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| **SECTION A. IS ETHICS REVIEW FROM THE MS IDREC NEEDED?** |

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| 1. **Is the secondary data obtained directly\* from an NHS care-giving organisation (e.g. clinical notes)?**   If yes, research cannot be reviewed by the MS IDREC. Do not complete this form. For more information, contact [rgea.sponsor@admin.ox.ac.uk](mailto:rgea.sponsor@admin.ox.ac.uk).  \*Note that secondary use of data that is no longer held within the NHS (e.g. patient data collected under NHS REC approval or data held in the RCGP ORCHID database) can be reviewed by applying to the MS IDREC using this form. | Yes | No |
| 1. **Does the data relate to, or is it derived from, individuals who are no longer alive?**   If yes, ethical approval is unlikely to be needed – please check with the MS IDREC before proceeding further.  For surveys and social media data (for example), there is usually a very clear clause in the consent and/or ethics documentation that data of deceased will be processed for X uses. | Yes | No |
| 1. **Could a living individual be identified (a) directly from the secondary data, or (b) indirectly, from those data and other information that is in the possession of, or is likely to come into the possession of, the** [**data controller**](https://compliance.admin.ox.ac.uk/glossary-of-data-protection#collapse2890531)**/user?**   *\* Please refer to* [*guidance*](https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/personal-information-what-is-it/what-is-personal-data/can-we-identify-an-individual-indirectly/#pd5) *from the Information Commisioner’s Office about indirect identification. \**  If no, ethical approval may not be needed – please check with the MS IDREC before proceeding further.  If yes, proceed to complete this form. | Yes | No |

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| **SECTION B. RESEARCH DETAILS** | |
| 1. **Title of research** |  |
| 1. **Principal Investigator (PI) name** | Only one person can be named as the PI. This is the person who accepts the overall responsibility for the research, provides oversight, and ensures that all staff and students working on the study are suitably trained and qualified by experience to conduct the research. For these reasons, a student cannot be the PI (their supervisor should be listed instead).  Co-investigators are to be listed in section B. |
| 1. **PI Department/Institute name** |  |
| 1. **Contact name and email address for correspondence about this application** |  |
| 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. **State any** [**conflicts of interest**](https://researchsupport.admin.ox.ac.uk/governance/integrity/conflict) **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. **Intended research start date** |  |
| 1. **Intended research end date**   (NB. A maximum of 5 years’ approval can be granted) |  |
| 1. **Provide a lay summary of the research involving secondary data**   Refer to the [National Statistician’s Data Ethics Advisory Committee’s Ethical Principles](https://uksa.statisticsauthority.gov.uk/the-authority-board/committees/national-statisticians-advisory-committees-and-panels/national-statisticians-data-ethics-advisory-committee/ethical-principles/) and ensure these are considered/covered in your summary. | | |
| Include here:  Aim/purpose - What question(s) are you trying to answer, and why (usefulness of research)?  Justification for / value of the research, including benefit to society  Lay description of the research design and methods proposed for data collection and analysis  Useful relevant background information | | |

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| **SECTION C. RESEARCHERS** | | |
| Copy and paste the below 4 sections as necessary to complete for **each researcher (including the PI and any students)** who will be involved in this study, then delete this entire row. | | |
| 1. **Researcher title and name** |  | |
| 1. **Department/ Institute name** | Add affiliation to the University of Oxford if not a staff or student researcher | |
| 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. | **Course Title** | **Date completed** |
| [Research Integrity Core Course](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) (New researchers & students) |  |
| [Research Integrity Refresher Course](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) (Experienced researchers) |  |
| Other - please specify title |  |
| 1. **Date of latest** [**Information Security Training**](https://www.infosec.ox.ac.uk/do-the-online-training) |  | |

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| **SECTION D. THE SECONDARY DATA**  You may find it useful to refer to the [Information Commissioner’s Office (ICO) code of practice on anonymisation](https://ico.org.uk/media/1061/anonymisation-code.pdf). | | | | |
| 1. **State the source(s) of the secondary data and provide further detail such as ethics approval reference, Website URL, etc.** | | | | |
| **Source of data** | | **Further detail about source** | | |
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| 1. **Could anyone (including members of the research team) link the data back to an individual or individuals via either formal linkage or other available information (i.e.** [**pseudonymised data**](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#P)**)?**   If this is a possibility, give detail of the pseudonymisation and explain how any associated ethical issues will be handled. In particular, where original participants could be identified if viewed in conjunction with other publicly available information, please explain what safeguards will be put in place to mitigate this risk.  *Then go to question 4.* | | | Yes | No |
| Examples:  Do not recontact someone if you identify them  use of randomly different IDs (overwriting original) for different secondary researchers, so that secondary users cannot link datasets  encryption of the data in transit and at rest  continued pseudonymisation of all data collected, with access to the key strictly controlled  technical security measures to avoid loss or damage | | | | |
| 1. **Will individuals be identifiable from the data?**   If yes:   * Justify why the data need to identify those from whom it came or why it cannot be anonymised. * Say how individual consent was obtained for the collection, use or disclosure of identifiable personal data, if applicable. Provide a copy of the terms of consent, if this is available. | | | Yes | No |
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| 1. **Does the project involve the use of** [**special category data**](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#S)**?**   If yes, provide details of the steps taken to address the associated ethical issues and to comply with [Article 9.2(j) of UK GDPR](https://gdpr-text.com/read/article-9/#:~:text=(j)%20processing%20is%20necessary%20for,right%20to%20data%20protection%20and). | | | | |
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| 1. **If you answered ‘yes’ to questions 2 to 4, how will any (potentially) identifiable data be transferred to you?**   Please describe the security arrangements for any physical and/or electronic transfer of data from which living individuals could be identified (including, but not limited to, paper records, virtual or cloud storage, and data captured electronically via portable media) from where you are obtaining it to local storage.  Refer to [Information Security’s guidance on classifying and handling data](https://www.infosec.ox.ac.uk/handling-information) | | | | |
| Include detail on password protection, encryption and/or 2 factor authentication | | | | |
| 1. **If you answered ‘yes’ to questions 2 to 4, where, and for how long, will data from which living individuals could be identified be stored by the researchers during and after the research?**   Explain what will happen to 1.) the secondary data (i.e. what you are analysing) and 2.) any data produced from the analysis at the end of the research. e.g. will it be deleted, made available for re-use etc? Outline and justify procedures for protecting privacy and confidentiality, e.g. security arrangements, pseudonymisation etc. | | | | |
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| 1. **Is there any reason why the population who provided the original data would object to the re-use of the data for the purpose of the current research proposed?**   **If yes,** please explain how you would mitigate this | | | | |
| Note that you may need to conduct a [PPI](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#P) exercise to answer this | | | | |
| 1. **Please indicate with an ‘X’:** | **Was the initial collection of the data conducted** [**fairly and lawfully**](https://compliance.admin.ox.ac.uk/personal-data-sharing)**?** | | Yes | No |
| **Is the data publicly available?** | | Yes | No |
| **Are data access agreements in place for access to, and use of, this secondary data?** (If so, please include these with your application) | | Yes | No |
| **Did the individuals agree that their data could be used for this purpose?**  (if so, please provide a copy of the original consent form(s) where applicable) | | Yes | No |
| 1. **Is this a** [**data linkage project**](https://researchsupport.web.ox.ac.uk/governance/ethics/faqs-glossary/glossary#D)**?**   If yes:   * Does this change how identifiable individuals are? * Could the research be perceived as profiling (collecting information about someone from various sources in order to describe/evaluate them) and thus not publicly acceptable? How will you mitigate this? | | | | |
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| 1. **Please give details of any other research-specific ethical considerations**   e.g. what you would do in the case of incidental and/or unexpected findings which may need to be reported to the individual and/or authorities | | | | |
| e.g. medical/genetic conditions; abuse; illegal mobility | | | | |
| 1. **Explain the steps you will take to ensure compliance with any relevant legislation. e.g. the Digital Economy Act, Data Protection Act 2018, UK GDPR,** [**Privacy and Electronic Communications Regulations**](https://compliance.admin.ox.ac.uk/mailing-lists)**.** | | | | |
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| 1. **What oversight will be in place to ensure the research is conducted as described?** | | | | |
| Give details of:  Frequency of meetings to discuss progress and/or issues, and who will be involved in these  Supervisory process for students (if applicable)  Any governance procedures required by the providers of the dataset (e.g. approvals, reports etc.)  Whether anyone will check procedures are being followed, and how  How you would handle and report adverse events, e.g. data breaches. | | | | |

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| **SECTION E. PUBLICATION AND DISSEMINATION OF RESULTS** | | |
| 1. **Please explain the steps that will be taken to address any risks associated with publishing the data or the research findings, such as minimisation or triangulation.**   You may find it useful to refer to the [Information Commissioner’s Office (ICO) code of practice on anonymisation](https://ico.org.uk/media/1061/anonymisation-code.pdf). | | |
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| 1. **Would it be possible to misuse the data?**   If yes, provide more details and explain the steps taken to reduce the risk of this. | | |
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| 1. **How do you intend to report and disseminate the results of the research? (Select all that apply with an ‘X’)** | Thesis publication |  |
| Publication in a peer reviewed journal |  |
| Publicly available report |  |
| Depositing in a specialist data centre or archive |  |
| Depositing in an institutional repository |  |
| Conference presentation |  |
| Publication on a project or institutional website |  |
| Pre-registration |  |
| Report to a research funder |  |
| Providing participants with a lay summary of the results |  |
| Submission for academic assessment |  |
| Other (please specify): |  |
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# DECLARATIONS AND SIGNATURES

**In providing signatures, the MS IDREC 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.

# PRINCIPAL INVESTIGATOR (AND STUDENT IF APPLICABLE)

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| I/We, the researcher(s):   1. Understand our responsibilities as outlined on this form and in the CUREC glossary and guidance; 2. Agree to start this research only after obtaining approval; 3. Understand that the Principal Investigator must ensure that all researchers are suitably qualified and trained to conduct the research described, or are appropriately supervised until deemed qualified/trained; 4. Agree to provide additional information as requested by the MS IDREC before approval is secured and as research progresses; 5. Agree to maintain the confidentiality of all data collected from or about participants; 6. Agree to notify the MS IDREC in writing immediately of any proposed change to the research, and await approval before proceeding with the proposed change; 7. Agree to notify the MS IDREC if the Principal Investigator changes and supply the name of the successor; 8. Will use the data collected only for the research for which approval has been given; 9. Will grant access to data only to authorised persons; and 10. Have made arrangements to ensure that [personal data](https://www.admin.ox.ac.uk/curec/faqs-glossary/glossary/#d.en.163302) collected from participants will be held in compliance with the requirements of the UK GDPR and the Data Protection Act 2018. | |
| **Principal Investigator (Name)** |  |
| **Principal Investigator (Signature)**  Pasted images of signatures cannot be accepted |  |
| **Date** |  |
| **Student (Name)** |  |
| **Student (Signature)**  Pasted images of signatures cannot be accepted |  |
| **Date** |  |

# ACCEPTANCE BY HEAD OF DEPARTMENT/FACULTY OR DESIGNATED NOMINEE\*

\*Another senior member of the department may sign where the head of department is the Principal Investigator, or where the head of department has appointed a nominee. Example nominees include Deputy Head of Department, Director of Research, or Director of Graduate/Undergraduate Studies – the MS IDREC and OxTREC hold a list of nominees for each department.

On the basis of the information available to me, I confirm that:

* I am aware of the research proposed and have read this application;
* To the best of my knowledge, the proposed design and scientific methodology do not raise ethical concerns;
* I support this research in principle, subject to ethical and other necessary reviews.

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| **Head of Department or designated nominee (Name)** |  |
| **Head of Department or designated nominee (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), [ethics@socsci.ox.ac.uk](mailto:ethics@socsci.ox.ac.uk) or [oxtrec@admin.ox.ac.uk](mailto:oxtrec@admin.ox.ac.uk) confirming the above |  |
| **Date** |  |