REQUEST FOR INFORMATION

for the

ESTABLISHMENT AND MAINTENANCE OF A BIOBANK

for

THE ISRAEL MINISTRY OF HEALTH

1. **Purpose**

It is incumbent upon the Israel Ministry of Health (hereinafter MOH) to promote precision medicine research. Consequently, the MOH instituted the Psifas Initiative (hereinafter "Psifas") to develop a national digital research platform based on genomic, clinical, and omics data.

This RFI solicits information regarding the establishment and operation of a biobank in which biological samples and relevant data associated with them are to be coded and stored under the appropriate conditions, transported for approved research, and/or for DNA sequencing in accordance with the specifications of a future applicable tender.

The information solicited should relate to the entire scope of biobanking activities, specifically information systems and database interfaces, operational procedures (collecting, storing, retrieving, etc.), security regulations, quality control, etc.

2. **Background**

The MOH and five other statutory authorities: the Israel Innovation Authority, the Planning and Budgeting Committee (PBC) of High Council for Education, the Digital Israel Office, the Ministry of Finance, and the Israel Defense Forces Medical Corps, set direction to Psifas, a national enterprise. All parties concurred to establish and fund it, for compliance with Israel government resolution no. 3709 to promote digital health by virtue of it being an engine of potential economic growth and a means for improving public health.

3. **Duties of a Biobank**

3.1 **Workflow**

The duties of a biobank are to provide comprehensive physical and digital services which will encompass the entire workflow designed for utilizing samples and/or biological specimens for an estimated duration of 30 years, including but not limited to:

3.1.1 Digitally bundling informed consent forms and volunteer info
3.1.2 Processing samples
3.1.3 Storing samples and data
3.1.4 Decoding data
3.1.5 Controlling quality
3.1.6 Transporting samples and providing data to approved studies and/or to a DNA sequencing facility

3.2 **Performance and Quality Control**

The biobank should perform quality control for collected samples and issue cohesive instructions to health organizations that collect samples from volunteers.

3.3 **Procedures and Regulations**

The biobank should follow proven procedures and practice in the simultaneous handling of a large volume of various kinds of biological samples (hundreds of thousands at a time), including but not limited to:

- Assuring that aliquoting of samples is performed according to specifications provided in writing (amount and number)
- Assuring that the storing of samples are controlled and monitored
- Assuring that samples/aliquots are properly coded
- Assuring that samples are safely stored and that access is limited to authorized personnel

3.4 **Types of Sample**

The biobank should have proven procedures regarding all repository conditions of all kinds of samples, for example: DNA, RNA, protein, plasma, serum, white blood cell, saliva, urine, stool, tissue biopsies, and any other body fluid or secretion.

3.5 **Sample Processing**

The biobank should be capable of simultaneously performing several biological analyses, including but not limited to:

- DNA extraction
- RNA extraction
- Plasma and serum separation
- White blood cells separation

3.6 **Repository Equipment**

The biobank should have the most appropriate equipment designed to prepare and store all types of samples specified hereinabove, including but not limited to:

- Freezers
- Freezing containers
- Biobanking tubes
- Barcode readers
- Cappers/decappers
- Reagents
- Kits for each specific type of sample

3.7 **Transporting Biological Samples**

The biobank should be capable of safely transporting biological samples and data to other labs under controlled conditions for the purpose of research and downstream analyses, DNA sequencing and the like.

3.8 **Streamlining Storage**

The biobank should be well-systematized, allowing easy tracking of and access to specific samples during all processes of the biobank, storing multiple samples for each and every volunteer, and enabling association between samples from a specific volunteer over time and an exclusive code.

3.9 **Availability of Service to Researchers**

The biobank services must be made available five days a week during working hours. Transporting samples to researchers, upon Psifas's approval, will have to comply with the physical conditions (temperature, etc.) specified by the researcher.

3.10 **Information Systems**

A designated information system should be installed at the biobank with a data back-up protocol.

3.11 **Information Security**

The biobank must comply with the Privacy Protection Regulations (Data Security) 5777-2017, and abide by the data security provisions of the Israel Privacy Protection Act, 5741-1981.[1]

3.12 **Electronic Reports**

The biobank must regularly issue electronic reports and provide similar documents upon request on topics such as:

- "Status of stored samples" report
- "Temperature per sample" report

[1] The Privacy Protection Regulations (Data Security) 5777-2017 can be accessed from the following web address: https://www.gov.il/BlobFolder/legalinfo/data_security_regulation/en/PROTECTION%20OF%20PRIVACY%20REGULATIONS.pdf

3.13 **Turnaround Time (TaT)**

The biobank should provide collection services within the timeframe that will be set by MOH (for example, discrete services), in the quality MOH will specify for each service.

3.14 **Financial Stability**

The biobank will be awarded a government subsidy for a limited period; consequently, the biobank will have to submit a preliminary business plan attesting to its tenable financial stability.

3.15 **Ethical Standards**

The biobank must comply with all applicable ethical codes.

4. **RFI Response**

All questions in the booklet hereinafter should be answered in full and emailed in a pdf or doc file attachment to *it.tenders@moh.gov.il* by **May 20th, 2019 at 10:00** (10 am Israel Standard Time). Documents not submitted via email (post, fax, etc.) will not be reviewed by the MOH, and will not bind MOH.

Questions or clarification requests relating to the subject matter of this RFI can only be emailed to the MOH Tender Committee, email address: *it.tenders@moh.gov.il*, no later than **May 1st, 2019 at 10:00** (10 am Israel Standard Time).

The following under this section, and the RFI in whole, refers to the MOH or Psifas acting on its behalf (once it is launched).

The response to this RFI does not commit the MOH to grant any rights hereunder or provide any information, and the responder shall not have any grievance or claim to Psifas or the MOH in this regard.

This Request For Information is not a Request For Proposal (RFP) of any kind, and is not part of a bidding procedure. It is therefore not binding and it shall not in any way be considered as a commitment by MOH towards any responder. The intent is to solely solicit information on the basis of which the MOH will consider professional and relevant criteria how to progress.

A reply to a response is not a requirement to submit a proposal to a future relevant bid, nor does it give a priority in the bidding procedure, and it should not be considered a commitment to include the responder in the bidding procedure, or to make any other association with a responder.

The MOH reserve the right to confidentially save submitted information and they commit not to disclose it to a third party, with the exception of consultants who signed a confidentiality agreement well in advance and were registered to provide services to the MOH.

Should the MOH, decide to release a tender, services different from the ones in the foregoing might be specified, and the MOH reserve the right to supplement or amend the provisions of the tender at their sole discretion.

The MOH reserve the right to request any clarifying information, submitting information omitted or further information from any or all responders or any other party they deem appropriate.

All responders grant MOH the right to make use of the information submitted, in whole or in part, for drafting a tender, especially the tender specifications and supplements, or for any other purpose the MOH deem necessary.

Any party that chooses to respond to this RFI agrees to indemnify and hold harmless the MOH, Psifas, their officials and employees and/or anyone acting on their behalf and/or on behalf of the State of Israel from against all liability demands, claims, suits, losses, damages, causes of action, fines and judgments, including but not limited to intellectual property rights infringements, resulting from any use or disclosure of such confidential and/or proprietary information, in part or in whole, by any responder or any person acquiring such information, directly or indirectly, from any responder.

a. Respondent Profile

Company title	
Head office	
Years in biobanking / Years serving this market	
Responder Contact Details: Name Title Telephones E-mail address	Office…….Mobile……..

b. General Consulting Questions

Please describe your solution for each module specified below. You may add any solution and information you believe to be relevant.

For each module, please specify whether your proposed solution was implemented and if yes, where.

1. Staff
   - A recommended organizational chart
   - The staff recommended for operating the biobank. Specify functions, academic degrees and professional experience. Include technicians, research assistants, etc.
2. Facility
   - Considerations that are relevant for choosing the location of the facility, such as accessibility and adjacent services
3. Partitioning

   The architectural and interior requirements, i.e. floor partitioning, and especially floor space needed, number of rooms, equipment, etc.
   - Number, dimensions, safety and backup measures (including fire extinguisher system and electrical power backups), etc.
   - Freezers, LN_2, nano-spectrophotometer, hoods, centrifuges, incubators, etc.
4. Information systems
   - An architecture diagram, including modules, a list of internal and external interfaces plus interface capabilities (unified interface/coded interface, etc.)
   - Safety and backup measures, supported languages, development environment
5. Volunteers
   - Examples of volunteer consent forms and information sheets
6. Standard Operating Procedure (SOP)
   - A review of processes**,** operations and Service Level Agreement (SLA)
7. Quality control
8. Information security
9. Work plan and budget
   - A detailed description of the work plan designed to establish a biobank with milestones and an estimated timeframe for accomplishing it
   - An estimation of the budget needed for establishing the biobank and for maintaining it, relating to the different modules and milestones
   - Features and other issues regarding the work plan and budget
10. Other professional matters not aforementioned

c. Additional Questions

1. Please specify what biological samples and data you currently recommend be collected and elaborate on the considerations guiding your recommendation:

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2. Please specify the lessons learned from your experience relating to the establishment and maintenance of a biobank:

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d. Referee Contact Information

Company name	Establishment date of biobank	Referee name and function	Referee contact details (tel., e-mail)	Specify the responder function & start and end working dates	Description of the project