## IN SENATE

## February 5, 2014

Introduced by Sens. GOLDEN, GALLIVAN, GRIFFO, HANNON, RANZENHOFER, ROBACH, TKACZYK, VALESKY -- 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:

Section 1. Intent. The legislature hereby finds and declares that a coordinated program of research, entrepreneurship, and public-private partnerships and collaborations, centered in and with the state's medical schools, can significantly increase the speed and amount of commercialization of research from lab to market, maintain the quality and increase the likelihood of high impact healthcare breakthroughs, and materially expand economic and job opportunities for all New Yorkers in this high growth sector.

The legislature further finds that although New York state's biomedical and biotechnological research infrastructure includes many of the nation's top institutions, researchers and scientists, and has many natural advantages compared to other states, it has lagged behind the nation as a whole and many states in growth in jobs, development, and economic activity for a decade; and further, that other states are making investments and developing incentives that are creating rapid growth in this sector and increasing the gap between New York and other states, and potential loss of top tier scientific and research talent as they migrate to other states in search of opportunity and professional advancement.

The legislature further finds that recent changes that have made New York's economic development programs more sophisticated and competitive can be combined with other approaches and statutory precedents to support and incentivize an effective and integrated plan for development of biomedical and biotechnological entrepreneurship by and through the state's medical schools, and declares that the program enacted by this

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

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act will expand economic activity and job development, maintain and attract high quality research, increase resources available to the schools and researchers from grants, private investments, and licensure, and leverage significant partnerships with public and private entities, to 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.

S 2. The economic development law is amended by adding a new article 22 to read as follows:

ARTICLE 22

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

SECTION 441. SHORT TITLE.

- 442. DEFINITIONS.
- 443. NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATION-AL RESEARCH AND ENTREPRENEURSHIP INITIATIVE COMMITTEE.
- 444. ADMINISTRATION.
- 445. APPLICATION FOR DESIGNATION AS A NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTRE-PRENEURSHIP INITIATIVE CENTER.
- 446. REVIEW AND APPROVAL OF APPLICATIONS.
- 447. WAIVER IN CERTAIN CASES.
- 448. OPERATION AND REDESIGNATION OF NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTRE-PRENEURSHIP INITIATIVE CENTERS.
- 449. SCIENTIFIC RESEARCH AND DISCOVERY BANK PROGRAM.
- 450. UNIFIED CONTRACT.
- 451. REPORT.
- S 441. SHORT TITLE. THIS ARTICLE SHALL BE KNOWN AND MAY BE CITED AS "THE NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE."
  - S 442. DEFINITIONS. AS USED IN THIS SECTION,
- 1. "MEDICAL SCHOOL" MEANS A PUBLIC OR PRIVATE MEDICAL SCHOOL 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 IN COLLABORATION WITH THE STATE INITIATIVE COMMITTEE, CONSISTING OF NON-NEW YORK STATE EXPERTS IN THE FIELDS OF BIOMEDICAL AND BIOTECHNOLOGICAL DEVELOPMENT, INCLUDING RESEARCHERS AND SCIENTISTS, AND COMPANY REPRESENTATIVES AT THE EXECUTIVE OFFICER LEVEL ENGAGED IN MAKING, DEVELOPMENT, AND FINANCING 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 BIOTECHNO-LOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTER.
- 5. "PROJECT" IS THE EXECUTION OF THE NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTER PLAN BY THE MEDICAL SCHOOL WHICH HAS BEEN DESIGNATED AS A NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTER.
- 6. "START-UP NY" PROGRAM MEANS THE START-UP NY PROGRAM AUTHORIZED PURSUANT TO ARTICLE TWENTY-ONE OF THIS CHAPTER, AND "TAX-FREE NY AREA" HAS THE SAME MEANING AS IN ARTICLE TWENTY-ONE OF THIS CHAPTER.

7. "STATE INITIATIVE COMMITTEE" MEANS THE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE COMMITTEE CREATED BY SECTION FOUR HUNDRED FORTY-THREE OF THIS ARTICLE.

- 8. "TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP CENTER" OR "CENTER" IS THE NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTER CREATED AT A MEDICAL SCHOOL UPON APPROVAL BY THE STATE INITIATIVE COMMITTEE PURSUANT TO THIS ARTICLE.
- 9. "UNIFIED CONTRACT" IS THE CONTRACT BETWEEN THE DEPARTMENT AND THE MEDICAL SCHOOL THAT INCLUDES ALL ITEMS NECESSARY TO THE EXECUTION AND ADMINISTRATION OF THE NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE PROJECT AS DESCRIBED IN THIS ARTICLE, INCLUDING FUNDING, ACTIVITIES, PERFORMANCE METRICS, DATA SHARING, AND OTHER ITEMS.
- S 443. NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE COMMITTEE. THE NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE COMMITTEE IS HEREBY CREATED, TO CONSIST OF THE COMMISSIONERS OF THE DEPARTMENTS OF HEALTH, EDUCATION, ECONOMIC DEVELOPMENT, LABOR, TAX AND FINANCE, THE CHANCELLOR OF THE STATE UNIVERSITY OF NEW YORK, THE PRESIDENT OF THE CHANCELLOR OF THE CITY UNIVERSITY OF NEW YORK, THE PRESIDENT OF THE EMPIRE STATE DEVELOPMENT CORPORATION, THE DIRECTOR OF THE DIVISION OF THE BUDGET, AND THE STATE COMPTROLLER. THE COMMITTEE SHALL BE CHAIRED BY THE COMMISSIONER OF ECONOMIC DEVELOPMENT, AND CO-CHAIRED BY THE COMMISSIONER OF HEALTH. COMMISSIONERS MAY BE REPRESENTED BY DESIGNEES AT MEETINGS OF THE COMMITTEE.
  - 1. POWERS AND DUTIES. THE COMMITTEE SHALL:
- (A) ESTABLISH GUIDELINES APPROPRIATE TO THE ACTIVITIES REQUIRED UNDER THIS ARTICLE.
- (B) ACCEPT AND REVIEW APPLICATIONS AND DESIGNATE MEDICAL SCHOOLS AS NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTERS USING THE CRITERIA ESTABLISHED IN THIS ARTICLE.
- (C) ACCEPT REQUESTS FOR AND APPROVE WAIVERS OF REGULATIONS AND PROCEDURES AS PROVIDED FOR IN SECTION FOUR HUNDRED FORTY-SIX OF THIS ARTICLE.
- (D) ESTABLISH A UNIFIED CONTRACT FOR ADMINISTRATION OF PROJECTS PURSUANT TO SECTION FOUR HUNDRED FIFTY OF THIS ARTICLE.
- (E) RECEIVE AND REVIEW REPORTS FROM CENTERS TO ASSURE THAT PERFORMANCE METRICS OF APPROVED PLANS ARE MET.
- (F) REDESIGNATE THE CENTERS EVERY THREE YEARS UNDER THE PROCEDURES ESTABLISHED PURSUANT TO THIS ARTICLE.
- (G) DEVELOP RESOURCES AND PROCEDURES TO AID IN ESTABLISHING A MORE RAPID PROCESS FOR COMMERCIALIZATION OF RESEARCH AND FUNDING OF ENTREPRENEURIAL EFFORTS CREATED AS A RESULT OF PROJECTS, INCLUDING BUT NOT LIMITED TO SUCH ACTIVITIES AS PROCUREMENT BY MEMBER AGENCIES OF THE COMMITTEE OF GOODS OR SERVICES FROM COMPANIES CREATED IN THE PROJECTS; ENDORSING, COLLABORATING, OR ACTING AS A CO-PRINCIPAL INVESTIGATOR OR OTHER LEVEL OF PARTICIPANT ON GRANTS OR OTHER ACTIVITIES THAT WILL AID IN FURTHERING PROJECT ACTIVITIES; AND SUCH OTHER APPLICATION OF THE RESOURCES OF THE STATE AND ITS AGENCIES TO RAPID COMMERCIALIZATION AS ARE PERMISSIBLE UNDER LAW.
- (H) OVERSEE AND MAKE RECOMMENDATIONS FOR APPROVAL OF APPLICATIONS TO THE SCIENTIFIC RESEARCH AND DISCOVERY BANK CREATED BY THIS ARTICLE FOR THE RECRUITMENT AND RETENTION OF STAR SCIENTISTS AND RESEARCHERS.
- (I) UPON REQUEST, PROVIDE TECHNICAL ASSISTANCE TO APPLICANTS, AND AS NEEDED FOR A PROJECT, INCLUDING BUT NOT LIMITED TO ASSISTANCE IN IDENTI-

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FYING AND OBTAINING RESOURCES AND FUNDING NECESSARY FOR THE SUCCESSFUL IMPLEMENTATION OF THE PLAN.

- (J) IDENTIFY STATUTORY REQUIREMENTS THAT THE COMMITTEE VIEWS AS IMPEDIMENTS TO SUCCESSFUL IMPLEMENTATION OF APPROVED PLANS AND, AS NECESSARY, SUBMIT REQUESTS TO THE LEGISLATURE IN ACCORDANCE WITH ARTICLE VII OF THE STATE CONSTITUTION FOR SPECIFIC LEGISLATIVE ENACTMENTS NECESSARY TO REMOVE SUCH IMPEDIMENTS.
- (K) ENTER INTO AGREEMENTS BETWEEN AND AMONG THE MEMBERS OF THE COMMITTEE AS NECESSARY TO DELINEATE THEIR RESPECTIVE ROLES REGARDING THE COOPERATIVE PROVISION OF PROGRAM FUNDING AND TECHNICAL ASSISTANCE.
- (L) REQUIRE SUCH ADDITIONAL REPORTS, INFORMATION, OR OVERSIGHT AS MAY BE NECESSARY TO THE SUCCESSFUL IMPLEMENTATION OF A PROJECT.
- 2. THE COMMITTEE MAY ACT THROUGH ITS CHAIRS IN ALL MATTERS OF OVERSIGHT AND IMPLEMENTATION OF THE PROGRAM AUTHORIZED BY THIS ARTICLE, INCLUDING RECEIPT OF APPLICATIONS, NOTIFICATION OF DESIGNATION, AND MONITORING OF APPROVED CENTERS TO ENSURE THAT SERVICES ARE PROVIDED IN ACCORDANCE WITH THE APPROVED PLAN AND THAT FUNDS ARE USED IN ACCORDANCE WITH APPLICABLE STATE AND FEDERAL LAW AND REGULATIONS.
- S 444. ADMINISTRATION. EXCEPT WHERE OTHERWISE PRESCRIBED, THE DEPART-MENT SHALL BE RESPONSIBLE FOR THE ADMINISTRATION OF THE PROVISIONS OF THIS ARTICLE.
- S 445. APPLICATION FOR DESIGNATION AS A NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTER. IN RESPONSE TO A REQUEST FOR PROPOSALS, A MEDICAL SCHOOL MAY APPLY FOR FUNDING AND DESIGNATION AS A NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTER BY SUBMITTING AN APPLICATION AND PLAN TO THE COMMISSIONER. THE COMMISSIONER SHALL FORWARD ALL SUCH PLANS TO THE PEER REVIEW COMMITTEE FOR ASSESSMENT AS HEREIN PROVIDED, AND THEN TO THE STATE INITIATIVE COMMITTEE. IN ADDITION TO SUCH OTHER ITEMS, WARRANTIES, AND INFORMATION AS THE STATE INITIATIVE COMMITTEE MAY REQUIRE, PLANS MUST SHOW AN INTEGRATED VISION FOR COMMERCIALIZING RESEARCH FROM LAB TO MARKETPLACE INCLUDING AN INTERRELATED DEMONSTRATION OF THE FOLLOWING:
- 1. COMMITMENT: A MULTI-YEAR COMMITMENT BY THE MEDICAL SCHOOL TO DEVELOPMENT AND IMPLEMENTATION OF THE PLAN, OVER A PERIOD OF NOT LESS THAN FIVE YEARS, SUCH COMMITMENT TO BE DEMONSTRATED BY A MULTI-YEAR COMMITMENT OF RESOURCES, PERSONNEL, AND FUNDS THAT THE SCHOOL WILL USE, DIRECTLY OR THROUGH PARTNERSHIPS AND COLLABORATIONS, TO PROVIDE AND/OR INCENTIVIZE INTEGRATED RESEARCH, EDUCATION, CLINICAL PRACTICE, ENTREPRENEURSHIP, FINANCING, PARTNERSHIPS, AND MORE RAPID COMMERCIALIZATION OF RESEARCH.
- 2. RESOURCES: A DESCRIPTION OF THE ACTIONS AND RESOURCES NECESSARY TO MEET THE PLAN OBJECTIVES OVER ITS DURATION; A DEMONSTRATION THAT THE MEDICAL SCHOOL HAS EXISTING OPERATIONAL CLINICAL FACILITIES AND EXPERTISE OR EVIDENCE OF BONA FIDE COLLABORATIONS AND PARTNERSHIPS THAT CAN PROVIDE SUCH FACILITIES AND EXPERTISE SUFFICIENT TO SUCCESSFULLY IMPLEMENT THE PLAN; A DEMONSTRATION THAT THE PROJECT WILL HAVE A PROFESSIONAL MANAGEMENT TEAM WITH EXPERIENCE, EXPERTISE, OR CREDENTIALS IN MANAGEMENT, ENTREPRENEURSHIP, BUSINESS DEVELOPMENT, OR OTHER EQUIVALENT AREAS. THE DEMONSTRATION MAY INCLUDE RECRUITMENT PLANS OR COMMITMENTS FOR HIGH LEVEL RESEARCH PROFESSIONALS, INCLUDING HOW THE SCHOOL WOULD MAKE USE OF THE SCIENTIFIC RESEARCH AND DISCOVERY BANK.
- 3. ENTREPRENEURIAL AND RESEARCH COLLABORATIONS: EVIDENCE INCLUDING WRITTEN PROTOCOLS OF BONA FIDE RELATIONS WITH ONE OR MORE INCUBATORS AND HOTSPOTS, FOR PROVISION OF ENTREPRENEURIAL SERVICES TO RESEARCHERS, WITH A START-UP NY TAX-FREE NY PROGRAM AREA TO PROVIDE LOCATION AND SERVICES

AS NEEDED FOR SUCH RESEARCHERS AND ACTIVITIES, AND SUBSTANTIVE COLLAB-ORATIONS WITH PRIVATE ENTITIES FOR TRAINING, COMMERCIALIZATION, FINANC-ING, OR OTHER ACTIVITIES INTEGRAL TO THE PLAN.

- 4. LEVERAGED AND APPLIED FUNDING: A DEMONSTRATION THAT THE SCHOOL HAS IN HAND OR WILL SHORTLY OBTAIN AND MAINTAIN DURING THE PLAN PERIOD THE REQUIRED FUNDING MATCH OF AT LEAST TWO NON-STATE DOLLARS FOR EVERY STATE DOLLAR PROVIDED PURSUANT TO THIS ARTICLE TO AN APPROVED PLAN. THE PLAN SHOULD INCLUDE A DEMONSTRATION OF HOW THE SCHOOL WOULD USE TAX CREDITS, PUBLIC FUNDS, OR OTHER INCENTIVES TO AID DIRECTLY OR INDIRECTLY IN DEVELOPMENT OF INVESTMENT VEHICLES FOR RESEARCHERS, AND TO ENGAGE IN ACTIVITIES CRITICAL TO THE COMMERCIALIZATION OF RESEARCH. SUCH FUNDING AND COLLABORATIONS SHOULD ALSO SHOW HOW THE CENTER HAS OR WILL DEVELOP LEVERAGED CREATIVE PARTNERSHIPS TO PROVIDE ANGEL, SEED, PRE-SEED, AND OTHER INVESTMENTS TO HELP EACH STAGE OF PRODUCT DEVELOPMENT, EVIDENCED BY WRITTEN AGREEMENTS, MEMORANDUMS OF UNDERSTANDING, LETTERS OF INTENT, OR OTHER ENDORSEMENTS ACCEPTABLE TO THE COMMITTEE.
- 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 JOBS, INVESTMENT, AND ECONOMIC AND OTHER ACTIVITY, STATED IN A SPECIFIC AND MEASURABLE WAY THAT IS ACHIEVABLE AND REALISTIC WITHIN THE PROJECT TIME FRAME AND THAT CAN BE QUANTIFIED AND COMPARED TO OTHER DATA FOR ANALYSIS.
- 9. ADVISORY COUNCIL: AN INDEPENDENT ADVISORY COUNCIL 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.
- S 446. REVIEW AND APPROVAL OF APPLICATIONS. REVIEW OF APPLICATIONS SHALL TAKE PLACE IN TWO STAGES, FIRST BY THE PEER REVIEW COMMITTEE AND THEN BY THE STATE INITIATIVE COMMITTEE WHICH SHALL HAVE SOLE POWER TO APPROVE AN APPLICATION, AS FOLLOWS:
- 1. THE COMMISSIONER SHALL REVIEW APPLICATIONS AND PLANS RECEIVED FOR COMPLETENESS, AND THEN FORWARD THEM TO THE PEER REVIEW COMMITTEE, AND TO THE STATE INITIATIVE COMMITTEE FOR ITS REVIEW AND FINAL DETERMINATION ONLY AFTER REVIEW BY THE PEER REVIEW COMMITTEE. NO PLANS SHALL BE APPROVED BY THE STATE INITIATIVE COMMITTEE UNTIL REVIEWED 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 CO-CHAIR OF THE STATE INITIATIVE COMMITTEE USING GUIDE-LINES 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.

- 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 INVESTIGATORS, 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;
- (G) APPROPRIATENESS OF INSTITUTIONAL SUPPORT, EQUIPMENT, AND OTHER PHYSICAL RESOURCES; AND
- (H) SUCH OTHER INFORMATION AS THE STATE INITIATIVE COMMITTEE SHALL REQUIRE.
- 4. AN APPLICATION RECEIVING A LOW SCORE BY THE PEER REVIEW COMMITTEE BASED ON THE CRITERIA IN SUBDIVISION THREE OF THIS SECTION, OR WHICH LACKS SIGNIFICANT AND SUBSTANTIAL MERIT, OR WHICH PRESENTS IN THE VIEW OF THE PEER REVIEW COMMITTEE SERIOUS ETHICAL PROBLEMS IN THE PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISKS, OR OTHER SERIOUS ETHICAL PROBLEMS, SHALL BE DESIGNATED NOT RECOMMENDED FOR FURTHER CONSIDERATION (NRFC). SUCH PLANS SHALL BE RETURNED TO THE COMMISSIONER AND BY THE COMMISSIONER TO THE STATE INITIATIVE COMMITTEE WITH WRITTEN RECOMMENDATIONS FOR CHANGE. THE STATE INITIATIVE COMMITTEE SHALL REVIEW SUCH RECOMMENDATIONS, AND MAY ADD TO THEM, PRIOR TO RETURNING THEM TO THE APPLICANTS.
- 5. THE STATE INITIATIVE COMMITTEE WILL REVIEW ALL ASPECTS OF THE APPLICATIONS AND PLANS SUBMITTED TO IT AND RECOMMEND CHANGES AND DETERMINE FUNDING LEVELS AND SOURCES TO BE INCLUDED IN THE UNIFIED CONTRACT IF THE APPLICATION IS APPROVED. THE COMMITTEE WILL TAKE INTO CONSIDERATION THE REVIEW OF THE PEER REVIEW COMMITTEE, AND SHALL NOT APPROVE A PLAN DESIGNATED BY THE PEER REVIEW COMMITTEE AS NOT RECOMMENDED FOR FURTHER CONSIDERATION (NRFC), BUT MAY ADD ITS OWN COMMENTS PRIOR TO RETURNING IT TO THE APPLICANT MEDICAL SCHOOL.
- 6. THE STATE INITIATIVE COMMITTEE SHALL REVIEW AND SCORE PLANS BASED ON THE CATEGORIES REQUIRED IN THE APPLICATION PURSUANT TO SECTION FOUR HUNDRED FORTY-FIVE OF THIS ARTICLE, AND INCLUDING THE FOLLOWING:
- (A) THE ANTICIPATED EFFECTIVENESS OF THE PLAN AS EVIDENCED BY THE EXISTENCE OF AVAILABLE RESOURCES DEDICATED TO THE PLAN AND THE COMMITMENT OF THE MEDICAL SCHOOL;
- (B) THE ABILITY OF THE APPLICANT TO UNDERTAKE AND COMPLETE THE PLAN, THE FEASIBILITY OF MEETING THE METRICS AND GOALS PROVIDED FOR DETERMINING THE SUCCESS OF THE PLAN, THE DURABILITY AND REACH OF THE COLLABORATIONS AND RELATIONSHIPS WITH INCUBATORS AND HOTSPOTS, AND WITH START-UP-NY PROJECTS, AND WITH PRIVATE AND OTHER PUBLIC COLLABORATORS;
- (C) THE ABILITY OF THE APPLICANT TO PROVIDE THE NECESSARY DATA FOR AN EFFECTIVE EVALUATION OF THE PROJECT; AND
- 54 (D) SUCH OTHER OBJECTIVE AND MEASURABLE CRITERIA AS SHALL BE DETER-55 MINED BY THE COMMITTEE.

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7. PLANS DESIGNATED AS NOT RECOMMENDED FOR FURTHER CONSIDERATION (NRFC) BY THE PEER REVIEW COMMITTEE OR THE STATE INITIATIVE COMMITTEE SHALL BE RETURNED TO THE APPLICANT WITH RECOMMENDATIONS FOR AMENDMENT AND MAY BE RESUBMITTED IN THE FOLLOWING YEAR.

- 8. INSOFAR AS PRACTICABLE, IN APPROVING APPLICATIONS, THE COMMITTEE SHALL SEEK TO PROVIDE A GEOGRAPHICALLY BALANCED DISTRIBUTION OF NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTERS AMONG THE REGIONS OF THE STATE.
- 9. NOT MORE THAN FORTY PERCENT OF FUNDS APPROPRIATED PURSUANT TO THIS ARTICLE SHALL BE USED FOR ANY SINGLE PROJECT.
  - 10. AS SOON AS PRACTICABLE AFTER APPROVING AN APPLICATION THE COMMITTEE SHALL NOTIFY THE TEMPORARY PRESIDENT OF THE SENATE AND THE SPEAKER OF THE ASSEMBLY OF ITS APPROVAL. SUCH NOTIFICATION SHALL IDENTIFY THE RECIPIENT AND STATE THE PROPOSED LOCATION, THE ESTIMATED PROJECT FUNDING AND AWARD AND A BRIEF DESCRIPTION OF THE PROJECT.
- 447. WAIVER IN CERTAIN CASES. TO PROMOTE INNOVATIVE APPROACHES AND MAXIMIZE EFFECTIVE USE OF PUBLIC MONIES AND THE LIKELIHOOD OF SUCCESS IN OPERATION OF APPROVED NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTERS, AND NOTWITHSTANDING ANY OTHER PROVISION OF LAW, THE COMMISSIONER OR DIRECTOR OF ANY STATE AGENCY THAT IS A MEMBER OF THE STATE INITIATIVE COMMITTEE WAIVE, UPON APPLICATION BY SUCH CENTER AND SUBJECT TO THE APPROVAL OF THE STATE INITIATIVE COMMITTEE AND THE DIRECTOR OF THE BUDGET, ANY OF SUCH AGENCY'S REGULATORY REQUIREMENTS THAT MAY IMPEDE THE SUCCESSFUL IMPLEMENTATION OF A PROJECT UNDERTAKEN PURSUANT TO THE APPROVED PLAN BY THE CENTER, PROVIDED THAT SUCH WAIVER IS CONSISTENT WITH APPLICABLE AND FEDERAL STATUTES AND WILL NOT IMPAIR THE GENERAL HEALTH OR STATE WELFARE OF THE PEOPLE RECEIVING SERVICES UNDER SUCH PROJECT OR OTHERS. SUCH COMMISSIONER OR DIRECTOR SHALL BE AUTHORIZED, IN CONSULTATION WITH THE DIRECTOR OF THE BUDGET, TO IMPOSE APPROPRIATE ALTERNATIVE STANDARDS IN PLACE OF ANY WAIVED REQUIREMENTS.
- S 448. OPERATION AND REDESIGNATION OF NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTERS. IN ADDITION TO ANY OTHER REQUIREMENTS OF THIS ARTICLE, A CENTER WILL AGREE TO MEET ALL REQUIREMENTS CONCERNING EXECUTION AND IMPLEMENTATION OF AN APPROVED PLAN FOR ITS PROJECT, TO MAINTAIN BEST PRACTICES, AND TO REPORT DATA AS REQUESTED OR REQUIRED TO THE DEPARTMENT AND/OR THE STATE INITIATIVE COMMITTEE USING APPROPRIATE CONFIDENTIALITY PROTOCOLS IN THE CASE OF BUSINESS OR TRADE SECRETS. SUCH DATA WILL INCLUDE A DEMONSTRATION OF THE SUCCESS IN MEETING PROJECT PLAN GOALS, INCLUDING YEAR BY YEAR COMPARISON OF RESEARCH ACTIVITY AND COMMERCIALIZATION THEREOF, FIRM FINANCING AND EQUITY CAPITAL RAISED, PROVIDED OR LEVERAGED FROM ALL SOURCES, PERSONNEL EMPLOYED ON THE PROJECT, AND JOBS CREATED BY AND THROUGH THE PROJECT. THE DEPARTMENT SHALL DESIGN SIMPLIFIED FORMS TO AID IN THE SUBMISSION OF SUCH DATA, WHICH MAY BE SUBMITTED ELECTRONICALLY.

47 THE COMMISSIONER ON BEHALF OF THE STATE INITIATIVE COMMITTEE SHALL 48 EVALUATE AND REPORT ON THE OPERATIONS OF THE CENTER USING METHODS 49 INCLUDING BUT NOT LIMITED TO SITE VISITS, REPORTS PURSUANT TO SPECIFIED 50 INFORMATION, AND REVIEW EVALUATIONS. IF THE STATE INITIATIVE COMMITTEE UNSATISFIED WITH THE PROGRESS OF A PROJECT, THE COMMISSIONER SHALL 51 NOTIFY SUCH CENTER OF THE RESULTS OF THE EVALUATIONS AND ANY FINDINGS OF DEFICIENCIES IN ITS OPERATIONS AND SHALL COOPERATE WITH SUCH CENTER 53 54 REMEDY SUCH FINDINGS IN A TIMELY MANNER. SUCH EVALUATIONS SHALL INCLUDE PEER REVIEW AND SHALL TAKE PLACE NO LESS THAN ONCE EVERY THREE YEARS 56 OFTEN FOR ANY INDIVIDUAL CENTER AT THE DISCRETION OF THE STATE MORE

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INITIATIVE COMMITTEE. SUCH PEER REVIEW SHALL RESULT IN A WRITTEN REPORT THAT INCLUDES PROGRAMMATIC AND FISCAL EVALUATION OF THE PROJECT AND RECOMMENDATIONS FOR IMPROVEMENT. MEMBERS OF SUCH PEER REVIEW GROUP SHALL BE CHOSEN IN THE SAME WAY AND HAVE THE SAME QUALIFICATIONS AS MEMBERS OF THE PEER REVIEW COMMITTEE.

FAILURE TO ABIDE BY THE REQUIREMENTS OF THIS SECTION OR TO CURE A DEFAULT AFTER REVIEW AND AGREEMENT WITH THE STATE INITIATIVE COMMITTEE SHALL RESULT IN DISQUALIFICATION AS A NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTER.

A CENTER SHALL BE DEEMED REDESIGNATED UPON APPLICATION EVERY THREE YEARS UNLESS IT SHALL RECEIVE A NEGATIVE EVALUATION FROM THE PEER REVIEW GROUP FOLLOWED BY A DETERMINATION BY THE STATE INITIATIVE COMMITTEE NOT TO REDESIGNATE THE CENTER BASED ON SUCH EVALUATION AND FAILURE TO REMEDY DEFECTS OR A DETERMINATION BY THE COMMITTEE THAT SUCH DEFECTS ARE OF SUCH A NATURE OR ARE OF SUCH EXTENT THAT THEY CANNOT BE REMEDIED.

S 449. SCIENTIFIC RESEARCH AND DISCOVERY BANK PROGRAM. THE SCIENTIFIC RESEARCH AND DISCOVERY BANK PROGRAM IS HEREBY CREATED, WHOSE PURPOSE SHALL BE TO PROVIDE FUNDS TO CENTERS FOR RECRUITMENT AND RETENTION OF SCIENTISTS AND RESEARCHERS NECESSARY TO THE SUCCESSFUL IMPLEMENTATION OF PROJECTS APPROVED PURSUANT TO THIS ARTICLE. MONIES SHALL BE MADE AVAIL-TO CENTERS FROM FUNDS APPROPRIATED PURSUANT TO THIS ARTICLE, AFTER REVIEW AND UPON APPROVAL BY THE STATE INITIATIVE COMMITTEE PURSUANT TO A PLAN SUBMITTED BY A CENTER. SUCH PLAN MUST DEMONSTRATE TO THE SATISFAC-TION OF THE COMMITTEE THAT THE CENTER HAS OR WILL HAVE DURING THE PERIOD THE GRANT A MATCH OF TWO NON-STATE DOLLARS FOR EVERY STATE DOLLAR PROVIDED PURSUANT TO THIS SUBDIVISION. PLANS MUST SHOW THE TIME-LINE AND USAGE OF FUNDS REQUIRED AND SUCH OTHER INFORMATION AS THECOMMITTEE SHALL REOUIRE, INCLUDING: THE NEED FOR SUCH FUNDS AND THE MANNER IN WHICH SUCH AWARD WOULD ENHANCE THE RESEARCH CAPABILITIES OF THE CENTER NECESSARY TO SUCCESSFUL IMPLEMENTATION OF THE PROJECT PLAN; THE ABILITY OF THE RESEARCHER TO LEVERAGE AND ATTRACT FEDERAL FUNDS, VENTURE CAPITAL AND PRIVATE INDUSTRY FUNDS; AND THE WILLINGNESS OF SUCH RESEARCHER TO PURSUE ENTREPRENEURIAL ENTERPRISES RESULTING IN NEW BUSINESS OR THE EXPANSION OF EXISTING BUSINESS IN THIS STATE. THE COMMITTEE SHALL ESTAB-LISH A SCHEDULE FOR PAYMENT OF THE AWARD. FUNDS PROVIDED PURSUANT THIS SECTION MUST BE APPLIED DIRECTLY TO NECESSARY EXPENSES FOR RECRUIT-MENT AND RETENTION OF SCIENTISTS AND RESEARCHERS, AND MAY NOT BE USED FOR INDIRECT OR OTHER OVERHEAD COSTS OF THE MEDICAL SCHOOL.

40 S 450. UNIFIED CONTRACT. THE COMMISSIONER ON BEHALF OF INITIATIVE COMMITTEE SHALL ENTER INTO A UNIFIED CONTRACT WITH EACH 41 CENTER. THE PROVISIONS OF SUCH CONTRACT SHALL INCLUDE, BUT NOT BE LIMIT-42 43 ED TO: A DESCRIPTION OF PROJECT SERVICES AND ACTIVITIES; THE ALLOWABLE PROJECT COSTS; SPECIFIC SOURCES OF FUNDS THAT WILL SUPPORT THE 45 APPROVED COSTS, INCLUDING GOVERNMENTAL AND NON-GOVERNMENTAL FUNDS OR REVENUES THAT ARE PROPOSED TO BE USED IN SUPPORT OF PROJECT COSTS, AND 47 ALLOCATION OF COSTS BY FUNDING SOURCE. THE FORM OF SUCH UNIFIED 48 CONTRACT SHALL BE DEVELOPED IN CONSULTATION WITH THE DIVISION OF 49 BUDGET AND THE DEPARTMENT OF AUDIT AND CONTROL. THE COMPTROLLER IS 50 AUTHORIZED PURSUANT TO A CERTIFICATE OF ALLOCATION SUBMITTED BY DIVISION OF THE BUDGET TO INTERCHANGE OR TRANSFER FROM APPROPRIATIONS 51 MADE TO THE AGENCIES OF THE COMMITTEE OR ANY OTHER APPROPRIATION, AS APPROPRIATE, SUCH AMOUNTS AS MAY BE REQUIRED TO FULFILL THE OBLIGATIONS 53 54 OF THE STATE PURSUANT TO SUCH UNIFIED CONTRACTS FOR PAYMENT OF SUCH 55 OBLIGATIONS. THE DIVISION OF THE BUDGET SHALL PROVIDE THE CHAIRMEN OF THE SENATE FINANCE COMMITTEE AND THE ASSEMBLY WAYS AND MEANS COMMITTEE

1 WITH QUARTERLY REPORTS OF ALL INTERCHANGES AND TRANSFERS WHICH OCCUR 2 PURSUANT TO THIS SUBDIVISION.

- 1. ALLOWABLE COSTS FOR A PROJECT SHALL INCLUDE, BUT NOT BE LIMITED TO COSTS REASONABLY INCURRED FOR:
  - (A) PREPARATION OF THE PLAN;

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- (B) ACTIVITIES AS APPROVED IN THE PROJECT APPLICATION;
- (C) EVALUATION OF THE APPROVED PROJECT; AND
- (D) RENOVATIONS TO EXISTING STRUCTURES AS MAY BE NEEDED IN FURTHERANCE OF THE PLAN, EXCEPT THAT IN NO CASE SHALL THE STATE SUPPORT OF SUCH COSTS EXCEED EITHER TWENTY-FIVE PERCENT OF THE AMOUNT TO BE PROVIDED PURSUANT TO THE CONTRACT OR FIFTY PERCENT OF THE TOTAL RENOVATION COSTS, WHICHEVER IS LESS.
- 2. FUNDING MADE AVAILABLE THROUGH THE CONTRACT SHALL NOT BE USED TO SUPPLANT OTHER FUNDS.
- 3. IN ADDITION TO THE FOREGOING REQUIREMENTS, A CENTER SHALL AGREE TO DEDICATE ALL FUNDS FROM ANY SUPPORT RECEIVED PURSUANT TO THIS ARTICLE, EXCEPT FOR FUNDS RECEIVED PURSUANT TO PARAGRAPH D OF SUBDIVISION ONE OF THIS SECTION, TO OPERATIONS OF THE CENTER WITHOUT DEDUCTIONS FOR OVERHEAD, INDIRECT COSTS, OR FACILITIES AND ADMINISTRATION CHARGES OF THE MEDICAL SCHOOL, AND TO LIMIT TO TEN PERCENT OR LESS THE ALLOCATION OF FUNDS RECEIVED THROUGH THIS ARTICLE TO ADMINISTRATIVE COSTS OF THE CENTER.
- S 451. REPORT. THE COMMISSIONER ON BEHALF OF THE COMMITTEE SHALL ISSUE AN ANNUAL REPORT TO THE PUBLIC, BEGINNING AT THE CONCLUSION OF THE FIRST FULL CALENDAR YEAR AFTER THIS ARTICLE SHALL HAVE BECOME LAW, WHICH SETS FORTH THE ACTIVITIES UNDERTAKEN PURSUANT TO THIS ARTICLE, INCLUDING THE NAMES OF APPROVED PLANS AND THE CENTER SPONSORS, AND THE FOCUS OF RESEARCH ACTIVITIES IN EACH SUCH PLAN; THE METRICS FOR EACH APPROVED PLAN; GRANTS AWARDED, GRANTS IN PROGRESS, AND RESEARCH AND ENTREPRENEU-RIAL ACCOMPLISHMENTS; FINANCING FROM EXTERNAL SOURCES FOR BRINGING PRODUCTS TO MARKET; THE PROJECTED NUMBER OF JOBS AND COMPANIES TO BE CREATED PURSUANT TO APPROVED PLANS AND THE ACTUAL NUMBER CREATED; ACTIV-ITY UNDER THE DISCOVERY BANK CREATED PURSUANT TO THIS ARTICLE; A SUMMARY FUNDING PROVIDED PURSUANT TO THE UNIFIED CONTRACTS EXECUTED PURSUANT TO THIS ARTICLE; WAIVERS GRANTED PURSUANT TO THE AUTHORITY PROVIDED UNDER THIS ARTICLE AND ACTIVITY UNDERTAKEN UNDER SUCH WAIVER; AND THE NUMBER OF AND REASONS WHY PROJECTS WERE DEEMED NOT RECOMMENDED FOR FURTHER CONSIDERATION.
- 39 S 3. This act shall take effect on the first of September next 40 succeeding the date on which it shall have become a law.