**UMRI Research Volunteer Consent Form**

I, the undersigned, consent to take part in data collection for the study

[Insert name of project below:]

conducted by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Principal Investigator) and

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Lead Researcher).

This document specifies the terms of my participation.

1. I have been given written and/or verbal information about the purpose of the study (in particular, I confirm that I have carefully read the **research volunteer information sheet** forwarded to me prior to the scanning session/s). I have had the opportunity to ask questions, and any queries I made were answered fully and to my satisfaction.
2. I understand that joining in is completely voluntary, and that I have the right to:
* decline to take part, and, should I opt in, to
* refrain from answering any questions I do not feel comfortable with
* quit at any time

without giving any reason or incurring any penalty. In the event that I choose to withdraw from the study, any data collected from me would still be stored and used as outlined in the research volunteer information sheet unless I explicitly request its erasure or a restriction of its processing. I am mindful of the fact that should I make such a request, the researchers might not be able to fully satisfy it (although they would try their best) if doing so would seriously jeopardise the study (for instance, the data could already have been combined with other people’s and analysed).

1. I understand that I have been invited to participate in [insert number of MRI scanning sessions] MRI scanning sessions in which the researcher will [explain what participants do or what is done to them] to investigate [state the aim of the research study]. I will also be filling in a questionnaire which will contribute to the analysis [remove if not relevant].I am aware that I am being requested to attend [insert number of data sessions] session/s of around [state the duration of data collection]. These sessions will take place at Mater Dei Hospital within approximately [insert time interval here, or remove this part of the sentence if not applicable] of each other, at a time that is convenient for both me and the researcher.

An example is provided below.

*I understand that I have been invited to participate in two MRI scanning sessions in which the researcher will display arousing and control audiovisual stimuli to investigate the neurophysiology underlying sexual arousal, as well as to test the reliability of the Vogt-Bailey toolbox, an MRI analysis software. I will also be filling in a questionnaire which will contribute to the analysis. I am aware that I am being requested to attend two sessions of around 40 minutes each. These sessions will take place at Mater Dei Hospital within approximately a month of each other, at a time that is convenient for both me and the researcher.*

1. I understand that the radiographer will ask me some questions at the start of the session, to determine whether scanning is safe for me. I commit myself to giving answers that are as accurate as possible, and will in no case provide false information.
2. I understand that it is possible for my MRI scans to reveal an abnormality I do not know about, and which a doctor believes to be relevant for my health. Should this happen, I will be informed by means of an email posted to the email address I am providing at the end of the document. In the unlikely event that the abnormality is critical, I would be contacted at the number I am also supplying below. In the case of a non-critical abnormality, I may also be contacted at the number provided below, if deemed necessary by UMRI.

**I am aware that neither the researchers nor UMRI (the University of Malta MRI Platform) can guarantee that if an abnormality exists, it will necessarily be detected.**

1. I understand that MRI is considered safe and does not have any known risks or side effects. Nonetheless, the scanning may, in a small number of people, cause slight twitches or a tingling sensation in peripheral parts of the body. Being in the magnetic field can additionally bring on vertigo (dizziness), although this is very rare. I am mindful of the fact that the inside of the scanner is quite restricted and thus not ideal for people who cannot tolerate confined spaces. I will therefore let the lead researcher know at my earliest if I suffer from claustrophobia (but still wish to take part). I have been informed that the scanner can produce loud noises and that for this reason I will be given earplugs or headphones, which will reduce the noise considerably but not eliminate it fully. I will have a buzzer in my hand which I can use to alert the radiographer if I feel in any way uncomfortable during the scan.
2. I am aware that data will be transferred from the MRI scanner to UM computers where it will be analysed. In any data transfer there is a minimal risk of a data breach associated with data transfer and storage. I am aware that to mitigate the risk of a data breach, data will only be transferred using current security standards.
3. I understand that participating in this study will not benefit me directly, but that the research for which my data will be utilised may contribute to

 Describe potential benefits of the research. An example is provided below.

*May contribute to the knowledge of sexual behaviour neurophysiology, which in turn can help improve diagnosis and treatment of sexual disorders.*

1. I understand that a copy of my data (scans and questionnaire/s - remove the latter if not relevant) will be kept **securely** in the repository owned by the University of Malta and managed by UMRI, and that apart from being used for this study and by members of the research team, the data may be released for future projects and teaching, **as detailed in the research volunteer information sheet.** I have been apprised of the following facts: i) the original scans collected from me will not be transferred to repositories for patient data at Mater Dei Hospital, but will remain on the scanner for about 4 weeks before being automatically deleted; ii) researchers receiving a copy of my scans will be obliged to store the data on an encrypted storage device and access/process it using properly secured computers.
2. I understand that, under the General Data Protection Regulation (GDPR) and national legislation, I have the right to request the following with respect to my data: access, rectification, erasure and restriction of processing. I may also object to processing of my personal data on grounds relating to my particular situation. I know, however, that the law allows for derogations from these rights in circumstances where exercising them would seriously impair scientific research. I understand that such requests should be made to UMRI by filling the GDPR form on the UMRI GDPR webpage: https://www.um.edu.mt/platforms/umri/gdprrights/.
3. I understand that my data (both imaging and questionnaire data - amend as necessary) will be stored and usedin pseudonymised form, in the sense that it will be assigned a code; once all the data needed has been collected, only the principal investigator will retain information that links the code to my identity. I am aware that the principal investigator will be responsible for keeping this information secure and confidential (and separate from scans/questionnaires),andwill dispose of it one year after the last day of data collection. He/she will not pass it to third parties, except to the designated UMRI personnel in the eventuality that an abnormality relevant to my health is discovered from my scans or if I specifically ask UMRI for a copy of my MRI data.
4. I understand that my identity will not be revealed in any dissertation, publications, reports and/or presentations arising from this research.
5. I understand that the University of Malta will store my data (scans and questionnaire/s - modify if necessary) in its repository for a period of 10 years from the date of last use, and that when the 10 years are up, the data will be deleted if it is no longer considered necessary for purposes of scientific research. I am mindful of the following: i) data which has been approved for use in certain projects may be kept longer; and ii) researchers who receive data from the University’s repository for a project will be obliged, once the project has been completed, to delete their copy of the data and any derivatives not in aggregate form (provided the material is not needed for a follow-up study, in which case a new application must be submitted to, and approved by, UMRI, and ethical clearance obtained from the relevant research ethics committee, before the data can be further processed or shared).

1. I confirm that I have familiarised myself with the details provided in the research volunteer information sheet about data confidentiality, as well as about the individuals and/or entities that may have access to my data.
2. Tick as appropriate:
* I give my consent
* I do not give my consent

 for my data to be used for teaching activities and dissemination. I understand that any data utilised for teaching and/or dissemination will not contain my name or national ID card number, and that personal attributes (like age, height and weight) will be kept to a minimum.

1. I acknowledge that I have been provided with a copy of this consent form and the information sheet.

**I hereby confirm that I am 18 years of age or older and have read and understood the above statements. I am aware that signing this form implies that I agree to participate in the study, and will be doing so out of my own free will and with full informed consent regarding the conditions listed above.**

Name of participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

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

Name of lead researcher Title and name of principal investigator (PI)

Email address of lead researcher Email address and office telephone number of PI

**Annex I**

Kindly write down your email address and telephone/mobile number so that we have a means of reaching you in case of an incidental finding. UMRI will only use the telephone/mobile number in the unlikely event of an incidental finding upon appropriate advice from the radiologist..

Kindly make sure that the email address that you specify is your personal email address. UMRI will contact you in the event of an incidental finding using this email. Apart from this, UMRI will satisfy requests made by yourself with respect to your data (see point 10) using the email address specified. Finally, we are also asking for an email address at which the Principal Investigator may send a summary of the research findings once the study has been completed [optional - remove if no such summary will be sent].

Telephone or mobile number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Pursuant to art. 13 of the General Data Protection Regulation (GDPR - EU Regulation 2016/679), we inform you that the particulars collected here will be used by UMRI and the researchers involved in this project (the data controllers) on the basis of their legitimate interest to ensure the research is conducted ethically, and solely for the purpose of (i) being certain that you are fully aware of what data collection will involve, how your data will be processed and your rights under the GDPR; and (ii) contacting you about an incidental finding should this be necessary. Your personal details will be deleted after a period of at most five years and will not be disclosed to any third parties unless this is strictly required by law. You may exercise the rights provided for in art. 15/16/17/18/21 GDPR (access, rectification, erasure, restriction of/objection to processing) by contacting UMRI at* ***umri.platform@um.edu.mt****. Complaints can be lodged with the data protection office of the University of Malta by sending an email at* ***dpo@um.edu.mt****.*

*Filling in this form is obligatory for research volunteers taking part in data collection for research projects endorsed by the University.*