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| **SECTION A. RESEARCH DETAILS** | |
| 1. **Full title of research** |  |
| 1. **Principal Investigator (PI)** | 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. **Student name and degree programme (if applicable)** | If there is no student involved, please state ‘not applicable’ |
| 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. **Where will the research be conducted (including any other countries)?** | e.g. Name of University department or building (including Country if abroad). |
| 1. **Intended research start date** |  |
| 1. **Intended research end date**   (n.b. A maximum of 5 years approval can be granted) |  |
| 1. **Provide a lay summary of the research involving human samples**   (n.b. Full information about the sample(s) to be used will be requested in section C) | Include here:  Aim/purpose - What question(s) are you trying to answer, and why (usefulness of research)?  Justification for / value of the research  Brief lay description of the research design and methods, including an overview of the laboratory tests/analyses that will be performed. |

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| **SECTION B. RESEARCHERS** | | |
| Copy and paste the below 4 sections as necessary to complete for **each researcher (including the PI)** who will be involved in this study, including student(s), 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 (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) |  |
| 1. **Training for work with human samples** | Training on compliance with the Human Tissue Act for human tissue research is compulsory for all researchers working with human samples at the University of Oxford ([Information about training](https://researchsupport.admin.ox.ac.uk/governance/human-tissue/training)). Please detail training undertaken with title and date completed | |

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| **SECTION C. SAMPLE DETAILS** | | | | | |
| 1. **What type(s) of human tissue or other biological sample will be used?** | | | | | |
| Blood |  | Serum | | |  |
| Urine |  | Plasma | | |  |
| Faeces |  | Tissue block/slides | | |  |
| Saliva |  | PBMCs | | |  |
| Buffy Coat |  | Other (Specify below) | | |  |
| Leucocyte Cone |  |  | | | |
| 1. **Are any of the samples considered relevant material under the Human Tissue Act?**   ***Information and guidance on relevant material under the Human Tissue Act*** *can be found on the* [*Research Governance, Ethics and Assurance website*](https://researchsupport.admin.ox.ac.uk/governance/human-tissue/faqs-glossary#tab-1836026)*.*  **If yes,** give the [HTA licence number for the location where samples of relevant material will be used/stored](https://researchsupport.admin.ox.ac.uk/governance/human-tissue/oxford) below.  **If no,** state how the absence of cellular material has been confirmed | | | Yes | No | |
|  | | | | | |
| 1. **How many samples will you receive?** | | | | | |
| An approximate figure or range, e.g. 10s, 100s should be given if the exact number is unknown. | | | | | |
| 1. **Please give the ethics approval reference for the study in which the original samples were collected, or other relevant approval for samples not originating from research** | | | | | |
| Either insert ethics approval reference, or state that samples will be purchased or obtained from NHSBT. | | | | | |
| 1. **Was informed consent obtained from the participants for the use of their samples by other researchers and/or for future research?**   *Note that if there is no consent, you can only apply to CUREC for ethical approval if the samples were collected from live individuals before 01 Sept 2006 and are anonymous*  Please provide details below | | | Yes | No | |
| Where consent has been obtained for use in future research, please indicate what assurance of consent is available to evidence that the consent obtained from the participants allows the use of the samples in this research project (i.e. scope of research, transfer outside of the country of origin if applicable). Enclose a copy of the information sheet and consent form where available. | | | | | |
| 1. **Will the samples be released to the researchers:** | | | | | |
| In fully anonymised form? (*link to stored tissue and data is broken*) | | | Yes | No | |
| In linked anonymised form? (*linked to stored tissue but donor not identifiable to researchers*) | | | Yes | No | |
| In a form in which the donor could be identifiable to researchers?  Please give details below | | | Yes | No | |
| Samples should not be directly identifiable where obvious identifiers (e.g. name, address, date of birth) are removed at the point of release. However, where donors could be identified if viewed in conjunction with other publicly available information (such as when researching a rare disease in a known area), please say what you will do to limit this. | | | | | |
| 1. **From where will the samples be obtained?** | | | | | |
| State Institution or company where samples are currently located/will be purchased from | | | | | |
| 1. **How will samples be transferred to the Oxford researchers, if applicable?** | | | | | |
| e.g. fresh/frozen; via courier/post etc. | | | | | |
| 1. **Will the research involve the analysis or use of human DNA in the samples?**   Answer ‘yes’ if the analyses may produce information that involves genetic sequence data, single nucleotide polymorphism data, genetic "finger print" data, ploidy data or cytogenetic data, including the detection of mutations or genetic variants.  **Please provide details below, and check** whether a separate [Data Protection Impact Assessment](https://compliance.admin.ox.ac.uk/privacy-by-design) will also be required for the research. | | | Yes | No | |
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| 1. **Please give details of any additional data you will receive about the samples** | | | | | |
| e.g. Health condition, age range, sex of donor, ethnicity, etc. | | | | | |
| 1. **Where and how will samples be stored (if applicable)?** | | | | | |
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| 1. **What will happen to the samples at the end of the research?** | | | | | |
| Return to current holder of the samples | | |  | | |
| Transfer to a research tissue bank that isn’t the current holder of the samples | | |  | | |
| Storage by research team pending ethical approval for use in another project (this must be under the HTA licence stated above) | | |  | | |
| Storage by research team of biological material which is not “relevant material” for the purposes of the Human Tissue Act | | |  | | |
| Disposal in accordance with the Human Tissue Act 2004 | | |  | | |
| Other (give details below) | | |  | | |
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| **SECTION D. ETHICAL CONSIDERATIONS**  For guidance on ethical issues, please see <http://researchsupport.admin.ox.ac.uk/governance/ethics/resources> | | |
| 1. **Could the proposed research affect your physical safety as a researcher (e.g. potential for sample-borne infection; needle-stick injuries)?**   **If yes,** describe the issue and how you will manage this. | Yes | No |
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| 1. **How will you ensure the research is conducted according to the details given in this form?** | | |
| 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)  Whether anyone will check procedures are being followed, and how  How you would handle and report adverse events, e.g. injury to researchers, data breaches etc. | | |
| 1. **Please give details of any other research-specific ethical and/or safety considerations** | | |
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| 1. **Is it possible that the research could produce findings of clinical significance? If so, how will these be handled?** | | |
| Such as medical conditions that are discovered unintentionally during the course of the research | | |

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| **SECTION E. DATA MANAGEMENT AND HANDLING** |
| The samples, and data derived from their analysis, are considered **research data** for the purpose of this form. Any research data from which participants could potentially be identified is known as [**personal data**](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#P).  Management of personal data, either directly or via a third party, must comply with the requirements of the UK General Data Protection Regulation (UK 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 (e.g. genetic analysis), 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). |
| **How and where will data derived from sample analysis be stored whilst the research is ongoing?**  List the data to be obtained from sample analysis, and explain how this will be physically transferred (including movement/sharing of 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. Do not store unencrypted data in freely available cloud services or unprotected USB drives.  Refer to Best Practice Guidance on data collection, protection and management ([BPG09](https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/bpg)). |
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| **Who will have access to the research data?** |
| Researchers listed on this form will have access to the research data. If other researchers/organisations (e.g. other universities, companies etc.) 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 |
| **When and how will any pseudonymous data be destroyed or deleted?** |
| e.g. any information provided for the purpose of sample traceability. |
| **Where will you store non-identifiable research data after the study has ended, and for how long?** |
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| **SECTION I. PUBLICATION AND DISSEMINATION OF RESULTS** | |
| 1. **How will you disseminate and feedback project outcomes at the end of the research?** | Please describe your plans with respect to participants as well as public dissemination of the results/data (e.g. academic thesis, journal publication, open science archive, etc.)  Please give details regarding any Open Science practices you will follow, e.g. open access to research data, publications etc. |

# DECLARATIONS AND SIGNATURES

**In providing signatures, the MS IDREC and OxTREC Secretariats 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 CUREC subcommittee 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 CUREC subcommittee in writing immediately of any proposed change to the research, and await approval before proceeding with the proposed change; 7. Agree to notify the CUREC subcommittee who approved the study 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 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.

* 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.

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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) confirming the above |  |
| **Date** |  |