

Consent Form
Collection of Biological Samples (Blood and Body Fluids)
for DwarnaBio and StudjuDWARNA
at the Centre for Molecular Medicine and Biobanking, University of Malta

The signed form is to be kept by DwarnaBio.
A copy of the signed form will be given to the research participant.

Date: _____

Sample Code:

By agreeing to take part in the Collection of Biological Samples for DwarnaBio,

I confirm that I have read and understood the **Information Sheet** for the **Collection of Biological Samples for DwarnaBio and StudjuDWARNA** at the Centre for Molecular Medicine and Biobanking; and

I understand that my participation is voluntary; and I understand that all information will be treated with the utmost confidentiality and will be stored in a secure location at DwarnaBio; and

I understand that my contact data will be stored separately from the sample associated data; and

I understand that I have the right to withdraw all or part of my consent at any time; and

I therefore give my consent to DwarnaBio:

		Yes	No
1.	I agree to provide the following samples and my demographic and health data for StudjuDWARNA: Blood Saliva Urine. I am aware that the samples and associated data will be stored in the Biobank for future research.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2.	I give permission for my samples and associated data (demographic and medical data) to be stored in DwarnaBio for 10 years. I understand that I will then be re-contacted to renew my consent.	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
3.	I give permission to DwarnaBio to request access to my health records from the Director of the Directorate for Health Information and Research, at the Ministry for Health and from the Data Controller at Mater Dei Hospital.	<input type="checkbox"/>	<input type="checkbox"/>
4.	I consent to the use of my samples and associated coded demographic and medical data in <u>StudjuDWARNA</u> .	<input type="checkbox"/>	<input type="checkbox"/>
5a.	I confirm that I want to be contacted and given adequate information before I decide whether to consent to the use of my samples and associated coded demographic and medical data, in ethically approved research projects.	<input type="checkbox"/>	
5b.	OR I consent to the use of my samples and associated coded demographic and medical data in future research projects that are formally and ethically approved by a recognised Research Ethics Committee, without the need to be re-contacted.	<input type="checkbox"/>	
6.	I consent to the sharing of aggregated data on the online biobank sample catalogue.	<input type="checkbox"/>	<input type="checkbox"/>
7.	I consent to be re-contacted by DwarnaBio, if it is in my interest to be re-contacted, and provided with specific results and/or information, which may affect my health and/or medical management.	<input type="checkbox"/>	<input type="checkbox"/>

Please Use Block Capital Letters

RESEARCH PARTICIPANT DETAILS		LEGAL REPRESENTATIVE/S DETAILS (if donor is < 18 years old or a vulnerable person)	
Write or Attach Label with Identity Card (or Passport) Number, Name, Surname, Address		1. 2. Write or Attach Label with Identity Card (or Passport) Number, Name, Surname, Address	
Gender	Female <input type="checkbox"/> Male <input type="checkbox"/> Other		
Age			
Telephone / Mobile Number		Telephone / Mobile Number 1	
		Telephone / Mobile Number 2	
E-mail address		E-mail address 1	
		E-mail address 2	
Signature of the Research Participant			
COLLECTION CURATOR or DELEGATE			
Name		Identity Card (or Passport) Number	
Surname		Signature of Collection Curator (or Delegate)	
WITNESS			
Name		Identity Card (or Passport) Number	
Surname		Signature of Witness	

Data Protection

The controller responsible for the processing of your personal data is DwarnaBio, established within the Centre of Molecular Medicine and Biobanking at the University of Malta.

Your personal data will be processed in accordance with the **Data Protection Act**, Chapter 586 of the Laws of Malta and **Regulation (EU) 2016/679, General Data Protection Regulation, GDPR**.

Your signed explicit consent will serve as the legal basis for processing your data, in line with Article 6(1)(a) of the GDPR.

The purpose of data collection is to build a repository of human biological samples with associated data to be used for medical research, only according to the specific options you choose on the Consent Form.

You have the right to request, in writing, a copy of the personal information held about you by the Controller. You also have the right to request correction or erasure of such data. You have the right to withdraw your consent at any time without giving a reason and without suffering any adverse consequences by contacting the Biobank Manager, Dr Lidia Ryabova, on email address lidia.ryabova@um.edu.mt or contact@dwarna.mt, or on contact number +356 2340 3272.

Your contact data will not be shared with researchers or any other third parties, unless this is legally required or otherwise ordered by the Maltese Courts of Justice.

Samples and/or associated data, which may be made available to researchers outside the European Economic Area (EEA), will be transferred in accordance with Chapter V of the **General Data Protection Regulation (GDPR)** and provided that the Controller is satisfied with the ethical approval formally obtained from a Research Ethics Committee. Researchers are required to sign a Material Transfer Agreement and a Data Transfer Agreement and will only receive pseudonymised samples and associated coded data.

Any query in relation to your data protection rights should be directed to the University Data Protection Officer, Dr Luisa Spiteri Baluci, on email address luisa.spiteri-baluci@um.edu.mt or dpo@um.edu.mt, or on contact number +356 2340 3233.

You have the right to lodge a complaint with the Office of the Information and Data Protection Commissioner, by completing and submitting the online form at <https://idpc.org.mt/file-a-complaint/>