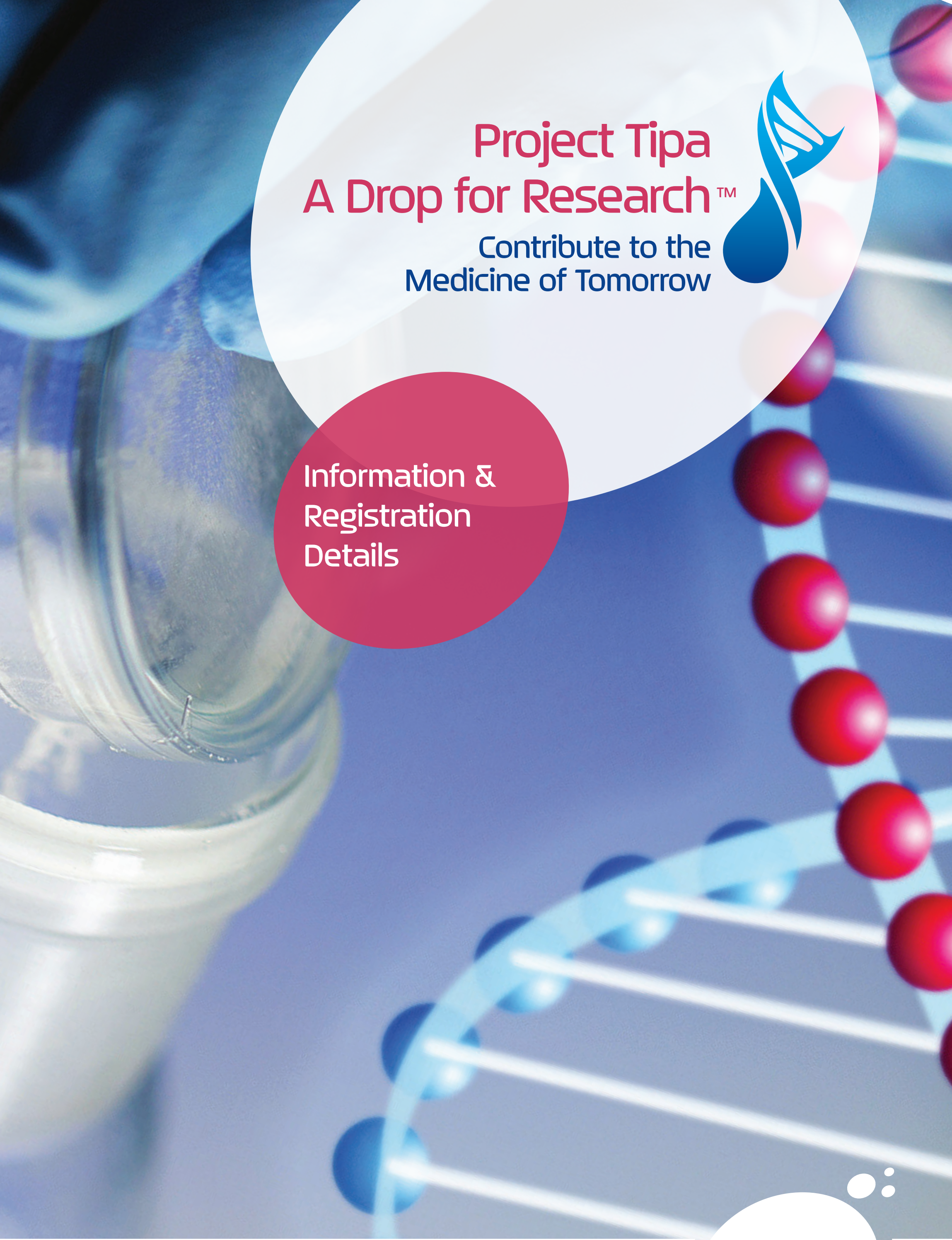


Project Tipa
A Drop for Research™

Contribute to the Medicine of Tomorrow

Information & Registration Details

There are healthcare services, and then there's Maccabi

Maccabi
The Best Healthcare Group in Israel

Background

Dear Maccabi Member,

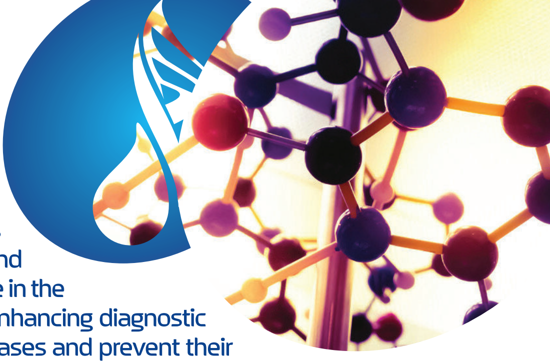
You have been invited to donate biological samples to the Tipa – A Drop for Research™ biobank, a project established by the Maccabi Research Institute, part of Maccabi Healthcare Services ("Maccabi"). Donated samples collected in the biobank are used for current and future scientific, medical, and genetic research. In this brochure, you will find detailed explanations about the biobank. It is important that you fully understand the project and its objectives, so that your decision to participate in the project is wholly informed and consenting.

Please read these pages carefully, and do not hesitate to reach out to the staff member who contacted you if you have any questions. If you decide to take part in Project Tipa – A Drop for Research™, please complete and sign the consent form.

For additional information, search for "Tipa – A Drop for Research™" in Google, or feel free to contact us: Email: tipa@mac.org.il Tel: 03-7462000

Version 5 | 26.05.19

What is medical research?



The purpose of every scientific-medical study is to broaden and develop our existing scientific and medical knowledge, and thereby improve medicine in the future. Improvements can be accomplished by enhancing diagnostic processes, as well as doctors' ability to cure diseases and prevent their development. The more we learn about why a disease develops, and how to treat it, the more we will be able to alleviate a patient's suffering.

Medical studies can be performed by giving patients new medications, or alternatively, through genetic testing. The genes that are passed down to us from our parents do not simply determine our eye color or physical appearance. They are also linked to our health: they can increase the risk of developing certain diseases, or conversely, protect us from the same diseases.

Today, we have already learned a great deal with the help of DNA testing, such as the risk a person has of developing specific types of cancer – which are related to certain inherited genetic mutations shared among family members, as well as unique, individualized, non-hereditary genetic mutations. Medical research that deals with genetics analyzes DNA from a group of people, with the goal of uncovering the connection between our health and genes. This connection is not only related to disease development – it can also teach us why a medication may heal one person, while having no effect at all on another. As our understanding of genetics grows, so does our ability to optimally customize treatments to each person's genetic profile. This type of medicine, based on a person's individual genetic profile, is known as "personalized medicine".

Medical studies of all kinds must first receive approval from an ethics committee acting on behalf of the Israeli Ministry of Health. The ethics committee, also known as the "Helsinki Committee", is comprised of senior doctors and public representatives. It is responsible for assessing the ethical aspects of medical studies, and as an independent body, its purpose is to protect the rights, safety, and interests of a study's participants. A study may only be conducted after receiving approval from the committee, which assesses all research requests.

How is the biobank related to medical research?

Project Tipa – A Drop for Research™ allows researchers to conduct medical studies that deal with topics such as those mentioned previously. The biobank makes medical studies easier to conduct by collecting samples from consenting participants of all ages, in both good and poor health. As these samples are immediately available to researchers, many more studies can be conducted on different topics and diseases, including cancer, Parkinson's, drug resistance, and so on. In this way, the biobank helps enhance our medical knowledge, so that doctors will one day be able to personalize medical treatments for their patients.

How does the Project Tipa – A Drop for Research™ biobank operate?

The Project Tipa – A Drop for Research™ biobank is a storage bank where samples are collected and stored in optimal conditions for future use. These samples come from various biological sources, such as: blood, tissue, and other bodily fluids. All Maccabi members – in good and poor health – are invited to participate, and all biological samples collected in the biobank may be used for future medical research. Studies on the samples will be conducted using a wide range of innovative technology, some of which is already in effect today, such as whole-genome sequencing, as well as prospective technologies that we have yet to master, but will be common during future studies. However, the samples on their own are not enough to conduct medical research – in order to learn from them, we also need to know the participant's medical information. This information is found in your personal Maccabi record.

Samples collected for Project Tipa – A Drop for Research™ are coded, without identifying information. A code may only be connected to a person's medical record once a researcher decides to use a certain sample for a study. This connection is created for the purpose of retrieving the relevant medical information from the samples chosen for the study. Even then, after retrieving the relevant information, the information seen by the researcher is strictly anonymous, safeguarding the participant's confidentiality and privacy. The process of retrieving information in this way is called "**de-identification**". In other words, ensuring that the information does not contain any identifying data (more on this later, in the confidentiality section).

The Purpose of the Biobank

We established the Project Tipa – A Drop for Research™ biobank in order to collect and store biological samples for research purposes. As mentioned before, the research is conducted with the help of information found in participants' medical records. The combination of samples and medical records allows researchers, whether from Maccabi or elsewhere, to conduct innovative medical studies. Research conducted on the biobank, like all medical research, must first be approved by the ethics committee. Biobank studies are conducted for the following purposes:

1. Examining the risk factors for disease development.
2. Identifying populations at risk of developing a specific disease.
3. Identifying early signs of disease.

4. Studying the resistance or sensitivity of diseased and healthy cells to different treatments.
5. Studying other diseases.
6. Any future study duly authorized by the committee.

Who can participate in the biobank, and how?

As a member of Maccabi Healthcare Services, you are invited to donate biological samples for research purposes. Biological samples collected from all willing participants who have signed the consent form are stored together in the biobank. Samples are collected during normal visits to Maccabi clinics throughout your life. This way, when you come to the clinic with a referral from your doctor for regular blood tests, you can also donate about 3 tablespoons of blood for research purposes at the same time. The various samples collected at Maccabi branches will be transferred to the biobank for storage. Maccabi will be responsible for all donated samples and their storage.

Voluntary Participation

Participation in Project Tipa – A Drop for Research™ is on a voluntary basis. You are entitled to withdraw your donation at any time (more on the withdrawal procedure later). Your donation will not have any effect on the treatments given to you, and you will not receive any monetary compensation or proprietary rights related to the results of any future research or the outcomes of such research. Consent to donate samples means consent to donate samples for advancing medical research, without compensation. Future medical advancements derived from biobank studies can be used to improve the lives of people in Israel and worldwide.

Establishing the Biobank and Research Activities

Maccabi is a non-profit organization (NPO). As stated by the National Health Insurance Law, all residents of Israel are entitled to receive healthcare services though their choice of NPO health maintenance organization (HMO). The law determines the basket of healthcare services to which residents are entitled, while subsidies from state budget funds and health taxes are granted to each HMO in relation to their number of insured members.

As an NPO, Maccabi must cover its operational expenses independently, including those from Project Tipa – A Drop for Research™. Establishing this project was therefore a complex process, requiring cutting-edge technological infrastructure, customized physical infrastructure, and the investment of many key resources. The project runs on financial donations (not from the HMO's funds) designated solely for this purpose.

As part of the project's ongoing activity, we conduct joint studies with research groups that have similar objectives, such as improving the diagnostic processes and treatments for patients suffering from various diseases. These research groups may be within or outside Maccabi, including academic institutions and commercial entities in Israel or overseas. Each research group pays its own expenses, and this money is used to support the biobank for future studies. Your personal participation in the project will contribute to the biobank by providing additional material for many more groundbreaking studies, which in turn will advance medical practices in Israel and around the world.

Confidentiality

Project Tipa – A Drop for Research™ is committed to all the regulations and requirements of the legal healthcare system, which include storing the biological samples in a professional manner, while taking care to keep all identifying information private. The personal details of all participants are kept confidential and are safeguarded by the Protection of Privacy Law and Genetic Information Law.

The samples are stored in the biobank by code, without identifying information. Even when your samples are used for research purposes, all your personal details, including medical, genetic, and sample information, remain confidential. Any data used for research is also coded without identifying information. This is called "**de-identification**". In other words, the coded information is free of personal details, such as your name, Israeli ID number, and address. Only a very small number of biobank staff members will be able to make the connection between you and your samples, if need be.

It is important to emphasize that only studies duly authorized by the ethics committee (Helsinki Committee), as previously described, may be conducted using the samples stored in the biobank. The ethics committee is comprised of doctors and public representatives who decide whether to approve studies on human subjects and samples. It is the responsibility of the committee to make sure that all studies are conducted in line with the code of ethics, which includes protecting participants' privacy and confidentiality.

Project Tipa – A Drop for Research™ is committed to upholding the confidentiality of information, which includes the storage of the biological samples. The samples are logged by their codes in the computer system, and then stored in special, secure refrigeration units, with access limited to biobank staff. All identifying data, such as participants' medical information, is stored separately, under an advanced information security system, to best protect your privacy. After each study is completed, the remaining samples are returned to the biobank.

Notification of Significant Genetic Findings in Your Samples

As part of the project, a special expert committee working in line with international professional standards – the Genetic Information Committee – was established to compile a list of certain genetic mutations. This way, if one of the mutations is discovered in a sample, we can notify the relevant donor. Mutations may be added to the list in the event that the committee answers "yes" to the following two questions: 1) Does the mutation have a strong connection to the development of disease? 2) Are there any preventative measures that can be taken before the disease appears, thanks to foreknowledge of the mutation? The list of mutations is updated periodically, at the professional discretion of the Genetic Information Committee.

It is important to understand that not all samples in the biobank will necessarily be used for research purposes, as each study will cover a different topic, requiring different samples. In fact, only a small percentage of participants are likely to receive genetic information about their samples. In light of this, please do not draw any conclusions if you do not receive any genetic information. That is to say, no conclusions should be drawn if you are not contacted about the use of your samples in a study. In addition, please do not infer that if no one has contacted you, it means that you are not a carrier of one of the tested mutations. Not all samples used in a study will be tested for all the genetic mutations on the list.

A lot can be learned from your DNA. For example, DNA can tell doctors if there is a medical treatment that's not right for you, or if you are at risk of developing certain diseases that can possibly be avoided through preventative treatments. As previously mentioned, experts compiled the list of mutations according to international standards. When a biobank study is conducted on one of the listed genes, the researchers are asked to test the samples (that are anonymous, as mentioned) for their tendency to develop the disease. If a mutation from the list is found in your sample, you will be notified by a genetic specialist from the biobank. This information will not be added to your medical record, and will not be passed on to your physician at Maccabi or any other party. After directly notifying you, and you alone, of this information, you will be referred to a genetic counselor from Maccabi.

Please note that there is no connection between members' medical records and the biobank. Maccabi does not add any information to members' medical records that has been derived from studies based on medical information or tested samples. The samples are managed independently of members' medical records. In other words, information derived from your samples will not be entered into your medical record, nor will it be passed on to any other party or Maccabi physician. This information will be sent directly to you by a specialist, so that you can arrange a consultation with a genetic counselor from Maccabi.

It is important to clarify that genetic information of this kind can have implications for your health and may also be significant to your family. Maccabi will provide you with the resources necessary to understand the results, in order to help you make the best decisions on the topic. The decision of whether or not to follow-up and start treatment is yours alone, but consulting with a doctor or genetic counselor is also critical to help you make the right decision.

Advantages and Risks

What are the advantages of participating in the biobank?

At this stage, we cannot guarantee that the project or its findings will have any personal significance or benefit to participants. That said, the most important advantage of participating in Project Tipa – A Drop for Research™ is helping future studies to take place, in which researchers may discover the connection between disease, its development, and the traits of certain genes. The hope is that, thanks to your sample, and the samples of other participants, researchers will be able to develop better tools to examine and treat diseases, helping people in the future.

As mentioned before, there is a certain risk that, as a result of participating in the biobank, you will be informed that you carry a mutation, but this is only likely to apply to a small percentage of donors. Since participants donate samples for storage and use in future studies (the results of which cannot be anticipated), we cannot guarantee that you will be notified of genetic information that can be used to personalize your medical treatments.

What are the medical risks associated with participating in the biobank?

There are no medical risks associated with donating samples.

Project Duration

Project Tipa – A Drop for Research™ is a long-term project. We want it to contribute to as many studies as possible, thereby advancing the future of medicine. For this reason, we have no plans to end the project, and therefore, on the consent form, we request your consent for an unlimited period of time, including posthumously. Your samples and information will be stored until they have no scientific use, or until the project ends. If we are compelled to close the biobank at any point, Maccabi will decide, with the help of a professional committee, if and how to transfer the remaining samples to an entity with similar research objectives.

Leaving the Biobank

You are entitled to withdraw your participation at any point. If you decide, for any reason, to cancel your donations and withdraw from Project Tipa – A Drop for Research™, you may send a written request to the biobank management by email at tipa@mac.org.il, or through the administrative offices at Maccabi branches, and your samples will be destroyed. That said, if your sample is sent to a study that has already begun before your withdrawal letter is received, the sample will not be removed from the study. However, from that moment on, your remaining samples will not be used for any additional studies.

For your information, there is also a tissue bank in Israel run by the MIDGAM project, which operates at four medical centers in the country: Hadassah, Rambam, Sheba, and Sourasky.

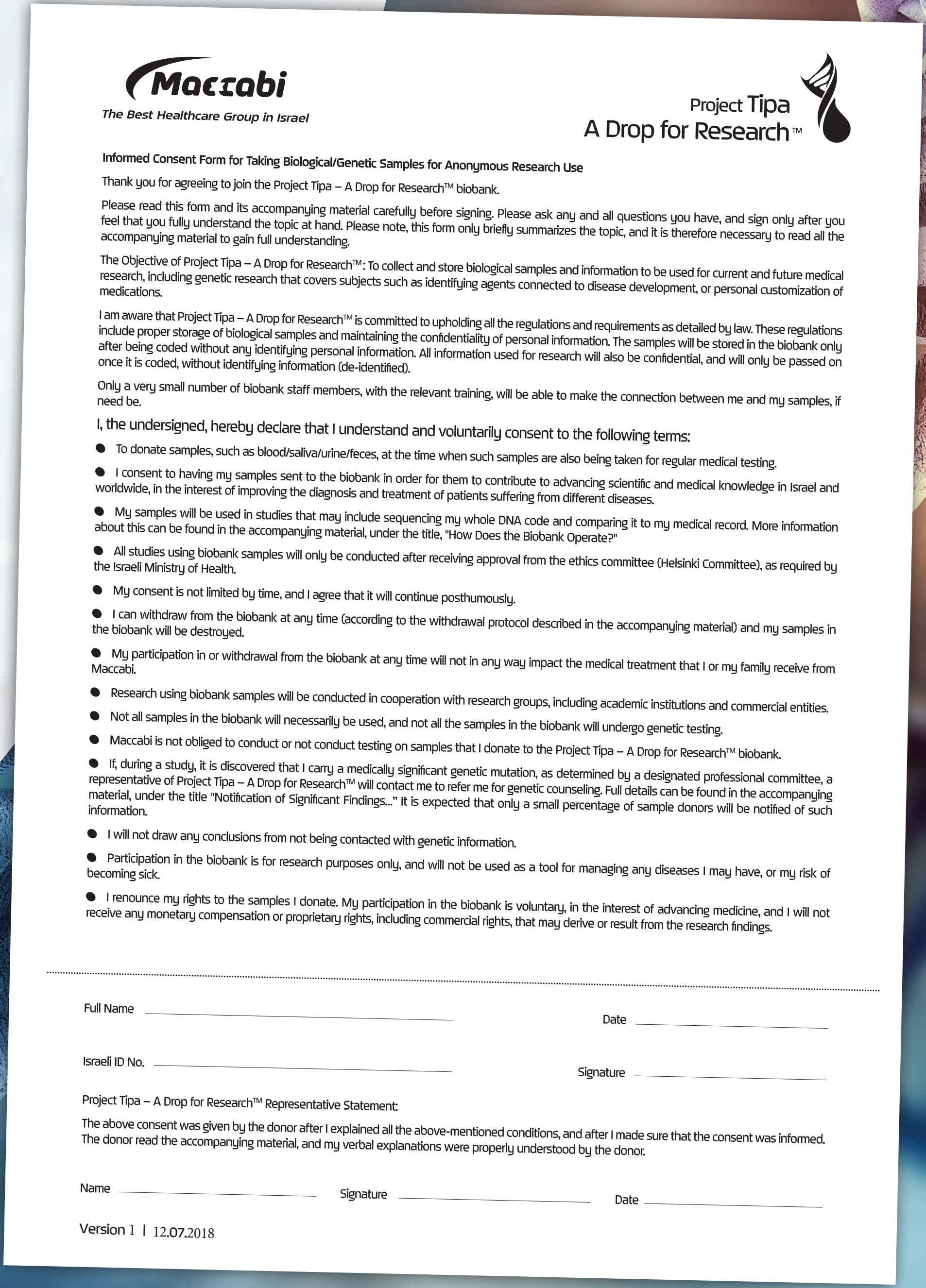
Biobank Activity Updates

Thank you for joining the project. We view Maccabi members who participate in Project Tipa – A Drop for Research™ as partners in the effort to advance medical research. Your willingness to donate samples allows us to build a biobank – a key research tool that will contribute to many studies, thereby improving medicine for everyone.

We invite you to get involved in the biobank and receive updates on its activities. Details and updates about Project Tipa – A Drop for Research™ are available at www.maccabi4u.co.il. Upon joining the biobank, a new personal page will be opened for you on Maccabi Online, at online.maccabi4u.co.il (which can also be accessed via the Maccabi app). After signing in with your password, you can view your personal information related to your participation in the biobank.

For additional information, search for "Tipa – A Drop for Research™" in Google, or feel free to contact us: Email: tipa@mac.org.il Tel: 03-7462000

Sample



Maccabi
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Project Tipa
A Drop for Research™

Informed Consent Form for Taking Biological/Genetic Samples for Anonymous Research Use

Thank you for agreeing to join the Project Tipa – A Drop for Research™ biobank.

Please read this form and its accompanying material carefully before signing. Please ask any and all questions you have, and sign only after you feel that you fully understand the topic at hand. Please note, this form only briefly summarizes the topic, and it is therefore necessary to read all the accompanying material to gain full understanding.

The Objective of Project Tipa – A Drop for Research™: To collect and store biological samples and information to be used for current and future medical research, including genetic research that covers subjects such as identifying agents connected to disease development, or personal customization of medications.

I am aware that Project Tipa – A Drop for Research™ is committed to upholding all the regulations and requirements as detailed by law. These regulations include proper storage of biological samples and maintaining the confidentiality of personal information. The samples will be stored in the biobank only after being coded without any identifying personal information. All information used for research will also be confidential, and will only be passed on once it is coded, without identifying information (de-identified).

Only a very small number of biobank staff members, with the relevant training, will be able to make the connection between me and my samples, if need be.

I, the undersigned, hereby declare that I understand and voluntarily consent to the following terms:

- To donate samples, such as blood/saliva/urine/feces, at the time when such samples are also being taken for regular medical testing.
- I consent to having my samples sent to the biobank in order for them to contribute to advancing scientific and medical knowledge in Israel and worldwide, in the interest of improving the diagnosis and treatment of patients suffering from different diseases.
- My samples will be used in studies that may include sequencing my whole DNA code and comparing it to my medical record. More information about this can be found in the accompanying material, under the title, "How Does the Biobank Operate?"
- All studies using biobank samples will only be conducted after receiving approval from the ethics committee (Helsinki Committee), as required by the Israeli Ministry of Health.
- My consent is not limited by time, and I agree that it will continue posthumously.
- I can withdraw from the biobank at any time (according to the withdrawal protocol described in the accompanying material) and my samples in the biobank will be destroyed.
- My participation in or withdrawal from the biobank at any time will not in any way impact the medical treatment that I or my family receive from Maccabi.
- Research using biobank samples will be conducted in cooperation with research groups, including academic institutions and commercial entities.
- Not all samples in the biobank will necessarily be used, and not all the samples in the biobank will undergo genetic testing.
- Maccabi is not obliged to conduct or not conduct testing on samples that I donate to the Project Tipa – A Drop for Research™ biobank.
- If, during a study, it is discovered that I carry a medically significant genetic mutation, as determined by a designated professional committee, a representative of Project Tipa – A Drop for Research™ will contact me to refer me for genetic counseling. Full details can be found in the accompanying material, under the title "Notification of Significant Findings..." It is expected that only a small percentage of sample donors will be notified of such information.
- I will not draw any conclusions from not being contacted with genetic information.
- Participation in the biobank is for research purposes only, and will not be used as a tool for managing any diseases I may have, or my risk of becoming sick.
- I renounce my rights to the samples I donate. My participation in the biobank is voluntary, in the interest of advancing medicine, and I will not receive any monetary compensation or proprietary rights, including commercial rights, that may derive or result from the research findings.

Full Name ______________________ Date ______________

Israeli ID No. ______________________ Signature ______________

Project Tipa – A Drop for Research™ Representative Statement:

The above consent was given by the donor after I explained all the above-mentioned conditions, and after I made sure that the consent was informed. The donor read the accompanying material, and my verbal explanations were properly understood by the donor.

Name ______________ Signature ______________ Date ______________

Version 1 | 12.07.2018

Project Tipa
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Data Pro | proximity

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