

Information sheet for the processing of patient MRI data

1. Background

1.1 The University of Malta Magnetic Resonance Imaging Platform (UMRI) is a leading multidisciplinary initiative that promotes the use of Magnetic Resonance Imaging (MRI) in research and teaching. UMRI aims to bring state-of-the-art MRI research to Malta and apply it for the benefit of patients, students and the wider community.

1.2 UMRI is asking you for your explicit consent to transfer, and store your MRI data in the University's institutional data repository, and use your data for the purpose of scientific research and teaching.

2. The aim of the document

2.1 The aim of this document is to serve as an information sheet. This document outlines the method by which UMRI would store and use your data, the benefits and risks associated with storage and usage of your data, and your legal rights concerning the data stored by UMRI.

3. What will happen to my data if I give consent to UMRI?

3.1 First, a copy of your MRI scans will be transferred to a dedicated storage system (repository) at the University of Malta (hereafter "institutional data repository"). Your data will go through a system that pseudo-anonymises your data to protect your identity. Pseudo-anonymization involves processing your MRI data in a manner that prevents the data from being attributed to your identity without the use of additional information.

3.2 Once the data has reached the institutional data repository, it will be stored there for up to a period of 10 years, after which it would be deleted. Copies of data used for research will be held in a secondary repository (hereafter "institutional project repository") for a period of *10 years from the initiation of the research project*. Specific study data may be kept longer provided that the request has been ethically approved.

3.3 **Following ethical approval by a relevant ethics committee (such as the University of Malta Research Ethics Committee ('UREC')) and, where required, approval by the Information and Data Protection Commissioner ('IDPC'), the data stored in the institutional data repository will be used in research projects. The results of any research may in turn be utilised for public outreach and/or teaching purposes, presented at scientific meetings, and written about in journals and/or dissertations. This will always be done in a manner which does not reveal your identity.**

3.4 **Following approval by the UMRI board**, the data may also be used for University teaching. This will always be done **in a manner which does not reveal your identity**.

4. What are the benefits of consenting to my data being stored in the institutional data repository?

4.1 There will not be any direct benefit to you. Any benefits will be indirect, in the sense that the outcomes of scientific research may be exploited for the good of society in general.

4.2 It is possible that some of the research conducted using your data could lead to new diagnostic tests, drugs, technology or other commercial products. If this happens, please note that you will not receive any portion of the profits generated from these products, nor will you have any ownership rights over them.

5. What are the risks of consenting to my data being stored in the institutional data repository?

5.1 MRI data will be transferred from Mater Dei Hospital to the institutional data repository where it will be stored. As with any data transfer and storage, there is a minimal risk of a data breach.

5.2 The highest risk of a data breach occurs when the data is transmitted to the University. This is because, at this point, the data will still contain your patient ID which is usually your national ID card number and/or hospital number.

5.3 After your data is received by the University, it is stored securely in temporary storage. At this point, it will be pseudo-anonymised and then transmitted to the institutional data repository. Your original data, which includes your ID card number, is deleted once pseudo-anonymisation has taken place. With current technology, it is highly unlikely to compute the original ID number from the pseudo-anonymised ID.

6. How will my identity be protected?

6.1 UMRI has put a lot of effort into ensuring that data transmission and storage are secured against unauthorised access. Hence, to mitigate the risk of a data breach, data will only be transferred using current security standards.

6.2 The data that is sent to the institutional data repository will go through a system that i) replaces your full name with dummy data and ii) hashes and encrypts your patient ID. This process is referred to as the pseudo-anonymisation process.

6.2.1 **Hashing**; First, your patient ID will be appended with a secret SALT. Then, it will be hashed meaning that it will be turned into a unique, fixed-size string of characters.

The hash is a one-way function, which means that once an input has been hashed, getting it back in its initial form is very difficult.

6.2.2 Encryption; To add another layer of protection, the hashed ID will also be encrypted. The type of encryption involves a process whereby an input (this case the hashed ID) is scrambled using a special code, called a *public key*. The output cannot be read without another key known as the *private key*.

6.3 For a more detailed description of the process of hashing and encryption, the reader is encouraged to read the “Encryption and Hashing” document found on the UMRI website [<https://www.um.edu.mt/platforms/umri/documents-forms/>].

6.4 Personal attributes that can be useful for research (such as date of birth, age, sex, height, weight and scan date) are not removed when the data is transferred to the institutional data repository, but will only be made available for research and/or teaching if strictly necessary.

6.5 Researchers working with data from the institutional data repository will be asked to declare, by filling in a compliance form, that they will in no way attempt to determine the identity of the people from whom the data was obtained.

7 Can my MRI scans be connected to my ID number?

7.1 In some cases, it is important for UMRI to be able to connect your ID to the MRI data stored in the repository. Therefore, UMRI does have a process, which consists of two steps, that allows UMRI to connect your ID to your pseudo-anonymised MRI data stored in the institutional data repository. Only a few individuals can carry out such a process, and those who perform the first step cannot execute the second step, and vice-versa.

7.2 Please note that this process can *only* be done in one direction. This means that while known ID card numbers may be linked to specific scans, we cannot link scans to ID card numbers. In other words, UMRI would still not be able to identify the patient in the MRI scan. More information is provided in section 8.

8 When and how would UMRI connect my ID number to my MRI data stored in the institutional data repository?

8.1 There are a few scenarios where it is important to perform a connection between your ID and your pseudo-anonymised MRI data stored in the institutional data repository;

8.1.1 Consider that we would like to study MRI scans of patients with a certain disease. Hence, we must first know which scans show the disease we're interested in. A third party (such as a doctor) would identify some patients having this disease and generate the list of hashes from their ID card numbers. The list of hashes (*not the ID numbers*) would

then be sent to UMRI (step 1). UMRI would then use the code to locate the relevant scans stored in the institutional data repository (step 2).

8.1.2 Note that the example in 8.1.1 is also applicable to longitudinal studies where we would be interested in seeing the progression of a condition. For example, Joe Borg is diagnosed with the beginnings of a chronic condition in 2020, and then scanned again in 2023. The hash generated by the third party from the ID card number of Joe Borg would be identical for the scans of 2020 and 2023. This would allow UMRI to know that the scans were retrieved from the same patient without knowing the true identity of Joe Borg.

8.1.3 Consider another case where you would like to have your data deleted. In that case, the Data Protection Officer at the University would ask you for your ID card number, produce the hash code, and forward it to UMRI (step 1). UMRI would then look for the data that matches the code (step 2).

9. Who will have access to the copy of my data stored in the institutional repositories?

9.1 In the institutional data repository, your data will be accessible to:

- 1) the University of Malta employees administering the system. Administrators will only access the data if absolutely necessary to deliver a task (such as for maintenance);
- 2) Designated UMRI employees such as the UMRI scientific officer, and specific UM employees tasked by UMRI to retrieve and maintain data stored in the institutional data repository.

9.2 A copy of your data in the institutional project repository specifically designed to house data approved for use in research and teaching will be made available to:

- 1) researchers working on projects that have been approved by a relevant ethical committee and the IDPC, or by a relevant legal process. A full list of studies currently in progress and the people leading them can be found here: <https://www.um.edu.mt/umri/projectsandpublications/>. Kindly note that in rare cases, examiners assessing student projects might need to view the data, usually for purposes of verification);
- 2) teaching personnel (and students attending their courses) at the University will have limited access to your data for teaching activities following UMRI approval;
- 3) technical administrators to provide support for the system.

10. What happens if I do not give my consent for my data to be stored in the institutional data repository?

10.1 Contributing your data to the institutional data repository is totally voluntary, and not giving consent or withdrawing that consent afterward will not affect in any way your medical care. Note that giving consent will not provide you with any medical advantage.

10.2 Please be aware that if you are scanned on the University's MRI machine on multiple occasions, your consent will be sought every time, and what you decide in relation to a particular scanning session will not influence what happens with the data collected during other sessions. You may, for instance, give your consent before the first session but not the next one. In such a case, only the data collected during your first session would be copied to the institutional data repository.

10.3 Kindly note that if you want UMRI to delete all of your data, **refer to section 16** for more information.

11. What is the legal basis for processing my data for research and teaching purposes?

11.1 Personal data shall be processed in line with the General Data Protection Regulation (GDPR – EU Regulation 2016/679), the Data Protection Act (Cap. 586 of the Laws of Malta) and any other applicable legislation.

11.2 The GDPR requires that all processing of personal data has a legal basis (justification). In our case, this basis is twofold:

- a) **Explicit consent** (GDPR Articles 6(1)(a) and 9(2)(a)) will be used for transfer and storage of your data.
- b) **Public interest for scientific purposes** (GDPR Articles 6(1)(e) and 9(2)(j)) will be used to process your data for purposes of scientific research.

12. What categories of personal data are concerned?

12.1 General personal data such as your name, age, and other similar demographics.

12.2 Health and biometric data, which are considered special (or sensitive) categories of personal data in the GDPR. Biometric data refers to unique physical or behavioural characteristics of a person that can be used for identification. In some cases, biometric data can be extracted from MRI images.

13. Who is the data controller for the data?

13.1 According to the GDPR, a 'data controller' is the person or entity that, alone or jointly with others, determines the purposes and means of the processing of personal data. While the University of Malta is the data controller, your initial point of contact regarding data matters should be the current Chair of the UMRI, Dr. Claude Julien Bajada. You can reach him at gdpr-umri.platform@um.edu.mt.

13.2 If you have any questions about a particular aspect of the data processing, kindly refer to the contact details provided at the end of this document.

14. How will you ensure that the data remains safe from unauthorised access when it is processed by researchers?

14.1 All researchers will be required to fill in a compliance form which binds them to processing your data in accordance with the safety standards guaranteed by the GDPR.

14.2 All researchers will be obliged to store data on an encrypted data storage device and access/process the scans using properly secured computers.

15. How long will the University of Malta store my data?

15.1 The University of Malta will store your data in its main institutional data repository for a period of 10 years, after which it will be deleted (backups will be retained for a further year).

15.2 Copies of data used for research will be held in the institutional project repository for 10 years *from the initiation of the research project*. This is important in case, for instance, other researchers want to check that a particular study was conducted according to established scientific norms. If, after 10 years, the data is no longer considered to be necessary for scientific research purposes, it will automatically be deleted. Researchers may request for an extension to retain specific study in the secondary research project repository for longer periods. Such requests must be reviewed and approved by a research ethics committee.

15.3 By completing the UMRI researcher compliance form, researchers commit themselves to erasing the original data (and any derived data that has not been combined with anyone else's) from their computers/personal storage systems once the project has been concluded (never longer than 10 years) - unless the data is needed for a follow-up study, in which case a new application has to be submitted to UMRI, and the data cannot be processed further or shared until authorization has been obtained from the relevant committees. We want you to be aware that any personal details (like age, sex, etc.) we forward to researchers will be kept to a minimum, and will **NEVER** include your name and national ID card number.

16. Can I object to my data being processed by the University of Malta?

16.1 Yes – under the GDPR and the Malta Data Protection Act 2018, you have the right to request, in relation to your personal data:

- 1) Access to all the information we hold about you, including details as to why we're keeping it and what we're using it for;
- 2) That any errors be corrected (rectification of inaccuracies);
- 3) That your data be deleted (erasure);
- 4) Restriction of processing;
- 5) A copy of your personal data (data portability).

16.2 Such requests should be made to UMRI in the first instance by filling the GDPR form on the UMRI webpage: <https://www.um.edu.mt/platforms/umri/gdprrights/>. Alternatively, you may also contact UMRI by sending an email at umri.platform@um.edu.mt or placing a call at +356 2340 3212, provided **they concern the data stored in the University**. At any time you may also object, on grounds relating to your particular situation, to processing of personal data concerning you. In other words, this means that if there's something you don't like about the way your personal information is being used by the University, you have the right to ask us to stop using it in that manner.

16.3 Please note that according to the Malta Data Protection Act and the GDPR, we do not need to satisfy the above-mentioned requests in circumstances where this would seriously hinder research objectives (for instance, if your data has already been processed for a specific study and you ask for it to be deleted, we are still allowed to use it for that study). However, UMRI will do its utmost to comply with your wishes. In situations where we are unable to do so, we will always explain the reason for this to you.

17. Where can I get more information?

17.1 More information **about the transfer, storage and use of MRI data by the University of Malta** may be obtained from:

- UMRI by sending an email at umri.platform@um.edu.mt or placing a call at +356 2340 3212. Ideally this is your first contact point. Kindly note that we cannot give medical advice.
- The UMRI's [website](http://www.um.edu.mt/umri) [www.um.edu.mt/umri]
- The Data Protection Officer of the University of Malta (dpo@um.edu.mt).

17.2 From time to time we may make changes to the information presented to you here. We will not notify you directly in such instances, but will make the latest version of this document available on the UMRI website.

18. Can I lodge a complaint with an independent entity?

18.1 **If your complaint is related to the transfer, storage and use of MRI data by the University of Malta**, we recommend that you contact the UMRI team or the University of Malta's Data Protection Office in the first instance.

18.2 Should the response you get be unsatisfactory, you may submit a complaint to the office of Malta's Information and Data Protection Commissioner. It has a [dedicated online form](https://register.idpc.org.mt/report-breach/complaint/) [register.idpc.org.mt/report-breach/complaint/] that makes the process easy. Further information may be obtained from www.idpc.org.mt/, or by contacting the office at idpc.info@idpc.org.mt or +356 2328 7100.