

# STATE OF NEW YORK

---

8549

## IN SENATE

May 9, 2018

---

Introduced by Sen. BOYLE -- read twice and ordered printed, and when printed to be committed to the Committee on Commerce, Economic Development and Small Business

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 ical 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  
25 and biotechnological entrepreneurship by and through the medical schools  
26 in this state, and declares that the program enacted by this act will  
27 expand economic activity and job development; maintain and attract high  
28 quality scientists and researchers; increase resources available to the  
29 schools and researchers from grants, private investments, patents,

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

LBD01066-01-7

royalties, and licensure, and leverage significant partnerships with public and private entities; enhance our scientific and research capabilities; and increase the speed of commercialization of research and the expansion of economic opportunity, which are in every sense to the benefit of the people of this state.

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

#### ARTICLE 23

#### THE NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE

##### Section 451. Short title.

##### 452. Definitions.

##### 453. New York state biomedical and biotechnological translational research and entrepreneurship initiative committee.

##### 454. Application for designation as a New York state biomedical and biotechnological translational research and entrepreneurship initiative center.

##### 455. Review and approval of applications.

##### 456. Waiver in certain cases.

##### 457. Operation and re-designation of New York state biomedical and biotechnological translational research and entrepreneurship initiative centers.

##### 458. Scientific research and discovery bank program.

##### 459. Unified contract.

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

§ 452. Definitions. As used in this article:

1. "Medical school" means a public or private medical school accredited by the liaison committee on medical education or the commission on osteopathic college accreditation, or such medical school and an affiliated entity, located in this state.

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

3. "Peer review committee" means the peer review committee created by the department and the department of health, consisting of scientific and research experts in biomedical and biotechnological development, and company representatives at the executive officer level engaged in making development, financing, and commercialization of biomedical and biotechnological research.

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

5. "Project" is the execution of an approved plan by a New York state biomedical and biotechnological translational research and entrepreneurship initiative center.

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

7. "State initiative committee" or "state committee" means the biomedical and biotechnological translational research and entrepreneurship initiative committee created by section four hundred fifty-three of this article.

1 8. "Translational research and entrepreneurship center" or "center" is  
2 the New York state biomedical and biotechnological translational  
3 research and entrepreneurship initiative center created at a medical  
4 school pursuant to this article.

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

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

22 1. Powers and duties. The committee shall:

23 (a) Establish guidelines appropriate to the activities required under  
24 this article.

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

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

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

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

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

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

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

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

51 (j) Identify statutory requirements that the committee views as imped-  
52 iments to successful implementation of approved plans, and as necessary,  
53 submit requests to the legislature in accordance with article VII of the  
54 state constitution for specific legislative enactments necessary to  
55 remove such impediments.

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

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

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

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

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

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

48 4. Leveraged and applied funding: a demonstration that the school  
49 already possesses or has a commitment for and will maintain during the  
50 plan period the required funding match ratio of at least two dollars for  
51 every state dollar provided pursuant to this article to an approved  
52 plan, and how the school will use other resources, partnerships, and  
53 collaborations to aid directly or indirectly in activities critical to  
54 the commercialization of research. Insofar as practicable, such matching  
55 funds should not consist of direct state grants from the department or  
56 from another state agency or state public authority, provided that noth-

ing in this subdivision shall be deemed to prohibit a medical school of the State University of New York which has been designated as a center from using a portion of its operating funds as matching funds.

5. Additional plans and programs: other plans and programs integral to the successful execution of the project, including but not limited to patent and intellectual property plans, training and educational programs, and educational integration with research and clinical activities.

6. Community support: a demonstration of community support from business and government leaders and organizations.

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

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

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

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

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

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

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

(a) scientific and technical merit;

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

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

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

(e) plans for protection of human subjects;

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



1 (g) appropriateness of institutional support, equipment, and other  
2 physical resources; and

3 (h) such other information as the state initiative committee shall  
4 require.

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

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

18 (a) the anticipated effectiveness of the plan as evidenced by the  
19 existence of available resources dedicated to the plan and the commit-  
20 ment of the medical school;

21 (b) the ability of the applicant to undertake and complete the plan,  
22 the feasibility of meeting the metrics and goals provided for determin-  
23 ing the success of the plan, the durability and extent of the relation-  
24 ships with incubators and hotspots, and with START-UP NY projects, and  
25 with private and other public collaborators;

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

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

31 (e) such other measurable criteria as shall be determined by the  
32 committee.

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

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

46 8. As soon as practicable after approving an application the committee  
47 shall notify the temporary president of the senate and the speaker of  
48 the assembly of its approval. Such notification shall identify the  
49 recipient and state the proposed location, the estimated project funding  
50 and award and provide a brief description of the project.

51 § 456. Waiver in certain cases. To promote innovative approaches and  
52 maximize effective use of public monies and the likelihood of success in  
53 operation of approved New York state biomedical and biotechnological  
54 translational research and entrepreneurship initiative centers, and  
55 notwithstanding any other provision of law, the commissioner or director  
56 of any state agency that is a member of the state initiative committee

1 may waive, upon application by such center and subject to the approval  
2 of the state initiative committee and the director of the budget, any of  
3 such agency's regulatory or procedural requirements that may impede the  
4 successful implementation of a project undertaken by the center,  
5 provided that such waiver is consistent with applicable state and feder-  
6 al statutes and will not impair the general health or welfare of the  
7 people receiving services under such project or others. Such commission-  
8 er or director shall be authorized, in consultation with the director of  
9 the budget, to impose appropriate alternative standards in place of any  
10 waived requirements.

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

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

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

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

40 § 458. Scientific research and discovery bank program. The scientific  
41 research and discovery bank program is hereby created, whose purpose  
42 shall be to provide funds to centers for recruitment of out of state and  
43 retention of in-state scientists and researchers necessary to the  
44 successful implementation of approved projects. Monies shall be made  
45 available to centers from funds appropriated for the purposes of this  
46 article, after review and upon approval by the state initiative commit-  
47 tee pursuant to a plan submitted by a center. Such plan may be submitted  
48 at the time of the application or at any time during the implementation  
49 of the multi-year approved plan and must demonstrate to the satisfaction  
50 of the committee that the center has or will have during the period of  
51 the grant a match of two dollars for every state dollar provided pursu-  
52 ant to this section. Plans must show the timeline and usage of funds  
53 required and such other information as the committee shall require,  
54 including: the need for such funds and the manner in which such award  
55 would enhance the research capabilities of the center necessary to  
56 successful implementation of the project plan; the ability of the

1 researcher to leverage and attract federal funds, venture capital and  
2 private industry funds; and the willingness of such researcher to pursue  
3 entrepreneurial enterprises resulting in new business or the expansion  
4 of existing business in this state. The committee shall establish a  
5 schedule for payment of the award. Funds provided pursuant to this  
6 section must be applied directly to necessary expenses for recruitment  
7 and retention of scientists and researchers, and may not be used for  
8 indirect or other overhead costs of the medical school. Insofar as prac-  
9 ticable, such matching funds should not consist of direct state grants  
10 from the department or from another state agency or state public author-  
11 ity, provided that nothing in this section shall be deemed to prohibit a  
12 medical school of the State University of New York which has been desig-  
13 nated as a center from using a portion of its operating funds as match-  
14 ing funds. Funds used for match may include reasonable administrative  
15 costs associated with out of state recruitment or in-state retention.

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

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

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

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

47 In addition to the foregoing requirements, a center shall agree to  
48 dedicate all funds from any support received pursuant to this article,  
49 except for funds received pursuant to paragraph (d) of subdivision one  
50 of this section, to operations of the center without deductions for  
51 overhead, indirect costs, or facilities and administration charges of  
52 the medical school, and to limit to ten percent or less the allocation  
53 of funds received through this article to administrative costs of the  
54 center.

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