

Establishment of a National Laboratory for Infectious Diseases Research

(Phase I- Virology Research Laboratory)

Call for proposals

March (2021)

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I. Introduction:

Threats from emerging and reemerging infectious diseases have increased globally. Pathogens from animal origin are the cause of zoonotic infections in humans¹ and there is a consensus that the origins of future human pandemics are likely to be also zoonotic.

The Eastern Mediterranean region is a hotspot for emerging and re-emerging infectious diseases. In Egypt emerging and re-emerging infectious diseases increasingly threaten public health and contribute substantially to the escalating costs of health care. Many of the countries in the region including Egypt, have witnessed outbreaks from emerging infectious diseases in recent years. These include, Middle East respiratory syndrome, cholera, avian influenza A (H5N1) infection, dengue fever, and chikungunya. hand, foot and mouth disease due to Enterovirus 71, MER CoV, tuberculosis infection, and infection with hepatitis C virus². Many risk factors contribute in the emergence and rapid spread of epidemic diseases in the region including acute and protracted humanitarian emergencies, resulting in fragile health systems, increased population mobility, rapid urbanization, degradation of ecosystems and loss of its biodiversity, climate change, weak surveillance, limited laboratory diagnostic capacity, and increased human-animal interaction³.

In 2019, COVID-19 emerged globally, claiming millions of lives and affecting millions more. In Egypt, the first case of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was reported on the 14th of February indicating the inception of epidemic in Egypt as a part of the worldwide pandemic of coronavirus disease 2019. The prevention and control of such diseases is primarily reliant on strong scientific foundation. Smallpox, the greatest human killer has been eradicated through a concerted global vaccination effort led by the World Health Organization. The global increase in life expectancy during the 20th century owed much to the containment of infectious diseases. The success in eradicating smallpox and containment of many other infectious diseases were largely inspired by the progress and advancement in the virology⁴.

Research not only support the development of effective vaccines and antiviral therapies but has also shed the light on the biology of cells that are infected with viruses which support in the discovery of cures for cancers and other relevant diseases⁵. Despite the tremendous progress that has been achieved in the medical arena, infectious diseases continue to emerge and reemerge indicating that much needs to be done.

¹ Morens DM, Fauci AS. Emerging Pandemic Diseases: How We Got to COVID-19. *Cell*. 2020 Sep 3;182(5):1077-1092. doi: 10.1016/j.cell.2020.08.021. Epub 2020 Aug 15. Erratum in: *Cell*. 2020 Oct 29;183(3):837. PMID: 32846157; PMCID: PMC7428724.

² The perpetual challenge of emerging and re-emerging infectious diseases in Egypt. 5th World Congress on Virology. December 07-09, 2015 Atlanta, USA. *Gamal El Sawaf*, Alexandria University, Egypt

³ Buliva, E., Elhakim, M., Tran Minh, N. N., Elkholy, A., Mala, P., Abubakar, A., & Malik, S. (2017). Emerging and Reemerging Diseases in the World Health Organization (WHO) Eastern Mediterranean Region-Progress, Challenges, and WHO Initiatives. *Frontiers in public health*, 5, 276. <https://doi.org/10.3389/fpubh.2017.00276>

⁴ Enquist LW; Editors of the Journal of Virology. Virology in the 21st century. *J Virol*. 2009 Jun;83(11):5296-308. doi: 10.1128/JVI.00151-09. Epub 2009 Mar 18. PMID: 19297504; PMCID: PMC2681991.

⁵ Imperiale, M. J., & Casadevall, A. (2015). The importance of virology at a time of great need and great jeopardy. *mBio*, 6(2), e00236. <https://doi.org/10.1128/mBio.00236-15>

II. Grant Aims and Objectives

The present call is the first phase of establishing a national laboratory for infectious diseases research and focusses on establishing an advanced virology research laboratory in Egypt. This research laboratory is expected to contribute to prevention and control of emerging and reemerging infections through the introduction of scientific, methodological and coordination activities in multi- and interdisciplinary approaches. It will also provide highly specialized infectious diseases diagnostics, hence supporting effective treatment for cases and prevent the development of anti-microbial resistance. It will enhance the knowledge in the field of infectious diseases' molecular biology, genetics and immunology which will be reflected on the health and wellbeing of all Egyptians. The research laboratory will be the hub for basic and pre-clinical research in a concerted effort to speed the development of diagnostics and discovery and development of therapeutics for a wide variety of endemic and emerging infectious diseases.

The main objective of this call is to support the establishment of a national laboratory for infectious diseases research and equipping it with the required human and material resources to conduct high quality research. The research laboratory's main objectives include *but not limited to*:

- Conduct basic/ pre-clinical research on priority infectious diseases;
- Contribute to drugs' and vaccines' research and development of clinical trials;
- Engage in reference and specialized testing;
- Build national capacities in the fields of infectious diseases' basic/preclinical research, immunology, molecular biology, genetics, bioinformatics and epidemiology.

III. Priority Areas

The aim of **phase I of this call** is to support the establishment of **a national virology research laboratory**. The laboratory will conduct research, and diagnostics. It will be a scientific edifice capable of building technical and research cadres and equipped with technologies qualified to confront endemic infectious diseases and epidemics in Egypt. The funding will only be provided for research projects which address the following **virology research priorities**:

- Molecular biology and genetics
- Immunology
- Genomics and bioinformatics
- Vaccine development research

The data will enhance knowledge regarding the etiology, epidemiology, prevention and treatment of emerging and reemerging viral Diseases.

IV. Contribution and Added Value

The establishment of a national virology research laboratory mandated in phase I of this call will reflect on both research and practice. **The expected contribution of the virology research laboratory should at least include:**

1. Detection, characterization, and mapping of the prevailing and emerging viral threats in Egypt;
2. Viral genotyping and resistance testing;
3. Host factors contributing to susceptibility and resistance;
4. Biological risk assessment;
5. Diagnostics and drug testing;
6. Vaccine research; and
7. Building research and technical capacities in virology research.

The virology research laboratory will therefore enhance country's emergency and disease threats' preparedness, recommend evidence-based interventions, policies, strategies and plans for prevention and control of viral infections as well as synergize collaboration between academic, governmental, civil society, pharmaceutical industry and other research entities in the field of viral diseases research. **In addition, establishment of the virology research laboratory will pave the way for the establishment of a state of art national laboratory for infectious diseases research in Egypt indicated in Phase III of this grant.**

V. Grant Phases and Deliverables

Grant Phases:

- **Phase-I:** Establishment and staffing of a national virology research laboratory. The staff that will be hired in phase I will be in charge of the routine operation of the national laboratory including technicians and administrative staff. A robust management and administration plan for Phase I will be funded under this call.
- **Phase-II:** Staffing and operating the national virology research laboratory with high caliber experts in the fields of virology, molecular biology, immunology, genetics, bioinformatics, and epidemiology. The scientists hired in this phase will be implementing priority research projects that will be announced in phase II call. Research teams from different academic institutions and research entities can apply in phase II grant that will be funded under a separate STDF call.
- **Phase-III:** Expanding the scope of the national virology research laboratory to cover other infectious diseases of public and national health importance. This will be funded also by a grant under a separate STDF call.

Phase I grant aims to establish a national virology research laboratory that fulfills World Health Organization (WHO) requirements for biosafety level 3 in addition to other supporting units. **The duration of this phase extends to up to 18 months.** This research laboratory should fulfill biosafety level 3 that is capable of handling indigenous or exotic agents where the potential for infection by aerosols is real and the disease may have serious or lethal consequences.

Collaborative proposals between multiple research entities can be submitted in this call. An endorsement letter signed by the leading research entity to facilitate the establishment of a national research laboratory (providing the suitable locations) should be provided in the application form. **The expected deliverable from this phase includes:**

- The research laboratory structure which should include *but not limited to*:
 - Laboratory facility for virology and molecular biology research;
 - Laboratory facility that fulfills WHO requirements for biosafety level 3;
 - Immunology unit;
 - Vaccine research unit (GMP facility);
 - Animal research unit;
 - Biobank facility;
 - Data science unit;
 - Administrative and financial unit.
- The laboratory equipment will be specified, ordered, established and accredited.
- The human resource plan and training needs' assessment will be also set during this phase.
- The strategic plan of the research laboratory will be also drafted and should include the networking, and collaborative activities with public and private stakeholders and institutions of relevance as well as the sustainability plans.

VI. Timeline

- Launch of the call for proposals submission: 3 March 2021
- Deadline for submission of full proposals: 4 April 2021 at 11:59 pm
- Funding decisions announcement: 15 May 2021

NB. Orientation sessions on the proposal will be held online on the 9th of March 2021, 11:00 am. Candidates who are interested to join the session can send an email to:
Eng. Marwa Alaa: marwa.alaa@stdf.eg

VII. Eligibility Criteria

Each proposal should be submitted **jointly between academics from at least two universities/research entities in Egypt**. The following eligibility criteria apply to this grant:

- Any Egyptian research entity (university, research institution/center, etc.); working in one of the outlined priority areas; is eligible for funding.
- The applying institution is allowed to submit one proposal only. Priority will be given to institutions that can express their ability to formulate a research proposal that enables the achievements of the grant objectives and to implement research of national and public health priority.
- The applying institution should provide a suitable location for establishing the national research laboratory. The cost of building or allocating building/s for the national research laboratory will not be funded under any phase of this grant (self-funded participation by the university/research entity).
- The applying institution has to nominate an Egyptian researcher who has a PhD degree and is currently affiliated (or committed to be affiliated) with the institution, to act as the project's principal investigator (PI). The PI must have high h-index, citation and publications in Scopus. If the proposal is approved for funding, the appointed nominated individual will act as the director/manager of the national virology research laboratory. The leading institution should also nominate a Co-PI, who will replace the PI in case he/she becomes, for any reason, unable to carry on with his role as the director/manager. The priority specialties (*but not limited to*) that can hold the positions of PI and Co-PI are virology/microbiology, epidemiology and public health as well as clinical pathology.
- For individuals who are the PIs of an "on-going" STDF-funded project, the current call requires that they must have finished their projects successfully before the date of submission.
- Including young researchers (under the age of 40) and/or graduate (PhD or MSc) students in the research team is encouraged.
- The proposal should also clearly state how the equipment requested will help achieving the addressed scope of deliverables as given in the proposal. Additional fund request and/or extra equipment apart from those required in phase I call should be clearly justified and linked to the projects' objectives in the submitted proposal.

VIII. Proposal Submission

All applications must be uploaded to the STDF website (www.stdf.org.eg), to which registration is required. The submission will be in one stage as full-proposal submission. Independent and qualified experts will evaluate the proposals, and STDF will ensure that the process is transparent, impartial and applicant supportive.

Upon the eligibility check phase, eligible proposals are technically evaluated for the final decision. STDF carries out an evaluation of recommendations with the assistance of national/international independent experts. Only accepted and eligible proposals from the first phase will be invited to submit for the following phases. STDF staff ensures that the evaluation process is transparent, robust and fair, and aligned with its rules and regulations. **Submissions should cover the following workpackages:**

- **Description of applicant and host institution/s**
 - Location and infrastructure
 - Scope of work and human resources (specialties, laboratories, units, technology, etc.). In addition to
 - Direct experience in handling pathogenic organisms according to acceptable bio-safety guidelines.
 - Well recognized expertise in the isolation and serotyping of viruses
 - Availability of specialists in multiple relevant disciplines
 - Track record and previous funding of similar projects in this field and outcomes
 - Levels of commitment of applicant and host institutions (laws/regulations that can facilitate the establishment of the national virology research laboratory and its operation to achieve the projects' objectives, successful achievements in similar projects, etc.)
 - Collaborative activities with research/academic institutions, governmental or private sector entities nationally, regionally or internationally. This might include memorandum of understandings, agreements etc.
- **Plans for design and operation of biosafety level 3 laboratory (BL3)**
- **Plans for equipment** (including acquisition and maintenance)
- **Quality control and accreditation**
- **Operational plans** which should cover:
 - The terms of reference and task assignment of the joint collaboration between the submitting institutions
 - Operational plan for establishing a national virology research laboratory (BL3) either as a new laboratory, an upgrade of an existing laboratory or through liaising and collaboration with other entities that have such capability.
- **Human resources** and capacity building plans
- **Management and administration plans.** This includes the legal and institutional administrative regulations and bylaws that facilitate the operation of the proposed project. This would also include the hierarchy and work flow regarding the administrative and management procedures of grant's fund.
- **Budget and financial management**
- **Networking and collaboration plans** in this project
- **Sustainability plans**
- **Risks and risk management**

IX. Evaluation Criteria

Proposals submitted to this grant will be subjected to three levels of evaluation:

- I. Experts' evaluation in the field of specialty of the submitted proposal.
- II. Interview and oral presentation.
- III. Site visit and meeting with the host institution's officials to assess the facility preparedness for hosting the national virology research laboratory.

The funds are awarded based on the following criteria:

- The scientific, technological and/or innovative quality of the proposed project.
- Convincing coverage of above mentioned workpackages
- A clear scope in phase I and the potential for extension of the spectrum in the following phases and the standard methods addressed with their reference.
- Potential for growing an endogenous knowledge in the proposed field will place Egyptian researchers at the forefront of this area.
- A track record of success in the field as well as proven experience in the field of the proposed activities and laboratory research functions for the PI & and project team.
- A suitable location for establishing the national research laboratory.
- The host institution's ability and commitment to run the national virology research laboratory according to international standards, as well as the institution's equipment's services sharing policy and its ability to enforce it.
- The institution's ability to effectively add to the value and credibility in scientific research in the field of infectious diseases and therefore contribute to public health and sustainable development.
- Cooperation with stakeholders/industry and collaboration with other research institutes is highly encouraged.

X. Budget Estimation

The applicant should request for a budget that is well justified according to a detailed financial plan after accurate estimation of required resources (time frame). Consultation fees are allowed in this grant. Co-funding should be highlighted and well explained. The applicant institution⁶ will be responsible for transferring any costs eligible to their host and partner institutes⁷. The budget format in the proposal should be signed and stamped by the PI applicant institution. Successful candidates in the first phase will be invited* to submit their proposals to the following phases of this grant.

⁶ The applicant institution: It is the institution in charge for coordinating the grant's overall financial and administrative aspects.

⁷ Host institute is the institute that will host the national virology research laboratory. It could be the applicant institute or one of the partner institutes, A partner institute participates actively in a formal partnership and contributes in a meaningful way to the success of the project. The partner organization is also expected to provide cash and/or in-kind contributions.

Overestimation of the budget will be considered in the evaluation process. For phase I projects, the eligible costs are as follows:

- **Eligible costs (Allowable)**

The research's eligible direct costs are the costs identified as specific costs directly linked to the study's performance. Consultation fees are allowed to establish and to operate a state of art national virology research laboratory that serves to achieve projects' objectives and national priorities.

- **The Cost of Equipment**

The allocated amount for the purchase of equipment should be utilized for the purchase of new equipment, and facilities that are directly related and necessary for establishment and accreditation of the national virology research lab. The budget format in the proposal should be signed and stamped by the PI applicant institution.

- **The Incentives of Team Members**

Monthly incentives are granted to members of the research team, based on their role/assigned tasks and time dedicated to the project (in reasonable rates).

- **Travel Cost**

The cost of a stay in other countries is calculated according to STDF rules and regulations. Justification for travel should be provided in the proposal. Training in one of the advanced universities/institutions in the field is allowed for up to one month.

- **The Cost of Organization of Workshops**

The allocated amount will be based on a favorable description of this activity that should promote the area of research specified in the proposal. The details of the activities and their cost should be listed in the proposal.

- **Indirect Costs**

Indirect costs can be allocated and payable to the researcher(s) host institution (where the researcher(s) is/are conducting the research work). Such indirect costs are payable for the usage of facility and infrastructure of the host institution and could cover the cost and salaries of administrative work.

XI. Payment Procedures

When STDF approves a project, a contract agreement will be signed between STDF, the principal investigator (PI), and the applicant institute. The budget will be disbursed as instalments. The number of instalments depends on the duration of the project. The first instalment will be spent at the beginning of the project. The other instalments will be paid after the receipt and approval of the progress reports provided by the PI and endorsed by the applicant institution.

XII. Follow Up

A-Technical Reports

Biannual technical progress reports should be submitted according to STDF progress reports formats. The project's final report should be submitted no later than one month after the official end date of the project and should follow the STDF final report format together with an Achievements Report.

Site Visit: By the end of each phase of the project, a visit by STDF representatives is expected, to assess the final status of the national research laboratory, and to ensure that it has fulfilled the fundamental technical and managerial requirements according to the approved proposal.

STDF's logo shall be added to all certifications released from the national research laboratory.

STDF evaluates all submitted reports, and feedback is sent to the project's PI and applicant institute. For rejected follow-up reports, STDF can impose additional follow-up and monitor progress reports independent from the usual way.

Suppose the submitted progress/final reports show that the team did not achieve the set objectives specified in the original proposal and/or the team is performing poorly. In that case, STDF will take all measures to stop the project and recover the budget allocated.

B- Financial Reports

Two reports are requested every year (biannually) signed and stamped from the institution as well as all the expenditure vouchers.

XIII. General Remarks and Conditions

- All proposals must be uploaded to the STDF website, proposals submitted by e-mail or send as hard copies will not be considered.
- All proposals must use the exact formatting requirements for the current call given in the attached Application Form. Failure to adhere to the precise format required will result in rejecting the proposal.
- All proposals MUST be written in English Language.
- The application must include a signed and a stamped endorsement letter from the institution's legal representative, as shown in the Application Form.
- The same proposal should not be submitted in more than one grant. (Duplicate submission of the same proposal is not allowed).
- Each PI can only submit a maximum of two proposals until notified with the evaluation results of his/her submitted proposals.
- DO NOT submit proposals previously funded either by STDF or any other funding agency. Submissions deemed to be supported by different grants will be disqualified & applicants will be banned from submitting proposals to STDF.
- Any publications delivered as a result of STDF funded proposals should acknowledge STDF funding in the publication and supporting conducting the results.
- STDF's intellectual property rules (IPR) and regulations in addition to the STDF code of ethics are applied to all submitted proposals.
- Foreign partners may be allowed in this grant only as consultants given that the relevant approvals have been obtained, and only consultants' fees are permitted for those partners.
- Equipment purchased using STDF funds must be made available to all Egyptian researchers, provided that the project work is not disrupted.
- If more than one institution is involved, it has to be clearly stated which institution is in charge and each partner institution's role has to be specified.
- Extending a project's duration is not allowed. Only under stringent justified conditions shall STDF allow project extension, and any request for project extension will affect negatively STDF future decisions regarding the performance of the research team members.
- Having members from different departments or research institutes in the same research team is allowed and encouraged.
- Conflict of interest should be avoided in any proposal application.
- All proposals will be evaluated on a competitive basis