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I N S E N A T E

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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:

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

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

20 The legislature further finds that recent changes that have made New
21 York's economic development programs more sophisticated and competitive
22 can be combined with other approaches and statutory precedents to
23 support and incentivize an effective and integrated plan for development
24 of biomedical and biotechnological entrepreneurship by and through the
25 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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1 act will expand economic activity and job development, maintain and
2 attract high quality research, increase resources available to the
3 schools and researchers from grants, private investments, and licensure,
4 and leverage significant partnerships with public and private entities,
5 to increase the speed of commercialization of research and the expansion
6 of economic opportunity, which are in every sense to the benefit of the
7 people of this state.

8 S 2. The economic development law is amended by adding a new article
9 22 to read as follows:

10 ARTICLE 22

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

13 SECTION 441. SHORT TITLE.

14 442. DEFINITIONS.

15 443. NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATION-
16 AL RESEARCH AND ENTREPRENEURSHIP INITIATIVE COMMITTEE.

17 444. ADMINISTRATION.

18 445. APPLICATION FOR DESIGNATION AS A NEW YORK STATE BIOMEDICAL
19 AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTRE-
20 PRENEURSHIP INITIATIVE CENTER.

21 446. REVIEW AND APPROVAL OF APPLICATIONS.

22 447. WAIVER IN CERTAIN CASES.

23 448. OPERATION AND REDESIGNATION OF NEW YORK STATE BIOMEDICAL
24 AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTRE-
25 PRENEURSHIP INITIATIVE CENTERS.

26 449. SCIENTIFIC RESEARCH AND DISCOVERY BANK PROGRAM.

27 450. UNIFIED CONTRACT.

28 451. REPORT.

29 S 441. SHORT TITLE. THIS ARTICLE SHALL BE KNOWN AND MAY BE CITED AS
30 "THE NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL
31 RESEARCH AND ENTREPRENEURSHIP INITIATIVE."

32 S 442. DEFINITIONS. AS USED IN THIS SECTION,

33 1. "MEDICAL SCHOOL" MEANS A PUBLIC OR PRIVATE MEDICAL SCHOOL LOCATED
34 IN THIS STATE.

35 2. "NEW YORK STATE INCUBATORS" AND "NEW YORK STATE INNOVATION
36 HOTSPOTS" OR "INCUBATORS" AND "HOTSPOTS" MEAN AND REFER TO "NEW YORK
37 STATE INCUBATORS" AND "NEW YORK STATE INNOVATION HOTSPOTS" DESIGNATED
38 PURSUANT TO SECTION SIXTEEN-V OF THE URBAN DEVELOPMENT CORPORATION ACT.

39 3. "PEER REVIEW COMMITTEE" MEANS THE PEER REVIEW COMMITTEE CREATED BY
40 THE DEPARTMENT IN COLLABORATION WITH THE STATE INITIATIVE COMMITTEE,
41 CONSISTING OF NON-NEW YORK STATE EXPERTS IN THE FIELDS OF BIOMEDICAL AND
42 BIOTECHNOLOGICAL DEVELOPMENT, INCLUDING RESEARCHERS AND SCIENTISTS, AND
43 COMPANY REPRESENTATIVES AT THE EXECUTIVE OFFICER LEVEL ENGAGED IN
44 MAKING, DEVELOPMENT, AND FINANCING OF BIOMEDICAL AND BIOTECHNOLOGICAL
45 RESEARCH.

46 4. "PLAN" MEANS THE MULTI-YEAR PLAN THAT ACCOMPANIES THE APPLICATION
47 OF A MEDICAL SCHOOL TO BECOME A NEW YORK STATE BIOMEDICAL AND BIOTECHNO-
48 LOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTER.

49 5. "PROJECT" IS THE EXECUTION OF THE NEW YORK STATE BIOMEDICAL AND
50 BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE
51 CENTER PLAN BY THE MEDICAL SCHOOL WHICH HAS BEEN DESIGNATED AS A NEW
52 YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND
53 ENTREPRENEURSHIP INITIATIVE CENTER.

54 6. "START-UP NY" PROGRAM MEANS THE START-UP NY PROGRAM AUTHORIZED
55 PURSUANT TO ARTICLE TWENTY-ONE OF THIS CHAPTER, AND "TAX-FREE NY AREA"
56 HAS THE SAME MEANING AS IN ARTICLE TWENTY-ONE OF THIS CHAPTER.

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

4 8. "TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP CENTER" OR "CENTER" IS
5 THE NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL
6 RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTER CREATED AT A MEDICAL
7 SCHOOL UPON APPROVAL BY THE STATE INITIATIVE COMMITTEE PURSUANT TO THIS
8 ARTICLE.

9 9. "UNIFIED CONTRACT" IS THE CONTRACT BETWEEN THE DEPARTMENT AND THE
10 MEDICAL SCHOOL THAT INCLUDES ALL ITEMS NECESSARY TO THE EXECUTION AND
11 ADMINISTRATION OF THE NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL
12 TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE PROJECT AS
13 DESCRIBED IN THIS ARTICLE, INCLUDING FUNDING, ACTIVITIES, PERFORMANCE
14 METRICS, DATA SHARING, AND OTHER ITEMS.

15 S 443. NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL
16 RESEARCH AND ENTREPRENEURSHIP INITIATIVE COMMITTEE. THE NEW YORK STATE
17 BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEUR-
18 SHIP INITIATIVE COMMITTEE IS HEREBY CREATED, TO CONSIST OF THE COMMIS-
19 SIONERS OF THE DEPARTMENTS OF HEALTH, EDUCATION, ECONOMIC DEVELOPMENT,
20 LABOR, TAX AND FINANCE, THE CHANCELLOR OF THE STATE UNIVERSITY OF NEW
21 YORK, THE CHANCELLOR OF THE CITY UNIVERSITY OF NEW YORK, THE PRESIDENT
22 OF THE EMPIRE STATE DEVELOPMENT CORPORATION, THE DIRECTOR OF THE DIVI-
23 SION OF THE BUDGET, AND THE STATE COMPTROLLER. THE COMMITTEE SHALL BE
24 CHAIRED BY THE COMMISSIONER OF ECONOMIC DEVELOPMENT, AND CO-CHAIRED BY
25 THE COMMISSIONER OF HEALTH. COMMISSIONERS MAY BE REPRESENTED BY DESIG-
26 NEES AT MEETINGS OF THE COMMITTEE.

27 1. POWERS AND DUTIES. THE COMMITTEE SHALL:

28 (A) ESTABLISH GUIDELINES APPROPRIATE TO THE ACTIVITIES REQUIRED UNDER
29 THIS ARTICLE.

30 (B) ACCEPT AND REVIEW APPLICATIONS AND DESIGNATE MEDICAL SCHOOLS AS
31 NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH
32 AND ENTREPRENEURSHIP INITIATIVE CENTERS USING THE CRITERIA ESTABLISHED
33 IN THIS ARTICLE.

34 (C) ACCEPT REQUESTS FOR AND APPROVE WAIVERS OF REGULATIONS AND PROCE-
35 DURES AS PROVIDED FOR IN SECTION FOUR HUNDRED FORTY-SIX OF THIS ARTICLE.

36 (D) ESTABLISH A UNIFIED CONTRACT FOR ADMINISTRATION OF PROJECTS PURSU-
37 ANT TO SECTION FOUR HUNDRED FIFTY OF THIS ARTICLE.

38 (E) RECEIVE AND REVIEW REPORTS FROM CENTERS TO ASSURE THAT PERFORMANCE
39 METRICS OF APPROVED PLANS ARE MET.

40 (F) REDESIGNATE THE CENTERS EVERY THREE YEARS UNDER THE PROCEDURES
41 ESTABLISHED PURSUANT TO THIS ARTICLE.

42 (G) DEVELOP RESOURCES AND PROCEDURES TO AID IN ESTABLISHING A MORE
43 RAPID PROCESS FOR COMMERCIALIZATION OF RESEARCH AND FUNDING OF ENTREPRE-
44 NEURIAL EFFORTS CREATED AS A RESULT OF PROJECTS, INCLUDING BUT NOT
45 LIMITED TO SUCH ACTIVITIES AS PROCUREMENT BY MEMBER AGENCIES OF THE
46 COMMITTEE OF GOODS OR SERVICES FROM COMPANIES CREATED IN THE PROJECTS;
47 ENDORSING, COLLABORATING, OR ACTING AS A CO-PRINCIPAL INVESTIGATOR OR
48 OTHER LEVEL OF PARTICIPANT ON GRANTS OR OTHER ACTIVITIES THAT WILL AID
49 IN FURTHERING PROJECT ACTIVITIES; AND SUCH OTHER APPLICATION OF THE
50 RESOURCES OF THE STATE AND ITS AGENCIES TO RAPID COMMERCIALIZATION AS
51 ARE PERMISSIBLE UNDER LAW.

52 (H) OVERSEE AND MAKE RECOMMENDATIONS FOR APPROVAL OF APPLICATIONS TO
53 THE SCIENTIFIC RESEARCH AND DISCOVERY BANK CREATED BY THIS ARTICLE FOR
54 THE RECRUITMENT AND RETENTION OF STAR SCIENTISTS AND RESEARCHERS.

55 (I) UPON REQUEST, PROVIDE TECHNICAL ASSISTANCE TO APPLICANTS, AND AS
56 NEEDED FOR A PROJECT, INCLUDING BUT NOT LIMITED TO ASSISTANCE IN IDENTI-

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

3 (J) IDENTIFY STATUTORY REQUIREMENTS THAT THE COMMITTEE VIEWS AS IMPED-
4 IMENTS TO SUCCESSFUL IMPLEMENTATION OF APPROVED PLANS AND, AS NECESSARY,
5 SUBMIT REQUESTS TO THE LEGISLATURE IN ACCORDANCE WITH ARTICLE VII OF THE
6 STATE CONSTITUTION FOR SPECIFIC LEGISLATIVE ENACTMENTS NECESSARY TO
7 REMOVE SUCH IMPEDIMENTS.

8 (K) ENTER INTO AGREEMENTS BETWEEN AND AMONG THE MEMBERS OF THE COMMIT-
9 TEE AS NECESSARY TO DELINEATE THEIR RESPECTIVE ROLES REGARDING THE COOP-
10 ERATIVE PROVISION OF PROGRAM FUNDING AND TECHNICAL ASSISTANCE.

11 (L) REQUIRE SUCH ADDITIONAL REPORTS, INFORMATION, OR OVERSIGHT AS MAY
12 BE NECESSARY TO THE SUCCESSFUL IMPLEMENTATION OF A PROJECT.

13 2. THE COMMITTEE MAY ACT THROUGH ITS CHAIRS IN ALL MATTERS OF OVER-
14 SIGHT AND IMPLEMENTATION OF THE PROGRAM AUTHORIZED BY THIS ARTICLE,
15 INCLUDING RECEIPT OF APPLICATIONS, NOTIFICATION OF DESIGNATION, AND
16 MONITORING OF APPROVED CENTERS TO ENSURE THAT SERVICES ARE PROVIDED IN
17 ACCORDANCE WITH THE APPROVED PLAN AND THAT FUNDS ARE USED IN ACCORDANCE
18 WITH APPLICABLE STATE AND FEDERAL LAW AND REGULATIONS.

19 S 444. ADMINISTRATION. EXCEPT WHERE OTHERWISE PRESCRIBED, THE DEPART-
20 MENT SHALL BE RESPONSIBLE FOR THE ADMINISTRATION OF THE PROVISIONS OF
21 THIS ARTICLE.

22 S 445. APPLICATION FOR DESIGNATION AS A NEW YORK STATE BIOMEDICAL AND
23 BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE
24 CENTER. IN RESPONSE TO A REQUEST FOR PROPOSALS, A MEDICAL SCHOOL MAY
25 APPLY FOR FUNDING AND DESIGNATION AS A NEW YORK STATE BIOMEDICAL AND
26 BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE
27 CENTER BY SUBMITTING AN APPLICATION AND PLAN TO THE COMMISSIONER. THE
28 COMMISSIONER SHALL FORWARD ALL SUCH PLANS TO THE PEER REVIEW COMMITTEE
29 FOR ASSESSMENT AS HEREIN PROVIDED, AND THEN TO THE STATE INITIATIVE
30 COMMITTEE. IN ADDITION TO SUCH OTHER ITEMS, WARRANTIES, AND INFORMATION
31 AS THE STATE INITIATIVE COMMITTEE MAY REQUIRE, PLANS MUST SHOW AN INTE-
32 GRATED VISION FOR COMMERCIALIZING RESEARCH FROM LAB TO MARKETPLACE
33 INCLUDING AN INTERRELATED DEMONSTRATION OF THE FOLLOWING:

34 1. COMMITMENT: A MULTI-YEAR COMMITMENT BY THE MEDICAL SCHOOL TO DEVEL-
35 OPMENT AND IMPLEMENTATION OF THE PLAN, OVER A PERIOD OF NOT LESS THAN
36 FIVE YEARS, SUCH COMMITMENT TO BE DEMONSTRATED BY A MULTI-YEAR COMMIT-
37 MENT OF RESOURCES, PERSONNEL, AND FUNDS THAT THE SCHOOL WILL USE,
38 DIRECTLY OR THROUGH PARTNERSHIPS AND COLLABORATIONS, TO PROVIDE AND/OR
39 INCENTIVIZE INTEGRATED RESEARCH, EDUCATION, CLINICAL PRACTICE, ENTRE-
40 PRENEURSHIP, FINANCING, PARTNERSHIPS, AND MORE RAPID COMMERCIALIZATION
41 OF RESEARCH.

42 2. RESOURCES: A DESCRIPTION OF THE ACTIONS AND RESOURCES NECESSARY TO
43 MEET THE PLAN OBJECTIVES OVER ITS DURATION; A DEMONSTRATION THAT THE
44 MEDICAL SCHOOL HAS EXISTING OPERATIONAL CLINICAL FACILITIES AND EXPER-
45 TISE OR EVIDENCE OF BONA FIDE COLLABORATIONS AND PARTNERSHIPS THAT CAN
46 PROVIDE SUCH FACILITIES AND EXPERTISE SUFFICIENT TO SUCCESSFULLY IMPLE-
47 MENT THE PLAN; A DEMONSTRATION THAT THE PROJECT WILL HAVE A PROFESSIONAL
48 MANAGEMENT TEAM WITH EXPERIENCE, EXPERTISE, OR CREDENTIALS IN MANAGE-
49 MENT, ENTREPRENEURSHIP, BUSINESS DEVELOPMENT, OR OTHER EQUIVALENT AREAS.
50 THE DEMONSTRATION MAY INCLUDE RECRUITMENT PLANS OR COMMITMENTS FOR HIGH
51 LEVEL RESEARCH PROFESSIONALS, INCLUDING HOW THE SCHOOL WOULD MAKE USE OF
52 THE SCIENTIFIC RESEARCH AND DISCOVERY BANK.

53 3. ENTREPRENEURIAL AND RESEARCH COLLABORATIONS: EVIDENCE INCLUDING
54 WRITTEN PROTOCOLS OF BONA FIDE RELATIONS WITH ONE OR MORE INCUBATORS AND
55 HOTSPOTS, FOR PROVISION OF ENTREPRENEURIAL SERVICES TO RESEARCHERS, WITH
56 A START-UP NY TAX-FREE NY PROGRAM AREA TO PROVIDE LOCATION AND SERVICES

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

4 4. LEVERAGED AND APPLIED FUNDING: A DEMONSTRATION THAT THE SCHOOL HAS
5 IN HAND OR WILL SHORTLY OBTAIN AND MAINTAIN DURING THE PLAN PERIOD THE
6 REQUIRED FUNDING MATCH OF AT LEAST TWO NON-STATE DOLLARS FOR EVERY STATE
7 DOLLAR PROVIDED PURSUANT TO THIS ARTICLE TO AN APPROVED PLAN. THE PLAN
8 SHOULD INCLUDE A DEMONSTRATION OF HOW THE SCHOOL WOULD USE TAX CREDITS,
9 PUBLIC FUNDS, OR OTHER INCENTIVES TO AID DIRECTLY OR INDIRECTLY IN
10 DEVELOPMENT OF INVESTMENT VEHICLES FOR RESEARCHERS, AND TO ENGAGE IN
11 ACTIVITIES CRITICAL TO THE COMMERCIALIZATION OF RESEARCH. SUCH FUNDING
12 AND COLLABORATIONS SHOULD ALSO SHOW HOW THE CENTER HAS OR WILL DEVELOP
13 LEVERAGED CREATIVE PARTNERSHIPS TO PROVIDE ANGEL, SEED, PRE-SEED, AND
14 OTHER INVESTMENTS TO HELP EACH STAGE OF PRODUCT DEVELOPMENT, EVIDENCED
15 BY WRITTEN AGREEMENTS, MEMORANDUMS OF UNDERSTANDING, LETTERS OF INTENT,
16 OR OTHER ENDORSEMENTS ACCEPTABLE TO THE COMMITTEE.

17 5. ADDITIONAL PLANS AND PROGRAMS: OTHER PLANS AND PROGRAMS INTEGRAL TO
18 THE SUCCESSFUL EXECUTION OF THE PROJECT, INCLUDING BUT NOT LIMITED TO
19 PATENT AND INTELLECTUAL PROPERTY PLANS, TRAINING AND EDUCATIONAL
20 PROGRAMS, AND EDUCATIONAL INTEGRATION WITH RESEARCH AND CLINICAL ACTIV-
21 ITIES.

22 6. COMMUNITY SUPPORT: A DEMONSTRATION OF COMMUNITY SUPPORT FROM BUSI-
23 NESS AND GOVERNMENT LEADERS AND ORGANIZATIONS.

24 7. BEST PRACTICES: A DEMONSTRATION THAT THE MEDICAL SCHOOL HAS OR WILL
25 ADOPT BEST PRACTICES AND USE OF MULTI-YEAR METRICS FOR PERFORMANCE, AND
26 THAT IT WILL REPORT DATA AS REQUESTED OR REQUIRED TO THE DEPARTMENT AND
27 THE STATE INITIATIVE COMMITTEE.

28 8. PERFORMANCE METRICS: ANTICIPATED ANNUAL AND CUMULATIVE OUTCOMES OF
29 THE PROJECT IN TERMS OF JOBS, INVESTMENT, AND ECONOMIC AND OTHER ACTIV-
30 ITY, STATED IN A SPECIFIC AND MEASURABLE WAY THAT IS ACHIEVABLE AND
31 REALISTIC WITHIN THE PROJECT TIME FRAME AND THAT CAN BE QUANTIFIED AND
32 COMPARED TO OTHER DATA FOR ANALYSIS.

33 9. ADVISORY COUNCIL: AN INDEPENDENT ADVISORY COUNCIL THAT INCLUDES ONE
34 OR MORE EXECUTIVE OFFICERS OF FIRMS THAT HAVE BEEN CREATED FROM RESEARCH
35 AT THE SCHOOL, AND INDIVIDUALS WITH EXPERTISE IN AREAS APPROPRIATE TO
36 THE SPECIFIC DEVELOPMENTAL SECTOR OR CONCENTRATION OF CLIENTS, OR TO
37 BIOMEDICAL AND BIOTECHNOLOGICAL RESEARCH AND DEVELOPMENT, AND TO THE
38 MISSION AND GOAL OF THE PROJECT.

39 S 446. REVIEW AND APPROVAL OF APPLICATIONS. REVIEW OF APPLICATIONS
40 SHALL TAKE PLACE IN TWO STAGES, FIRST BY THE PEER REVIEW COMMITTEE AND
41 THEN BY THE STATE INITIATIVE COMMITTEE WHICH SHALL HAVE SOLE POWER TO
42 APPROVE AN APPLICATION, AS FOLLOWS:

43 1. THE COMMISSIONER SHALL REVIEW APPLICATIONS AND PLANS RECEIVED FOR
44 COMPLETENESS, AND THEN FORWARD THEM TO THE PEER REVIEW COMMITTEE, AND TO
45 THE STATE INITIATIVE COMMITTEE FOR ITS REVIEW AND FINAL DETERMINATION
46 ONLY AFTER REVIEW BY THE PEER REVIEW COMMITTEE. NO PLANS SHALL BE
47 APPROVED BY THE STATE INITIATIVE COMMITTEE UNTIL REVIEWED BY THE PEER
48 REVIEW COMMITTEE. NO PLANS SHALL BE FORWARDED BY THE COMMISSIONER TO
49 EITHER COMMITTEE THAT REQUIRE THAT FUNDS MADE AVAILABLE PURSUANT TO THIS
50 ARTICLE SHALL BE DIRECTLY OR INDIRECTLY UTILIZED FOR RESEARCH INVOLVING
51 HUMAN REPRODUCTIVE CLONING.

52 2. THE MEMBERS OF THE PEER REVIEW COMMITTEE SHALL BE SELECTED BY THE
53 CHAIR AND THE CO-CHAIR OF THE STATE INITIATIVE COMMITTEE USING GUIDE-
54 LINES APPROVED BY SUCH COMMITTEE, WHICH SHALL INCLUDE REQUIREMENTS
55 CONCERNING EXPERTISE AND AVOIDANCE OF CONFLICT OF INTEREST. IF NECESSARY

1 AND DEEMED APPROPRIATE BY THE STATE INITIATIVE COMMITTEE, PLANS MAY BE
2 SUBMITTED BLIND TO THE PEER REVIEW PANEL.

3 3. THE PEER REVIEW COMMITTEE SHALL REVIEW AND SCORE PLANS BASED ON THE
4 FOLLOWING CRITERIA:

5 (A) SCIENTIFIC AND TECHNICAL MERIT;

6 (B) THE LEVEL OF SCIENTIFIC KNOWLEDGE, TECHNICAL CAPABILITY, AND/OR
7 CLINICAL PRACTICE AND OTHER NECESSARY PLAN COMPONENTS THAT WOULD BE
8 REQUIRED TO BE HOUSED AT THE MEDICAL SCHOOL, INCLUDING IMPROVEMENTS THAT
9 MAY BE ANTICIPATED BASED ON THE PLAN;

10 (C) THE SUITABILITY OF PRINCIPAL INVESTIGATORS, COLLABORATORS, AND
11 OTHER RESEARCHERS TO THE PROJECT, INCLUDING THE EXPERIENCE AND TRAINING
12 OF STAFF AND COLLABORATORS;

13 (D) THE ONGOING RECORD OF ACCOMPLISHMENTS AND INTEGRATED EXPERTISE AT
14 THE SCHOOL OR AS PROPOSED IN THE PLAN, INCLUDING LEADERSHIP APPROACH,
15 GOVERNANCE AND ORGANIZATIONAL STRUCTURE;

16 (E) PLANS FOR PROTECTION OF HUMAN SUBJECTS;

17 (F) THE SCIENTIFIC ENVIRONMENT IN WHICH THE WORK WILL BE DONE;

18 (G) APPROPRIATENESS OF INSTITUTIONAL SUPPORT, EQUIPMENT, AND OTHER
19 PHYSICAL RESOURCES; AND

20 (H) SUCH OTHER INFORMATION AS THE STATE INITIATIVE COMMITTEE SHALL
21 REQUIRE.

22 4. AN APPLICATION RECEIVING A LOW SCORE BY THE PEER REVIEW COMMITTEE
23 BASED ON THE CRITERIA IN SUBDIVISION THREE OF THIS SECTION, OR WHICH
24 LACKS SIGNIFICANT AND SUBSTANTIAL MERIT, OR WHICH PRESENTS IN THE VIEW
25 OF THE PEER REVIEW COMMITTEE SERIOUS ETHICAL PROBLEMS IN THE PROTECTION
26 OF HUMAN SUBJECTS FROM RESEARCH RISKS, OR OTHER SERIOUS ETHICAL PROB-
27 LEMS, SHALL BE DESIGNATED NOT RECOMMENDED FOR FURTHER CONSIDERATION
28 (NRFC). SUCH PLANS SHALL BE RETURNED TO THE COMMISSIONER AND BY THE
29 COMMISSIONER TO THE STATE INITIATIVE COMMITTEE WITH WRITTEN RECOMMENDA-
30 TIONS FOR CHANGE. THE STATE INITIATIVE COMMITTEE SHALL REVIEW SUCH
31 RECOMMENDATIONS, AND MAY ADD TO THEM, PRIOR TO RETURNING THEM TO THE
32 APPLICANTS.

33 5. THE STATE INITIATIVE COMMITTEE WILL REVIEW ALL ASPECTS OF THE
34 APPLICATIONS AND PLANS SUBMITTED TO IT AND RECOMMEND CHANGES AND DETER-
35 MINE FUNDING LEVELS AND SOURCES TO BE INCLUDED IN THE UNIFIED CONTRACT
36 IF THE APPLICATION IS APPROVED. THE COMMITTEE WILL TAKE INTO CONSIDER-
37 ATION THE REVIEW OF THE PEER REVIEW COMMITTEE, AND SHALL NOT APPROVE A
38 PLAN DESIGNATED BY THE PEER REVIEW COMMITTEE AS NOT RECOMMENDED FOR
39 FURTHER CONSIDERATION (NRFC), BUT MAY ADD ITS OWN COMMENTS PRIOR TO
40 RETURNING IT TO THE APPLICANT MEDICAL SCHOOL.

41 6. THE STATE INITIATIVE COMMITTEE SHALL REVIEW AND SCORE PLANS BASED
42 ON THE CATEGORIES REQUIRED IN THE APPLICATION PURSUANT TO SECTION FOUR
43 HUNDRED FORTY-FIVE OF THIS ARTICLE, AND INCLUDING THE FOLLOWING:

44 (A) THE ANTICIPATED EFFECTIVENESS OF THE PLAN AS EVIDENCED BY THE
45 EXISTENCE OF AVAILABLE RESOURCES DEDICATED TO THE PLAN AND THE COMMIT-
46 MENT OF THE MEDICAL SCHOOL;

47 (B) THE ABILITY OF THE APPLICANT TO UNDERTAKE AND COMPLETE THE PLAN,
48 THE FEASIBILITY OF MEETING THE METRICS AND GOALS PROVIDED FOR DETERMIN-
49 ING THE SUCCESS OF THE PLAN, THE DURABILITY AND REACH OF THE COLLAB-
50 ORATIONS AND RELATIONSHIPS WITH INCUBATORS AND HOTSPOTS, AND WITH START-
51 UP-NY PROJECTS, AND WITH PRIVATE AND OTHER PUBLIC COLLABORATORS;

52 (C) THE ABILITY OF THE APPLICANT TO PROVIDE THE NECESSARY DATA FOR AN
53 EFFECTIVE EVALUATION OF THE PROJECT; AND

54 (D) SUCH OTHER OBJECTIVE AND MEASURABLE CRITERIA AS SHALL BE DETER-
55 MINED BY THE COMMITTEE.

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

5 8. INsofar AS PRACTICABLE, IN APPROVING APPLICATIONS, THE COMMITTEE
6 SHALL SEEK TO PROVIDE A GEOGRAPHICALLY BALANCED DISTRIBUTION OF NEW YORK
7 STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTRE-
8 PRENEURSHIP INITIATIVE CENTERS AMONG THE REGIONS OF THE STATE.

9 9. NOT MORE THAN FORTY PERCENT OF FUNDS APPROPRIATED PURSUANT TO THIS
10 ARTICLE SHALL BE USED FOR ANY SINGLE PROJECT.

11 10. AS SOON AS PRACTICABLE AFTER APPROVING AN APPLICATION THE COMMIT-
12 TEE SHALL NOTIFY THE TEMPORARY PRESIDENT OF THE SENATE AND THE SPEAKER
13 OF THE ASSEMBLY OF ITS APPROVAL. SUCH NOTIFICATION SHALL IDENTIFY THE
14 RECIPIENT AND STATE THE PROPOSED LOCATION, THE ESTIMATED PROJECT FUNDING
15 AND AWARD AND A BRIEF DESCRIPTION OF THE PROJECT.

16 S 447. WAIVER IN CERTAIN CASES. TO PROMOTE INNOVATIVE APPROACHES AND
17 MAXIMIZE EFFECTIVE USE OF PUBLIC MONIES AND THE LIKELIHOOD OF SUCCESS IN
18 OPERATION OF APPROVED NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL
19 TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE CENTERS, AND
20 NOTWITHSTANDING ANY OTHER PROVISION OF LAW, THE COMMISSIONER OR DIRECTOR
21 OF ANY STATE AGENCY THAT IS A MEMBER OF THE STATE INITIATIVE COMMITTEE
22 MAY WAIVE, UPON APPLICATION BY SUCH CENTER AND SUBJECT TO THE APPROVAL
23 OF THE STATE INITIATIVE COMMITTEE AND THE DIRECTOR OF THE BUDGET, ANY OF
24 SUCH AGENCY'S REGULATORY REQUIREMENTS THAT MAY IMPEDE THE SUCCESSFUL
25 IMPLEMENTATION OF A PROJECT UNDERTAKEN PURSUANT TO THE APPROVED PLAN BY
26 THE CENTER, PROVIDED THAT SUCH WAIVER IS CONSISTENT WITH APPLICABLE
27 STATE AND FEDERAL STATUTES AND WILL NOT IMPAIR THE GENERAL HEALTH OR
28 WELFARE OF THE PEOPLE RECEIVING SERVICES UNDER SUCH PROJECT OR OTHERS.
29 SUCH COMMISSIONER OR DIRECTOR SHALL BE AUTHORIZED, IN CONSULTATION WITH
30 THE DIRECTOR OF THE BUDGET, TO IMPOSE APPROPRIATE ALTERNATIVE STANDARDS
31 IN PLACE OF ANY WAIVED REQUIREMENTS.

32 S 448. OPERATION AND REDESIGNATION OF NEW YORK STATE BIOMEDICAL AND
33 BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE
34 CENTERS. IN ADDITION TO ANY OTHER REQUIREMENTS OF THIS ARTICLE, A CENTER
35 WILL AGREE TO MEET ALL REQUIREMENTS CONCERNING EXECUTION AND IMPLEMENTA-
36 TION OF AN APPROVED PLAN FOR ITS PROJECT, TO MAINTAIN BEST PRACTICES,
37 AND TO REPORT DATA AS REQUESTED OR REQUIRED TO THE DEPARTMENT AND/OR THE
38 STATE INITIATIVE COMMITTEE USING APPROPRIATE CONFIDENTIALITY PROTOCOLS
39 IN THE CASE OF BUSINESS OR TRADE SECRETS. SUCH DATA WILL INCLUDE A
40 DEMONSTRATION OF THE SUCCESS IN MEETING PROJECT PLAN GOALS, INCLUDING
41 YEAR BY YEAR COMPARISON OF RESEARCH ACTIVITY AND COMMERCIALIZATION THER-
42 EOF, FIRM FINANCING AND EQUITY CAPITAL RAISED, PROVIDED OR LEVERAGED
43 FROM ALL SOURCES, PERSONNEL EMPLOYED ON THE PROJECT, AND JOBS CREATED BY
44 AND THROUGH THE PROJECT. THE DEPARTMENT SHALL DESIGN SIMPLIFIED FORMS TO
45 AID IN THE SUBMISSION OF SUCH DATA, WHICH MAY BE SUBMITTED ELECTRON-
46 ICALLY.

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
51 IS UNSATISFIED WITH THE PROGRESS OF A PROJECT, THE COMMISSIONER SHALL
52 NOTIFY SUCH CENTER OF THE RESULTS OF THE EVALUATIONS AND ANY FINDINGS OF
53 DEFICIENCIES IN ITS OPERATIONS AND SHALL COOPERATE WITH SUCH CENTER TO
54 REMEDY SUCH FINDINGS IN A TIMELY MANNER. SUCH EVALUATIONS SHALL INCLUDE
55 PEER REVIEW AND SHALL TAKE PLACE NO LESS THAN ONCE EVERY THREE YEARS OR
56 MORE OFTEN FOR ANY INDIVIDUAL CENTER AT THE DISCRETION OF THE STATE

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

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

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

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

40 S 450. UNIFIED CONTRACT. THE COMMISSIONER ON BEHALF OF THE STATE
41 INITIATIVE COMMITTEE SHALL ENTER INTO A UNIFIED CONTRACT WITH EACH
42 CENTER. THE PROVISIONS OF SUCH CONTRACT SHALL INCLUDE, BUT NOT BE LIMIT-
43 ED TO: A DESCRIPTION OF PROJECT SERVICES AND ACTIVITIES; THE PLAN;
44 ALLOWABLE PROJECT COSTS; SPECIFIC SOURCES OF FUNDS THAT WILL SUPPORT THE
45 APPROVED COSTS, INCLUDING GOVERNMENTAL AND NON-GOVERNMENTAL FUNDS OR
46 REVENUES THAT ARE PROPOSED TO BE USED IN SUPPORT OF PROJECT COSTS, AND
47 THE ALLOCATION OF COSTS BY FUNDING SOURCE. THE FORM OF SUCH UNIFIED
48 CONTRACT SHALL BE DEVELOPED IN CONSULTATION WITH THE DIVISION OF THE
49 BUDGET AND THE DEPARTMENT OF AUDIT AND CONTROL. THE COMPTROLLER IS
50 AUTHORIZED PURSUANT TO A CERTIFICATE OF ALLOCATION SUBMITTED BY THE
51 DIVISION OF THE BUDGET TO INTERCHANGE OR TRANSFER FROM APPROPRIATIONS
52 MADE TO THE AGENCIES OF THE COMMITTEE OR ANY OTHER APPROPRIATION, AS
53 APPROPRIATE, SUCH AMOUNTS AS MAY BE REQUIRED TO FULFILL THE OBLIGATIONS
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
56 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.

3 1. ALLOWABLE COSTS FOR A PROJECT SHALL INCLUDE, BUT NOT BE LIMITED TO
4 COSTS REASONABLY INCURRED FOR:

5 (A) PREPARATION OF THE PLAN;

6 (B) ACTIVITIES AS APPROVED IN THE PROJECT APPLICATION;

7 (C) EVALUATION OF THE APPROVED PROJECT; AND

8 (D) RENOVATIONS TO EXISTING STRUCTURES AS MAY BE NEEDED IN FURTHERANCE
9 OF THE PLAN, EXCEPT THAT IN NO CASE SHALL THE STATE SUPPORT OF SUCH
10 COSTS EXCEED EITHER TWENTY-FIVE PERCENT OF THE AMOUNT TO BE PROVIDED
11 PURSUANT TO THE CONTRACT OR FIFTY PERCENT OF THE TOTAL RENOVATION COSTS,
12 WHICHEVER IS LESS.

13 2. FUNDING MADE AVAILABLE THROUGH THE CONTRACT SHALL NOT BE USED TO
14 SUPPLANT OTHER FUNDS.

15 3. IN ADDITION TO THE FOREGOING REQUIREMENTS, A CENTER SHALL AGREE TO
16 DEDICATE ALL FUNDS FROM ANY SUPPORT RECEIVED PURSUANT TO THIS ARTICLE,
17 EXCEPT FOR FUNDS RECEIVED PURSUANT TO PARAGRAPH D OF SUBDIVISION ONE OF
18 THIS SECTION, TO OPERATIONS OF THE CENTER WITHOUT DEDUCTIONS FOR OVER-
19 HEAD, INDIRECT COSTS, OR FACILITIES AND ADMINISTRATION CHARGES OF THE
20 MEDICAL SCHOOL, AND TO LIMIT TO TEN PERCENT OR LESS THE ALLOCATION OF
21 FUNDS RECEIVED THROUGH THIS ARTICLE TO ADMINISTRATIVE COSTS OF THE
22 CENTER.

23 S 451. REPORT. THE COMMISSIONER ON BEHALF OF THE COMMITTEE SHALL ISSUE
24 AN ANNUAL REPORT TO THE PUBLIC, BEGINNING AT THE CONCLUSION OF THE FIRST
25 FULL CALENDAR YEAR AFTER THIS ARTICLE SHALL HAVE BECOME LAW, WHICH SETS
26 FORTH THE ACTIVITIES UNDERTAKEN PURSUANT TO THIS ARTICLE, INCLUDING THE
27 NAMES OF APPROVED PLANS AND THE CENTER SPONSORS, AND THE FOCUS OF
28 RESEARCH ACTIVITIES IN EACH SUCH PLAN; THE METRICS FOR EACH APPROVED
29 PLAN; GRANTS AWARDED, GRANTS IN PROGRESS, AND RESEARCH AND ENTREPRENEU-
30 RIAL ACCOMPLISHMENTS; FINANCING FROM EXTERNAL SOURCES FOR BRINGING
31 PRODUCTS TO MARKET; THE PROJECTED NUMBER OF JOBS AND COMPANIES TO BE
32 CREATED PURSUANT TO APPROVED PLANS AND THE ACTUAL NUMBER CREATED; ACTIV-
33 ITY UNDER THE DISCOVERY BANK CREATED PURSUANT TO THIS ARTICLE; A SUMMARY
34 OF FUNDING PROVIDED PURSUANT TO THE UNIFIED CONTRACTS EXECUTED PURSUANT
35 TO THIS ARTICLE; WAIVERS GRANTED PURSUANT TO THE AUTHORITY PROVIDED
36 UNDER THIS ARTICLE AND ACTIVITY UNDERTAKEN UNDER SUCH WAIVER; AND THE
37 NUMBER OF AND REASONS WHY PROJECTS WERE DEEMED NOT RECOMMENDED FOR
38 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.