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| Section A. Research details | | | | |
| 1. **Full title of research** | Insert full title including brief reference to the design, product being studied, and primary objective | | | |
| 1. **Short title of research** | For example, the simpler title you intend to use on participant-facing documents | | | |
| 1. **MS IDREC reference** | To be completed when approved | | | |
| 1. **Date and version number** | It is advisable to use versions 0.1, 0.2 etc. up until the point of ethics approval, when version 1.0 is to be used | | | |
| 1. **Principal Investigator (PI)** | Only one person can be named as the PI – this cannot be a student. Co-investigators are to be listed in section B. | | | |
| 1. **PI’s training in research ethics and/or research integrity**   Research integrity training within the past 3 years is compulsory for all University research staff and students. Please enter date of relevant course completion (one of 1a, 1b or 1c must be completed). | **Course Title** | | **Date completed** | |
| 1a. [Research Integrity Core Course](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) (New researchers & students) | |  | |
| 1b. [Research Integrity Refresher Course](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) (Experienced researchers) | |  | |
| 1c. Other (please specify title) | |  | |
| 2. [Supplementary Module](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) – Research involving human participants | |  | |
| 3. [Information Security Training](https://www.infosec.ox.ac.uk/do-the-online-training) | |  | |
| 1. **Student name and degree programme (if applicable)** |  | | | |
| 1. **Department/Institute name** |  | | | |
| 1. **University email address** |  | | | |
| 1. **University telephone number** |  | | | |
| 1. **Medically qualified collaborator (Licensed doctor)** | Insert name, medical qualification and contact details (including institutional affiliation). If the PI or student is medically qualified, then insert their details here. | | | |
| 1. **Funding source** | Insert details of key organisation(s) funding the research (If departmental funding, please state this)  Give funding reference number(s) if applicable  Note - Funding source is required to correctly categorise your application in the Research Services database | | | |
| 1. **Will you submit or have you submitted this research to another ethics committee?** | | Yes | | No |
| If other relevant approvals for this research are required (e.g. from other universities’ ethics committees) please attach them and give more details below: | | | | |
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| 1. **State any** [**conflicts of interest**](https://researchsupport.admin.ox.ac.uk/governance/integrity/conflict/policy) **and explain how these will be addressed** | The University's [conflict of interest policy](https://researchsupport.admin.ox.ac.uk/governance/integrity/conflict/policy) requires all staff and students 'to recognise and disclose activities that might give rise to actual or perceived conflicts of interest’ and to ensure that such conflicts are seen to be properly managed or avoided  If none, please state ‘none’. | | | |
| 1. **Confidentiality Statement** | This document contains confidential information that must not be disclosed to anyone other than the authorised individuals from the University of Oxford, the Investigator Team and members of the Medical Sciences Interdivisional Research Ethics Committee (MS IDREC), unless authorised to do so. | | | |

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| Section B. Researchers | | |
| Copy and paste the below 4 questions as necessary to complete for each researcher who will be involved in this study, including student(s), then delete this entire row. Note that **the PI does not need to be entered again** in this section. | | |
| 1. **Researcher title and name** |  | |
| 1. **Department / Institute name** | Add affiliation to the University of Oxford if not a staff or student researcher | |
| 1. **Role in research** | e.g. ‘will obtain informed consent and conduct research activities with participant’, or ‘only role is to input data onto a spreadsheet’ – this helps us determine if training given below is sufficient | |
| 1. **Training in research ethics and/or research integrity**   Research integrity training within the past 3 years is compulsory for all University research staff and students. Please enter date of relevant course completion (one of 1a, 1b or 1c must be completed). | **Course Title** | **Date completed** |
| 1a. [Research Integrity Core Course](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) (New researchers & students) |  |
| 1b. [Research Integrity Refresher Course](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) (Experienced researchers) |  |
| 1c. Other (e.g. GCP - please specify title) |  |
| 2. [Supplementary Module](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) – Research involving human participants |  |
| 3. [Information Security Training](https://www.infosec.ox.ac.uk/do-the-online-training) |  |

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| Section C. synopsis | | |
| 1. **Please state why this research is not considered a Clinical Trial of an Investigative Medicinal Product** | Note that, typically, studies suitable for review by CUREC are conducted on volunteers (not NHS patients) and will specify non-clinical end-points. If you are in any doubt consult a PI experienced in writing appropriate descriptions of Experimental Medicine (EM) studies. Note that, while an EM study may eventually inform clinical practice and appear to be justified by its potential to do so, the actual design will not directly support a particular clinical indication and should not be described as if it will.  If you have sought opinion from the MHRA include details here | |
| 1. **List all places where research will be conducted** |  | |
| 1. **Age range of participants** |  | |
| 1. **Anticipated number of participants** |  | |
| 1. **Anticipated research start date** |  | |
| 1. **Anticipated research end date** |  | |
|  | **Objectives** | **Outcome Measures** |
| **Primary** | What question(s) are you trying to answer? Your answers should be succinct, excluding methodology, and realistic.  Example: To investigate how drug X influences brain function during a working memory task. | Describe the outcome measures and how/when they will be measured during the research.  Outcome measures should be chosen in advance as part of a pre-specified analysis plan. It is often wise to specify outcomes/measures of primary and secondary interest |
| 1. **Name of drug/substance** | You will be asked for more details in section H | |
| 1. **Purpose of drug/substance use in this research** |  | |
| 1. **Adverse reactions and side effects posing a particular risk with this drug/substance** |  | |

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| Section D. Abbreviations Define all unusual or ‘technical’ terms related to the research. Add or delete rows as appropriate. Maintain alphabetical order for ease of reference. | |
| CUREC | Central University Research Ethics Committee |
| GCP | Good Clinical Practice |
| GP | General Practitioner |
| ICF | Informed Consent Form |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| MS IDREC | Medical Sciences Interdivisional Research Ethics Committee |
| PI | Principal Investigator |
| PIS | Participant Information Sheet |
| SOP | Standard Operating Procedure |

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| Section E. Background and rationale |
| Please be brief: this is an explanation not a justification. Include the following:  Brief background to the research, including scientific justification.  Outline of the research question(s) - state the objectives of the research as clearly, and unambiguously as possible.  Brief description of the intervention. Note: full details of drug/substance to be administered will be requested in section H: do not duplicate here.  Summary of the known and potential risks, if any, to human participants.  References to literature and data that are relevant to the research and that provide background for the research. |

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| Section F. Participants |
| 1. **Description of research participants** |
| e.g. x number of Healthy Volunteers aged between y and z years |
| 1. **Inclusion Criteria** |
| Example criteria only (amend as appropriate):   * Participant is willing and able to give informed consent for participation in the research * Not currently taking any medications (except the contraceptive pill) * Additional research specific criteria as required |
| 1. **Exclusion criteria** |
| Include consideration as to whether exclusion from other studies would be required – it is advised that participants do not take part in multiple intervention studies (including, for example, brain stimulation, drug involvement and sleep intervention) at the same time, or for at least one week after completion of another intervention study.  Example criteria only (amend as appropriate):  The participant may not enter the study if ANY of the following apply:   * Specify any diseases/disorders/ conditions that would preclude entry into the study * Pregnant or breast feeding * History or current psychiatric illness * History or current neurological condition (e.g. epilepsy) * Additional research specific criteria as required |
| 1. **Recruitment** |
| Describe how potential participants will be identified, approached, screened and recruited.  Example: Participants will be recruited by word of mouth, emails to departmental mailing lists and posters located in University Departments. |
| 1. **Eligibility assessment** |
| Describe the screening procedures used to determine study eligibility, such as demographics, medical history and physical examination.  Specify the maximum duration allowed between screening and recruitment (if applicable).  If any screening procedures (such as blood sampling) require prior informed consent, then this must be stated. |
| 1. **Information Provided to Participants and Informed Consent** |
| Informed consent is the foundation of ethical research and provision of accurate and proportionate information is critical, and should be considered as a process. Accordingly, the Participant Information Sheet (PIS) is the most important document you will prepare. Please ensure this describes any known adverse effects or risks involved in taking part.  Please provide a copy of the PIS the participant will receive separately (with the relevant institutional heading).  You need to specify how and when the process of taking informed consent will be conducted, and who will take consent. Informed Consent must be obtained prior to any research related procedures being undertaken (including most screening).    Example:  Written and verbal versions of the Participant Information will be presented to the participants. The PIS will detail the practical demands of the research, written from the participant’s perspective and in simple non-technical language.  It will be clearly stated that the participant is free to withdraw from the research (at any time) for any reason and with no obligation to give the reason for withdrawal.  The participant will be allowed time to consider the information, ask questions of the Investigator or other independent parties, and to decide whether they will participate in the research.  Written Informed Consent will be provided by dated signature from the participant and the person who presented and obtained the Informed Consent. The person who obtains the consent will be suitably trained and experienced, and have been authorised to do so by the Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site. |

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| Section G. Research Procedures |
| 1. **Baseline Assessments and Procedures** |
| Outline where this first visit will take place, what participants will be asked to do and approximately how much time it will take them.  You will have specified and described all baseline assessments and procedures on the participant information sheet (PIS). This section must align with the relevant section of the PIS, and add any further technical detail, if necessary, from the investigator’s perspective. Include duration of procedures/session.  In particular, confirm that you will perform:   * An eligibility check * assessments of safety including general (e.g. physical examination), specific safety assessments (e.g. adverse event collection) * dispensing of study product (if applicable at this visit) * assessment of compliance with study product * recording of concomitant medications (if applicable)   Provide a description sufficient to demonstrate adequate compliance with research objectives. If you will be following an approved procedure, do not duplicate here, but cite the procedure.  If there will only be one visit, this section should be renamed ‘Study Visit’ and the next section ‘Subsequent Visits’ can then be deleted. |
| 1. **Subsequent Visits** |
| Outline any subsequent visits, where they will take place and what participants will be asked to do at these.  This must align with the relevant sections of the PIS here, but add any further technical detail, if necessary, from the investigator’s perspective.  **Number these visits clearly and state the visit duration for each**  For each visit, consider inclusion of the following, where appropriate:   * dispensing of study product * assessment of outcome measures * assessments of safety including general (e.g. physical examination), specific safety assessments (e.g. adverse event collection) * adherence to dosing of study product * recording of concomitant medications (if applicable)   Provide a description sufficient to demonstrate adequate compliance with research objectives. If you will be following an Approved Procedure, do not duplicate here, but cite the procedure. |
| 1. **Biological Sample Handling** |
| Describe any samples that will be taken from each participant (e.g. blood, urine, saliva, faeces), the volume of sample, and the frequency of sampling. Describe briefly how the sample will be processed and stored once taken, and confirm that it will be rendered into a form not [relevant under the Human Tissue Act](https://www.hta.gov.uk/policies/list-materials-considered-be-‘relevant-material’-under-human-tissue-act-2004) within 7 days (and before use in the research). Stored samples should be de-identified (labelled only with a study code) so that they are either anonymised (no means of linkage to direct identifiers exists) or pseudonymised (samples may be re-identified via a linkage document securely held elsewhere). Please say which will apply to your samples, and for how long, by whom, and where any linkage document will be held.  Identify who will have access (i.e. researchers only for use in this research), and whether it will be stored long-term for use in future ethically approved studies). Provide a brief overview of the laboratory analyses that will be performed and how the samples will be destroyed (if appropriate).  If no samples will be taken, please state this. |
| 1. **Will the research include any audio, video or photographic recordings?** |
| State ‘yes’ or ‘no’ and **if yes,** please give details as to what will be recorded, and when. |
| 1. **Discontinuation/Withdrawal of Participants** |
| Example:  Each participant has the right to withdraw from the research at any time. In addition, the Investigator may discontinue a participant from the research at any time if the Investigator considers it necessary for any reason including:  Delete/add as appropriate   * Pregnancy * Ineligibility (either arising during the research or retrospectively having been overlooked at screening) * Significant protocol deviation * Significant non-compliance with treatment regimen or research requirements * Withdrawal of Consent * Loss to follow up   If (for example) a participant is withdrawn due to an adverse reaction, specify any procedures and/or observations that will continue to be required until resolution of the reaction or the end of the research. Why will this be necessary?  State whether withdrawal from the research will result in exclusion of the data for that participant from analysis.  State whether or not withdrawn participants will be replaced.  The reason for withdrawal will be recorded. |
| 1. **Definition of End of Study** |
| The definition of end of study (for participant involvement) should be provided. In most cases the end of study will be the date of the last visit of the last participant. Any exceptions should be justified.  Example:  The end of participant involvement in the research is the date of the last visit / telephone follow up / home visit of the last participant. |
| 1. **Please detail all expenses or gifts that will be offered to participants.**   Guidance is available in [Best Practice Guidance: 05 Payments and incentives in research](https://researchsupport.admin.ox.ac.uk/files/bpg05paymentsandincentivesinresearchv10pdf). |
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| **Section H. Interventions** | |
| **Drug/Substance 1** | |
| **Name of drug/substance to be used** |  |
| **Formulation, dose and route of administration for research** |  |
| **Duration of treatment for research** |  |
| **Licence status of this drug/substance** |  |
| **Usual Indication** |  |
| **Usual Dose** |  |
| **Usual duration of treatment** |  |
| **Where will drug/substance be sourced from?** | Give name and address of manufacturer and/or supplier |
| **Where will drug/substance be stored at site?** | Give location (building/room) and storage facility/temperature (room temp, fridge etc.). Ensure that storage is correct for this drug/substance |
| **How will drug/substance be dispensed?** |  |
| **How will the drug/substance be prepared by the researchers for use in this research?** | Give details of any preparation or modification (such as over-encapsulation) |

If more than one drug or substance will be administered (e.g. additional placebo), please also complete the below table. Delete if not necessary, and duplicate further as needed.

|  |  |
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| Drug/Substance 2 | |
| **Name of drug/substance to be used** |  |
| **Formulation, dose and route of administration for research** |  |
| **Duration of treatment for research** |  |
| **Licence status of this drug/substance** |  |
| **Usual Indication** |  |
| **Usual Dose** |  |
| **Usual duration of treatment** |  |
| **Where will drug/substance be sourced from?** | Give name and address of manufacturer and/or supplier |
| **Where will drug/substance be stored at site?** | Give location (building/room) and storage facility/temperature (room temp, fridge etc.). Ensure that storage is correct for this drug/substance |
| **How will drug/substance be dispensed?** |  |
| **How will the drug/substance be prepared by the researchers for use in this research?** | Give details of any preparation or modification (such as over-encapsulation) |

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| **Section I. Safety** | |
| 1. **Definitions** | |
| **Adverse Event (AE)** | Any untoward medical occurrence in a participant to whom a substance has been administered, including occurrences which are not necessarily caused by or related to that substance. |
| **Adverse Reaction (AR)** | An untoward and unintended response in a participant to a substance, which is related to any dose administered to that participant.  A causal relationship between the administered substance and an AE is at least a reasonable possibility, i.e. the relationship cannot be ruled out. |
| **Serious Adverse Event (SAE)** | A serious adverse event is any untoward medical occurrence that:   * results in death * is life-threatening * requires inpatient hospitalisation or prolongation of existing hospitalisation * results in persistent or significant disability/incapacity * consists of a congenital anomaly or birth defect.   Other ‘important medical events’ may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.  NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. |
| **Serious Adverse Reaction (SAR)** | An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to one of the research treatments, based on the information provided. |
| **Suspected Unexpected Serious Adverse Reaction (SUSAR)** | A serious adverse reaction, the nature and severity of which is not consistent with the information about the medicinal product set out in its summary of product characteristics (SmPC). |

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| 1. **Reporting procedures for serious adverse events or reactions** |
| Any adverse event (AE) occurring to a participant will be reported to the MS IDREC.  Reports of related (resulted from administration of any of the research procedures) and unexpected (the type of event is not listed in the protocol as an expected occurrence) adverse events will be reported as soon as possible once the Principal Investigator becomes aware of the event. Unrelated/expected adverse events will be reported within 10 working days of the Principal Investigator becoming aware of the event.  All SUSARs will be reported to the MHRA in addition to the MS IDREC. For fatal and life-threatening SUSARs, this will be reported as soon as possible, but no later than 7 calendar days after the PI is first aware of the reaction.  Any additional relevant information will be reported within 8 calendar days of the initial report. Non-fatal or non-life-threatening SUSARs will also be reported as soon as possible, and no later than 15 days after the PI is first aware of the reaction.  All reports to the MHRA will be via the [Yellow Card Scheme](https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/). |

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| 1. **Safety of participants** |
| 1. **What level of baseline safety screening will take place for this research?** |
| Give details as to what needs to be checked to ensure that it is safe to administer the drug/substance to the participant.  Include consideration as to whether exclusion from other studies would be required – it is advised that participants do not take part in multiple intervention studies (including, for example, brain stimulation, drug involvement and sleep intervention) at the same time, or for at least one week after completion of another intervention study. |
| 1. **Provide details about the safety monitoring of participants and the staff/researchers carrying this out** |
| Specify whether any research procedures require observation of, or ongoing communication with, the participant. If they do, detail how this will be carried out, and by whom |
| 1. **Give details on the medical cover required and who will provide this cover** |
| Specify whether or not research procedures require specific observation/monitoring by a medically-qualified professional. If they do, detail how this will be carried out |
| 1. **Will the participants’ GP be informed about their participation in the research? In not, please justify** |
|  |
| 1. **What is your planned procedure if an incidental finding is suspected?** |
| e.g. previously undiagnosed medical or psychiatric conditions that are discovered unintentionally during the course of the research |
| 1. **If an incidental finding has clinical implications, what action will you take?** |
| Include details of any departmental SOP that will be followed in the case of an incidental finding. |

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| 1. **Ethical considerations**   Research usually carries the risk of some ethical challenge. If this is the case you need to demonstrate your awareness of the problem and your response to mitigate ethical objections.  For guidance on ethical issues, please see <http://researchsupport.admin.ox.ac.uk/governance/ethics/resources>, however the following areas are often a cause for concern: | | |
| 1. **Will the research involve any participants considered** [**vulnerable**](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#V) **in the context of the research (e.g. children, elderly, prisoners, adults at risk)?**   **If yes,** please describe how they are defined as vulnerable and detail any CUREC Approved Procedures or guidance that will be applied to the research (for current documents and templates see <https://researchsupport.admin.ox.ac.uk/governance/ethics/resources>). | Yes | No |
|  | | |
| 1. **Will the research involve deliberate** [**deception**](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary/#D) **of participants?**   **If yes**, justify why deception is used, describe deception and debriefing process, and include debriefing documents in the application | Yes | No |
|  | | |
| 1. **Could the proposed research affect your own physical and/or psychological safety as a researcher?**   **If yes,** describe how this will be mitigated. | Yes | No |
|  | | |
| 1. **Does your research raise issues relevant to the Counter-Terrorism and Security Act** ([**the Prevent Duty**](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/445916/Prevent_Duty_Guidance_For_Higher_Education__England__Wales_.pdf))**, which seeks to prevent people from being drawn into terrorism?**   **If yes,** please say how you plan to address any related risks. Please see advice on this on our [Best Practice Guidance Web Page](http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/bpg). | Yes | No |
|  | | |
| 1. **Please list any stakeholder or community engagement that has been, or will be, undertaken in relation to the research** | | |
|  | | |
| 1. **Please give details of any other research-specific ethical and/or safety considerations, not related to drug/substance administration** | | |
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| 1. **Will any data or information from this study be provided to individual participants?** | | |
| State ‘yes’ or ‘no’ and **if yes,** please give details. | | |

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| **Section J. Statistics and analysis** | | |
| 1. **Do you have a statistical plan?**   **If no,** please justify. | Yes | No |
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| 1. **Number of Participants** | | |
|  | | |
| 1. **Have you done a sample size calculation?**   If yes, please give details below  If no, please give details to indicate you have considered the implications the selected sample size will have on the research outcome | Yes | No |
|  | | |
| 1. **Analysis of Outcome Measures** | | |
| It is recommended that you pre-specify how you will analyse your data. Please indicate briefly how far you have considered this: for example, with a statistician or with your supervisor and what principles will guide your analysis (e.g. whether you have a primary outcome, how you will limit the number of post hoc comparisons, etc.). | | |

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| **Section K. Data management and handling** | | | | |
| All information provided by participants is considered **research data** for the purpose of this form. Any research data from which participants can be identified is known as [**personal data**](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#P); any personal data which is sensitive is considered [**special category data**](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#S).  Management of personal data, either directly or via a third party, must comply with the requirements of the UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018, as set out in the [University’s Guidance on Data Protection and Research](https://researchsupport.admin.ox.ac.uk/policy/data). In answering the questions below, please also consider the points raised in the [Data Protection Checklist](https://researchsupport.admin.ox.ac.uk/policy/data/checklist) and whether, for higher-risk data processing, a separate [Data Protection Impact Assessment](https://compliance.admin.ox.ac.uk/privacy-by-design) may also be required for the research. Advice on research data management and security is available from [Research Data Oxford](http://researchdata.ox.ac.uk) and your local IT department. Advice on data protection is available from the [Information Compliance team](mailto:information.compliance@admin.ox.ac.uk).  **Please mark ‘X’ against the data you will collect for your research** | | | | |
| Screening documents |  | Audio recordings | |  |
| Consent records including participant name or other identifiers (e.g. written consent forms, audio-recorded consent, assent forms) |  | Video recordings | |  |
| Consent obtained [anonymously](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#A) (e.g. via online survey) |  | Transcript of audio/video recordings | |  |
| Opt-out forms |  | Photographs | |  |
| Contact details for the purpose of this research only |  | Information about the health of the participant (including mental health) | |  |
| Contact details for future use ([guidance](https://compliance.admin.ox.ac.uk/mailing-lists#collapse1041266)) |  | Physiological test results / measurements | |  |
| Task results (e.g. questionnaires, diary completion) |  | Scans (e.g. MRI, Ultrasound) | |  |
| Data already in the public domain.  Specify the source of the data: |  | IP addresses (refer to [Best Practice Guidance 09: Data collection, protection and management](https://researchsupport.admin.ox.ac.uk/files/bpg09datacollectionandmanagementpdf) for guidance) | |  |
| Previously collected (secondary) data |  | Other (please specify below) | |  |
| Bank (or other) details required for reimbursement |  |  | | |
| **How and where will each type of data be stored whilst the research is ongoing (until the end of all participant involvement)?**  List each type of data selected above, and explain how each will be physically transferred (including movement/sharing of audio files, paper records, electronic downloads etc.) from where it is collected to a suitable storage site (e.g. [Nexus365 OneDrive for Business](https://help.it.ox.ac.uk/nexus365/which-onedrive), SharePoint, University servers). State the storage location for each.  Refer to Best Practice Guidance on data collection, protection and management ([BPG09](https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/bpg)). | | | | |
| Examples:  “Paper consent records will be collected from participants and placed in a folder for transfer from the lab to the researcher’s office, where they will be stored in a locked filing cabinet. Researchers will ensure that they go directly from the lab to the office in order to ensure paper records are not inadvertently left in an intermediate location”  “Survey data will be downloaded from the online survey provider, and transferred electronically to storage in password-protected Excel files on encrypted computers within the University network”  “Audio recordings will be transferred from the recording device to be stored as password-protected files on an encrypted computer within the University network. They will then be deleted from the original recording device. Nexus365 OneDrive for Business will be used to share the audio files with the company that will transcribe and anonymise these audio files. Transcriptions will be returned to us via the same means. The audio recording held by the researchers will then be deleted. The transcription will be stored as a Word file on encrypted computers within the University network [or stored in written form on paper in a locked filing cabinet within the office of the Principal Investigator]” | | | | |
| **Will you use a unique participant number on research data instead of participant name?**  **If yes,** state whether or not you will retain a list of participant names against numbers ([pseudonymisation](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary" \l "P) via a linkage list).  **Where will the list be stored, and when will it be destroyed?** | | | | |
|  | | | | |
| **Who will have access to the research data?** | | | | |
| Researchers listed on this form will have access to the research data. Access will be granted to the MS IDREC for the purposes of monitoring and/or audit of the research. If other researchers/organisations (e.g. other universities, transcription services) will also have access, then please add details. | | | | |
| **If research data is to be shared with another organisation, how will it be transferred / disclosed securely?** | | | | |
| Give details of transfer procedures, stating whether or not the data will be identifiable | | | | |
| **When and how will identifiable data be destroyed or deleted?**  N.B. If any identifiable data will be retained beyond the end of the study and/or indefinitely, please state what data this is, and the reasons for retention (e.g. contact details for future studies; photos used in publication). This must be clearly stated on participant information, and specific consent obtained. | | | | |
| **NB**. Records of consent should be retained for a minimum of three years after publication or public release. However, some funders may require longer periods (see <http://www.dcc.ac.uk/resources/policy-and-legal/overview-funders-data-policies>).  To comply with the UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018, other personal data should not be retained when no longer needed for the research (e.g. ‘when individual participant involvement is complete’, or ‘once all data has been analysed/anonymised’). | | | | |
| **Please confirm that you will store other (non-identifiable) research data safely for at least 3 years after final publication or public release and adhere to any** [**additional research funder policies**.](http://researchdata.ox.ac.uk/funder-requirements/)  For more information about the University policies, please see the University’s web pages on [research data management](http://researchdata.ox.ac.uk/).  **If ‘Yes’**, please give details of who will store the data and on storage format, location and security.  **If ‘No’**, please provide further details. | | | Yes | No |
| Note that open science is encouraged – see <https://www.universitiesuk.ac.uk/policy-and-analysis/research-policy/open-science> | | | | |

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| **Section L. Monitoring and oversight** |
| 1. **Who will be responsible for day-to-day supervision of the research?** |
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| 1. **Give information about frequency of meetings that will be held to discuss progress/problems. Who will be present at the meetings?** |
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| **Section M. Ethical and regulatory considerations** |
| **Declaration of Helsinki**  The Investigator will ensure that this research is conducted in accordance with the principles of the Declaration of Helsinki. |
| **Approvals**  Consider the following text:  The application form/protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to the Medical Sciences IDREC, and host institution(s) for written approval.  The Investigator will submit and, where necessary, obtain approval from the above parties for all amendments to the original approved documents. |
| **Annual Progress Report**  The CI shall submit an Annual Progress Report to the Medical Sciences IDREC within one month of the anniversary of approval. |

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| **Section N. Insurance** |
| The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd’s of London). |

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| **Section O. Dissemination and feedback of research outcomes** | | | |
| 1. **Will you preregister this research?** | | Yes | No |
| 1. **If yes, please state the platform where it will be preregistered** | (e.g. [Open Science Framework](https://osf.io)) | | |
| 1. **How will you disseminate project outcomes at the end of the research?** | Please describe your plans with respect to participants as well as public dissemination plans, e.g. in academic thesis, journals and conferences. If the research results form part of a Masters or DPhil dissertation, please refer to Departmental policy on publications.  Please give details regarding any [open science](https://www.universitiesuk.ac.uk/policy-and-analysis/research-policy/open-science) practices you will follow, e.g. open access to research data, publications etc. | | |

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| **Section P. References** |
| Insert references used in text (preferably numbered, or in alphabetical order of first author). Insert a new line for each citation. |
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| **Section Q. Declarations and signatures of researchers** | |
| **In providing signatures, the MS IDREC Secretariat will accept either:**  **Option 1:** Email confirmations sent from a University of Oxford email address. Separate emails should be sent by each of the relevant signatories as outlined below, indicating acceptance of their responsibilities.  **Option 2:** That the form be fully-signed with handwritten (wet-ink) signatures. Please scan these and the rest of the form pages to create a single PDF document and email to us. | |
| **I/We, the researcher(s) agree:**   1. To start this research only after obtaining approval from MS IDREC/CUREC; 2. To carry out this research only if funding is adequate to enable it to be carried out according to good research practice and in an ethical manner; 3. That it is the responsibility of the Principal Investigator to ensure that all researchers working on this project are qualified and either experienced, or have received appropriate ethical training, to conduct the research described; 4. To provide additional information as requested by MS IDREC/CUREC before approval is secured and as research progresses; 5. To maintain the confidentiality of all data collected from or about participants; 6. To notify the MS IDREC in writing immediately of any proposed change which would increase the risks that any participant is exposed to and await approval before proceeding with the proposed change; 7. To notify the MS IDREC if the Principal Investigator on the research changes and supply the name of the successor; 8. To notify the MS IDREC in writing within seven days if any serious \*adverse event\* occurs in the course of research; 9. To use data collected only for the research for which approval has been given; 10. To grant access to data only to authorised persons; and 11. To maintain security procedures for the protection of personal data, including (but not restricted to): removal of identifying information from data collection forms and computer files, storage of linkage codes in a locked cabinet and password control for access to identified data on computer files. | |
| **Principal Investigator (Name)** |  |
| **Principal Investigator (Signature)**  Pasted images of signatures cannot be accepted |  |
| **Medically qualified collaborator (Name)** |  |
| **Medically qualified collaborator (Signature)**  Pasted images of signatures cannot be accepted |  |
| **Student (Name)** |  |
| **Student (Signature)**  Pasted images of signatures cannot be accepted |  |

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| **Section R. Acceptance by Head of Department/Faculty\***  \*orother senior member of the department if the Principal Investigator is the Head of Department. Example nominees include Deputy Head of Department, or, for student projects, Director of Graduate Studies. | |
| * I have read this application, and am aware of the research proposed. * To the best of my knowledge, the proposed design and scientific methodology do not raise concerns. * I support this research in principle, subject to ethical and other necessary reviews. | |
| **Head of Department (Name)** |  |
| **Head of Department (Signature)**  Wet-ink signature (not pasted electronic image)  *or*  The Head of Department/nominee can send an email (including PI name and study title) to [ethics@medsci.ox.ac.uk](mailto:ethics@medsci.ox.ac.uk) confirming the above |  |
| **Date** |  |

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| **Section S. Amendment history**  List details of all protocol amendments here whenever a new version of the protocol is produced.  ***This is not necessary prior to initial ethics submission.*** | | | | |
| **Amendment No.** | **Protocol Version No.** | **Date issued** | **Author(s) of changes** | **Details of Changes made** |
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