

**Request for Proposals to Develop
the Long Island Center for Cell and Gene Therapy (“RFP”)**

Addendum #13

Release Date: February 29, 2024

- 1) **RFP Inquiries:** The following is a list of responses to questions submitted by prospective respondents (“Respondents”) to the Request for Proposals to Develop the Long Island Center for Cell and Gene Therapy between January 25, 2024 and February 28, 2024. A copy of the RFP is available at: <https://esd.ny.gov/sites/default/files/rfp/12-12-23-LI-CGT-Center-RFP.pdf>.

Addendum 8, which provided answers to questions received by January 24, 2024, has been added as an attachment to this document.

Please note that all capitalized terms used below and not otherwise defined in the below list of responses will have the meanings set forth in the RFP. In addition, some questions have been paraphrased or combined with other similar questions for which one response has been given for these questions in the list below. Finally, some responses below clarify or correct responses given by presenters during previous site visits or virtual presentations.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

Long Island Center for Cell and Gene Therapy RFP Responses to Questions

No.	Question	Answer
25)	Can an alternative site be used?	The Site located at 1 Marcus Avenue, Lake Success, NY as defined on p. 9 of the RFP, is the only site that will be used for the development and operation of the Long Island Cell and Gene Therapy Center.
26)	Will the site’s existing building and parking lot be delivered vacant?	The RFP site will be delivered vacant and in “as is” and “where is” condition. Both the parking lot and existing building will not have any remaining Northwell presence at time of delivery. Please also see response to Question 22.
27)	What is the anticipated Project construction completion and occupancy date?	The timeline for construction completion, land use and related approvals, and occupancy of the Project will depend on the plans and requirements of the selected RFP Proposal date. ESD will work with the Designated Developer to develop an appropriate timeline once it has been chosen. Respondents are also reminded that an estimated development timeline is required as part of their Proposals to the RFP. Please see. P. 25 of the RFP for more information.

No.	Question	Answer
28)	What is the timeline for grant disbursement?	<p>After designation, the Designated Developer will receive from ESD an “Incentive Proposal” document(s) that will define the parameters, timeline, and requirements of the Grants. Following acceptance of the Incentive Proposal, the Designated Developer may begin work on the Project. ESD will begin the approval process for a Grant Disbursement Agreement(s) (“GDA”) based on the terms and conditions outlined in the Incentive Proposal around the time the Grant Project is ready for it’s first reimbursement. The GDA approval process involves several steps, including ESD Board approval, public hearings, and approval by the Public Authorities Control Board (“PACB”).</p> <p>Disbursements of the capital construction Grants will be given on a reimbursement basis for construction and fit out costs for the Project. Any capital grant funds disbursed during the construction period are given pro rata with other non-ESD funding sources on a quarterly basis and are also subject to submission and approval of documentation as described on p. 20 of the RFP.</p> <p>Disbursements of the working capital grant would be given during operation of the Project to support operation of the CGT Business Incubator. Please see p. 19 of the RFP for more information.</p>
29)	Is the developer expected to bring in a design team?	<p>The RFP seeks Respondents who will successfully finance, <i>design</i>, construct, market and tenant, fit out, operate, and maintain the Project. To fulfill this objective, the Designated Developer is responsible for bringing in a design team. Please see p. 24 of the RFP for design materials required to be submitted as part of a Proposal.</p>
30)	Is Northwell allowed to submit a bid?	<p>Northwell is not submitting a Proposal in response to the RFP to develop and operate the the Long Island Center for Cell and Gene Therapy.</p>

No.	Question	Answer
31)	Did ESD consider other sites to build the Long Island CGT Center on?	ESD did a comprehensive review of potential sites for the RFP. After analyzing the cost of construction across the State, the ownership structure of potential sites, a potential site’s proximity to existing cell and gene therapy research and academic centers, and the land area of and possibility for future expansion on a site, ESD chose the Site at 1 Marcus Avenue, Lake Success, NY.
32)	Why is there a split in funding between the Incubator and larger CGT Center?	<p>The CGT Business Incubator is a critical and distinctive component of the State’s strategy and plans to expand the life science ecosystem in New York State and establish New York State as the leading center for CGT research, development, and patient care in the nation. Because the CGT Business Incubator is a distinct component of the Project, ESD established a separate grant for it.</p> <p>As described on pp. 8 & 19 of the RFP, the Grants are allocated as up to \$100M for the Long Island CGT Center, and up to \$50M for the CGT Business Incubator. The \$50M in potential grants for the CGT Business Incubator is split as up to \$25M for the construction and up to \$25M for the operation of the CGT Business Incubator for the first five years of its operations.</p> <p>The structure of the Grants would allow a developer to potentially phase the Project over time, while still allowing for reimbursement for the main CGT facility.</p>

No.	Question	Answer
33)	<p>What is the approval process for the RFP?</p> <p>Will ESD and Northwell be involved in reviewing and approving the design?</p> <p>What is Dark Horse’s role in the RFP?</p>	<p>ESD shall establish a selection committee to evaluate Proposals and select a Designated Developer in accordance with the Selection Criteria listed on pp. 30-31 of the RFP. The Selection Criteria will be assessed against the materials submitted as part of a Proposal and a Proposal’s achievement of the Development Objectives listed on pp. 13-14 of the RFP.</p> <p>After a Designated Developer has been selected, the Designated Developer’s Proposal will be subject to further approvals as described in the response to Question 8.</p> <p>Northwell will act in a advisory capacity during the proposal selection process, but will not have voting power on the selection committee that makes the final decision on which bid is selected. However as part of discussions associated with the ground lease and/or in its role as ground lessor, Northwell may ask for certain design considerations.</p> <p>Dark Horse was contracted as a consultant to assist ESD with the technical aspects of the project relative to cell and gene therapies. Dark Horse will provide expertise on these therapies and will advise ESD during the selection process. Like Northwell, Dark Horse does not have a voting role on the RFP selection committee that will review submitted proposals.</p>

No.	Question	Answer
34)	Will funding to go companies doing research at the completed facility?	<p>The grants available to the successful respondent are for the construction and operation of the Long Island Cell and Gene Therapy Center. Grants earmarked for the RFP are not directly available to future tenants of the completed site. However, other grant sources or programs within ESD’s purview may be available to tenants in the future. Information on other incentive programs offered by ESD or other public entities can be found at these links:</p> <ul style="list-style-type: none"> • Excelsior Jobs Program • Long Island Investment Fund ▪ Regional Council Capital Fund Program ▪ Nassau County Industrial Development Agency ▪ NYS Real Property Law 485-B ▪ US Economic Development Administration
35)	How important is additional development on the site?	<p>The Program and Facility Requirements section found on pp. 17-18 of the RFP includes the “Reservation of space at the Site for future expansion. As the Long Island CGT Center and its tenants grow, it is essential to ensure the site is developed in such a way as to enable growth in the number of occupants and expansion space (for existing and new tenants).”</p> <p>ESD will evaluate Proposals on the degree to which a Proposal meets the Development Objectives and Requirements of the RFP, including the reservation of space at the site for future expansion. The Selection Criteria section of the RFP can be found on pages 30-32.</p>
36)	Will you put out an RFP for an Owners Representative?	ESD is currently evaluating the appropriate process for procuring an Owner’s Representative, which may include an RFP after a Designated Developer has been selected.
37)	What is Northwell’s role in the RFP?	Please see responses to Questions 2 and 33.

No.	Question	Answer
38)	<p>Regarding materials access for CGT researchers and developers, particularly around vector and plasmid production and associated manufacturing services, how much emphasis should be put on starting cellular materials for development research and clinical production, including disposables, reagents, etc.?</p>	<p>Access to starting materials in research, clinical, and commercial phases can be a major issue. For example, in the research and clinical phases material that may be less than GMP standard could be sourced, but the FDA requires validation on agents in the commercial process. CGT companies sourcing critical components run into issues with materials producers having a lack of experience with the FDA, and many materials vendors have not been through a PLI or PAI process with the FDA. Having to go through that for the first time is challenging and costly and can lead to major delays in commercial filing. The future of vector production hinges on producers hiring scientists and industry veterans with significant experience in designing quality vectors that can help academic or industry partners move towards commercialization of their therapies.</p> <p>Disposable and reagent producers are largely single source. A majority of the equipment is made by a single brand or producer. It's extremely difficult to find commercially viable alternatives with suitable experience. If there's a company that makes cell isolation equipment, it's difficult to find a second source to do cell isolation that might have enough commercial experience. Which is a major supply chain issue. Reagents are ideally GMP at the clinical stage, but GMP quality reagents aren't always available due to need or cost.</p> <p>The increased capacity and expertise that the LI CGT Center will develop could be very helpful in increasing the availability of GMP-quality cellular materials, reagents, and disposables, and alleviate the materials access supply chain issues experienced by CGT researchers and developers.</p>

No.	Question	Answer
39)	What is the importance of digital process control for compliance with Chain of Identity regulatory requirements with capabilities for data provenance throughout the entire value chain?	<p>Data integrity is critical during all aspects of GMP and manufacturing. Digital process controls and automation are even more important during the commercial phase to reduce COGS, given the higher throughputs commercial work entails.</p> <p>For early phase work, compliance with FDA data regulations is also critical. The FDA provides regulatory guidance for digital process control, but it is also important to be aware of other federal and State regulations.</p>
40)	Will you be posting any of the market data or studies that have been completed in connection with demand and NYS capabilities?	<p>Helpful information, market data, and studies relative to CGT demand and capabilities found in NYS can be found on the Alliance for Regenerative Medicine’s website, as well as Dark Horse Consulting Group’s website. Additional information on the future of CGT and life sciences in NYS can be found in the ESD Life Science Strategic Plan, found here.</p>
41)	To what extent does a CGT hub need to be integrated with advanced genomic testing for diagnosis, treatment response prediction and response monitoring?	<p>Having those services could be a major asset to the LI CGT Center but doesn’t necessarily need to be included. ESD is open to all ideas as to what could be contained in the center. There is an extensive amount of testing that happens at all stages of development, and most of this testing is not something that a therapeutic developer may have the capability to do themselves, especially early on in therapy development. Having the ability to perform advanced genomic testing for diagnostics, as well as treatment response prediction and monitoring, would be valuable offerings for therapeutic developers.</p>

Each of the foregoing and attachments are added to and made part of the RFP. Any questions regarding this addendum may be submitted to the designated contact account for this solicitation at CGTHubLongIslandRFP@esd.ny.gov. To receive an update when a new addendum is posted to the ESD website, please email CGTHubLongIslandRFP@esd.ny.gov. If you have already emailed this account, you will be notified of future updates.

Attachment 1

Responses to Questions Received by 1/24/24 (Addendum 8)

No.	Question	Answer
1)	<p>What are the building air rights at One Marcus Ave?</p> <p>Are land use approvals the responsibility of the development team?</p>	<p>Respondents are responsible for analyzing and obtaining all required land use and related approvals, including compliance with zoning, to effectuate the Project. As part of the zoning analysis to be submitted with Proposals, Respondents should include any building density calculations or analyses or building height variances needed for the proposed Project. As described on p. 25 of the RFP, Respondents must identify all desired zoning overrides, and any required permits and authorizations to effectuate the Project.</p> <p>The Site is subject to the zoning ordinance of the Village of Lake Success, which would be the entity to which the Designated Developer would need to apply for any changes to zoning required to implement its project. ESD and Northwell would consider the Designated Developer’s efforts to obtain the necessary municipal zoning changes, variances, and/or approvals.</p> <p>The Village of Lake Success would also be the lead agency for any required environmental review for the Project, and ESD would be an involved agency in such review. Please see p. 12 of the RFP for more information on environmental review of the Project.</p>

No.	Question	Answer
2)	<p>Is Northwell the land owner and/or lease owner?</p> <p>Will Northwell consider a 99 year ground lease in lieu of the 40-50 year ground lease state in the RFP?</p>	<p>Northwell Health, as the fee-owner of the Site, will negotiate to enter into a development agreement and long-term net ground lease with the Developer selected through the RFP process for the Site pursuant to which the Developer would design, finance, build, market and lease, and operate the Project. Please see p. 7 of the RFP for more information.</p> <p>Northwell will consider a ground lease term longer than 40-50 years. Respondents may be asked to provide the reason(s) why a longer lease term is sought.</p>
3)	<p>What is the relationship between Empire State Development and Northwell?</p>	<p>ESD and Northwell Health have a cooperative agreement, memorialized in a memorandum of understanding, to collaborate on the development of the Long Island Cell and Gene Center on the Northwell-owned Project Site in Lake Success, Nassau County. The successful Respondent would be required to enter into a long-term lease agreement with Northwell Health following the review and selection of the successful Respondent by ESD.</p>
4)	<p>Where are the loading docks located?</p>	<p>The loading dock is located on the southeast side of the building at ground level and leads below grade into the building. Please see "Attachment 2" to this addendum for a map.</p>
5)	<p>Will the list of site visit attendees be posted?</p>	<p>Please see the answer to question #1 on p. 1 of this addendum (Addendum #8)</p>
6)	<p>Will the RFP deadline be extended?</p>	<p>On January 10, 2024, ESD announced that the deadline to submit Proposals has been extended to March 26, 2024, 5:00PM. Please see Addendum #2 for more information.</p>
7)	<p>Are there any additional as-builts of the current building or other existing site plans of the current site?</p>	<p>ESD and Northwell are searching for any additional available surveys, drawings, maps, reports, site plans etc. and will post any available surveys as an additional addendum. All materials available thus far can be found in the RFP and in Appendix A of the RFP.</p> <p>The handout provided at the prior two site visits is attached to this addendum as "Attachment 3."</p>

No.	Question	Answer
8)	<p>The site is partially in Queens, have there been any discussions with the municipalities or in place agreements on who has jurisdiction for these parcels? (that portion of the site is zone R3-2)</p> <p>Has the Village of Success Lake been apprised of this pending development?</p>	<p>The Site is located at One Marcus Avenue, Lake Success, NY 11042, and an approximately 15.32-acre tax lot <u>entirely</u> within the Village of Lake Success in the Town of North Hempstead in Nassau County (Assessors Map Parcel ID: 8-J-10). No part of the Site is located within the Borough of Queens, New York City.</p> <p>ESD and Northwell have apprised local Village officials of the Project and the Village has expressed support for the proposed project. As described in the answer to Question #1, the Designated Developer must apply to the Village for needed zoning approvals, rezoning, or variances for the Site to achieve the Development Objectives of the RFP. The Village of Lake Success would also be the lead agency for any required environmental review for the Project, and ESD would be an involved agency in such review. Please see p. 12 of the RFP for more information on environmental review of Project. In addition, please see p. 13 of the RFP for information on taxing jurisdiction of the Site.</p>
9)	<p>What are the terms of the lease of the parcel that is part of the golf course? Can the open space of that site be used to add to the site coverage on this parcel?</p>	<p>The Site does not include the contiguous tax lot also owned by Northwell that is leased to an adjacent golf course. The adjacent golf course cannot be incorporated in any way as a part of Respondents' Proposals.</p>
10)	<p>The development to the east is sharing the curb cut and entry road from Marcus Avenue – will that need to be maintained? Is there an agreement or easement?</p>	<p>The entry road and curb cuts to the Site as indicated in Attachment 2 to Addendum 7 are completely on the Project Site and do not provide shared access to any other properties. The maintenance of these curb cuts and entry roads would be the responsibility of the Developer.</p>

No.	Question	Answer
11)	Is LEED certification required?	<p>Respondents are not required to propose LEED certification as part of their Proposals. However, Respondents must incorporate sustainable features and green building practices into the Project during the construction and operation that help meet the carbon reduction goals of the New York State Climate Leadership and Community Protection Act (“CLCPA”). Please see p. 25 of the RFP for more information.</p> <p>In addition, the Development Objectives on p. 14 of the RFP include the incorporation of green building and sustainable design practices. This Development Objective may be supported by LEED or LEED-equivalent standard certification and will be considered as part of the Scoring Criteria listed on p. 31 of the RFP.</p>
12)	Are incoming utility services sufficient to support the program?	Information on current utility service providers to the Site can be found on p. 12 of the RFP. Respondents must perform their own analyses to determine whether current utility infrastructure is sufficient to service their proposed Project.
13)	Please confirm that geotechnical services are directly contracted to ESD.	The Designated Developer will be responsible for contracting its own geotechnical services should those services be necessary. ESD will not contract any geotechnical services for the Project.
14)	Is the RFP to design, build, and operate- not just one or the other?	The RFP is seeking a Developer to design, finance, build, market and lease, and operate the Project.

No.	Question	Answer
15)	Are there restrictions on employment for the design-build? Does it have to be a New York firm or New York State certified?	<p>ESD does not have preferred firms for professional services provided to Respondents. However, as described on p. 45 of the RFP, ESD strongly encourages Respondents to use New York State businesses. Respondents are also encouraged to use Socially and Economically Disadvantaged Individual-Owned Businesses (“SEDI”) as mentioned on p. 14 of the RFP.</p> <p>In addition, Respondents are reminded that they are required to demonstrate good faith efforts to achieve the applicable Minority and Women-Owned Business Enterprises (“MWBE”) participation goal set forth on pp. 40-41 of the RFP. Respondents may search for MWBE firms at https://ny.newnycontracts.com. The MWBE goal applies only to the Grant amount for eligible activities and not to total Project costs.</p> <p>In order to qualify for the MWBE participation goal, businesses must be MWBE-certified with New York State. MWBE certification with the City of New York or The Port Authority of New York and New Jersey does not qualify for MWBE participation goal. A business must be certified by the time of contract execution to receive credit towards the MWBE participation goal.</p>
16)	Is a conceptual design ok for the RFP?	<p>Conceptual design documents will be accepted as part of a Respondent’s Proposal. ESD may ask for additional details or design plans or drawings upon reviewing Respondents’ design submissions. Respondents are also encouraged to refer to pp. 23-25 of the RFP for a description of required elements of submitted Proposals including a site plan, massing diagram, and design narrative.</p>

No.	Question	Answer
17)	<p>Are there any commitments to lease space within the development?</p> <p>Are Respondents required to have committed tenants at the time of submitting a Proposal?</p> <p>Will Northwell lease space at the Long Island (LI) Cell and Gene Therapy (CGT) Hub?</p>	<p>Neither ESD nor Northwell have obtained any commitments from potential tenants to lease space at the Project. The Designated Developer is responsible for the marketing and lease-up of future space at the Project.</p> <p>Respondents are not required to have committed tenants at the time of submission of their Proposals. However, Respondents are required to submit a list of potential tenants and any available letters of interest/intent as part of their submission. Respondents are also encouraged to submit additional information regarding potential tenants/occupants such as documentation supporting potential tenant’s technical and financial capacity to fit out and occupy the space at the LI CGT Hub and/or documentation supporting potential tenant’s ability to perform its services at the LI CGT Hub. Please see p. 24 of the RFP for more information on required the Required Proposal component regarding potential tenants at the LI CGT Hub.</p> <p>Northwell has a strong interest in leasing space at a future development at the Site subject to its space needs and will discuss any possible leasing with the Designated Developer.</p>
18)	<p>Are there requirements for developers on how they deliver the facility to tenants?</p>	<p>The Designated Developer may deliver space at the Project to its tenants in any condition subject to negotiations between the Designated Developer and tenants at the Project. In all cases, the delivery of space to tenants must meet the Program and Facility Requirements of the RFP described on pp. 17-18 of the RFP.</p>
19)	<p>Are there area requirements in the space or in the incubator?</p>	<p>Respondents should propose a development plan that includes the construction of approximately 25,000 gsf of CGT Business Incubator space as an included component of the approximately 200,000 gsf Long Island CGT Center and should also leave additional space for future expansion of the Long Island CGT Center on the Site. Please see p. 7 of the RFP for more information.</p>

No.	Question	Answer
20)	Is the incubator CGT-focused also?	Yes, the mission of the CGT Business Incubator is to increase the number and speed with which CGTs are translated from discovery to the clinic. The CGT Business Incubator will foster CGT companies emerging out of the research conducted throughout New York State and beyond, as well as startups seeking support on their way to product commercialization. Please see pp. 6 and 18 of the RFP for more information on the focus of the CGT Business Incubator.
21)	Does this state funding trigger PACB approval?	Yes, execution of the Grant Disbursement Agreement and disbursement of funding of the grant will be subject to approval by the Public Authorities Control Board (“PACB”). In addition, approval by the ESD Directors; a public hearing; SEQRA review will be required for the grant. Please see p. 19 of the RFP for more information.
22)	Is the building still occupied?	The building and parking lot located at the Site are currently used on a limited basis by Northwell. However, both the building and parking will be delivered vacant prior to the start of construction of the Project.
23)	Would having a hospital other than Northwell as a tenant at the LI CGT hub be a possibility or would it be considered competing with Northwell?	The LI CGT Hub may include a hospital other than Northwell and/or facilities for clinical research, clinical trial services, a CDMO, clinical genomics laboratories, clinically based AI services, other advanced research, diagnostic, manufacturing, and treatment services, and related companies and startups. However, the LI CGT Hub may not have a tenant that is a hospital or a medical, surgical, rehabilitation, diagnostic, or laboratory enterprise that provides in-person services to patients unless such tenant is a Northwell or Northwell-affiliated entity. Please see pp. 18-19 of the RFP for more information on permitted tenant uses at the LI CGT Hub.
24)	Would having a pilot manufacturing space at the LI CGT hub be a possibility?	It is expected that the facility will include cGMP manufacturing space that would support pilot production and clinical manufacturing. Please see pp. 18-19 of the RFP for more information on permitted tenant uses at the LI CGT Hub.

Attachment 2

One Marcus Avenue Loading Dock

Loading Dock



Loading Dock



Entry/Curb Cut



Entry/Curb Cut

