

Participants` Information Sheet

Dear Participant,

My name is **[Add name]** and I am currently reading for a **[Name the title of your degree**] at the [**Name the University**]. As part of my course requirements I am conducting a research study entitled**, “[Write the title of your research]”**.The aim of this study is to explore the [**Provide the aim of the study].** Your participation in this study would help us gain a better understanding about [**state the Benefit of the study**]. Furthermore, all data collected from this research shall be used solely for the purpose of this study.

The project will be explained to you in detail. You can take some time to consider participation. If you agree to participate you will be asked to **[here describe briefly what participation will entail, what samples or measurements need to be taken, specify if these are over and above what would be required for routine testing, and whether any other information needs to be collected, including access to medical records if needed]**. There may be some **[here state any risks (e.g. bruising after phlebotomy)].** Should you require any medical attention the qualified professional collecting the sample will be able to provide the necessary treatment or referral. Participation will take approximately **[here give the duration e.g. 30 min]** of your time.

Confidentiality will be maintained throughout the study and your identity and personal information will not be revealed in any publications, reports or presentations arising from this research. [If there is any chance that pedigrees or patient descriptions can make the individual recognizable add the following: **However, there is a chance that you may be indirectly identifiable in publications**.] All data collected will **[here state whether data will be coded or anonymized, how it will be stored, how codes and data will be kept separate]**. This data may only be accessed by the researcher. The academic supervisor/s and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes. All data will be stored in encrypted or password protected files. Hard copies of consent forms and any questionnaire data will be stored in a locked cupboard.

Participation in this study is completely voluntary and you are totally free to accept or refuse to take part. You may withdraw from the study at any time without giving a reason. Furthermore, withdrawal from the study will not have any negative repercussions on you and your sample and data will be destroyed. Data will be stored anonymously if it is impossible to delete (e.g. if it has already been anonymised). As a participant, you have the right under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning you to be erased, unless this data has already been anonymized and cannot be traced back to you. Once the study is completed and the results are published, all data collected will be **[here state whether the data will be erased, anonymized or retained indefinitely]**. All personal details will be destroyed. A copy of this information sheet and consent form will be provided for future reference.

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on **[here give your telephone number]** or by e-mail **[provide a University of Malta email]** or my supervisor **[Name your supervisor]** on **[provide an email and office contact number]**.

Yours Sincerely,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 [**Name of Researcher**]

 Researcher

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[**Name of Supervisor**]

Research Supervisor



Participants` Consent Form

 **[Title of Research]**

I, the undersigned, give my consent to take part in the study conducted by [**Name of Researcher]**. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I give my consent for my **[state what sample, and how much will be collected]** to be taken along with **[state any measurements to be taken, and explicitly state if medical records will be accessed]** and for these to be processed for the purpose of this study.
3. I understand that these samples and data will be retained **[here state how long the samples and data will be kept].**
4. I am aware that my participation will take approximately **[State the duration]**.
5. I am aware that the samples and data will be **[coded or anonymized]** and that all results will be stored securely and separately from any codes and personal data.
6. I am aware that the researcher is the only person who has access to this data. The academic supervisor/s and examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes.
7. I am aware that my identity and personal information will not be revealed in any publications, reports or presentations arising from this research but accept that there is a risk that people who know me may identify me indirectly **[delete latter phrase if not applicable]**.
8. I also understand that I am free to accept, refuse or stop participation at any time without giving any reason. This will have no negative repercussions and that any data collected from me will be erased. Data will be stored anonymously if it is impossible to delete (e.g. if it has already been anonymised).
9. I understand that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation I have the right to access, rectify, and where applicable ask for the data concerning me to be erased unless this has been anonymized and cannot be traced back to me.
10. I also understand that once the study is completed and results are published, the data will be **[state whether erased, anonymized or retained]**. All personal details will be destroyed.
11. I am aware that I will not benefit financially in any way even if the results from this study may lead to the development of tests or other commercial applications.
12. **[Here add any study specific points, such as a provision for sharing of data, or delete this point completely]**.

I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researcher: **[Name]**

**Contact details**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Supervisor: **[Name]**

**Contact details**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_