**COVER PAGE - Submit this as the cover page to your project abstract.**

Select the type of Empire Clinical Research Investigator Program project you are submitting (check only one):

 Empire Clinical Research Investigator Program (Primary)

 Empire Clinical Research Investigator Program (Secondary)

Project Theme**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Name of Project**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Name of Teaching Hospital: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

New York State Department of Health Operating Certificate #: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Information for an Empire Clinical Research Investigator Program principal contact at your institution:

Name: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Address: \_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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Office Telephone #**: (\_\_\_\_)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Cell phone # **(\_\_\_\_\_)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Email**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Name, title and signature of an officer of the institution authorized to attest to the accuracy of the information included in this abstract and agree that all individuals involved in this project shall abide by the requirement of the program.

Name: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Title**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Institution: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**INSTRUCTIONS**

**Cover Page**

Please check only one box to indicate the type of abstract being submitted.

A teaching hospital may submit either: (1) an abstract for a primary project without submitting an abstract for a secondary project; or (2) an abstract for a primary project and an abstract for a secondary project.

**Abstract**

**Please submit the information requested in the order indicated below, labeled by section and question number/heading using a 12 font document format for all responses. Responses should be clear, concise, comprehensive and organized and include only relevant and sufficient detail addressing the specific question. (Do not include these written instructions with your abstract.)**

**Section A. Funding**

Any costs associated with the project in excess of the funding amounts described below are expected to be supported by the teaching hospital.

**Empire Clinical Research Investigator Program** **Projects**

Two-year Empire Clinical Research Investigator Program awards are intended to promote the development of clinician researchers while providing seed funding for new federal center-type funding. Award amounts will be based on the number of projects that meet program requirements and are funded. The total annual funding for the program is up to $3.445 million. Funds will be equally divided among all qualified teaching hospitals that meet program requirements.

A secondary project will only be supported if: (1) both the primary and secondary projects meet all program requirements; and (2) at least $400,000 is available to that hospital, which depends on the number of other qualifying projects. If a secondary abstract is submitted, both the primary and secondary projects must meet all program requirements. If the primary project does not meet the program requirements, neither project will be funded. However, if the secondary project does not meet the program requirements, but the primary project meets the program requirements, the primary project would qualify for the full award.

For every $100,000 of annual State funding, the institution would be required to train at least one research fellow. The New York State Department of Health will require a detailed budget for the entire project after awards are made and prior to the distribution of funds.

In addition, regardless of the amount of the State funding, all teaching hospitals receiving awards must include a $100,000 commitment by the institution with real (not in-kind) funds per year. This $100,000 institutional commitment applies to the hospital, not to both a primary and secondary project. The abstract **must** be accompanied by a letter from the institution demonstrating its commitment and identifying the source of these funds.

**Section B. Research Project Information**

1. **Type of Clinical Research**:

Indicate the type of clinical research that will be addressed in the research project: Patient-Oriented, Epidemiologic, Behavioral Studies, Outcome Research, Health Services Research or Translational Research.

1. **Research Project (500 word limit):**

Identify a research theme topic (in layman’s terms) and project title for the proposed research project. No projects that have previously received Empire Clinical Research Investigator Program support will be funded. A theme may not be one that currently has federal center-type funding (e.g., National Institutes of Health P01 or U19 grants) at the institution. The research theme should represent a strategically important growth area for the institution, associated with one or more federal funding opportunities with a realistic project timeline outlined in questions 6 and 11.

1. **Research Project Summary and Objective(s) (500 word limit):**

Provide a clear and comprehensive summary with sufficient detail about the research project objectives, hypotheses to be tested and state what is intended to be accomplished through the research. Include the significance of the site(s) in the project. Also, note if the project is part of a larger study at the institution and indicate how these projects relate to each other and include funding sources and other details.

1. **Research Project Background (500 word limit):**

Provide background information on the research project. Include the scientific relevance and the health implications of the research project, as well as the need for this type of research.

1. **Describe Data and Methodology (500 word limit):**

Explain the necessary methods for collecting, analyzing and reporting the data to proceed with the research project. Include how patients will be identified for the research and the number and length of time patients will be involved in the research. Also describe the contact methods the researcher will have with the patients and any control group, if applicable. Such data and methodology should be statistically valid, rigorous and consistent to the project objective(s).

1. **Project Timeline (500 word limit):**

Provide a timeline for the entire project, including a breakdown of the tasks, project deliverables and major project milestones indicated on a periodic (such as quarterly) basis. Include information for both years of the project, if applicable. Projects may begin after awards are made but must begin no later than March 20th 2025. Research fellows must be hired and begin their Empire Clinical Research Investigator Program training within these dates.

1. **Research Fellow(s) Tasks and Locations (500 word limit):**

Provide a description of the specific tasks the research fellow(s) will perform during the research project and the overall responsibilities he/she/they will have in advancement of their research capabilities. Include the locations of these tasks if the research fellow(s) is training at multiple sites. Note that the research fellow(s) must spend a substantial portion of their research training at the teaching hospital that is submitting this abstract, in addition to training at any other site(s). Include anticipated seminars or conferences that the research fellow(s) will be participating in related to this project.

1. **Project Expected Measurable Outcomes (500 word limit):**

Provide the measurable outcomes that you expect to obtain through this research project. This should be provided as results reported at scientific meetings and in peer-reviewed journals.

1. **Tracking of the Career Development of Participating Researcher Fellow(s) (500 word limit):**

Describe the methods, sources and systems that the institution will use to track the career development of the participating research fellow(s) to determine if the physician(s) pursued a career in research.

1. **Significance of Research: (500 word limit):**

Describe how this project will modify or add to the body of knowledge within the area of research and could significantly impact the health of people specifically residing in New York State.

1. **Future Funding: (500 word limit):**

Identify realistic subsequent federal or other sources the institution will target for future research project funding, including timeframes, based on this research project.

**Section C. Project Director & Research Sponsor -Mentor(s) Information**

1. **Project Director/ Sponsor-Mentor Information (500 word limit per person)**:
2. Provide the name, address, phone numbers (office and cell) and email address of an individual who is responsible for the overall project (project director) and all individuals who are responsible for sponsoring-mentoring research fellows at all sites. Note that the director may also be a sponsor/mentor. A sponsor/mentor can train up to a maximum of two research fellows from all institutions at one time.
3. Indicate which federal research or patient-centered outcomes research institute grant (that is also included in the bio-sketch) qualifies the project director to meet the Empire Clinical Research Investigator Program requirement. The project director must have been a principal investigator, co-primary investigator or co-investigator of a federal research or patient-centered outcomes research institute grant that ended no earlier than July 2022. Include the Notice of Grant Award or other documentation to demonstrate proof of the principal investigator, co-primary investigator, or co-investigator status. If the project director was a subcontractor within a multi-site grant, provide a budget justification or other appropriate documentation to demonstrate overall responsibility and budget authority for the research at the site and substantial involvement in the development of the overall multi-site project beyond enrolling research participants. The project director must substantially work or practice at the teaching hospital that is submitting the abstract. Non-research grants or grants for conferences or for commercial product development are excluded.
4. **Project Director and Sponsor/Mentor(s) Bio-sketch Information**:

Using the attached biosketch format, provide education, training, position, honors and publications in peer-reviewed publications (in chronological order) for each sponsor-mentor(s). Include any papers that included past Empire Clinical Research Investigator Program fellows with their names underlined. (Researchers are not required to have mentored or published papers with past Empire Clinical Research Investigator Program fellows.) List selected ongoing or completed clinical research projects during the last five years from government and non-governmental support. Begin with the projects that are most relevant to the research in this project abstract. Briefly indicate the overall goals of these past projects and your role (e.g., principal investigator, co-primary investigator, or co-investigator status, consultant). List award amounts and percent of effort for these projects. Do not send the researchers’ entire curriculum vitae.

1. **Sponsor/Mentor(s) Experience in Mentoring (500 word limit):**

For each sponsor/mentor, describe their experience mentoring researchers, fellows, residents and graduate or medical students. All sponsor-mentors must have mentoring experience for at least one of these graduate levels.

**Section D. Research Fellow(s) Information**

1. **Goals and Objectives for the Research Fellow(s) (500 word limit)**:

For each research fellow, describe the knowledge and training experience expected to be gained by the research fellow(s) in the clinical research project. Such goals and objectives should be clear, reasonable and challenging for the research fellow. Also include the specific role the sponsor-mentor(s) shall provide to the research fellow(s).

1. **Qualifications Required for the Research Fellow position(s) (500 word limit)**:

Provide the qualifications necessary for a physician to be accepted by the institution in order to take part in the research project. In addition, describe the process by which the research fellow(s) long term career interest in clinical research can be evaluated. These should be in addition to the research fellow requirements in the regulations (Clinical research position) that include but are not limited to the following:

* Research fellow(s) must be filled by a physician, dentist or podiatrist who is enrolled in or has completed a residency in any specialty.

* Research fellow(s) shall be:

(a) enrolled or have completed a graduate medical education program; and

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

(c) a graduate of a medical (allopathic or osteopathic), dental or podiatric school located in New York State, a resident or graduate of a residency training program sponsored by an institution located in New York State, or reside in New York State at the time the clinical research plan is submitted to the commissioner which is July 11th 2024.

* Positions are full-time of no less than 35 hours per week.
* Existing faculty at the institution may participate as a research fellow, provided that such faculty are pursuing career development in clinical research.
1. **Formalized Instruction** **(500 word limit**)

Provide information that will ensure that the research fellow has been or will be involved in formalized instruction, including didactic training, in clinical research, such as clinical trial design, research ethics, course-work in biostatistics and grant writing.

1. **Research Fellow Information (if known**):

Provide name, address, phone numbers (office and cell) and email address.

 **Submission Deadline**

Empire Clinical Research Investigator Program project abstracts, biosketches and a letter demonstrating the teaching hospital’s funding commitment, must be submitted to New York State Department of Health **electronically (in Microsoft Word or PDF format) to** **doh.sm.ecrip@health.ny.gov** **any time but no later than 4:00 p.m. on July 11th 2024).** Please include “Empire Clinical Research Investigator Program Abstract” in the subject heading.