committee as well as changes in the appropriation for this initiative by the Legislature.

Michigan's Governor and Legislature funded this initiative to develop Michigan into a world-class life sciences research and commercial center. To achieve this requires a concentration of both world-class research and world-class industry. One cannot happen without the other. World-class research done at one location does not necessarily result in the development of world-class industry at the same location. Michigan has seen examples of this time and time again, with life science start-up companies emerging from Michigan institutions then leaving the state. However, it is equally true that without the foundation of world-class research, Michigan has little hope of developing and standing as a world-class center of the life sciences industry.

The Corridor initiative will continue to learn from past experiences and will avoid strict interpretations of these guidelines. Steering committee members want to encourage creativity and learn how the program can and should evolve over time. As the program evolves with the Steering Committee will periodically review and update these guidelines.

In addition, the Steering Committee will also provide advice on a broad range of factors, including those falling outside the parameters of this program that will influence whether Michigan can support itself as a Life Sciences Corridor. Workforce development, tax, university patent and royalty, faculty compensation, regulatory and many other factors will play an equal or larger role in our success than how the Life Sciences Corridor monies are spent.

2. Legislative Language and Background

The Michigan Public Act 120 of 1999 created and provided a funding appropriation for the "Michigan Health and Aging Research and Development Initiative." Given that the impetus for this appropriation is the desire to build both the stature of life sciences research and the level of life sciences-related economic activity in the State, the term Life Sciences Corridor is being used. The current Public Act 80 of 2001 regarding the appropriation for the "Life Sciences Corridor Fund" Section 410 of this Act states:

Sec. 410.
(1) From the funds appropriated in part 1 for the fund, $50,000,000.00 is appropriated for a health and aging research and development initiative to support basic and applied research in health-related areas, with emphasis on issues related to aging. The program shall be administered by the Michigan economic development corporation.

(2) A health and aging steering committee, appointed by the governor, shall consist of 14 members including the CEO of the Michigan economic development corporation, a member from Michigan State University, the University of Michigan, Wayne State University, the Van Andel Institute, and 2 members from the private sector. The remaining members shall be appointed at large and may include members from the private sector, public sector, or other Michigan universities. The committee members are authorized to designate alternate members. The purpose of the steering committee is to provide advice and oversight of the initiative, including the development of criteria for the award of contracts or grants to qualifying universities, institutions, or individuals. The steering committee will make decisions regarding distribution of these grant funds and has the authority to make minor adjustments to the category funding percentage based upon the demands within the categories and the quality of applications received.
(3) Of the funds appropriated, 40% is allocated for a basic research fund, to be distributed on a competitive basis to Michigan universities or nonprofit research institutes, or both, for basic research in health-related areas. Not less than $5,000,000 is allocated to research related to aging diseases and health problems. Fifty percent of the appropriated funds are earmarked for a collaborative research fund to support peer-reviewed collaborative grants among Michigan universities and/or private research facilities, with emphasis on testing and developing emerging discoveries. Up to 10% of the appropriated funds may be used to support a commercial development fund to support commercialization opportunities for life science research in Michigan. Appropriated funds must be matched with other university, private, or federal funding. Up to $2,500,000 of the total appropriated funds may be used for administering the initiative.
(4) Repayment of any funds received as a result of awards made under 1999 PA120, 2000 PA 292, or this act including, but not limited to, funds received as interest or return on investment shall be deposited in the fund described in subsection (3) from which it was awarded to be expended for the same purposes. These funds bare authorized for expenditure upon receipt and shall not lapse to the general fund.
(5) The records of the health and aging steering committee involving a proposal submitted by an eligible entity that are of a scientific, technical, or proprietary nature, the release of which could cause competitive harm to the eligible entity as determined by the

health and aging steering committee, are exempt from disclosure under the freedom of information act, 1976 PA442, MCL 15.231 to 15.246.

This act was modified by the Public Act 120 Section 601 of 2001 to change subsection (3) to read:

(3) Of the funds appropriated, up to $2,500,000 may be used for administering the initiative and not less than $5,000,000 shall be used to support a commercial development fund to support commercialization opportunities for life science research in Michigan. Of the remaining funds appropriated, 45% are allocated for basic research fund, to be distributed on a competitive basis to Michigan universities or Michigan non-profit research institutes, or both, for basic research in health-related areas. Not less than $4,000,000 is allocated to research related to aging diseases and health problems. In addition, 55% of the remaining appropriated funds are earmarked for a collaborative research fund to support peer-reviewed collaborative grants among Michigan universities and/or private research facilities, with emphasis on testing or developing emerging discoveries.

In addition, the Executive Order 2001-9 (5. i. Sec. 4) reduced the appropriation provided in Public Act 80 by $5,000,000.

3. Purpose and Intent of the Life Sciences Corridor Initiative

Mission. Consistent with the above-cited legislation, the mission of the program is:

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.

Goals. Consistent with this legislation and mission, the primary goals of the Life Sciences Corridor are fourfold:

- To support and enhance world-class science and support and develop world-class scientists in Michigan's universities and research institutions
- To establish a culture and practice of inter-institutional and industrial collaboration among Michigan's universities, research institutions, and firms to the benefit of Michigan citizens and Michigan-based companies
- To foster a network of entrepreneurial, fast-growing life science firms working in partnership with Michigan's universities and research institutions
- To preserve and enhance the health and quality of life for the people of Michigan, the U.S., and the world.

Objectives.

Objectives for the Life Sciences Corridor include:

- To position the State of Michigan to be a major global center for both life sciences research and development and its resultant commercial use and applications
- To support the generation of life sciences research results that are significant in both human and scientific terms
- To use funds in ways that improve and enhance scientific stature and research reputation of the State's higher education and private and public research organizations
- To use funds in ways that improve and enhance the State's technological capabilities, infrastructure for research discoveries, and technology transfer and commercialization capabilities and impacts
- To support the expansion of the well-educated life sciences workforce in the State
- To leverage strategically the State's investment through the Life Sciences Corridor in ways that attract additional private, federal, and philanthropic resources to address life sciences research, development, and deployment

4. Expected Program Expenditures by Major Category

The biological and biomedical sciences are experiencing revolutionary changes, both in terms of basic scientific content and linkage to applied problems and commercialization. The legislation cited above reflects this by appropriating funds in various categories. Life Sciences Corridor funds have been appropriated to support basic and applied research in health-related areas, with emphasis on issues relating to aging. Consistent with the legislation and executive order, Life Sciences Corridor funds will be awarded as follows in the Fiscal Year 2002 competition:

Basic Research Fund (Category I). $16,875,000 is allocated for basic research. These are to be distributed on a competitive basis to Michigan universities and non-profit research organizations for basic research in health-related areas. Not less than $4,000,000 is allocated to research related to aging diseases and health problems.

Collaborative Research Fund (Category II). $20,625,000 is allocated for a collaborative research fund to support peer-reviewed collaborative grants among Michigan universities and/or private or non-profit research facilities (including private life sciences companies), with an emphasis on testing or developing [1] emerging discoveries.

Commercial Development Fund (Category III). $5,000,000 is allocated to support a commercial development fund to support commercialization opportunities for life science research in Michigan.

Administration. Up to $2,500,000 of the funds may be used for program administrative costs including peer review agency fees, legal fees, consultant fees and other unique expenditures related to the program.

The above funding categories should not be viewed as constraints but as linked categories representing the continuum from basic research to applied research to commercialization that will permit the various fund sources to support phases of a project, in cases where such phased support may be appropriate. Applicants may request funding in a single category or may propose a project that includes requests for funding from more than one of the above categories in the same year, or over multiple years of a project. In some cases, projects initially funded under one category may receive funding in later years from other categories. The Steering Committee will monitor and assess this Program portfolio and the mix of projects within it each year to insure that fund awards are consistent with the legislative language regarding both use and fund allocations.

5. Science and Technology Focus Areas

Given the dynamic nature of life sciences, the Program will initially refrain from defining highly specific substantive areas of R&D emphasis. Moreover, the broad and promising areas of life sciences research that have been identified are likely to change over the course of the Program, reflecting both shifts in the underlying science and the dynamics of the market for biomedical and life science technologies.

6. Funded Research Grants and Commercialization Activities

This section describes the research grants and commercialization activities that will be supported, assuming they advance the purposes and legislative context of the Life Sciences Corridor. All activities funded through the Michigan Life Sciences Corridor program require substantive and quantifiable industrial participation regardless of funding category. Additionally, applicants are encouraged to collaborate with other eligible applicants in every proposed project or activity.

Eligible Applicants. Under the statute creating the Michigan Life Sciences Corridor, eligibility to be the lead proposal applicant is different for each funding category:

Category I (Basic Research Fund) awards can be made only to Michigan universities and Michigan non-profit research institutes. Additionally, collaboration between Michigan higher education institutions and non-profit research institutes is encouraged in the use of these funds.

Category II (Collaborative Research Fund) awards can be made to Michigan higher education institutions and Michigan-based private research facilities, including private for profit and non-profit organizations. If a non-profit research organization applies for funding under this category, collaboration with the private sector is required. In extraordinary circumstances, private for profit applicants may apply individually, but collaboration with Michigan universities and non-profit research organizations is encouraged.

Category III (Commercial Development Fund) awards can be made to Michigan-based [2] higher education institutions, public and private non-profit organizations, and private for-profit firms.

Across all three categories, consortia of eligible organizations are encouraged to apply but a single organization must be designated for overall management and regulatory responsibility. Individuals, acting independently of an eligible organization, will not be permitted to apply or receive funds.

Note: After evaluating and selecting awards a determination will have to made as to the proportion of each award to be allocated by funding category. A portfolio management approach will be followed in which individual proposals may be funded in various combinations from the three categories, with the objective being to ensure that, *in toto*, funding awards in the three categories comply with the available funding for each category as established by the enabling legislation. Applicants will identify in their budgets the amount of requested and matching funds by fund category.

Types of Activities. The program will strive to be flexible and creative in terms of the range of permissible funded grants and commercialization activities. It intends to support high-impact and high-risk peer-reviewed research, development, and commercialization initiatives. Applicants will be encouraged to propose integrated proposals that include project, infrastructure, equipment, and personnel elements likely to be supported on a multi-year basis. A proposed multi-year plan should include milestones, amounts, sources of match by fund category, financial plan, and other items as detailed elsewhere in these guidelines should be included. Applicants should be cognizant of the need to communicate their plans in ways that permit reviewers to determine the significance of the proposed funding requests. Reviewers need to be able to understand the proposal in terms of undertaking important, world-class research and how the applicant proposes to capture that research in innovation that industry, particularly Michigan-based industry, can take advantage. Applicants are also encouraged to propose activities that complement and build upon existing strengths and past investments by government (federal and state), industry and higher education. Such investments should be noted and an explanation provided of how proposed activities build on such past investments.

The following are illustrative rather than prescriptive of the types of activities that can be undertaken:

Research and Development Projects. The submitting organizations may propose an organized plan for a defined body of R&D work. It will generally follow a prescribed format (see Section 9), including a schedule of work, milestones, and potential results and impacts. Funds may be requested for project personnel, necessary equipment otherwise unavailable, laboratory supplies and associated services, travel, and miscellaneous costs.

Technology Infrastructure (Shared Core Facilities, Cutting-Edge Equipment). The submitting organizations can propose financial assistance for the establishment of a shared core facility or acquisition of a major piece of equipment that:

- is key to the R&D agenda of the organization(s) and the Corridor, enabling both high priority research and research collaboration
- can be shared with other interested organizations

- represents a major, non-incremental improvement in capacities within Michigan.

Funds may be requested for technology purchase, lease, and installation, operating personnel, and maintenance. Necessary support personnel (technicians) to operate equipment and facilities may be supported under the Program. Ideally, such equipment and shared core facilities should be linked or associated with projects identified above.

Establishment of Prototype Development Funds. Moving from basic and applied research results to a technology with commercial potential may hinge upon the quick availability of small amounts of applied research funding for prototype development and proof-of-concept work. For example, a university consortium might establish a fund that could be allocated for small awards for emergent mini-projects of this type.

Technology Transfer. The bulk of Life Sciences Corridor investments in all categories will be directly tied to a public or private research enterprise. Nonetheless, given that downstream economic development and impact in Michigan is a major goal, Category III proposals will also be entertained for non-technical projects or activities that enhance the State's technology transfer infrastructure and are critical to the technological success of the Michigan Life Sciences Corridor. Potential uses for these funds may include support for a technology-oriented business incubator, market analysis of emerging technologies, industry brokering services, enhanced staffing of university technology transfer offices, market commercialization services, regulatory assistance, funding for enhanced and innovative approaches to intellectual property and patent protection, and related commercialization services. Projects that will enhance inter-institutional capacity to manage and protect the intellectual property emerging from investment of Life Sciences Corridor funds are strongly encouraged. All such Category III technology transfer infrastructure proposals must demonstrate coordination with other existing State of Michigan programs (e.g., "State Smart" initiatives).

Programmatic Leveraging of Federal Agency Funds. Clear benefit accrues from securing Federal awards for major new programs, centers, institutes, and consortia in Michigan. Corridor funds may provide partial or start-up support for what could become a multi-year, industry-supported center or institute in the life sciences, both after, as well as prior to, achieving Federal designation as a national center or program. These are not normally individual, principal investigator projects (e.g., RO1). The intended use of Corridor funds is to leverage Federal programs where such Federal investments can help build stature and reputation of the Corridor in life sciences and build research excellence in ways that can increase partnerships between industry and research organizations in the State.

Activities that will be discouraged and receive lower priority include the following:

Incremental Research. Michigan Life Sciences Corridor funds are not intended to supplant or replace traditional sources of research funding (e.g., NIH or NSF), nor is the Program intended to be a source of last resort for projects that have been rejected by such agencies. Each applicant will be asked to show what efforts have been accomplished or

proposed to secure Federal funds. Applicants will also be asked to affirm that these funds are not being used to replace Federal funds.

Replacement Funding for Normal Faculty Turnover. Michigan Life Sciences Corridor funds are not intended to support normal faculty tenure line hiring, including normal attrition replacement.

Substitution of Funding from the State of Michigan Capital Budget. The Michigan Life Sciences Corridor funds are not intended to be used for higher education capital projects that have not received an appropriation from the State's capital budget. Activities eligible for funding under the State of Michigan capital budget should not normally be requested.

Establishment of Institutional Funds. In most cases the Michigan Life Sciences Corridor will not encourage block grants or similar formula approaches.

Traditional "Bricks and Mortar" New Building Construction. New buildings will not be normally supported by Michigan Life Sciences Corridor funds except, for example, when a major piece of new equipment needs to be housed in a new facility or when a shared core facility is being proposed by several eligible applicants.

7. Proposal Requirements and Policies

The Michigan Life Sciences Corridor can only accomplish its goals if funded activities can "leverage" themselves and bring additional intellectual, technical, and financial resources to bear on furthering the Corridor's mission. Based on legislative intent, this leveraging is referred to in this document as "match." In practice, this means special efforts will be made to support activities that involve multiple stakeholders, significant research collaboration, and financial contributions by all parties. The following areas are of particular importance:

Industry Involvement. Every proposed project or activity, wherever it lies on the basic research to applied research to commercialization continuum, should preferably include a significant, substantive, and quantifiable and/or investment role for private life sciences industry. Companies must be Michigan-based, or have major business interests/facilities in the State. If a proposal does not have Michigan industry involvement, it must have a credible and cogent plan for how the applicant plans to seek and secure such Michigan involvement and interest. For multi-year projects, future year funding should be predicated on continued and sustained industry support and involvement.

Matching Commitments. Allocated funds need to be matched in each category. Match may be in the form of allocated funds (cash), in-kind personnel, equipment or material donations, federal funds, university, institute, or company internal sources (e.g., waiver of overhead; overhead differential between state and federal overhead rates, depreciated value of directly involved assets, pro-rated operational costs) or combinations of the above. The Program will be particularly flexible regarding matching from start-up companies and will permit inclusion of equity shares. Proportion of matching and industry participation is expected to vary by funding category.

Inter-Institutional Collaboration. The goals, objectives and review criteria provide a funding preference for Category I and II projects involving more than one participating institution.

For example, equipment requests should articulate how the acquired capacities will be shared among the institutions. Similarly, project proposals should describe roles and tasks for the various academic partners. Proposals should strive to maximize shared or collaborative research activities in their applications. For example, shared core facilities, provided there is also shared programmatic use of such facilities and equipment, may represent the ultimate in collaboration. However, a shared core facility built for use by each research organization independently would not meet the requirement of sufficient collaborative activity.

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.

Internal Linkages and Life Cycle Integration. As described above, the overall portfolio of expenditures will be split among Category I -- Basic Research, Category II -- Collaborative Research, and Category III -- Commercial Development. Proposed projects or activities that encompass all of these stages and phases of the innovation life cycle will be strongly encouraged, to the extent that the integration of the multiple phases can be foreseen with scientific credibility. For example, a consortium of universities and companies might propose acquisition of or access to a major piece of equipment. Both will benefit, although they will have different patterns of use. Moreover, the interaction occurring as a by-product of parallel use can stimulate a variety of R&D partnerships. Similarly, a project might be proposed in which there is huge and obvious commercial potential if some fundamental questions of cellular processes are resolved. Such a project

might be significantly more attractive if one or more potential commercializing partner were involved substantively and financially at the outset.

Size and Scope of Proposed Projects and Activities. There is no restriction on the minimum or maximum size of proposed projects or activities. However, the Michigan Life Sciences Corridor intends to adopt a portfolio strategy for its investments, and will carefully balance capacity-building and early-impact activities, and large and small investments. The priority for funding will be projects that demonstrate potential for enhancing Michigan's life sciences research, development and commercialization capabilities and in so doing create critical mass that in turn will attract external funding and other resources to Michigan.

Intellectual Property Principles and Requirements. The Program assumes that issues of potential and existing intellectual property will be present throughout the portfolio. Given that the Life Sciences Corridor is an investment program of the State of Michigan, certain principles regarding intellectual property have been adopted and proposals and applicants will be strongly encouraged to address these issues forthrightly. These principles and issues include:

- developing intellectual property that stimulate new or enhance existing Michigan-based businesses
- articulating a strategy and plan for allocating interests, protecting and commercializing intellectual property
- development of high quality and commercially useful patents
- providing evidence for seamless, industry-friendly, and flexible policies and practices regarding intellectual property
- dedicating needed project resources and tasks for this purpose
- making significant attempts to first license resulting intellectual property to a Michigan firm or to a firm with a Michigan-based facility that will directly benefit from the licensing efforts with out-of-state entities.

The Steering Committee may (on a case by case basis), in each of it's final grant or investment contracts, include a provision reserving the right to ask for a repayment of a grant or investment in the event that such monies are used to develop technologies that are licensed to out-of-state firms, resulting in little or no economic development return to the state.

8. Life Sciences Corridor Management and Advisory Structure.

Steering Committee. In accordance with Michigan Public Act 120 of 1999, 292 of 2000, and 80 and 120 of 2001, final decision-making authority on how the Michigan Life Sciences Corridor funds are to be used rests with a 14 member Steering Committee, appointed by the Governor. The Steering Committee (also known as the Life Sciences Steering Committee) consists 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
- 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
- B. Joseph White, Interim President, University of Michigan.

As stated in the legislation its primary charter is to set policy, provide advice and oversight for the Michigan Life Sciences Corridor funds, including the development of award criteria and making decisions regarding distribution of these funds
Among the roles and duties foreseen for the Steering Committee are the following:

- Establish overall policies, vision, mission, goals and objectives for the Life Sciences Corridor
- Establish overall strategies to achieve goals and vision, e.g., business and investment strategy
- Establish and measure accountability of the Program, including measures of success, with a reporting system to measure progress, outcomes, and impacts from the Program's investments
- Prepare (in conjunction with the Corridor's Executive Director) an Annual Report detailing program investments and citing specific accomplishments and scientific and economic results

- Establish an annual and multi-year financial plan and budget for the Corridor Program and review the allocation of commitments by Category
- Approve priorities and programs to accomplish such priorities
- Set program guidelines and proposal criteria to be used in making funding awards in the various programs it may wish to establish from time to time
- Complete at least every two years, an assessment of the life sciences technology infrastructure needs in the State and a comparative benchmark analysis of Michigan's life sciences performance both in R & D and in its industrial base in comparison to leading life sciences states and regions
- Approve the issuance of solicitations, program announcements, and requests for proposals from time to time
- Oversee and continually assess an established peer review process for the solicitation, receipt, and review of requests for investments from the Life Sciences Corridor funds.

Technical Advisory Committee. An 10-member Technical Advisory Committee (TAC) will provide the broad-scope programmatic and operating advice, as well as specific program design advice, to the Michigan Life Sciences Corridor Steering Committee and MLSC staff. The Steering Committee will appoint the members of the Technical Advisory Committee in the proportion outlined below among three groups:

- Two outstanding scientists (from non-Michigan institutions) with no current or recent association with a Michigan university or research organization likely to participate in this Program.

- Four industry/private sector representatives (two from within Michigan and two from outside Michigan) with expertise in the scientific and commercialization aspects of the life sciences (including industrial research, venture capital, entrepreneurship, business development, and technology transfer expertise), to ensure that these issues are being addressed sufficiently and advice in this area is being provided to the Steering Committee in selection of all projects.

- Two representatives from Michigan universities or research institutions serving two-year terms.

- Two non-voting representatives from Michigan universities or research institutions serving two-year terms.

The Chair of the Technical Advisory Committee will be appointed by Steering Committee from among the Technical Advisory Committee's non-Michigan members.

Members of the TAC will be appointed with four-year terms with one-half of the Committee being replaced by new appointments at the end of every second year, except for the four Michigan university representatives who will serve two-year terms. Initial appointments will be staggered so that at the end of the second year of its operation one individual from each category is replaced.

The principal advisory duties of the Technical Advisory Committee are to advise the Steering Committee and MLSC staff on:

- Strategies and priorities (grant mechanisms, scientific focus, commercialization focus) for both short and long term use of the Corridor Funds.

- Policies and procedures by which the programs supported by the Corridor Funds should operate including the review process, intellectual property policies, its quality control, application and award criteria, and reporting and evaluation requirements.

- Ways for the funds to be marketed to faculty and industry to build awareness and encourage participation in the Program.

The principal operational role of the TAC is to assure a high-quality, unbiased and un-conflicted review of pre-proposals and invited proposals for all categories of funding from MLSC.

The exercise of the TAC's strategic duties will require at least 3 activities or meetings each year, each of which should result in a formal report to the Steering Committee:

1. Review of the grants awarded during the immediately proceeding cycle, review and analysis of total MLSC grants to date, review of grant administration, especially as it affects the program's effectiveness at reaching the desired goals.

2. Discussion of strategy (scientific and commercialization) and development of program recommendations for the Steering Committee for the upcoming funding cycle(s). This activity should be broadly consultative, perhaps beginning with a public meeting at which the TAC solicits and hears testimony from a variety of Michigan companies and research organizations.

The TAC will also provide ongoing operational advice and counsel to the Steering Committee and MLSC staff on:

- Design and execution of a pre-proposal evaluation and triage process for all categories of funding that culminates in a recommendation to the Steering Committee each year of which applicants should be asked to submit full proposals.

- Design and execution of an invited full proposal peer review process for all categories of funding that culminates in awards recommendations to the Steering Committee each year.

Given conflict of interest concerns, representatives of the Technical Advisory Committee will excuse themselves and not participate in review or discussion of activities, especially

but not limited to pre-proposals, in which their institution or firm participates. Further, to avoid conflict and over-representation of particular institutions in the process, no member of the Steering Committee, or alternate, can serve on the TAC.

To execute its responsibilities the TAC will depend on the MLSC staff for support both in performing work and in selecting and retaining contractors capable of assisting in such tasks.

Conflict of Interest Issues. Care should be exercised and the Steering Committee should early in its tenure establish Conflict of Interest and Disclosure policies applicable to the Steering Committee, Executive Committee, any such advisory committees it may wish to establish, including the Technical Advisory Committee, and any MEDC staff or external consultants employed on behalf of or coordinating with the Program.

Staffing. The Michigan Life Sciences Corridor staff shall be employees of the Michigan Economic Development Corporation and jointly responsible to the MEDC and the Michigan Life Sciences Corridor Steering Committee. These employees shall be located at MEDC offices or appropriate locations. Any and all decisions regarding the hiring, performance appraisal, and compensation of the Executive Director will be made by the MEDC with the concurrence of the Steering Committee or it's Executive Committee. The Executive Director should have life sciences scientific knowledge and experience. Ideally, the Executive Director should also be knowledgeable of the peer review system, Michigan's life sciences industry, and business-higher education-government partnerships. The staff for the Corridor should be small in number but senior in knowledge and experience and have the ability to guide, broker, and facilitate relationship building and accountability. The Executive Director will participate in an appropriate fashion in any and all committees of the Life Sciences Corridor.

9. Proposal Processes, Review Procedures, and Award Cycle

General Parameters. Corridor staff and or contractors may, for practical purposes, need to deviate from the following processes, review procedures and award cycle parameters. This section should be interpreted as "guiding principles" not "specific requirements" for the application and review process.

Program Announcement and Requests for Proposal. A Program Announcement and Request for Proposals will be issued annually, with content patterned after these Guidelines. The content and processes of the annual program and request for proposal may be changed for practical and programmatic considerations during the course of the annual application cycle, including amending deadlines for pre-proposal and proposal submissions. As part of the Life Sciences Corridor marketing and outreach strategy the Program Announcement and Request for Proposals will be extensively circulated throughout the Michigan life science R&D community, across public, private, and non-profit sectors.

Use of Pre-Proposals. A pre-proposal binding to the content of the full proposal is required from all applicants. The applicants will have at least ten weeks from the release of the Request for Proposal to prepare and submit a pre-proposal. The pre-proposals are evaluated for meeting eligibility requirements and responsiveness to category requirements for that year's program. The Steering Committee will determine the proportion of applicants that will be invited to submit full proposals based on the rating of pre-proposal quality and availability of funds.

The MLSC staff will prepare a Request for Proposals (RFP) with the advice and input of the Technical Advisory Committee for the Steering Committee to review and approve for each annual application cycle. The RFP will describe in detail the requirements for the applicants for each funding category as well as the application submission format, instructions and timelines.

The Peer Review Process. The peer review process will be managed by an experienced external peer review agency under the guidance of the Steering Committee and the MLSC staff and with the advice of the Technical Advisory Committee. The review agency will be required to establish procedures that ensure timely and high quality review of scientific, technical, and economic merits of the applications, as appropriate for each category of funding. The peer review agency will provide a report to the Steering Committee on the review results. It will also provide review summaries as feedback to the applicants at each phase of the review process.

10. Post-Award Management and Program Evaluation

Reporting Requirements During the Project. Each funded project will be required to provide an annual report describing the overall project, its progress and results, and plans for the future. Additionally, each funded project will provide a simple 1-2 page Quarterly Progress Report on progress achieved relative to the schedule, milestones, and deliverables that were described in the proposed Plan of Work.

Post Project Reporting Requirements. At the close of a funded project and at the one-year anniversary thereafter, each project is to provide information on the following indices of outcomes attributable to the funded effort:

Science outcomes

- Publications
- Citation, as reported in major indices
- Subsequent federal, industry, or foundation research funding
- Enhancement of scientific stature of Michigan's research programs, as reported by rankings
- Enhancement of Michigan's research and development capability and capacity

Economic development and impact measures

- Industry partnerships and funding
- Start-up companies built on MLSC-supported technologies
- Growth in life sciences commercialization capabilities and infrastructure
- Investment in Michigan-based companies
- Enhancement of the valuation of Michigan-based companies
- New jobs and wages associated with new jobs
- New products introduced
- Graduates in Life Sciences Corridor supported programs (new degrees, upgrading, retraining)
- Retention rate of graduates in Michigan five years after graduation

Commercialization measures

- Patents
- Licenses
- Status and results of clinical trials and attainment of other product development milestones
- Sales revenues
- Royalty income

Programmatic Reporting Requirements. In addition to the above performance measures, additional programmatic measures may be developed and incorporated into an overall annual report by MEDC (in accordance with the Steering Committee when appointed) to the Governor and State Legislature to gauge both the success of individual projects and the long term (20 year) impact of the Michigan Life Sciences Corridor investments. Such an overall assessment should include the following:

- Documented improvement in the research stature and reputation of programs and departments at the State's primary research universities (rankings)
- An increase in the birthrate of new biotechnology and biomedical firms established within the State of Michigan and an increased survival rate of these firms over the 1999 baseline
- Measurable increases in the percentage of the State's GDP represented by the State's biomedical industry sector over the 1999 baseline
- Measurable increase in Michigan's share of the U.S. life sciences industry in terms of firms, jobs, and sales over the 1999 baseline
- Improvement of Michigan's life sciences industry ranking vis-à-vis other states measured by sales revenues, number of companies and employees
- Long term reductions in incidence rates of diseases in which Michigan exceeds nation, e.g., diabetes
- A return on investment from the Corridor Program that leverages the Program's funds with industry, federal, and university funds.

Projects funded by this Program will be expected to cooperate in the collection of the data sets for such reports for a period of up to seven years after project completion.

Program Evaluation. Through a contracted third-party, the Program will commission an evaluation every three to four years of the program, which will involve aggregation of project-by-project outcomes, internal and external comparisons, and qualitative assessment.

[1] As used here, the terminology "testing and developing" should be broadly construed to include not only activities such as late stage clinical trials and proof-of-concept work, but also much earlier research investigations of an emerging discovery.

[2] Since many organizations, particularly corporations, will have activities in several states or countries, the term "Michigan-based" for purposes of this Program will be construed to mean that the primary locus of the proposed project's activities and downstream impacts, must be based in Michigan (e.g., where the research will be performed, where intellectual property rights will reside, where the processing, testing, and evaluation will be performed, where production of the product will occur).

[3] With these as guiding principles, the Program will allow sufficient time for applicants to build relationships with industry, higher education institutions, research organizations, and other potential collaborators. Thus, a "ramped" approach to the minimum requirements will be used.

[4] Based on the enabling legislation the Michigan Life Sciences Corridor Steering Committee has the ultimate decision making authority. Within this authority the Steering Committee has the ability to accept or reject for funding any and all proposals submitted for funding.