

Logo The medical institution	Accompanying Information Sheet for the Consent Form - Adults To donate information and biological samples for use in clinical trials, including genomic studies Page 1 of 7	Logo The new Psifas project
---	---	--

Donor Information Sheet

Greetings,

You are invited to join Psifas - the National Project for Personalized Medicine Ltd. (Psifas), and thereby contribute, along with hundreds of thousands of other Israelis, to medical and genomic research that will significantly advance medicine in Israel. In these Informaiton Sheets, we will explain and detail what the Psifas project is, why it was established and what it means for you to join the Psifas Medical Database, and this in order to accompany your decision to join the project. It is important that your decision will be voluntary after you have received all the required information about the Psifas project and understood the content of the information and its meaning. You have the right to choose not to join, or to cancel your joining at any time. A decision not to join the project or to withdraw your consent to join will not in any way affect the treatment and medical treatment of you now or in the future, both at the medical institution through which you are asked to donate, at the HMO where you are insured, and at any other medical institutions.

For any question or problem related to the Database and Samples, please contact:

Database manager: Email: info@psifas.org.il

For more information: www.psifas.org.il

1. Background

- 1.1 The world of medicine is progressing towards personalized medicine, according to which it will be possible in the future to offer people tailored treatments for their disease or even disease prevention based on their unique personal information. Millions of patients in the world and in Israel often come to get treatment with severe symptoms and advanced disease. Our goal is to advance the processes of early diagnosis and treatment of many diseases such as dementia, cancer, diabetes, heart disease and diseases of the nervous system, so that we can prevent them or treat them in the early stages before they cause irreversible damage. This approach is based on research and complex statistical analyzes of large databases, the information is taken from a large group of people of different types.
- 1.2 In the medical file of each and every one of us there is health information collected during the treatment and medical service we receive. Cross-referencing this information with information obtained from various tests of biological samples in a large group of people, will make it possible to carry out a wide range of medical and genetic studies that will help to better understand the mechanisms of diseases.
- 1.3 Precisely for this purpose, Psifas was established as a new national project to promote research in the fields of genomics and personalized medicine in Israel. For this purpose, a number of medical and academic organizations joined together with the aim of providing the infrastructure to allow conducting such research. The insights from the research to be conducted through Psifas will enable the development of methods for disease prevention, detection and earlier and more accurate treatment through personalized medicine.

גרסה: 5.1	אנגלית	פרטים לצורך יצירת קשר:	דף הסבר לתורם, "פסיפס"
תאריך גרסה: 02 March 2026		info@psifas.org.il	בגיר

<i>Logo</i> <i>The medical institution</i>	<u>Accompanying Information Sheet for the Consent Form - Adults</u> To donate information and biological samples for use in clinical trials, including genomic studies Page 2 of 7	<i>Logo</i> <i>The new Psifas project</i>
---	---	--

2. Psifas Database (the "Database")

2.1 Psifas will rely on a community of donors that will include hundreds of thousands of people, who upon joining will donate biological samples such as blood, saliva, urine, skin tissue or other body fluid to perform genomic and other tests and in addition will allow Psifas to receive their medical information both close to consent and in the future, whenever the information is requested by Psifas.

The medical information exists about you in the HMO, hospitals in Israel, or in any other medical institution or health organization in Israel (currently and in the past). The information to be collected as part of Psifas and the results of the tests of the biological samples (or occasionally the samples themselves) will be used as part of future medical studies to be legally approved, to be conducted in bodies such as hospitals, HMOs, academic institutions and the biomedical industry, while maintaining confidentiality and protecting privacy, all in accordance with the laws and procedures applicable in Israel on this issue.

2.2 The purpose of the Database to be established with your help, Psifas, will ensure available access to medical, genetic and imaging information for investigators engaged in important scientific and medical research designed to expand and develop existing knowledge and try to prevent diseases, improve their diagnosis and treatment, ease patients suffer and find a cure for them. In Psifas's Database, medical information, including imaging information, stored about the participants in the health organizations where they were treated will be cross-referenced with genetic or other tests obtained from biological samples to be donated and medical questionnaires to be completed by you or by the medical staff to Psifas. The information of all participants in Psifas is collected in a secure and encrypted Database and will be used for future studies. In the individual Databases for the future studies, the information will be non-identifiable towards the studies conductors.

2.3 It is important to emphasize that medical studies on humans, including genetic studies, which include testing of the hereditary material DNA, using innovative technologies, are only conducted after receiving approval according to the law and only if they protect the rights of the participants, including their privacy. The Psifas project and the research Database, in which you are asked to participate, has received such approval.

3. How to join the Database?

3.1 Joining the Database involves signing a Consent Form, which allows Psifas to use your blood/saliva/urine/skin/other body fluid sample (a sample that is taken anyway as part of medical procedures that you will perform from time to time or to be taken proactively for the purpose of the project), as well as the collection of health information as described above. The use described above may also include the transfer of the sample in coded form (without your identifying information) to those parties requesting to conduct a clinical study (including a genetic study) that have received lawful authorization to conduct said research.

3.2 The samples will be used as mentioned for the purpose of future medical studies that also allow the production of DNA. By signing this Consent Form, you also confirm the donation of additional future samples that may be taken as described above.

3.3 The Database will include your medical information from the hospital and the community, information from medical questionnaires to be completed by you and by the medical staff as well as the results

גרסה: 5.1	אנגלית	פרטים לצורך יצירת קשר: info@psifas.org.il	דף הסבר לתורם, "פסיפס"
תאריך גרסה: 02 March 2026			בגיר

<i>Logo</i> <i>The medical institution</i>	<u>Accompanying Information Sheet for the Consent Form - Adults</u> To donate information and biological samples for use in clinical trials, including genomic studies Page 3 of 7	<i>Logo</i> <i>The new Psifas project</i>
---	---	--

of the genetic processing of the biological samples you have donated and will donate. Everything will be saved in the Database in an encrypted form, without direct identification of your personal details. The secure Database will be regularly updated on your medical condition by reviewing the medical file at the medical center, once in a while or also through medical information we receive from your HMO and other health organizations where you are treated.

- 3.4 The sample you donate now or in the future can be used for research initiated by the medical institution where you signed this form and/or at the initiative of the HMO to which the medical institution is associated and/or startup companies that received lawful approval to conduct a study and not just Psifas.
- 3.5 Investigators will be granted permission to explore the imaging clinical-genetic Database for legally approved studies only. The investigators will have access to a huge Database that includes thousands of patient records, while they are non-identified. Your information will be available to investigators only in a non-identified form.
- 3.6 It is important for you to know that the clinical-genetic and imaging information accumulated in the Psifas Database will be accessible to investigators at the medical centers where they were collected, to other investigators in Israel as well as for use as part of commercial development, provided that the study in which they will be used has been legally approved. It is also possible that the information in the Database will be used for a study abroad, but only after the study has been legally approved according to the approval of the Ethics Committee in Israel for each study individually. All studies will be performed on anonymous information and without identifying details. Only Psifas Database administration, the hospitals and HMOs that treat you will have the identification code.

4. How will your samples and information be collected?

- 4.1 The sample will be taken when you perform a routine test as part of treatment or follow-up. It is possible that you will be contacted to ask for your contribution to the Psifas Database proactively for the purpose of the project even outside of such a treatment framework.
- 4.2 At the same time, we will transfer to the Psifas research Database your medical information (coded and encrypted) from the information systems of the hospital or the HMO about your medical condition, medical treatments you have undergone, your medical history and your ethnicity.
- 4.3 The medical information is personal and the Database team is obligated to keep it confidential. Your consent to the collection will be documented and may appear in your medical records, including hospital admission and discharge letters.

5. How will the samples be kept and what will be done with them?

- 5.1 Your samples will be collected from the hospital or the community clinic where they were taken and will be transferred by the medical team to a dedicated laboratory for genetic processing. Genetic processing will be conducted under adequate research conditions and after the processing the sample will be destroyed. In studies where it is necessary to transfer the sample itself to the study sponsors for medical processing, and provided that such transfer has been lawfully approved by a national committee at the Ministry of Health, the sample, or part thereof, will also be transferred to the aforementioned study sponsors for processing. Upon completion of its use, the sample will be destroyed. No permanent cell lines will be derived from it for use in other studies.

גרסה: 5.1 תאריך גרסה: 02 March 2026	אנגלית	פרטים לצורך יצירת קשר: info@psifas.org.il	דף הסבר לתורם, "פסיפס" בגיר
--	---------------	--	--

<i>Logo</i> <i>The medical institution</i>	<u>Accompanying Information Sheet for the Consent Form - Adults</u> To donate information and biological samples for use in clinical trials, including genomic studies Page 4 of 7	<i>Logo</i> <i>The new Psifas project</i>
---	---	--

- 5.2 The collected sample - will be delivered with only a random code without your identifying details such as name, address, social security number, etc.
- 5.3 Until they are sent for processing, the samples will be kept by the health organizations that will take part in the project.
- 5.4 Storing the genetic information, after performing the tests, will be conducted in a dedicated secure cloud service. The information will be stored encrypted, that is, without a link to your identifying information.

6. Use of information and samples:

- 6.1 After your donation, the health information and the information produced from the samples you donated will be used as part of medical studies to be conducted in accordance with the laws and procedures in Israel. You cannot choose in which studies it will be used or to receive information about this use. However, the Psifas website will have a regular report on the project, its progress, its achievements, including the studies conducted within it.
- 6.2 The investigators' access to the information held by Psifas and its use will be made in return, at rates to cover expenses to be determined. Receiving the payment from the investigators and health organizations will allow the Psifas project, which is a national non-profit project, to cover current expenses and be financially balanced, so that it can continue to promote science and medicine and expand and improve the research platform.
- 6.3 Psifas will periodically examine the characteristics of the studies conducted at Psifas, including the factors that finance studies conduct, and accordingly, will be entitled to determine the prioritization or incentive of studies of the types to be defined. Psifas will act transparently and publish its policy on these issues.
- 6.4 Psifas will operate as equitably as possible. On studies approval process, it will be possible to use the information stored in Psifas also by investigators from abroad, who will submit a request for study approval like the other investigators, and will be able to conduct research on the information in the Database through collaboration with an Israeli investigator.

7. Your privacy is important to us!

- 7.1 Your privacy and the security of the information in Psifas Databases are very important to us. As a national project - Psifas is committed to privacy protection laws and maintaining medical information at the highest standards and operates according to the guidelines of the Privacy Protection Authority and the various government ministries.
- 7.2 All required and binding rules by law and by the health system are applied to the Database, while ensuring that the rules are observed in the most professional manner and that maintaining medical information confidentiality.
- 7.3 Access to information will be encrypted, secure and in accordance with all accepted rules and standards. Identifying information such as name, ID number, address, will be removed and will not be included in the research Database, as well as from the test results of your samples.

גרסה: 5.1 תאריך גרסה: 02 March 2026	אנגלית	פרטים לצורך יצירת קשר: info@psifas.org.il	דף הסבר לתורם, "פסיפס" בגיר
--	---------------	--	--

<i>Logo</i> The medical institution	<u>Accompanying Information Sheet for the Consent Form - Adults</u> To donate information and biological samples for use in clinical trials, including genomic studies Page 5 of 7	<i>Logo</i> The new Psifas project
---	---	--

7.4 In a safe place, and with access to a limited number of employees, a table will be kept in Psifas and the medical institution where you signed the informed Consent Form in which it will be possible to link the research record to the donors behind the record - this is to allow us to get back to you in the event that we find in the research a finding that has medical significance for you, or in order to offer you to participate in future studies.

7.5 It is important to emphasize that investigators who will conduct research based on the research Database will not have access to your identifying details.

8. Participant rights and withdrawal of consent

8.1 Participation in the Database is voluntary, and you will not receive any financial compensation or proprietary right that may be derived from the results of any future research for your consent to participate in it.

8.2 You have the right to choose not to participate in the Database, or to stop your participation at any time and for any reason. If you wish to cancel your participation in this project, you must send Psifas the cancellation request form attached to these information sheets, which will also be available on Psifas's website.

8.3 Participation cancellation will not affect in any way the attitude or the decisions concerning your medical treatment now or in the future.

8.4 Your request will result in the destruction of your samples (as long as they have not been destroyed by that date) and stop transfer of the medical information that continues to be updated about you in the various health organizations to the secure research servers of Psifas. In addition, any information that has already been transferred and stored encrypted in a dedicated Database for the project will be deleted. However, since the use of your samples and information for the studies themselves is done without your identifying details (completely non-identified), they will not be traceable to a study that has already started using them before your withdrawal request is received. Therefore, even after your participation is terminated, your non-identified information will continue to be used for studies that have already started within the project and in relation to that study only.

9. Benefits and risks

Are there any benefits for participants in the Database?

It cannot be guaranteed that you will benefit from your participation in the Database. However, the studies to be conducted on the large Database will advance medical knowledge, and will contribute to improve the diagnosis and medical treatment of patients in Israel and around the world. Therefore, you and future generations will greatly benefit from the advancement of medicine as a result of the research conducted in Psifas.

In addition, if a genetic finding of medical significance is found as part of the research (as defined in the Ministry of Health's procedures), the medical team of the medical institution (where you signed the Consent Form) will inform you of this and you will be able to receive genetic counseling at no cost on your part.

Does participation in the Database involve any risks?

גרסה: 5.1 תאריך גרסה: 02 March 2026	אנגלית	פרטים לצורך יצירת קשר: info@psifas.org.il	דף הסבר לתורם, "פסיפס" בגיר
--	--------	--	--------------------------------

<i>Logo</i> <i>The medical institution</i>	<u>Accompanying Information Sheet for the Consent Form - Adults</u> To donate information and biological samples for use in clinical trials, including genomic studies Page 6 of 7	<i>Logo</i> <i>The new Psifas project</i>
---	---	--

There is no direct or indirect medical risk. The biological sample (such as blood) is taken in any case, for treatment and diagnosis, which is medically required for you. If you are asked to donate to the Database outside of a routine medical treatment or diagnosis, the only risk is that which is posed by providing any routine blood/saliva/skin/urine sample.

Regarding your privacy and confidentiality of information

The information collected in the Database, and in particular your personal information, is confidential and protected by law, including under the Privacy Protection Act and the Genetic Information Act, 5761-2000. The Database Director is obliged to take care of all the arrangements required to maintain information confidentiality detailed above and so that no party, except for the Database team, or the investigators in the legally approved future studies, will be able to look at it or make use of it that would reveal the donor personal details.

Psifas Database information security and the information traffic to and from it was formulated in cooperation with the cyber units of the Ministries of Health, Justice, the Privacy Protection Authority and the National Cyber Authority. The Database itself and its work procedures are regularly monitored by the National Cyber Authority.

Donors will not be provided with a summary of results. Identifying details of the donors will not appear in any publication. Studies results **in no way will be individual results**, but the results of large groups of donors.

10. Genetic counseling and medical examination

Your samples are taken for research use and not for medical treatment. Samples processing should not demonstrate findings of any medical significance and there is no assurance that such findings will indeed be demonstrated. However, since you and your information are not identified in the project's Databases, we have asked for your consent that if a medically significant genetic finding is demonstrated for you or your family, the authorized parties will use the coding conversion table to identify your record in the Database in order to allow the attending physician at the hospital or at the HMO to get back to you with the genetic medical information that was demonstrated in the study. If required – you will be provided with genetic counseling, all according to what is customary in accordance with the findings demonstrated in the research.

גרסה: 5.1	אנגלית	פרטים לצורך יצירת קשר: info@psifas.org.il	דף הסבר לתורם, "פסיפס"
תאריך גרסה: 02 March 2026			בגיר

<i>Logo</i> <i>The medical institution</i>	<u>Accompanying Information Sheet for the Consent Form - Adults</u> To donate information and biological samples for use in clinical trials, including genomic studies Page 7 of 7	<i>Logo</i> <i>The new Psifas project</i>
---	---	--

Request to withdraw consent for donation to Psifas

Dear "Psifas" administration

Address

Email

Fax

I am Mr./Ms. _____ ID No. _____ who signed a Consent Form for donating samples and information to Psifas, request to perform all of the following actions:

- Withdraw my consent
- Destroy my blood/saliva/urine/skin/other samples that are kept for the purpose of the project and have not yet been destroyed.

I am aware that after my participation termination no new information will be collected and that any information collected so far, which is still stored in an encrypted form, will be deleted from the Psifas project Databases. However, I am aware that my non-identified information, if it has already been transferred for the benefit of certain studies, will continue to be used for these studies within the framework of the project and in a non-identified form.

Signature: _____ date: _____

For use by "Psifas":

The following samples were destroyed:

.....

On date: _____ by: _____

גרסה: 5.1 תאריך גרסה: 02 March 2026	אנגלית	פרטים לצורך יצירת קשר: info@psifas.org.il	דף הסבר לתורם, "פסיפס" בגיר
--	--------	--	--------------------------------