

	<p align="center"><b><u>Explanation Sheets</u></b></p> <p align="center"><b><u>For donor of biological samples and information for collection and storage for use in a future medical study, including genetic study</u></b></p> <p align="center"><b><u>Adults</u></b></p> <p align="center">(written in male form but refers to both Genders)</p>	 <p>Name and last name: Date of birth: Gender: Address: Telephone:</p> <p align="right">www.midgam.org.il</p>
<p align="center"><b>דפי ההסבר יימסרו לתורם</b></p>		

## 1. General

Greetings, you are being asked to donate your biological samples and medical information to the biorepository for future clinical studies, including genetic studies.

The following is an explanation about the details of sample collection for the repository and its purposes.

It is important to us that you understand the significance of the repository and its purposes, so that your consent to participate in it is given out of knowledge and understanding.

Read the following explanation carefully, do not hesitate to ask for explanation or clarification from the team member who addressed you. If you decide to agree to donate to the repository, fill in your details and sign in the designated place in the attached Consent Form.

The purpose of the repository is to guarantee available access to information and samples, for investigators engaged in scientific and medical research, in order to expand and develop the existing knowledge, and try to prevent diseases, find a cure for them, or alleviate patients' suffering. Clinical studies in human beings, including genetic and whole-genome studies, which include an examination of the hereditary material, DNA, using innovative technologies, receive approval by law only if they protect the rights of the participants including their privacy. The repository, in which you are being asked to participate, has received such approval.

The investigators are obligated to make every effort to maintain the confidentiality of the information resulting from your genetic sequence, however even if the sample *is not identified / coded*, it is theoretically possible to link between you and your entire genetic information, if another person has information about part of your genetic sequence.

<p><b>With any question or problem related to the repository and your samples, you can refer to:</b>  <b>The medical institution, in which the repository is located:</b>  <b>Director of the biorepository:</b>  <b>Telephone:</b>  <b>E-mail:</b>  For further information: <a href="http://www.midgam.org.il">www.midgam.org.il</a></p>
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## 2. The repository

2.1. The purposes of the repository are collection, processing and storage of biological samples and information about you, and their transfer for future studies, intended, for example, to improve the diagnosis and treatment of patients suffering from various diseases. The

biorepository will allow investigators to try and detect environmental or genetic factors that may affect the propensity for morbidity or the propensity for causing diseases, or the ways diseases progress and the response of "sick" and healthy cells to different treatments.

These studies are done for the following purposes:

1. Examination of the risk factors for development of diseases,
  2. Detecting populations at risk of developing diseases,
  3. Detecting signs for early discovery of diseases,
  4. Developing new treatments,
  5. Investigating the resistance or sensitivity of sick and healthy cells to the different treatments (such as chemical treatments, radiation),
  6. Investigating other diseases,
  7. Any legally approved future study.
- 2.2.** The repository is a repository that processes and stores the samples, and does not engage in research. All the rules required and obligated by law and by the health system apply to the repository, while retaining the biological samples in the most professional manner, and maintaining the confidentiality of the medical information.
- 2.3.** The repository includes biological samples such as tissue/blood/saliva/urine/DNA/cells/spinal fluid/samples from various bodily fluids, from sick and healthy people, as well as medical information. In order for the information and biological samples to be used in the future in legally approved studies, it is necessary to keep an ongoing update of the medical state of the donors, which will be performed by reviewing the medical file at the medical center, periodically, as well as by using a questionnaire, which you will receive from us or from the attending physician at the health maintenance organization.
- 2.4.** The repository is part of the "Israeli Repository for Biological Samples for Research" – MIDGAM. The party sponsoring the operation of the repository is the Israeli government. The Ministry of Health and MIDGAM Administration supervise the operation of the repository. In general, the repository is a non-profit organization, however it is important to mention that it must cover its operation expenses independently, and therefore the samples stored in it will be transferred to investigators for the purpose of research in return for payment, under governmental supervision and according to the rules set for this purpose. The intention is to allow investigators to perform studies on the samples stored in the repository in the future, after they are legally approved.

**Participation in the repository involves provision of medical information and/or biological sample or samples, which will be collected during the medical treatment or surgery, which you are going to have regardless (without additional intervention), for future medical studies, which also allow production of DNA.**

### **3. Participants' rights**

- 3.1.** You are being offered to donate medical information and/or biological sample to the biorepository, which contains samples of additional people, who have agreed to donate their samples.
- 3.2.** Participation in the repository is done voluntarily, and you will not receive for your consent to participate in it any financial reward, or proprietary right that may result from the results of any future studies.
- 3.3.** The consent or refusal to participate in the repository will in no way affect the quality of the medical care that you will receive, or the way professionals treat you.
- 3.4.** Your personal details and the details of the sample you have provided will remain confidential in order to maintain your privacy, and will only be used by the authorized repository staff.
- 3.5.** You have the right to choose not to participate in the repository, or to discontinue your participation at any time, as long as the identifying details of the biological samples you have donated to the repository have not been destroyed. If you decide, for any reason, to cancel your donation and withdraw from the repository, a written request can be sent to the Director of the Repository. This request will cause the removal of all your medical and personal information from the repository, the transfer of the tissue samples from the repository to the

pathology institute at the medical center, for storage as customary, and the destruction of your other samples in the repository. However, it will not be possible to locate your samples, which have already been transferred to investigators prior to your notice.

**Your donation in itself will not have any affect on the treatment provided to you.**

## 4. The samples

### How will the samples and information be collected?

- 4.1. A skilled professional will collect from you approximately 20 ml of blood (approximately 4 teaspoons) as part of the surgical process / medical procedure; you might feel a prick or develop a slight hemorrhage. According to your consent, blood samples will only be collected when you perform a routine blood test within follow-up / treatment. According to your consent, additional blood samples (up to 5 times) may be collected during additional inspections (such as follow-up at the clinic or continued treatment at the clinic / institute). On each donation, the volume of the sample collected will not exceed 20 ml. In addition, samples of your saliva/urine/skin/other bodily fluids can be collected, according to your consent.
- 4.2. If you are scheduled to have a surgery or biopsy, the tissues, which will be removed during the procedure regardless, will be processed by a specialist pathologist for diagnosis, leaving a sufficient amount of the sample at the Pathology Institute Archive. Only after it is verified beyond doubt that the ability to diagnose or treat the disease is not harmed or jeopardized, the rest (remainder) of the tissue will be forwarded to the biorepository. Use of the samples for research will not jeopardize the possibility to use the pathological material in the future for the benefit of the participant, which is a condition for the release of the samples for research.
- 4.3. The consent to this collection will be accompanied by a personal interview with a staff member and the completion of a questionnaire, in which you will be asked about **your medical condition**, about **medical treatments** that you have had, about your or your family's **medical history**, and about **your ethnic origin**. The medical information is personal, and the repository staff must keep it in full confidentiality. Your consent for the collection will be documented, and may appear in your medical records, including in the hospital admission and discharge letters.
- 4.4. Upon signing the Informed Consent Form, the repository staff at the medical center will have access to your medical file, in order to collect medical and pathological information attached to the sample. Access to your medical file will be done proactively by the Director of the Repository at the medical center, or by referring to your medical file at the health maintenance organization. This access to your medical information will be performed while maintaining confidentiality, in accordance with the laws and regulations for maintaining confidentiality. You or anyone from your family will not be contacted. Occasionally, the repository will update your medical state proactively, and this up to 10 years from the time of the donation. Your attending physician may later address you with a request to authorize continued update.
- 4.5. By signing this Consent Form, the sample donation will be valid for a period of six months. In case no medical procedure has been performed, following this period of time, you will be asked to renew your consent, otherwise your consent will be cancelled.

### What will the samples be used for?

- 4.6. The investigators may use your information and biological samples only for legally approved studies. Until their provision, your biological samples will be held by and under the responsibility of the repository.
- 4.7. Your consent to donate samples and/or medical information to the repository is for future studies. During the transfer of your samples to legally approved studies, the investigators who will use your samples will not re-address you, in order to request your consent for this.
- 4.8. If you agree that the repository employees and/or the investigators prepare permanent cell lines from the samples (i.e., will reproduce some of the cells in a laboratory, in order to continue using the samples for additional studies), please check this option in the Consent Form.

**4.9.** It is important that you know, that your samples and information collected in this study will be accessible to investigators at the medical centers in which they were collected, to other investigators in the State of Israel, as well as for use as part of commercial development, as long as the study in which they will be used has received approval by law. The samples and the information may also be used for research abroad, only following approval of the study by law. Use of the samples abroad will be made possible according to the approval of an ethics committee in Israel for each study specifically, and not before examination will be performed by the Director of the Repository, that the samples are not required by investigators in Israel. In any case of transfer of samples and information to a study, taking place outside the hospital in Israel or abroad, the samples will be transferred anonymously or in a coded manner and without identifying details. The identification code will only be held by employees of the repository at the medical center.

#### **How will the samples be kept and what will be done with them?**

**4.10.** The samples will be kept as identifiable\* samples for 25 years as of the time of donation, in the biorepository at the medical center and under the responsibility of the Director of the Repository, according to an official designation. After this time an extension application will be submitted for continued retention of the samples as identifiable\*.

***Identifiable sample** – by law, is a sample that allows the identification of the person who provided it, even if it is marked with a code, and does not bear the participant's identifying details, such as: name, ID no. etc.*

**4.11.** The samples and the information will be stored in specially designated rooms at the medical center. The rooms will be protected with limited access, when only the repository staff will have access to the samples and the information donated to the repository.

**4.12.** The identifiable information regarding the samples and regarding the donors will be kept in a computerized database in a coded manner at the medical center. Access to the identifiable information will only be granted to the repository staff in order to update the details throughout the follow-up.

**4.13.** It should be clarified that samples and/or information provided to the investigators for future research on these samples, will be provided in a coded (encrypted) manner or in a completely unidentifiable (anonymous) manner, in accordance with the specific study layout, as approved by the ethics committee for the study.

**4.14.** Upon study completion, if samples or products remain with the investigators, they will be returned to the repository.

## **5. Benefits and risks**

### **5.1. Are there benefits to participants in the repository?**

Since you are donating the samples for their storage in the repository for a future study, and its results are unknown, it cannot be guaranteed that they will have direct significance or benefit, for you. You know and agree that it will not be possible to inform you on whether or not you are a carrier of a gene for any disease, or about any risks to your health.

Nevertheless, the results may promote medical knowledge, and contribute to diagnosis and treatment of people with the same disease, or with diseases similar to yours.

### **5.2. Does participation in the repository involve any risks?**

There is no direct risk from collection of the sample and/or bodily fluids for the repository, since they are being collected in any way, for treatment and diagnosis, which are medically required for you. There might be slight discomfort in the collection of a blood sample.

### **5.3. On the matter of your privacy and information confidentiality**

The information collected in the repository, and especially your personal information, is confidential and protected by law, including under The Privacy Protection Act and the Genetic Information Act, 2000. The Director of the Repository is obligated to handle all of the above-specified necessary arrangements for maintaining information confidentiality, and to see that no party, except for the

repository staff, can review it or use it in a way that exposes the donor's personal details. This also applies to the investigators in the legally approved future study.

The donors will not be provided with a summary of the results. Identifying details of the donors will not appear in any publication. Results will be presented in groups and will not be personal.

## **6. Information for the attending physician**

As a future or present patient in any medical institution, your medical file will not contain any results from studies based on your donation to the biorepository.

## **7. Genetic counseling and medical examination**

Although you and your information are identified in the repository, you know and agree that even if medically significant information for you or for your family is detected, in any case the repository or the attending physician and/or the investigator will not return to you in order to provide any medical information.

	<p><b><u>Consent Form</u></b>  <b><u>for donor of biological samples and information</u></b>  <b><u>for collection and storage for use in future</u></b>  <b><u>medical study, including genetic study</u></b>  <u>Adults</u>          (written in male form but refers to both genders)</p>	 <p>Name and last name: _____          Date of birth: _____          gender: _____          Address: _____          Telephone: _____</p> <p style="text-align: right;">www.midgam.org.il</p>
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**Subject of repository: Collection and storage of biological samples and information in a repository, or use in future medical study, including genetic study.**

I confirm that I have received information about the biological biorepository, and I have read and understood the attached Explanation Sheet. By signing this Consent Form I voluntarily agree to donate **remains** from samples, which will in any way be removed during the medical procedure, in addition to my blood/saliva/urine/other bodily fluids, for the purpose of processing, and storage as **coded** samples in the repository. All of this is in order to perform studies after they are approved by law. The purpose of the repository is to allow investigators in the future to improve the diagnosis and treatment of patients suffering from various diseases, detect environmental or genetic factors that may affect the propensity for morbidity or the propensity to cause disease or the ways in which diseases progress and the response of "sick" cells to different treatments.

I know and agree that I will not receive any personal results or will have any personal benefit from the sample donation, and that my donation to the repository is exempt from any payment on my side. I know that my decision whether or not to donate to the repository will in no way affect decisions regarding my or my family's medical treatment. I have the right to cancel my donation at any time, by providing the Repository Director a written notice, stating that I do not want any use to be done with the sample I have donated to the repository.

I know that cancellation of my consent will cause deletion of all of my medical and personal information from the repository, the transfer of the tissue samples from the repository to the pathology institute in the medical center, for storage as per standard practice, and the destruction of my other samples in the repository. However, it will not be possible to locate my samples, which have already been transferred to investigators, prior to my notice.

With my signature I agree that my biological samples (including the hereditary material) and medical information will be used for legally approved studies, and that I will not receive any medical information found in the studies that used my donation.

*In addition, I agree (please check the options to which you agree):*

That the repository employees and/or the investigators prepare from my sample permanent cell lines, i.e. reproduce some of the tissue and/or blood cells, in order to continue using the samples for studies as much as they require.

That the repository employees and/or the investigators will grow cells from my tissue in trial animals in order to develop specific treatments for diseases.

I also authorize use of biological samples previously collected from me during my diagnosis / treatment, which are found in the pathology institute archive at the hospital. The use will be for the same needs and purposes to which I have agreed to donate a sample now and under the same conditions, as long as there is a sufficient amount of sample in the pathology archive, from which a section can be collected without jeopardizing the possibility to use the pathological material for my benefit in the future.

Name (first and last)	ID no.	Year of birth
Signature date	<b>Signature</b>	
Name of attending physician	Health maintenance organization	Branch address

**Declaration of the person collecting the donation at the medical center:**

The abovementioned consent has been given by the patient after I have explained to the donor all of the abovementioned. In addition, I have made sure that they have read the explanation forms and the Informed Consent, and that my verbal explanations have been properly understood by them.

Name of person providing explanation: \_\_\_\_\_

Signature and stamp of person providing explanation: \_\_\_\_\_ Date: \_\_\_\_\_

גרסה: 3.1 תאריך גרסה: 29/5/2016	אנגלית	טלפון לצורך יצירת קשר:	טופס הסכמה מדעת, מאגר דגימות ביולוגיות בגירים
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