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## **Program Overview**

## Background

Since March of 2020, Puerto Rico, like most jurisdictions in the United States and countries around the world, has experienced an unprecedented emergency caused by the Coronavirus Disease 2019 ("COVID-19") pandemic. To slow the spread of the disease and ensure stability of its healthcare system, the Government of Puerto Rico has implemented measures to address the emergency.

On March 12, 2020, the Government of Puerto Rico issued Administrative Bulletin OE-2020-020 through which formally declared a state of emergency due to the imminent impact of the coronavirus in Puerto Rico. During the state of emergency, Puerto Rico suffered great loss of life and severe economic hardships which have impacted a Commonwealth still reeling from natural disasters. Puerto Rico lost over 2,500 citizens, tourism dwindled with hotel registrations falling 95% from February to April 2020, and ~460,000 residents of Puerto Rico experienced unemployment, twice the previous number of unemployed individuals. Despite these hardships, Puerto Rico persevered, and with over 2,600,000 doses of COVID-19 vaccines administered, Puerto Rico is positioned to emerge from the COVID-19 pandemic.

To help Puerto Rico emerge from the COVID-19 pandemic, Congress passed the American Rescue Plan Act of 2021 ("ARP Act"), and the President signed it into law on March 11, 2021. To assist state governments with addressing the lingering public health emergency while targeting areas and industries in needs of economic development, the ARP Act established the Coronavirus State and Local Fiscal Recovery Fund, which provides \$350 billion in direct assistance to states, territories, counties, metropolitan cities, tribal governments, and non-entitlement units of local governments. As part of the Coronavirus State and Local Fiscal Recovery Fund, Puerto Rico received \$2.47 billion under the Coronavirus State Fiscal Recovery Fund ("CSFRF").

To ensure the expeditious processing of apportioned funds from the CARES Act, the Government of Puerto Rico established the Disbursement Oversight Committee, consisting of the Secretary of the Department of the Treasury, the Director of the Office of Management and Budget (OGP), and the Executive Director of the Puerto Rico Fiscal Agency and Financial Advisory Authority (AAFAF). The Committee was created on May 15, 2020, by means of Executive Order No. 2020-040, and on May 7, 2021, by means of Executive Order No. 2021-034, the Governor of Puerto Rico extended the Committee's oversight to include CSFRF.

#### **Program Description**

Given the stage of the pandemic, Puerto Rico has identified an opportunity of accelerating the development of new medications and treatments for COVID-19. This will also be an opportunity to further stimulate the Life Science economic sector in Puerto Rico, promoting the drug and product discovery with research and development programs, such as this one. This will be a grants program for research and development projects for the development of new treatments and or/ drugs to treat COVID-19. The projects evaluated can be either academic projects or projects performed by companies. All will be evaluated and scored based on public health impact and its economic development potential.

Disbursement of Program funds will be subject to the strictest standards to ensure compliance with federal regulations and best practices. Therefore, each request for disbursement will be duly documented and subject to control and audit.

### Points of Contact

The Program will be administered by the Coronavirus Relief Fund Disbursement Oversight Committee (Committee) in conjunction with the Puerto Rico Department of Economic Development and Commerce (PR-DEDC), and the Puerto Rico Fiscal Agency and Financial Advisory Authority (AAFAF).

## Eligibility Criteria

#### Eligible entities are:

- Businesses established and operating in Puerto Rico
- Academic institutions or academic researchers
- Private research organizations

#### Eligible activities for the grants:

- Lab research and development (academic or industrial)
- Pre-clinical research
- Clinical trials

#### Eligible expenses

- Operational expenses such as: wages and salaries of researchers, students or PIs participating in the project, materials needed for the research, professional technical services needed, among others
- Capital expenses: acquisition or construction of facilities needed strictly to perform the project

### Eligible applicants must meet the following criteria:

- The applicants that apply must be operating in Puerto Rico and all the R&D and/or manufacturing
  activities must be performed in Puerto Rico. If there are co-developments happening with nonPuerto Rico entities, the applicant must submit proof that 50% or more of the activities are
  happening in Puerto Rico.
- Businesses must have at least one year of operations.
- Documents:
  - I. No debt Certifications of the Government of Puerto Rico
    - a. Treasury
      - i. Merchant Registration
      - ii. No tax debt
      - iii. Tax return submission certificate for 5 years
      - iv. Sales and use tax Debt
      - v. Sales and use tax debt submission
    - b. Labor Department
      - i. Debt Certificate Labor Department
      - ii. Debt Certificate Unemployment Insurance
      - iii. Debt Certificate Disability insurance and driver insurance

- If the applicants are University professors and the R&D is through the university, the applicants must submit evidence that their programs are supported and validated by the University.
- Commit to abiding by the Program's terms and conditions, and agree to return the Program funds, if it is determined that they did not comply with any of the Program eligibility requirements, or if the Program funds were not spent on eligible expenses by December 31, 2024.

#### **Evaluation Process**

The projects applying for these grants will be evaluated with the following criteria:

Description	Evaluation criteria
How ready is this product/treatment	Clinical phase approved, FDA approvals
for the market?	
What economic impact will this	Jobs created during and after the process, wages, IP
project have?	creation and licensing, etc.
How much support does the project	Funding sources (federal, private, etc.)
have?	
How viable is the project?	Market study, peer reviewed papers published, etc.
What is the public health impact?	Population impacted, by geography, by ethnicity.

• The projects will be evaluated by a multi-disciplinary committee that will include people with experience in the Life Sciences sector, in evaluating R&D projects and in the public health sector. The projects will be scored on a scorecard based on the above mentioned criteria.

#### Selection Process:

- Once the PR-DEDC publicly announces the program, applicants will have 30 days to submit applications.
- After the 30 days, the PR-DEDC team will have 10 days to request additional information from all applicants.
- After that, the PR-DEDC will carry out its selection process based on the criteria established in these guidelines. This process should not take more than 30 additional days, from the close of the period for submitting documents.
- The PR-DEDC will form a selection committee led by the Deputy Secretary for Strategic Sectors.
  - Selection committee will be composed of individuals with expertise in the public health sector and in research and development, both for industrial and academic purposes.

## **Grants & Requirements**

- The grant amount will be determined by the committee, based on the amount requested, scoring and number of applicants.
  - Academic projects will have a cap of \$250,000 per fiscal year.
- The disbursement of the grant will be made in stages as the applicant must submit documentation showing milestones completed.
- In addition, the applicant must submit the invoices or evidence related to the project costs.

• The evaluation of the documents to claim the corresponding payment by the PR-DEDC should not exceed 45 days.

### **AAFAF & Grant Process Overview**

The following is intended to outline the process by which funds from the CSFRF will be distributed to the Puerto Rico Department of Business Development and Commerce (DEDC).

October 4, 2021	Award Announced
April 25, 2022	Funds Advanced to Department of Economic Development and
	Commerce
May 2022	PR-DEDC Publishes Guidelines and announces timeline for the program
June 2022 – Funds Expended	Biweekly Use of Funds Report
July 2022– Funds Expended	Monthly Performance Report
December 31, 2024	Deadline for award to be used
January 2025 – February 2027	Program Audits and Compliance Review

#### Requests

Requests will be submitted electronically to <u>COVIDgrant@DDEC.pr.gov</u> or by phone at 787-758-4747. Upon submission, Applicants will receive a confirmation via electronic mail.

Additional information for the COVID-19 R&D and Treatment grant program will be posted at <a href="http://www.ddec.pr.gov">http://www.ddec.pr.gov</a>. Supplier and beneficiaries' registration will be through <a href="http://www.refuerzoeconomico.com">http://www.refuerzoeconomico.com</a>.

More information on forms, documents, and eligibility can be found on the web at: <u>Coronavirus State and Local Fiscal Recovery Funds – AAFAF (pr.gov)</u>.

#### **Evaluation**

For all requests, decisions will be evaluated for completeness and eligibility, and final determinations will be made by representatives of DEDC. Each Request will be evaluated, and Program funds allocated using a standard of necessity.

The Disbursement Oversight Committee will receive a final report of Funding award decisions.

#### Award and Funding

Requestors will be notified via electronic mail of funding decisions. Subsequent funding opportunities (including expansion of eligible institutions and use of funds) will be determined based upon availability of funds remaining after completion of initial awards.

## Ineligible Expenditures

Ineligible expenses will be determined by the Committee, the U.S. Department of the Treasury, the Office of Inspector General (OIG), and other regulatory bodies, and under this award include, but are not limited to:

- · Payments to any institution that does not meet the Eligibility Criteria
- Necessary expenses that have been covered or reimbursed, or that will be covered in the future, by other state or federal programs, including funds received through the CARES Act or from FEMA

For further guidance please refer to the Guidance published by the U.S. Treasury at <a href="https://home.treasury.gov/policy-issues/coronavirus/assistance-for-state-local-and-tribal-governments/state-and-local-fiscal-recovery-funds">https://home.treasury.gov/policy-issues/coronavirus/assistance-for-state-local-and-tribal-governments/state-and-local-fiscal-recovery-funds</a>.

## Compliance

Any government entity receiving funds must adhere to the Uniform Guidance, 2 C.F.R § 200 ("Uniform Guidance"). This Uniform Guidance outlines the "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards". Recipients and their personnel are responsible for reviewing, understanding, and applying the complete underlying legislation and guiding documents. For complete details on 2 CFR 200, visit the Electronic Code of Federal Regulations at <a href="https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200">https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200</a> main 02.tpl. Topics included in the Uniform Guidance include, but are not limited to:

- Procurement standards and requirements
- Contract cost and price principles
- Bonding requirements
- Document retention and auditing provisions

Any government and non-government entity receiving Program funds will be required to retain use of funds records and supporting documentation for a period of five (5) years. Furthermore, by accepting CSFRF funds, government and non-government entities are required to certify proper and legal use of the funds and agrees to cooperate in any audit proceedings requested by the Government of Puerto Rico or other governing entity responsible for the compliant use of Program funds.

## Reporting Requirements

On an annual basis, the Government of Puerto Rico is required to submit a performance report detailing the progress and impact of the use of CSFRF funds. This Recovery Plan Performance Report will include descriptions of the projects funded and information on the performance indicators and objectives of each award, helping residents understand how their governments are using the substantial resources provided by Coronavirus State and Local Fiscal Recovery Funds program.

The key output performance indicators for this Program include:

- Amount disbursed
- Treatments and diagnostic technologies funded for COVID-19
  - o Effectiveness of treatments by variant

The key outcome performance indicators for this Program include:

- Number of subjects tracked and/or studied
- Numbers of variants identified

To ensure timely reporting, the Government of Puerto Rico requires the Lead Agency to adhere to the following reporting frequency:

- On a weekly basis, the Puerto Rico Department of Treasury will provide a summary of all program disbursements to date.
- On a monthly basis, the lead agency will provide a report of all performance indicators

To ensure timely reporting, the Government of Puerto Rico requires the Recipients to adhere to the following reporting frequency:

- On a biweekly basis recipients will be required to submit financial reports using the reporting template provided by the Program. Upon program close, recipients will be required to submit a comprehensive final financial reconciliation report detailing the use of program funds.
- On a monthly basis the Lead Agency will report the number of subjects treated or studied, and the variants identified in these studies.

As reporting needs may change over time, the Program reserves the right to request additional data from the Lead Agency or Recipients at any time.