Pursuant to the authority vested in the Commissioner of Health by subparagraph (H) of paragraph (b) of subdivision (5-a) of section 2807-m of the Public Health Law, section 86-1.46 of Subpart 86-1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to be effective upon Notice of Adoption in the New York State Register.

Subparagraphs (i), (viii) and (ix) of paragraph (2) and paragraphs (3) and (14) of subdivision (a) of section 86-1.46 are amended to read as follows:

(2) Clinical research plan means a plan submitted by a consortium or teaching general hospital for a research fellow position which demonstrates, in a form to be provided by the commissioner, the following:

(i) experience the sponsor-mentor [,] and [for center distributions the] director [, has] <u>have</u> in clinical research and the medical field of the study;

* * *

(viii) [for center distributions,] <u>after awards are made,</u> a budget including matching funds; and

(ix) any other information required by the commissioner to implement [subparagraph (i) of] paragraph (b) of subdivision five-a of section 2807-m of the public health law. The clinical research plan submitted in accordance with this paragraph may be reviewed by the commissioner in consultation with experts outside the department of health.

* * *

(3) Clinical research <u>fellow</u> position means a post-graduate residency position which:

(i) shall not be required in order for the research fellow to complete a graduate medical education program;

(ii) may be reimbursed by other sources but only for costs in excess of the funding distributed in accordance with [subparagraph (i) of] paragraph (b) of subdivision five-a of section 2807-m of the public health law;

(iii) shall exceed the minimum standards that are required by the residency review committee in the specialty the research fellow has trained or is currently training;

(iv) [shall not be previously funded by the teaching general hospital or supported by another funding source at the teaching general hospital in the past three years from the date the clinical research plan is submitted to the commissioner;

(v)] may supplement an existing research project;

[(vi)] (v) shall be equivalent to a full-time position comprising of no less than 35 hours per week;

[(vii)] (vi) shall provide, or be filled by a research fellow who has formalized instruction in clinical research, including biostatistics, clinical trial design, grant writing and research ethics; [and further provides that:

(a) for individual distributions, shall be supervised by a sponsor-mentor who must have been a principal investigator, co-principal investigator or co-investigator of a federal research grant in the past five years from the date the clinical research plan is submitted to the commissioner; or

(b) for center distributions,] (vii) shall be supervised by a sponsor-mentor who is a member of a research team directed by a [current] researcher who must have been a principal investigator or co-principal investigator [for an active grant from the National Institutes of Health and be supervised by a sponsor-mentor who must have been a principal investigator or co-principal

investigator of a federal research grant within one year from the date the clinical research plan is submitted to the commissioner] of a federal research grant or a Patient-Centered Outcomes Research Institute grant, excluding a grant for a conference or for commercial product development, in the two years preceding the date the clinical research plan is submitted to the commissioner; and

(viii) shall be filled by a research fellow who is:

(a) enrolled or has completed a graduate medical education program, as defined in paragraph (11) of this subdivision;

(b) a United States or Canadian citizen, national, or permanent resident of the United States or Canada; and

(c) a graduate of a medical, dental or podiatric school located in New York State, a graduate or resident in a graduate medical education program, as defined in paragraph (11) of this subdivision, where the sponsoring institution, as defined in paragraph (16) of this subdivision, is located in New York State, or resides in New York State at the time the clinical research plan is submitted to the commissioner.

* * *

(14) Research theme means a clinical research topic that represents a strategically important growth area for the consortium or teaching general hospital. Such theme shall be in a field of study suitable to train a resident or residents and cannot be one that [currently] has [Federal research] funding in the form of one or more federal center-type grants, such as a National Institutes of Health program project grant, specialized center grant, or research program grant or cooperative agreement at the consortium or teaching general hospital.

Subdivision (b) of section 86-1.46 is amended to read as follows:

(b) Within funding amounts set forth in paragraph (b) of subdivision (5-a) of section 2807-m of the public health law and appropriated to ECRIP, and with the objective of securing federal funding for biomedical research, training research fellows, recruiting national leaders as faculty to act as mentors, and training residents and fellows in biomedical research skills, the following distribution methodology shall apply:

(1) Distributions shall [first be made to consortia and teaching general hospitals to fund individual ECRIP projects in accordance with subparagraph (i) of this paragraph with remaining funds being] <u>be</u> divided equally [to fund center ECRIP distributions in accordance with subparagraph (ii) of this paragraph as follows:

(i) Individual distributions shall be made in the amount of $75,000 per research fellow position for up to two such positions within a two year period subject to a funding cap of $150,000. Consortia and teaching general hospitals may fund such positions in consecutive or concurrent years.

(ii) Center distributions shall be made by dividing the remaining funds equally] amongst all consortia and teaching general hospitals eligible for such distributions; provided that the consortia and teaching general hospitals are required to fund and train one research fellow position per <u>each</u> $100,000 received and shall provide a $100,000 match in each distribution period regardless of the dollar amount distributed pursuant to this subparagraph. If a consortium or teaching general hospital receives a distribution of $400,000 or more, excluding matching funds, in any distribution period then it may implement a secondary research theme in addition to

the primary research theme provided both projects demonstrate all requirements. Distributions shall be made in increments determined by the commissioner.

(2) In order to be eligible for [center] distributions pursuant to [subparagraph (1)(ii)] this subdivision, each consortium and teaching general hospital shall provide [a letter of intent to the commissioner indicating a primary research theme and may indicate a secondary research theme and a list of institutions collaborating in the clinical research plan. In addition, in order to be eligible for individual and center distributions pursuant to this section, each consortium and teaching general hospital shall provide] to the commissioner by [July first of each distribution period] a date specified by the commissioner, the following data and information on a hospital-specific basis. Such data and information shall be certified as to accuracy and completeness by the chief executive officer, chief financial officer or chair of the consortium governing body of each consortium or teaching general hospital and shall be maintained by each consortium and teaching general hospital for five years from the date of submission. Such data and information shall only be submitted by teaching general hospitals currently receiving Medicaid reimbursement for direct or indirect graduate medical education and such submission is limited to [either an individual] a single distribution per operating certificate issued by the commissioner pursuant to subparagraph (1)(i) of this subdivision [or a center distribution pursuant to subparagraph (1)(ii) of this subdivision], provided however, that a teaching general hospital with two or more campuses where one campus is the major teaching affiliate with one medical school and the other campus is the major teaching affiliate with another medical school each of which provides clinical services and research facilities at their respective campuses associated with the medical school, shall be eligible for a separate ECRIP distribution at each campus.

(i) For each research fellow position, information on the type, scope, training objectives, institutional support, clinical research experience of the sponsor-mentor, the name of a principal contact person responsible for tracking the career development of researchers placed in clinical research positions, as defined in paragraph (a)(3) of this section, and who is authorized to certify to the commissioner that all the requirements of the clinical research training objectives set forth in this subparagraph shall be met.

(ii) General information on all institutions collaborating on the clinical research plan, including each institution's role in the research and specific budget information.

(iii) Information for each sponsor/mentor, including experience in mentoring and current and pending federal research funding distribution.

(iv) Tracking information for all current and past research fellows, including but not limited to: (a) background information; (b) employment history; (c) research status; (d) current research activities; (e) research grants and support; (f) publications and presentations; and (g) any other information necessary to track and obtain outcome data for all research fellows.

(v) [For center distributions pursuant to subparagraph (1)(ii) of this subdivision, a] <u>A</u> description of the primary research theme and secondary research theme, if applicable, and how such themes build upon the existing research activities within the consortium or teaching general hospital.

(vi) [For center distributions pursuant to subparagraph (1)(ii) of this subdivision, a] <u>A</u> description of relevant federal research funding opportunities (if any) and how the research team plans to target such funding.

(vii) [For center distributions pursuant to subparagraph (1)(ii) of this subdivision, identification] <u>Identification</u> of the research team director who must [be] <u>have been</u> a principal investigator or

co-principal investigator of [an active National Institutes of Health] a federal research or a Patient-Centered Outcomes Research Institute grant within the two years prior to the submission of data pursuant to this subparagraph.

(viii) Identification of all sponsor/mentors who [: for center distributions pursuant to subparagraph (1)(ii) of this subdivision, must have been principal investigators or co- principal investigators of a federal research grant within one year of submission of data pursuant to this subparagraph; and, for individual distributions pursuant to subparagraph (1)(i) of this subdivision, must have been principal investigators, co- principal investigators or co-investigators of a federal research grant within five years of submission of data pursuant to this subparagraph] shall participate in the project.

(ix) [For center distributions pursuant to subparagraph (1)(ii) of this subdivision, a] A letter from the chief executive officer, chief financial officer or chair of the consortium governing body of each consortium or teaching general hospital attesting to the $100,000 match required pursuant to subparagraph (1)(ii) of this subdivision.

(x) Information on collaborations with entities located within New York State, including but not limited to, teaching general hospitals, universities, local health departments, government laboratories, and federally qualified health centers if applicable.

(xi) For each research fellow position, information on the name, citizenship status, medical education and training, and medical license number of the research fellow, if applicable, shall be provided by December 31st of the calendar year in which the distribution is made provided that if a change is requested in relation to the individual holding such position after that date, such

information shall be submitted to the commissioner for approval, together with the reasons for such change.

(xii) Information on the status of the clinical research plan, accomplishments, changes in research activities, progress, and performance of the research fellow shall be provided upon completion of one-half of the award term.

(xiii) A final report detailing training experiences, accomplishments, activities and performance of the research fellow, and data, methods, results and analyses of the clinical research plan shall be provided three months after the research fellow position ends.

(xiv) Any other data or information required by the commissioner to implement this section.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 2807-m(5-a)(b)(H) authorizes the Commissioner of Health to issue regulations pertaining to the Empire Clinical Research Investigator Program (ECRIP) to address matters such as the qualifications of researchers and the methodology for distribution of ECRIP funds.

Legislative Objectives:

ECRIP provides funding to eligible institutions to train physicians in clinical research and support projects to advance biomedical research in New York State. Specifically, as set forth in PHL § 2807-m(5-a)(b)(H)(1), the objective of ECRIP is to secure federal funding for biomedical research, train clinical researchers, recruit national leaders as faculty to act as mentors, and train fellows in biomedical research skills.

Current Requirements:

Pursuant to PHL § 2807-m(5-a)(b)(H), 10 NYCRR § 86-1.46 defines key terms which set forth parameters for ECRIP projects and researchers and establishes a methodology for the distribution of funds to institutions that receive ECRIP awards. As set forth in 10 NYCRR § 86-1.46(b)(2), institutions that are eligible for ECRIP awards are: (1) teaching hospitals that receive Medicaid reimbursement for direct or indirect graduate medical education; or (2) consortia comprised of general hospitals that receive Medicaid reimbursement for graduate medical education, which may include other providers and medical schools.

These institutions (collectively referenced herein as "teaching hospitals") may submit a proposed clinical research plan, also known as an abstract, to the Department of Health. Abstracts that meet all program requirements receive either an Individual Award or a Center Award, which are two-year awards, subject to available funding. Individual Awards are available to teaching hospitals which are capable of training clinician researchers through one-on-one mentoring. Center Awards, available to teaching hospitals with advanced research capacity, are intended to promote the development of clinician researchers while also providing seed funding for other grants by requiring teaching hospitals to form research teams around themes. Hospitals are not eligible to apply for both an Individual Award and a Center Award during the same ECRIP cycle.

As set forth in 10 NYCRR § 86-1.46(b)(1), Individual Awards are funded at $75,000 per year to support a minimum of one fellow, provided that only one Individual Award can be made per hospital. Institutions are expected to provide whatever additional funding and resources may be needed to support and train the research fellows. Section 86-1.46(b)(1) provides that after Individual Awards are allocated, the remaining amount appropriated is provided for Center Awards by equally dividing this amount among all qualified Center abstracts who meet the program criteria.

Teaching hospitals applying for Center Awards may submit a primary abstract and also may submit a secondary abstract. If there is sufficient funding available to provide at least $400,000 for every qualifying primary abstract, then the teaching hospital receives a Center Award that is to be split between the primary and secondary projects. Each institution receiving a Center Award must train at least one ECRIP fellow for every $100,000 in annual State funding it receives, and further must commit $100,000 in matching funds each year.

Section 86-1.46(a)(3), which defines "clinical research position," provides that research fellows who carry out ECRIP projects must be supervised by a faculty member known as a sponsor-mentor. For an Individual Award, the sponsor-mentor must have been a principal investigator, co-principal investigator or co-investigator of a federal research grant within the last five years prior to submission of an ECRIP abstract. See 10 NYCRR § 86-1.46(a)(3)(vii)(a). For a Center Award, the fellow must be a member of a research team directed by a principal investigator or co-principal investigator currently working on an active grant from the National Institutes of Health (NIH), and must be supervised by a sponsor-mentor who has been a principal investigator or co-principal investigator within the year prior to submission of an abstract. See 10 NYCRR § 86-1.46(a)(3)(vii)(b). In addition, the regulation provides that fellows cannot have been funded by the teaching hospital or supported by another funding source at the teaching hospital within the past three years. See 10 NYCRR § 86-1.46(a)(3)(iv).

Section 86-1.46(b)(2) requires recipients of the two-year ECRIP awards to submit certain information to the Department, generally by July 1 of each year for which funds are distributed, related to ECRIP projects and the personnel working on such projects. In particular, 10 NYCRR § 86-1.46(b)(2)(vii) requires a Center Award recipient to identify the research team director and 10 NYCRR § 86-1.46(b)(2)(viii) requires Individual and Center Award recipients to identify sponsor-mentors. Section 86-1.46(b)(2)(xi) requires that information about individual research fellows supported by ECRIP funding be submitted each year by December 31.

Needs and Benefits:

This proposal will make five changes to 10 NYCRR § 86-1.46. First, since the regulation was first promulgated, there has been an expansion of the types of research opportunities that are

available at the national level. While the NIH historically has been and continues to be the primary source of federal biomedical research funding, other federal agencies offer grants that provide valuable research experience. Moreover, grants are now available through the Patient-Centered Outcomes Research Institute (PCORI), a non-profit corporation established by the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152) (collectively ACA). PCORI, charged with setting national research priorities and making research grants to support such priorities, receives funding from various federal sources for these purposes but is not a federal agency. See ACA, Title VI, Subtitle D, section 6301.

It is important to clarify, however, that grants for conferences or for commercial product development should not serve as qualifying research experience. These types of research activities are not as closely aligned to the purposes of ECRIP, which rely on experienced researchers to serve as mentors to train fellows in carrying out biomedical research. Therefore, this proposal will amend 10 NYCRR § 86-1.46(a)(3) to include federal research grants other than those provided by the NIH as qualifying grants for research team directors and sponsor-mentors working on Center Awards, include PCORI grants as qualifying grants for research team directors working on Center awards, and exclude grants for conferences or commercial product development.

Second, the requirement that the project director currently have an active grant from the NIH unnecessarily limits the pool of eligible faculty since it can take time for faculty to identify, apply and be awarded new research funding after existing grants conclude. Therefore, this proposal will amend 10 NYCRR § 86-1.46(a)(3) to revise the period for qualifying grants from a current active grant to a grant within the past two years. This proposal further will make

conforming changes to 10 NYCRR § 86-1.46(b)(2)(vii), requiring submission of information about the research team director, and 10 NYCRR § 86-1.46(b)(2)(viii), requiring submission of information about sponsor-mentors, to reflect the foregoing changes in type and duration of experience.

Third, as indicated, the current version of the regulation also provides that fellows funded under proposed projects cannot have been previously funded by the teaching hospital within the past three years. While this provision was meant to ensure that ECRIP funds supplemented rather than supplanted other hospital spending on research, it has inadvertently prevented residents currently employed by the teaching hospital from remaining at that hospital to participate in an ECRIP project. Accordingly, this proposal will amend 10 NYCRR § 86-1.46(a)(3)(iv) to eliminate that restriction.

Fourth, 10 NYCRR § 86-1.46(b)(2)(xi) currently provides for recipients of two-year ECRIP awards to provide the Department with information about individual research fellows each year by December 31. Because the program is designed to train research fellows, there is a general expectation that a fellow who begins a training period will complete it. However, there may be legitimate reasons why a fellow cannot do so. Therefore, this proposal will amend the regulation to require that the Department be notified of and approve any subsequent changes in the individual holding a research fellow position. Such request must include the reason for such change, enhancing the Department's oversight of the program.

Finally, Individual awards are eliminated allowing ECRIP to focus on larger Center projects in consortia and teaching hospitals in order to promote greater collaboration among research fellows.

Overall, these changes will expand the type of research experience that mentoring researchers bring to ECRIP projects and promote the high quality of research projects submitted and approved under the program.

COSTS:

Costs to Private Regulated Parties:

Teaching hospitals are not required to request ECRIP funding, and the clarifications made by the proposed regulatory changes will not substantially alter the way in which abstracts are submitted. Therefore, the proposed regulatory amendments would not create any mandatory burdens or costs to regulated parties.

Costs to Local Government:

The proposed regulatory amendments will not impose any costs on local government, except to the extent that a local government operates a teaching hospital that chooses to request ECRIP funding. In such case, the analysis set forth above regarding costs to private regulated parties would apply.

Costs to the Department of Health:

The proposed regulatory changes will not result in any additional costs to the Department.

Costs to Other State Agencies:

The proposed regulations will not result in any costs to other state agencies.

Local Government Mandates:

The proposed regulations will not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

Paperwork is required for the submission of ECRIP abstracts. While the proposed regulatory changes alter some of the criteria pertaining to ECRIP eligibility, these changes will not result in any additional paperwork.

Duplication:

There are no relevant State regulations which duplicate, overlap or conflict with the proposed regulation.

Alternatives:

An alternative to the proposed regulatory changes would have been to leave the existing language as set forth in the current regulation. However, this would have precluded addressing the issues outlined in the Needs and Benefits section.

Federal Standards:

The proposed regulations do not duplicate or conflict with any federal regulations.

Compliance Schedule:

The regulations will be effective upon publication of a Notice of Adoption in the New York State Register.

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STATEMENT IN LIEU OF

REGULATORY FLEXIBILITY ANALYSIS

FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act because the proposed rule will not have a substantial adverse impact on small businesses or local governments. ECRIP awards are made only to teaching hospitals that voluntarily submit an abstract to the New York State Department of Health and none of the teaching hospitals are small businesses. Further, for local governments that operate teaching hospitals that voluntarily submit abstracts in compliance with the requirements of the proposed regulations, the financial and programmatic benefits far exceed the reporting requirements.

STATEMENT IN LIEU OF

RURAL AREA FLEXIBILITY ANALYSIS

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act because the proposed amendments will not impose an adverse impact on facilities in rural areas, and will not impose reporting, record keeping or other compliance requirements on most facilities in rural areas. For any teaching hospital located in a rural area that voluntarily submits an abstract to the New York State Department of Health in compliance with the requirements of the proposed regulations, the financial and programmatic benefits far exceed the reporting requirements.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act because the proposed regulations will not have a substantial adverse impact on jobs and employment opportunities. In fact, the proposed regulations will result in an increase in the number of jobs and employment opportunities in teaching hospitals that submit an abstract to the New York State Department of Health and receive an ECRIP award. The proposed regulations require teaching hospitals that receive an ECRIP award to hire a full-time physician researcher fellow(s) to train in clinical research projects. In addition, ECRIP funding may be used to support faculty to mentor the fellow(s) and other administrative staff to support the training project.