Logo *The medical institution*	**Consent Form - Adults** To donate information and biological samples for use in clinical trials, including genomic studies	*Logo* *The new Psifas project*

The Government of Israel decided on the establishment of the "Psifas Project", a joint national project of the Ministries of Health, Finance, Defense, Education through the Planning and Budgeting Committee, "Digital Israel" and the Innovation Authority. Psifas project goal is to establish a national information infrastructure for health research in the field of genetics and medical information for the development of future solutions of personalized medicine. Psifas - The National Project for Personalized Medicine Ltd. is a non-profit organization (public benefit company) that was established on the basis of the aforementioned Psifas project and seeks to realize the goals of the Psifas project through the establishment of a clinical, genetic and imaging Database that will be available for research by industry and the academy (the "**Database**").

This Database will allow investigators to improve diagnosis and treatment of patients suffering from various diseases, to find environmental or genetic factors that may affect the tendency to morbidity and disease-causing, the ways in which diseases develop, as well as to monitor and characterize the treatment response.

We ask your consent to participate in this national project. For your participation, you are asked to donate a blood sample and/or other biological samples of yours such as saliva, urine, skin or other body fluid ("**Sample**") as well as your medical information. All this for the benefit of the Database that will be used for future medical studies, once lawfully approved, including genetic studies, while maintaining confidentiality and protecting your privacy.

We consider it important for you to understand the Database importance and goals, so that your consent to participate in it is provided based on knowledge and understanding. Therefore, please carefully read the information sheet provided below, and don't hesitate to ask the team member who contacted you for any explanation or clarification. If you decide to agree to donate to the Database, fill in your details and sign in the appropriate place in this Consent Form.

By signing I agree:

- To donate a sample that is taken from me anyway as part of a medical examination, or alternatively a completely new sample that is not related to a medical examination, for the purpose of genetic processing as a coded sample for the benefit of the Database that will be established by Psifas and/or for the benefit of the existing Database at the medical institution where I signed this form (hereinafter the "**Medical Institution**") and/or the existing Database at the HMO to which the medical institution is associated and/or to benefit another clinical study that was lawfully approved (genetic or not genetic). The sample and the results of its processing will be preserved according to the information security procedures and the terms of use of the sample as detailed in this form below.
- That Psifas will collectת including questionnaires that I will complete myself or that will be completed by the medical staff about me, my medical information of any kind, including but not limited to, imaging tests (photographs) and digital images of pathology tests, found in the information systems of various medical institutions or organizations (including hospitals and HMOs) where I have been treated in the past, I am currently being treated in and will be treated in the future ("**Health Organizations**"). All this, in order to carry out studies after they are legally approved;
- That the health organizations where I was treated in the past, I am treated now and will be treated in the future, will transfer to Psifas's secure research servers all the medical information accumulated about me throughout my medical treatment, in the past and in the future. For this purpose, I agree and authorize Psifas to contact the aforementioned health organizations on my behalf for the purpose of receiving my medical information as stated and I hereby instruct the health organizations to transfer my medical information to Psifas without any restriction, impediment or condition.
- For Psifas and its representatives contact me in the future for the purpose of collecting information for the purpose of further research, or to offer me to join some study or other.
- That the medical institution and/or the HMO to which the medical institution is associated, will contact me in the future, to the extent that findings related to my health are discovered as part of the studies in which I will participate, as well as for the purpose of future follow-up studies.
- That the sample products I donate as part of my consent can also be used in other studies initiated by the medical institution where I signed this form and the existing Database in the HMO to which the medical institution is associated and not only Psifas, without the need to provide an additional sample.

I understand, acknowledge and agree that:

- I know that I am not obligated to sign this Consent Form and I volunteer to donate my medical information and sample of my own free will.
- I received information about the Psifas project, I read and understood the accompanying Information Sheet and my questions were answered to my satisfaction.
- I know that the samples are taken for research use and not for medical treatment and their processing should not reveal findings of any medical significance.
- I am not guaranteed that I will receive personal results or that I will have any personal benefit from donating my sample and medical information.
- My decision whether or not to donate to the Database, in no way will affect decisions regarding my medical treatment.
- My contribution to the Database is exempt from any payment on my part and I will not receive any personal, financial, proprietary or other compensation for this or from the results of studies or the results that will arise from them.
- I know that the sample you took from me will be transferred for genetic (or not genetic) processing in Psifas or with any bodies conducting the lawfully approved studies without specifying my personal details, that is, the sample will be encoded using a random number and will not have any information indicating my identity. My medical information from the health organizations will also be transferred to the Psifas Database without specifying personal details.
- At the same time, in the possession of Psifas and /or the medical institution where I signed this form and/or the HMO to which the medical institution is associated, a table will be kept in which there is a link between my identifying details and the random code associated with me, so that I can be contacted in the future in the following cases: 1. If on the genetic tests it will be found a genetic change defined in the Ministry of Health procedures as a finding that justifies genetic counseling 2. If it will be asked to contact me for updating me on my health status or 3. In order to offer me to participate in another study.
- All future studies to be conducted based on my information found in the Psifas Database will be approved in advance by a higher committee of the Ministry of Health. Also, all these future studies, which seek to make use of the Psifas Database, will be conducted on the basis of non-identifiable information, that is, the investigators will not have any access to the above coding table, which allows a link to the personal details, and they will not be able to go back and find out my identity.
- My non-identifiable information as well as the sample I donated will also serve the start-up companies, the academia and the industry.
- Access permissions to my non-identifiable information will be given to authorized parties only within the framework of the studies.
- My identifying information will not appear in any scientific or other publication.
- My consent in this form is not limited in time, and if I will not withdraw it, my medical information including the genetic information extracted from the sample I donated will continue to be used for research even after my death.

- **I have the right to withdraw this consent at any time at my sole discretion, by sending a written message to the Database administrator via email info@psifas.org.il and that my consent withdrawal will not in any way affect my medical treatment now or in the future.**

- I know that withdrawing my consent will result in the destruction of the sample I donated (if it has not yet been destroyed after processing). In addition, as soon as I withdraw my consent, the health organizations where I am being treated now or in the future, will stop transferring to Psifas's secure research servers the medical information that has been updated about me throughout my medical treatment. However, it will still be possible to make research use of the information accumulated about me so far, where it is anonymous and does not include my identifying details.
- I will not be informed in which studies the information or sample I donated was used, and I will not receive the results of these studies.
- There is no certainty that my medical information or the information produced from the sample(s) I donated will be used in any way.
- I know that I can contact at any time and with any problem the person responsible for the relationship with the donors in Psifas as detailed below, as well as the medical institution through which I donated to the Database through the contact details that appear on the attached Information Sheet.
- My responsibility in this framework is limited to signing this form and providing the sample and I will not be required to do any additional action for the purpose of conducting the studies.
- There are no known risks or discomfort expected as a result of participating in the Database or as a result of the future studies that will be carried out using the Database.

Updating participants regarding a random genetic finding discovered during sample processing:

If genetic findings of medical significance are incidentally found for you (in accordance with the Ministry of Health's definitions based on the recommendations of international professional bodies), then these findings will be brought to your attention by the medical institution and you will be entitled to receive genetic counseling. In such a case, the sequencing results will be forwarded to the medical institution where you were enrolled and/or to the HMO where you are insured so that genetic counseling can be given to you, at no cost to you. However, you can refuse to receive the results and transfer the findings to the medical institution and the HMO where you are insured, by checking in the following box:

☐ I refuse to receive a report on a random genetic finding that may be found in me. I understand that as a result of my refusal, I will not receive genetic counseling regarding medically significant findings.

Date:	Signature:	I.D number:	First and last name:

Statement of the person who takes the donation at the medical center on behalf of Psifas:

The aforementioned consent was given after I explained to the donor all of the above and answered the questions he/she had. I also made sure that he/she read the Consent Form and the Information Sheets and I to my understanding the oral explanations were understood by the donor at a sufficient level, and he/she gave and informed consent:

Date:	Signature and stamp of the explaining person:	Name of the explaining person: