

Empire Clinical Research Investigator Program (ECRIP)

Effective date: 2/19/14

### **SUMMARY OF EXPRESS TERMS**

This rule establishes a redesigned Empire Clinical Research Investigator Program (ECRIP) that will continue individual physician research awards as well as provide larger center awards to teaching hospitals. Individual teaching hospitals are eligible to submit for funding under either the individual award program or the center award program, but may not submit an abstract for both awards. An institution that has a major partnership with two medical schools may submit for two center awards. The award will include specific funding amounts. Any costs associated with the project in excess of the funding amounts described below are expected to be supported by the institution. All hospitals that submit an abstract for either type of award and meet the minimum requirements will receive funding.

#### Individual Award

These awards will promote development of clinician researchers by funding physician ECRIP fellows for one or two years of research training under a classic paradigm of one-on-one mentoring. Sponsor/mentors must have been a principal investigator, co-principal investigator or co-investigator of a federal research grant within five years of the abstract deadline. There will be one two-year award made per teaching hospital at \$75,000 per year. Institutions are encouraged to train two fellows at the same time in a team-based collaborative training model using additional in-kind or other grant funds. In no event will an institution receive more than \$150,000 for an individual award during the two-year period. The institution is expected to

provide whatever additional funding and resources may be needed for support and training of the fellows.

#### Center Award

These two-year awards will promote development of clinician researchers while providing seed funding for new center grants by requiring teaching hospitals to form research teams around themes, such as ‘improved therapies for type 2 diabetes’. A theme may not be one that currently has federal center (P- or U-type) funding at the institution. The research theme must represent a strategically important growth area for the applicant institution, preferably associated with one or more federal funding opportunities with a realistic project timeline. In the event that more than three ECRIP fellow positions are funded, the abstract may describe two research teams formed around two different themes. Each research team must be led by a director who will sponsor/mentor one project and coordinate the research team’s activities. The director must be a PI of an active NIH research grant and the other project sponsor/mentors must have been a PI of an NIH or other federal research grant within one year of the abstract deadline. For every \$100,000 annually in State funding, the institution will be required to train at least one ECRIP fellow. Inter-institutional collaborations (with shared funding) involving other NY teaching hospitals and other NY entities such as private and public universities and colleges, government laboratories (e.g., Wadsworth Center, Nathan Kline Institute), local health departments, HHC and FQHCs are encouraged. All center awards must include a \$100,000 match, per year, by the institution with real (not in-kind) funds. All ECRIP fellows will be expected to work in a collaborative team-based training model.

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, Subpart 86-1 of Part 86 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by adding a new section 86-1.46, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

86-1.46 Empire Clinical Research Investigator Program (ECRIP)

(a) Definitions. For purposes of this section, the following definitions shall apply:

(1) *Clinical research* means patient-oriented research, epidemiologic and behavioral studies, or outcomes research and health services research that are approved by an institutional review board by the time the research fellow position is filled.

(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 in clinical research and the medical field of the study; (ii) methods, data collection and anticipated measurable outcomes of the clinical research to be performed; (iii) training goals, objectives and experience the research fellow will be provided to assess a future career in clinical research; (iv) scientific relevance, merit and health implications of the research to be performed; (v) clear and comprehensive details on the research fellow position; (vi) non-duplication with other clinical research positions from the same teaching general hospital or consortium; (vii) methods to track the career of the research fellow once the term of the position is complete; (viii) for center distributions, 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 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) shall be equivalent to a full-time position comprising of no less than thirty-five hours per week; (vii) 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 (viii) (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, shall be a member of a research team directed by a current 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; and (ix) 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.

(4) *Co-Investigator* shall mean a person who collaborates with the principal investigator or co-principal investigators in a grant proposal approved and awarded by a federal agency. Such person is responsible for certain aspects of the grant work but has no budget control.

(5) *Consortium* means an organization or association, approved by the commissioner in consultation with the council, of general hospitals which provide graduate medical education, together with any affiliated site; provided that such organization or association may also include other providers of health care services, medical schools, payors or consumers, and which meet other criteria pursuant to subdivision six of section 2807-m of the public health law.

(6) *Co-Principal investigator* shall mean one of two people, if applicable, who conceived of and submitted a grant proposal approved and awarded by a federal agency. Such person is typically responsible for different aspects of the grant work with a separate budget from the second co-principal investigator.

(7) *Council* means the New York State Council on Graduate Medical Education.

(8) *Direct medical education* means the direct costs of residents, interns and supervising physicians.

(9) *Distribution period* means each calendar year set forth in subdivision two of section 2807-m of the public health law.

(10) *Faculty* means persons who are employed by or under contract for employment with a teaching general hospital or are paid through a teaching general hospital's affiliated faculty practice plan and maintain a faculty appointment at a medical school. Such persons shall not be limited to persons with a degree in medicine.

(11) *Graduate medical education program* means a post-graduate medical education residency in the United States or Canada which has received accreditation from a nationally recognized accreditation body or has been approved by a nationally recognized organization for medical, osteopathic, podiatric or dental residency programs including, but not limited to, specialty boards.

(12) *Indirect medical education* means the estimate of costs, other than direct costs, of educational activities in teaching hospitals as determined in accordance with the methodology applicable for purposes of determining an estimate of indirect medical education costs for reimbursement for inpatient hospital service pursuant to title XVIII of the federal social security act (medicare).

(13) *Principal investigator* shall mean the person who conceived of and submitted a grant proposal approved and awarded by a federal agency. Such person directs the work and controls the budget of such a grant.

(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 National Institutes of Health program project grant,

specialized center grant, or research program cooperative agreement at the consortium or teaching general hospital.

(15) *Resident* means a person in a graduate medical education program that has received accreditation from a nationally recognized accreditation body or in a program approved by any other nationally recognized organization for medical, osteopathic or dental residency programs including, but not limited to, specialty boards.

(16) *Sponsoring institution* means the entity that has the overall responsibility for a program of graduate medical education. Such institutions shall include teaching general hospitals, medical schools, consortia and diagnostic and treatment centers.

(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 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 seventy-five thousand dollars per research fellow position for up to two such positions within a two year period subject to a funding cap of one hundred fifty thousand dollars. 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 one hundred thousand dollars received and shall provide a one hundred thousand dollar 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 four hundred thousand dollars or more, excluding matching funds, in any distribution period then it may implement a secondary research theme in addition to the primary research theme. Distributions shall be made in increments determined by the commissioner.

(2) In order to be eligible for center distributions pursuant to subparagraph (ii) of paragraph (1) of 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, 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 distribution pursuant to subparagraph (i) of paragraph (1) of this subdivision or a center

distribution pursuant to subparagraph (ii) of paragraph (1) 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 (3) of subdivision (a) 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 (ii) of paragraph (1) of this subdivision, a 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 (ii) of paragraph (1) of this subdivision, a 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 (ii) of paragraph (1) of this subdivision, identification of the research team director who must be a principal investigator or co- principal investigator of an active National Institutes of Health research grant;

(viii) Identification of all sponsor/mentors who: for center distributions pursuant to subparagraph (ii) of paragraph (1) 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 (i) of paragraph (1) 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;

(ix) For center distributions pursuant to subparagraph (ii) of paragraph (1) of this subdivision, 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 one hundred thousand dollar match required pursuant to subparagraph (ii) of paragraph (1) 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; and

(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 thirty-first of the calendar year in which the distribution is made;

(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:**

The requirement to distribute Empire Clinical Research Investigator Program (ECRIP) funding pursuant to regulation is set forth in paragraph (b) of subdivision (5-a) of section 2807-m of the Public Health Law.

### **Legislative Objectives:**

The proposed rule redesigns ECRIP to maximize the impact of ECRIP funding, make New York State teaching hospitals more competitive for large NIH center awards and stimulate collaboration within and among New York's teaching institutions. This redesigned program will continue individual physician research awards as well as provide larger center awards to teaching hospitals. Awards will be distributed using a reimbursement-type methodology to teaching hospitals that meet specific program requirements.

### **Needs and Benefits:**

The ECRIP was created by the NYS Council on Graduate Medical Education in 2000 to promote training of physicians in clinical research in order to advance biomedical research in New York State. The program was created as a result of research that demonstrated that NYS slipped from first to third nationally in its share of National Institutes of Health (NIH) research funding and was not producing the necessary clinical researchers to remain highly competitive. The importance of training clinical researchers for New York to regain its competitive edge has been heightened by new policies at NIH that will increase funding for clinical and translational

research. Moreover, New York is well below the national average in its share of NIH funding received as large center grants as compared to individual investigator grants.

Since 2001, 827 project abstracts have been submitted for funding with 529 awarded to 65 teaching hospitals, totaling over \$64 million in funding. Each teaching hospital must provide matching funds to support the ECRIP researcher. These matching funds can be provided as in-kind support from the hospital directly or from other research entities such as national research institutes or private companies. These matching funds demonstrate the willingness of the institution to support a research agenda.

Sample data from the first eight years of the program show that 73 percent of ECRIP funded researchers have continued in research and 81 percent of those that continued in research have remained in NYS. Of the total positions awarded to the teaching hospitals, 92 percent were filled.

ECRIP provides funding for community-related research that is specific to an institution's region or population served. It is an open and flexible program, allowing for teaching hospitals to hire physicians in all subject areas of clinical research to perform patient-oriented, epidemiologic, behavioral, outcomes, health services and translational research. ECRIP is also leveraged by teaching hospitals to draw additional and substantial research funding from other sources (e.g. NIH, pharmaceutical companies, foundations) to continue the research.

**Costs:**

**Costs to the State Government:**

There will be no additional costs to the state government as a result of implementing the redesigned program. The total annual funding to implement ECRIP will remain at \$8.6 million per year.

**Costs to Local Government:**

There will be no additional costs to the local government as a result of implementing the redesigned program.

**Costs to Private Regulated Parties:**

There will be no additional costs to private regulated parties as a result of implementing the redesigned program.

**Costs to the Regulatory Agency:**

There will be no additional costs to the regulatory agency as a result of implementing the redesigned program.

**Local Government Mandate:**

The redesigned program does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

**Paperwork:**

The redesigned program does not require any additional paperwork to be completed by regulated parties.

**Duplication:**

The redesigned program does not duplicate any existing federal, state, or local regulation.

**Alternatives:**

No significant alternatives are available. The Department is required to promulgate implementing regulations pursuant to Public Health Law §2807-m(5-a)(b)(H).

**Federal Standards:**

The proposed rule does not exceed any minimum standards of the federal government for the same or similar subject area.

**Compliance Schedule:**

The proposed rule establishes distribution requirements for ECRIP funding; there is no period of time necessary for regulated parties to achieve compliance.

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**STATEMENT IN LIEU OF  
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The proposed rule does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments. The proposed rule governs distribution of ECRIP funding and participation is voluntary.

**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. The proposed rule does not impose an adverse impact on rural areas, and it does not impose reporting, recordkeeping or other compliance requirements on public or private entities in rural areas. The proposed rule governs distribution of ECRIP funding and participation is voluntary.

## **JOB IMPACT STATEMENT**

### **Nature of Impact:**

ECRIP encourages teaching hospitals to conduct and train physicians in clinical research that will result in new positions in these facilities. Since 2001, 529 clinical research positions have been funded in 65 teaching hospitals, for a total of over \$64 million. Funding for research generates an enormous return on investment. According to a 2010 Associated Medical Schools of New York study, for every dollar in federal and state research funding invested in New York medical schools, New York State receives a return of \$7.50. Sample data from the first eight years of the ECRIP program show that 73 percent of ECRIP funded researchers have continued in research and 81 percent of those that continued in research have remained in NYS.

### **Categories and Numbers Affected:**

Jobs directly funded by this program are for physicians in clinical research. Other indirect job positions that are created include research fellows, faculty, administrative support and laboratory positions.

### **Regions of Adverse Impact:**

There is no adverse impact on regions.

### **Minimizing Adverse Impact:**

Not applicable.

## ASSESSMENT OF PUBLIC COMMENT

The Department received only one comment during the notice of proposed rulemaking comment period and it relates to the timing of ECRIP awards, not to the express terms of the proposed regulations or methodology therein.

COMMENT: The commenter expressed concern over the January 15, 2014 deadline to hire research fellows for first year awards and requested consideration be given to coordinating the hiring deadline with the academic calendar and graduate medical education program completion date of June 30 which is when graduating physicians are likely to consider fellowship opportunities. This would enable institutions the opportunity to recruit quality fellows before they commit to out-of-state programs.

RESPONSE: The January date was chosen in order to make first year awards prior to the end of the State fiscal year, March 31, 2014, otherwise awardees would have lost an entire year of funding. Now that regulations governing the program have been adopted, the timing of future awards will be improved and institutions will have ample time to recruit quality fellows. There is no hiring deadline in regulation, so the express terms of the proposed regulations do not need to be revised to incorporate this comment.