

Biomaterial Research Storage Consent Form

Background:

You are being asked to participate in sample storage for later use in Research. Your sample(s) will be stored at the IRMC Biobank for an unspecified time for later use in Research by different Researchers. A variety of Research is carried out at the IRMC, at this present time; there is no specification as to how your samples will be used. We are asking you to donate your sample because ______.

Purpose:

The purpose of collecting the samples is to store samples for further Research intended to improve the analysis, treatment and prevention of disease.

Procedures:

If you agree to participate in the sample storage for future Research, you will be asked to donate a sample of ______ during the procedure done for your clinical analysis. Your Doctor will explain in detail what the procedure will include. You can also donate a sample without having a clinical analysis. In this case, The Doctor collecting the sample will explain the procedure in detail. The research sample will be taken at the same time the clinical analysis sample is taken. The donated sample will be sent to the IRMC Biobank for storage and future Research. This sample will be coded, however, if necessary, your private information/clinical data will be available for the Researchers.

Please feel free to ask any questions if you have any unclear or ambiguous issues concerning your sample storage and usage.

Confidentiality and Access to your Records:

Based on the rules and guidelines of the National Committee of Bio Ethics (NCBE) and Standing Committee for Research Ethics on Living Creatures (SCRELC), your confidentiality will be maintained at all times. However, data obtained from the research will be used for publications, your name will not be included in the publications. IRMC is obliged to allow the Saudi Food and Drug Administration to view the research procedures for the benefit of the Research subjects. Various monitors from the Institution Review Board and the Research Compliance Office will also examine the Research procedures randomly.

Risks:

The normal risks associated to this sample donation include general discomfort from the sample collection procedure, possible infection, minimal bleeding, bruising and minor swelling, potential for discrimination in employment and insurability, risks associated with false positive/negative results and psychological or emotional burden related to results.







To get the application (IRMC.08) in word scan the following barcode:



Possible Benefits:

The Research may or may not benefit you, however, the results may contribute to future alternative treatments.

Alternatives to Participation:

The alternative is not to participate. Your participation in the research part of the sample collection is entirely voluntary. You have the right to discontinue or refuse to take part in the research sample collection. Refusal to take part in the research sample collection will not have any negative consequences for you. Please take time to ask any questions that you may have. You can also talk to your family, friends or personal doctor before you decide to take part.

Costs and Compensation:

In case of any unexpected injury or illness, medical care will be provided, however, you or your Insurance company will be responsible for the payments. There will be no monetary compensation for donated samples.

Contact Information:

In	the	event	that	you	have	any	quest	ions	or	con	cerns	, pleas	e conta	nct D	r.			at
ema	ail:				Ad	dress:						Tele	phone:			at any	time	e. In
the	eve	nt tha	t you	deci	ide t	o wi	thdraw	conse	ent	in	the	future,	please	send	а	letter/email	to	Dr.

I have read or listened to the above information and I have decided that I will participate in the project as described above. The Researcher has explained to me in detail what is going to happen to the samples I donate. I also understand what is expected of me and that my participation is voluntary. I understand that if I decide not to participate or if I later decide to withdrawal my consent, there will be no penalty or loss of rights. I agree to participate in the sample donation and for my samples to be kept and used for future research.

My signature below also indicates that I have received a copy of this English consent form together with an official translation of this document in Arabic.

Participant's Name:	Date:					
Participant's Signature:						
Principle Investigator:	Date:					
Principle Investigator's signature:						
Witness - I						
Witness –II						

To get the application (IRMC.08) in word scan the following barcode:





