

STATE OF NEW YORK

1801

2017-2018 Regular Sessions

IN ASSEMBLY

January 13, 2017

Introduced by M. of A. MORELLE, LUPARDO, STIRPE -- read once and referred to the Committee on Economic Development

AN ACT to amend the economic development law, in relation to the New York state biomedical and biotechnological translational research and entrepreneurship initiative

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. Legislative intent. The legislature hereby finds and
2 declares that a coordinated program of research, entrepreneurship, and
3 public-private partnerships and collaborations centered in and with the
4 state's public and private medical schools can significantly increase
5 the speed and amount of commercialization of research from lab to
6 market, materially expanding economic and job opportunities for all New
7 Yorkers in this high growth sector and increasing the likelihood of high
8 impact healthcare breakthroughs, which will improve the health and well-
9 being of New Yorkers and potentially reduce health care costs.

10 The legislature further finds that although New York state's biomed-
11 cal and biotechnological research and infrastructure includes many of
12 the nation's top institutions, researchers and scientists, and has many
13 natural advantages compared to other states, development has lagged
14 behind the nation as a whole and many states in job growth and economic
15 activity for a decade; and further, that as other states make signif-
16 icant and targeted investments to recruit top tier scientists and
17 researchers, and develop incentives that are creating rapid growth, the
18 gap between New York and other states will increase, along with a poten-
19 tial migration of scientific and research talent to other states in
20 search of opportunity and professional advancement.

21 The legislature further finds that recent changes that have made New
22 York's economic development programs more sophisticated and competitive
23 can be combined with other statutory approaches and precedents to
24 support and incentivize an effective plan for development of biomedical

EXPLANATION--Matter in italics (underscored) is new; matter in brackets
[-] is old law to be omitted.

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1 and biotechnological entrepreneurship by and through the medical schools
2 in this state, and declares that the program enacted by this act will
3 expand economic activity and job development; maintain and attract high
4 quality scientists and researchers; increase resources available to the
5 schools and researchers from grants, private investments, patents,
6 royalties, and licensure, and leverage significant partnerships with
7 public and private entities; enhance our scientific and research capa-
8 bilities; and increase the speed of commercialization of research and
9 the expansion of economic opportunity, which are in every sense to the
10 benefit of the people of this state.

11 § 2. The economic development law is amended by adding a new article
12 23 to read as follows:

13 ARTICLE 23

14 THE NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL
15 TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE

16 Section 451. Short title.

17 452. Definitions.

18 453. New York state biomedical and biotechnological translation-
19 al research and entrepreneurship initiative committee.

20 454. Application for designation as a New York state biomedical
21 and biotechnological translational research and entre-
22 preneurship initiative center.

23 455. Review and approval of applications.

24 456. Waiver in certain cases.

25 457. Operation and re-designation of New York state biomedical
26 and biotechnological translational research and entre-
27 preneurship initiative centers.

28 458. Scientific research and discovery bank program.

29 459. Unified contract.

30 § 451. Short title. This article shall be known and may be cited as
31 the "New York state biomedical and biotechnological translational
32 research and entrepreneurship initiative".

33 § 452. Definitions. As used in this article:

34 1. "Medical school" means a public or private medical school accred-
35 ited by the liaison committee on medical education or the commission on
36 osteopathic college accreditation, or such medical school and an affil-
37 iated entity, located in this state.

38 2. "New York state incubators" and "New York state innovation
39 hotspots" or "incubators" and "hotspots" mean and refer to "New York
40 state incubators" and "New York state innovation hotspots" designated
41 pursuant to section sixteen-v of the urban development corporation act.

42 3. "Peer review committee" means the peer review committee created by
43 the department and the department of health, consisting of scientific
44 and research experts in biomedical and biotechnological development, and
45 company representatives at the executive officer level engaged in making
46 development, financing, and commercialization of biomedical and biotech-
47 nological research.

48 4. "Plan" means the multi-year plan that accompanies the application
49 of a medical school to become a New York state biomedical and biotechno-
50 logical translational research and entrepreneurship initiative center.

51 5. "Project" is the execution of an approved plan by a New York state
52 biomedical and biotechnological translational research and entrepreneur-
53 ship initiative center.

54 6. "START-UP NY" program means the START-UP program authorized pursu-
55 ant to article twenty-one of this chapter, and the "tax-free NY area"
56 has the same meaning as in article twenty-one of this chapter.

1 7. "State initiative committee" or "state committee" means the biomed-
2 ical and biotechnological translational research and entrepreneurship
3 initiative committee created by section four hundred fifty-three of this
4 article.

5 8. "Translational research and entrepreneurship center" or "center" is
6 the New York state biomedical and biotechnological translational
7 research and entrepreneurship initiative center created at a medical
8 school pursuant to this article.

9 9. "Unified contract" is the contract between the department and a
10 medical school that includes all items necessary to the implementation
11 and administration of the New York state biomedical and biotechnological
12 translational research and entrepreneurship initiative project as
13 described in this article by a center.

14 § 453. New York state biomedical and biotechnological translational
15 research and entrepreneurship initiative committee. The New York state
16 biomedical and biotechnological translational research and entrepreneur-
17 ship initiative committee is hereby created, to consist of the commis-
18 sioners of the departments of health, education, economic development,
19 labor, tax and finance, the chancellor of the state university of New
20 York, the chancellor of the city university of New York, the president
21 of the empire state development corporation, the director of the divi-
22 sion of the budget, and the state comptroller. The committee shall be
23 chaired by the commissioner of economic development, and co-chaired by
24 the commissioner of health. Commissioners may be represented by desig-
25 nees at meetings of the committee.

26 1. Powers and duties. The committee shall:

27 (a) Establish guidelines appropriate to the activities required under
28 this article.

29 (b) Designate as New York state biomedical and biotechnological tran-
30 sitional research and entrepreneurship initiative centers medical
31 schools which meet the criteria established in this article.

32 (c) Approve waivers of regulations and procedures pursuant to section
33 four hundred fifty-seven of this article.

34 (d) Establish a unified contract for projects pursuant to section four
35 hundred fifty-nine of this article.

36 (e) Receive and review performance metrics reports from centers.

37 (f) Re-designate the centers every five years pursuant to this arti-
38 cle.

39 (g) Develop resources and procedures to aid in commercialization of
40 research and funding of entrepreneurial efforts created as a result of
41 projects, including but not limited to such activities as procurement of
42 goods or services from companies created in the projects; endorsing,
43 collaborating, or upon request of a center, acting as a co-principal
44 investigator or other level of participant on grants or other activities
45 that will aid in furthering project activities; and such other activ-
46 ities as can aid rapid commercialization as are permissible under law.

47 (h) Oversee and make recommendations for approval of applications to
48 the scientific research and discovery bank created by this article for
49 the recruitment of out of state and retention of in-state star scien-
50 tists and researchers.

51 (i) Upon request, provide technical assistance to applicants, and as
52 may be needed for successful implementation of a project, including but
53 not limited to assistance in identifying and obtaining resources and
54 funding.

55 (j) Identify statutory requirements that the committee views as imped-
56 iments to successful implementation of approved plans, and as necessary,

1 submit requests to the legislature in accordance with article VII of the
2 state constitution for specific legislative enactments necessary to
3 remove such impediments.

4 (k) Enter into agreements between and among the members of the commit-
5 tee as necessary to delineate their respective roles regarding the coop-
6 erative provision of funding and assistance.

7 2. The committee may act through its chairs in all matters of over-
8 sight and implementation of the program authorized by this article.

9 § 454. Application for designation as a New York state biomedical and
10 biotechnological translational research and entrepreneurship initiative
11 center. In response to a request for proposals, a medical school or a
12 medical school and an affiliated entity may apply for funding and design-
13 ation as a New York state biomedical and biotechnological translational
14 research and entrepreneurship initiative center by submitting an appli-
15 cation and plan to the commissioner. The commissioner shall forward all
16 such applications to the peer review committee for review and recommen-
17 dation as herein provided, and then to the state committee. In addition
18 to such other items, warranties, and information as the state initiative
19 committee may require, plans must show that the activities to be under-
20 taken will commercialize research from lab to marketplace, demonstrate
21 that the center meets the matching funds and entrepreneur relationship
22 requirements hereunder, and meet a majority of the remainder of the
23 following items:

24 1. Commitment: a multi-year commitment to implement the plan, over a
25 period of not less than five years, demonstrated by a commitment of
26 resources, personnel, and funds that the school will use, directly or
27 through partnerships and collaborations, to provide and/or incentivize
28 an integrated program of research, education, clinical practice, entre-
29 preneurship, financing, partnerships, and rapid commercialization of
30 research. Such demonstration may also include capital investments made
31 or planned for new or rehabilitated research or laboratory space,
32 continued support for activities after the conclusion of the project,
33 and other activities demonstrating commitment.

34 2. Resources: a description of the actions and resources necessary to
35 meet the plan objectives over its duration; a demonstration that the
36 medical school has or is developing operational clinical facilities and
37 expertise or evidence of bona fide collaborations and partnerships that
38 can provide such facilities and expertise to successfully implement the
39 plan; a demonstration that the project will have a professional manage-
40 ment team with experience, expertise, or credentials in areas including
41 but not limited to management, entrepreneurship, business development,
42 or other equivalent areas. The demonstration may include recruitment
43 plans or commitments for high level research professionals, including
44 how the school would make use of the scientific research and discovery
45 bank.

46 3. Entrepreneurial and research collaborations: evidence of bona fide
47 entrepreneurial relationships with one or more incubators or hotspots,
48 and research collaborations with other entities including but not limit-
49 ed to other research institutions, pharmaceutical and biomedical and
50 biotechnology companies.

51 4. Leveraged and applied funding: a demonstration that the school
52 already possesses or has a commitment for and will maintain during the
53 plan period the required funding match ratio of at least two dollars for
54 every state dollar provided pursuant to this article to an approved
55 plan, and how the school will use other resources, partnerships, and
56 collaborations to aid directly or indirectly in activities critical to

1 the commercialization of research. Insofar as practicable, such matching
2 funds should not consist of direct state grants from the department or
3 from another state agency or state public authority, provided that noth-
4 ing in this subdivision shall be deemed to prohibit a medical school of
5 the State University of New York which has been designated as a center
6 from using a portion of its operating funds as matching funds.

7 5. Additional plans and programs: other plans and programs integral to
8 the successful execution of the project, including but not limited to
9 patent and intellectual property plans, training and educational
10 programs, and educational integration with research and clinical activ-
11 ities.

12 6. Community support: a demonstration of community support from busi-
13 ness and government leaders and organizations.

14 7. Best practices: a demonstration that the medical school has or will
15 adopt best practices and use of multi-year metrics for performance, and
16 that it will report data as requested or required to the department and
17 the state initiative committee.

18 8. Performance metrics: anticipated annual and cumulative outcomes of
19 the project in terms of direct, indirect, and retained jobs, investment,
20 and economic and other activity, stated in a specific and measurable
21 way, and research findings and progress.

22 9. Advisory council: an advisory council of five members or more that
23 includes one or more executive officers of firms that have been created
24 from research at the school, and individuals with expertise in areas
25 appropriate to the specific developmental sector or concentration of
26 clients, or to biomedical and biotechnological research and development,
27 and to the mission and goal of the project.

28 § 455. Review and approval of applications. Review of applications
29 shall take place as follows:

30 1. The commissioner shall review applications and plans received for
31 completeness, and then forward them to the peer review committee. No
32 plan shall be approved by the state initiative committee that has
33 received a designation of not recommended for further consideration
34 (NRFC) by the peer review committee. No plans shall be forwarded by the
35 commissioner to either committee that require that funds made available
36 pursuant to this article shall be directly or indirectly utilized for
37 research involving human reproductive cloning.

38 2. The members of the peer review committee shall be selected by the
39 chair and the co-chair of the state initiative committee using guide-
40 lines approved by such committee, which shall include requirements
41 concerning expertise and avoidance of conflict of interest. If necessary
42 and deemed appropriate by the state initiative committee, plans may be
43 submitted blind to the peer review panel. Peer review panels shall
44 include a minimum of five members.

45 3. The peer review committee shall review and score plans based on the
46 following criteria:

47 (a) scientific and technical merit;

48 (b) the level of scientific knowledge, technical capability, and/or
49 clinical practice and other necessary plan components that would be
50 required to be housed at the medical school, including improvements that
51 may be anticipated based on the plan;

52 (c) the suitability of principal investigations, collaborators, and
53 other researchers to the project, including the experience and training
54 of staff and collaborators;

1 (d) the ongoing record of accomplishments and integrated expertise at
2 the school or as proposed in the plan, including leadership approach,
3 governance and organizational structure;

4 (e) plans for protection of human subjects;

5 (f) the scientific environment in which the work will be done;

6 (g) appropriateness of institutional support, equipment, and other
7 physical resources; and

8 (h) such other information as the state initiative committee shall
9 require.

10 4. An application receiving a low score by the peer review committee
11 based on the criteria in subdivision three of this section, or which
12 lacks significant and substantial merit, or which presents in the view
13 of the peer review committee serious ethical problems in the protection
14 of human subjects from research risks, or other serious ethical prob-
15 lems, shall be designated not recommended for further consideration
16 (NRFC). Such plans shall be returned to the commissioner and by the
17 commissioner to the state initiative committee with written recommenda-
18 tions for change.

19 5. The state initiative committee shall review and score plans based
20 on the categories required in the application pursuant to section four
21 hundred fifty-four of this article, and shall additionally consider the
22 following:

23 (a) the anticipated effectiveness of the plan as evidenced by the
24 existence of available resources dedicated to the plan and the commit-
25 ment of the medical school;

26 (b) the ability of the applicant to undertake and complete the plan,
27 the feasibility of meeting the metrics and goals provided for determin-
28 ing the success of the plan, the durability and extent of the relation-
29 ships with incubators and hotspots, and with START-UP NY projects, and
30 with private and other public collaborators;

31 (c) the ability of the applicant to provide the necessary data for an
32 effective evaluation of the project;

33 (d) the amount of federal and private grants, or other resources that
34 will be incentivized and made available to the school to assist in fund-
35 ing of the project; and

36 (e) such other measurable criteria as shall be determined by the
37 committee.

38 6. Plans designated as not recommended for further consideration
39 (NRFC) by the peer review committee or the state initiative committee
40 shall be returned to the applicant with any recommendations for amend-
41 ment and may be resubmitted in the following year.

42 7. The state initiative committee shall review the applications and
43 plans submitted to it and recommend changes and determine funding levels
44 and sources to be included in the unified contract, provided that not
45 more than forty percent of funds, appropriated pursuant to this article
46 shall be used for any single project in any year. Insofar as practicable
47 in approving applications, the committee shall seek to provide a
48 geographically balanced distribution among the regions of the state in
49 designating New York state biomedical and biotechnological translational
50 research and entrepreneurship initiative centers.

51 8. As soon as practicable after approving an application the committee
52 shall notify the temporary president of the senate and the speaker of
53 the assembly of its approval. Such notification shall identify the
54 recipient and state the proposed location, the estimated project funding
55 and award and provide a brief description of the project.

1 § 456. Waiver in certain cases. To promote innovative approaches and
2 maximize effective use of public monies and the likelihood of success in
3 operation of approved New York state biomedical and biotechnological
4 translational research and entrepreneurship initiative centers, and
5 notwithstanding any other provision of law, the commissioner or director
6 of any state agency that is a member of the state initiative committee
7 may waive, upon application by such center and subject to the approval
8 of the state initiative committee and the director of the budget, any of
9 such agency's regulatory or procedural requirements that may impede the
10 successful implementation of a project undertaken by the center,
11 provided that such waiver is consistent with applicable state and feder-
12 al statutes and will not impair the general health or welfare of the
13 people receiving services under such project or others. Such commission-
14 er or director shall be authorized, in consultation with the director of
15 the budget, to impose appropriate alternative standards in place of any
16 waived requirements.

17 § 457. Operation and re-designation of New York state biomedical and
18 biotechnological translational research and entrepreneurship initiative
19 centers. In addition to any other requirements of this article, a center
20 will agree to provide data showing its success in meeting project plan
21 goals, including year by year comparison of research activity and
22 commercialization thereof, firm financing and equity capital raised,
23 provided or leveraged from all sources, personnel employed on the
24 project, and jobs created by and through the project. The department
25 shall design simplified forms to aid in the submission of such data,
26 which may be submitted electronically.

27 The chairs of the state initiative committee shall evaluate and report
28 on the operations of the center using methods including but not limited
29 to site visits, reports pursuant to specific information, and review
30 evaluations. If the chairs determine the project is not progressing as
31 agreed, the center will be notified of deficiencies and the center shall
32 remedy any deficiencies in its operations in a timely manner. Such eval-
33 uations shall take place no less than once every three years or more
34 often for any individual center at the discretion of the chairs, and
35 shall result in a written report that includes programmatic and fiscal
36 evaluation of the project and recommendations for improvement.

37 Failure to timely cure a deficiency after review shall result in
38 disqualification of the medical school as a center.

39 A center shall be deemed re-designated upon application every five
40 years unless it shall receive a negative evaluation from the peer review
41 group on its application for re-designation, or if it shall fail to
42 remedy identified defects in its operation made known to it pursuant to
43 this section, or if the state initiative committee determines that such
44 defects are of such a nature, involve fraud, or are of such extent that
45 they cannot be remedied.

46 § 458. Scientific research and discovery bank program. The scientific
47 research and discovery bank program is hereby created, whose purpose
48 shall be to provide funds to centers for recruitment of out of state and
49 retention of in-state scientists and researchers necessary to the
50 successful implementation of approved projects. Monies shall be made
51 available to centers from funds appropriated for the purposes of this
52 article, after review and upon approval by the state initiative commit-
53 tee pursuant to a plan submitted by a center. Such plan may be submitted
54 at the time of the application or at any time during the implementation
55 of the multi-year approved plan and must demonstrate to the satisfaction
56 of the committee that the center has or will have during the period of

1 the grant a match of two dollars for every state dollar provided pursu-
2 ant to this section. Plans must show the timeline and usage of funds
3 required and such other information as the committee shall require,
4 including: the need for such funds and the manner in which such award
5 would enhance the research capabilities of the center necessary to
6 successful implementation of the project plan; the ability of the
7 researcher to leverage and attract federal funds, venture capital and
8 private industry funds; and the willingness of such researcher to pursue
9 entrepreneurial enterprises resulting in new business or the expansion
10 of existing business in this state. The committee shall establish a
11 schedule for payment of the award. Funds provided pursuant to this
12 section must be applied directly to necessary expenses for recruitment
13 and retention of scientists and researchers, and may not be used for
14 indirect or other overhead costs of the medical school. Insofar as prac-
15 ticable, such matching funds should not consist of direct state grants
16 from the department or from another state agency or state public author-
17 ity, provided that nothing in this section shall be deemed to prohibit a
18 medical school of the State University of New York which has been desig-
19 nated as a center from using a portion of its operating funds as match-
20 ing funds. Funds used for match may include reasonable administrative
21 costs associated with out of state recruitment or in-state retention.

22 § 459. Unified contract. The commissioner on behalf of the state
23 initiative committee shall enter into a unified contract with each
24 center. The provisions of such contract shall include, but not be limit-
25 ed to: a description of project services and activities; the plan;
26 allowable project costs; specific sources of funds that will support the
27 approved costs, including governmental and non-governmental funds or
28 revenues that are proposed to be used in support of project costs; and
29 the allocation of costs by funding source. The form of such unified
30 contract shall be developed in consultation with the division of the
31 budget and the office of state comptroller. The comptroller is author-
32 ized pursuant to a certificate of allocation submitted by the division
33 of the budget to interchange or transfer from appropriations made to the
34 agencies of the committee or any other appropriation, as appropriate,
35 such amounts as may be required to fulfill the obligations of the state
36 pursuant to such unified contracts for payments of such obligations. The
37 division of the budget shall provide the chairs of the senate finance
38 committee and the assembly ways and means committee with quarterly
39 reports of all interchanges and transfers which occur pursuant to this
40 subdivision.

41 1. Allowable costs for a project shall include, but not be limited to
42 costs reasonably incurred for:

43 (a) preparation of the plan;
44 (b) activities as approved in the project application;
45 (c) evaluation of the approved project; and
46 (d) renovations to existing structures as may be needed in furtherance
47 of the plan, except that in no case shall the state support of such
48 costs exceed either twenty-five percent of the amount to be provided
49 pursuant to the contract or fifty percent of the total renovation costs,
50 whichever is less.

51 2. Funding made available pursuant to this article shall not be used
52 to supplant other funds for operations or projects of a center.

53 In addition to the foregoing requirements, a center shall agree to
54 dedicate all funds from any support received pursuant to this article,
55 except for funds received pursuant to paragraph (d) of subdivision one
56 of this section, to operations of the center without deductions for

1 overhead, indirect costs, or facilities and administration charges of
2 the medical school, and to limit to ten percent or less the allocation
3 of funds received through this article to administrative costs of the
4 center.

5 § 3. This act shall take effect on the first of September next
6 succeeding the date on which it shall have become a law.