The University of Oxford places a high value on the knowledge, expertise, and integrity of its members and their ability to conduct research to high standards of scholarship and ethics. The research ethics clearance procedures have been established to ensure that the University is meeting its obligations as a responsible institution. They start from the presumption that all members of the University will take their responsibilities and obligations seriously and will ensure that their research with human participants is conducted according to the established principles and good practice in their fields and in accordance, where appropriate, with legal requirements.

|  |
| --- |
| **ONLY WORD-PROCESSED APPLICATIONS THAT ARE SENT BY EMAIL WILL BE ACCEPTED.****PLEASE ENSURE THAT YOUR FORM BEARS THE NECESSARY SIGNATURES.** |

This form is designed for **minimal risk medical or health-related research** that will be conducted **outside the United Kingdom and the European Union** (or research that is funded by US federal funding agencies). Please visit the [OxTREC application process page](https://researchsupport.admin.ox.ac.uk/governance/ethics/apply/oxtrec#collapse404371) to view the full set of criteria for minimal risk applications. Applicants planning research that carries more than minimal risk should complete the [full OxTREC application form](https://researchsupport.admin.ox.ac.uk/governance/ethics/apply/oxtrec#collapse404376).

**Before completing this application form** please refer to the [guidance](https://researchsupport.admin.ox.ac.uk/governance/ethics/apply/oxtrec) and [flowchart](https://researchsupport.admin.ox.ac.uk/governance/ethics/apply) on the Research Support website.

**Please complete the sections that follow.**

|  |
| --- |
| **SECTION A1: FILTER FOR STUDIES THAT ARE NOT APPROPRIATE FOR OxTREC REVIEW** |
| 1. Does your study involve human participants outside the UK and the EU?YES/NO |
| 2. Is your study funded by the US National Institutes of Health (NIH) or another federal funding agency?YES/NO |
| If you have answered ‘**no**’ to questions 1 **and** 2, your study **does not fit the criteria for ethical review by OxTREC**. It may instead require review by another University ethics committee. Please consult <https://researchsupport.admin.ox.ac.uk/governance/ethics/apply> for further details.If you have answered ‘yes’ to at least one of the questions above, please proceed to the next section**.** |

|  |
| --- |
| **SECTION A2: FILTER FOR STUDIES THAT DO NOT REQUIRE ETHICAL REVIEW** |
| 1. Is your study an audit or service review?Please refer to the [OxTREC application process page](https://researchsupport.admin.ox.ac.uk/governance/ethics/apply/oxtrec#collapse404361) for definitions of these terms.YES/NO |
| 2. Does your study involve data only (i.e. no biological samples/specimens), and are all the data about people to be used in the study previously collected anonymised data which no one involved in the study can trace back to the individuals who provided them (e.g. census data, administrative data, secondary analysis)?Please refer to the [definition of personal data](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#P) in the CUREC glossary and [FAQ A.3](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/faqs#collapse1-2) for further guidance.YES/NO  |
| If you have answered ‘**yes**’ to either of these questions, you **do not need to submit** your study for ethical review. If you have answered ‘no’ to both these questions, please proceed to the next section. |

|  |
| --- |
| **SECTION A3: FILTER FOR STUDIES THAT REQUIRE FULL COMMITEEE REVIEW** |
| 1. Does your study involve a drug or medical device?YES/NO  |
| 2. Does your study involve an invasive procedure ([class A in the CUREC glossary](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#I))?YES/NO  |
| 3. Does your study involve venous blood sampling from children, or from adults who are unwell?YES/NO  |
| 4. Does your study involve venous blood sampling from **healthy** adults to avolume **greater than 1ml/kg in 8 weeks**?YES/NO  |
| 5. Does your research raise issues relevant to the **Counter-Terrorism and Security Act (the** [**Prevent Duty**](https://www.gov.uk/government/publications/prevent-duty-guidance/prevent-duty-guidance-for-higher-education-institutions-in-england-and-wales)**)**, which seeks to prevent people from being drawn into terrorism? Please see advice on this in [Best Practice Guidance 07: Prevent Duty](https://researchsupport.admin.ox.ac.uk/files/bpg07preventdutypdf).YES/NO  |
| If you have answered ‘**yes**’ to any of these questions, then your study needs to be **submitted for full committee review**. Please stop work on this application form and refer to the [OxTREC application process page](https://researchsupport.admin.ox.ac.uk/governance/ethics/apply/oxtrec) for details of how to apply for full committee review.If you have answered ‘no’ to all of these questions, please proceed to the next section. |

|  |
| --- |
| **SECTION B: INVESTIGATOR AND STUDY DETAILS** |
| Principal investigator/student researcher name and title |  |
| Full title of project |  |
| Short title of project (this should be in lay language and suitable for use on the PIS and consent form) |  |
| Study design (e.g. qualitative, mixed methods; online survey; secondary analysis of data/samples; prospective observational, etc.) |  |
| Name and title of supervisor (for student research projects only) |  |
| Degree programme (for student research projects only) |  |
| Department or institute |  |
| Address of PI/student researcher for correspondence |  |
| Email and telephone contact of PI/student researcher |  |
| Names and status of other investigators taking part in the project |  |
| State any [conflicts of interest](https://researchsupport.admin.ox.ac.uk/governance/integrity/conflict#/) and explain how these will be addressed  |  |
| Anticipated duration of project | **\_\_\_\_** months |
| Anticipated start date |  / /  |
| Anticipated end date |  / /  |
| Study funder |  |
| Study [sponsor](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#S) (for clinical research) or institution/organisation leading the study (for non-clinical research) |  |

|  |
| --- |
| **SECTION C. DESCRIPTION OF STUDY** |
| Brief (no more than 500 words) description of the study, its purpose, and the use to which the results/data will be put |
|  |
| Primary objective of study (this is the key question that your research aims to answer) |
|  |
| Primary endpoint/outcome measure |
|  |
| Secondary objectives of study (these are the other questions that your research aims to answer) |
|  |
| Secondary endpoints/outcome measures |
|  |
| Please list **all** procedures, e.g. blood and other **samples taken**, **tests performed**, **questionnaires**, **interviews**, etc. Include a description of the procedure, when it occurs, how long it takes, and who administers it. |
| Procedure | When | Average time taken | Administered by whom |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| For blood samples: give the total volume of blood to be taken and over what time period |
|  |
| List all sites where project will be conducted |  |
| If your research involves overseas travel or fieldwork and your Department requires a travel risk assessment, will you have completed and returned a risk assessment beforehand?This must be approved by your department before you travel. If you are travelling overseas, you are strongly advised to take out [University travel insurance](http://www.admin.ox.ac.uk/finance/insurance/travel). Refer to guidance available from your Department, the [Safety Office](https://safety.admin.ox.ac.uk/overseas-travel), and [travel for University business](https://safety.admin.ox.ac.uk/coronavirus#collapse1916536). | YES/NO/NOT APPLICABLE |

|  |
| --- |
| **SECTION D. SCREENING PROCESS** |
| 1. Give an overall description of the study participants (e.g. healthy volunteers aged…) |
|  |
| 2. What are the inclusion criteria of the study? |
|  |
| 3. What are the exclusion criteria of the study? |
|  |
| 4. Please identify any potential safeguarding issues that may arise and explain how these will be addressed. Your attention is drawn to the [University’s Safeguarding Code of Practice](http://www.admin.ox.ac.uk/personnel/cops/safeguarding/) and its implications for research involving children or adults at risk, including the need for the work to be risk assessed and for researchers to undertake related training. |
|  |
| 5. How will the potential participants be identified, approached, screened and recruited? |
|  |
| 6. How many participants will be recruited? Give the total sample size and justify the sample size. |
|  |
| 7. Describe groups and numbers per group (if appropriate). |
|  |
| 8. Has statistical advice been sought in calculating the sample size? Please specify and give details of statistical methods. |
|  |
| 9. Please give details of the [consent process](https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent), including details of who will take consent and how it will be done. Please submit copies of the consent form and any information provided to participants (e.g. written information sheets, videos, interactive material) with this application. |
|  |
| 10. Will there be advertisement for recruitment of participants, e.g. posters, flyers, emails, social media posts? If so, please provide copies. |
|  |
| 11. Describe the arrangements for withdrawal of participants from the study. Participants should have the right to withdraw from the study at any time. State whether withdrawal will result in exclusion of that participant’s data/samples from the analysis. State whether withdrawn participants will be replaced. |
|  |

|  |
| --- |
| **SECTION E. ETHICAL ISSUES** |
| 1. What are the potential adverse effects, pain, distress, inconvenience, risks or hazards for participants from your research? |
|  |
| 2. Are there any potential benefits to the participants?  |
|  |
| 3. Are there any risks or benefits to the wider community? |
|  |
| 4. What are the main ethical issues? How do you propose to address them?Please do not answer ‘none’. OxTREC needs to see evidence that you have identified potential ethical issues with respect to your research and have taken steps to address them. These issues might relate to: data protection; participant confidentiality; researcher safety (refer to [Best Practice Guidance 01: Researcher safety](https://researchsupport.admin.ox.ac.uk/files/bpg01researchersafetypdf)), etc. Please also ensure that any ethical issues specific to the local context are addressed (refer to [Best Practice Guidance 16: Social science research conducted outside the UK](https://researchsupport.admin.ox.ac.uk/files/bpg16ethicalreviewofsocial-sciencebasedresearchoverseasv10pdf) and to the [Global Code of Conduct for Research in Resource-Poor Settings](http://www.globalcodeofconduct.org/)). |
|  |
| 5. Will participants receive reimbursement of expenses or any payment or gifts? If yes, how much? (Guidance is available in [Best Practice Guidance 05: Payments and incentives in research](https://researchsupport.admin.ox.ac.uk/files/bpg05paymentsandincentivesinresearchv10pdf).) |
|  |

|  |
| --- |
| **SECTION F: DATA MANAGEMENT AND SAMPLE STORAGE**  |
| 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/data-protection-forms) 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](https://compliance.admin.ox.ac.uk/#/).For guidance on conducting internet-mediated research, refer [Best Practice Guidance 06: Internet-mediated research](https://researchsupport.admin.ox.ac.uk/files/bpg06internet-basedresearchpdf).  |
| 1. Will your research involve any of the following data: |
| Screening documents | YES/NO |
| Records of consent including participant identification, e.g. written consent forms, audio-recorded consent, assent forms (for research involving minors) | YES/NO |
| Online consent (which may be anonymous) | YES/NO |
| Contact details collected for research purposes only (destroyed when no longer needed for this research) | YES/NO |
| Contact details kept for future studies | YES/NO |
| Information about the health of the participant (including mental health) | YES/NO |
| Accessing medical records | YES/NO |
| Physiological test results/measurements | YES/NO |
| Accessing mobile phone data | YES/NO |
| [Audio recordings](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/faqs#collapse2796916) | YES/NO |
| [Video recordings](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/faqs#collapse2796916) | YES/NO |
| Transcripts of audio/video recordings | YES/NO |
| Photographs | YES/NO |
| Task results (e.g. paper/online tasks, questionnaires, diaries) | YES/NO |
| IP addresses (refer to [Best Practice Guidance 09: Management](https://researchsupport.admin.ox.ac.uk/files/bpg09datacollectionandmanagementpdf) and protection of data collected for research purposes for guidance) | YES/NO |
| Field notes | YES/NO |
| Data already in the public domain. Specify the source of the data below: | YES/NO |
|  |
| Previously collected (secondary) data | YES/NO |
| Other data collection activities (please specify below): |
|  |
| 2. For each type of data selected above, please state how it will be physically transferred from where it is collected to a [secure local storage site](https://researchdata.ox.ac.uk/home/managing-your-data-at-oxford/storage-and-backup/) (and backed up as necessary). This includes both paper records and data captured electronically.  |
|  |
| 3. How and where will each type of data be stored during the research (until the end of all participant involvement)? Describe the arrangements for ensuring confidentiality, i.e. location of storage (e.g. [Nexus 365 OneDrive for Business, SharePoint](https://help.it.ox.ac.uk/nexus365/which-onedrive)), security arrangements and de-identification of the data. NB: Do not store unencrypted data in freely available cloud services or unprotected USB drives. Refer to the [Best Practice Guidance 06: Internet-mediated research](https://researchsupport.admin.ox.ac.uk/files/bpg06internet-basedresearchpdf) and [Management](https://researchsupport.admin.ox.ac.uk/files/bpg09datacollectionandmanagementpdf) and protection of data collected for research purposes for guidance. |
|  |
| 4. Will you use a unique participant number on research data instead of a participant name? If yes, state whether or not you will retain a list of participant names against numbers (i.e. [pseudonymisation](https://researchsupport.admin.ox.ac.uk/policy/data/scope#collapse461586) via a linkage list). Where will the list be stored, and when will it be destroyed? |
|  |
| 5. Who will have access to the research data? |
|  |
| 6. If your research involves the use of secondary (i.e. previously collected) data complete this section. | Are data access agreements in place for access to and use of this secondary data? (If so, please attach these.) | YES/NO |
| Did the individuals agree that their data could be used for this purpose? (If so, please provide a copy of original consent forms.) | YES/NO |
| Could anyone (including members of the research team) link the data back to an individual or individuals?If this is a possibility, please explain below how the associated ethical issues will be addressed: | YES/NO |
|  |
| 7. If research data is to be shared with another organisation, how will it be [transferred/disclosed](https://researchsupport.admin.ox.ac.uk/policy/data/transfer#/) securely? |
|  |
| 8. Explain what will happen to the data at the end of the research project. This question must be answered for each type of data, including completed consent forms.Please confirm that you will store 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).Describe how and where the data will be stored.Explain any arrangements for making the data available for reuse, including any arrangements for archiving the data. Explain your approach to keeping any personal data. For example, if you wish to retain contact details in order to re-approach participants about future studies, you must explain this to them and obtain specific consent for this.If it is no longer needed, or will not be archived, personal data should be destroyed in order to comply with the UK General Data Protection Regulation and the Data Protection Act; please confirm you will use a secure destruction process and confirm when and how each type of identifiable data will be destroyed.  |
|  |
| 9. What are the arrangements for storage and disposal of the biomedical samples (if applicable)? |
|  |
| 10. Will the study involve exporting any human tissue/fluid samples to Oxford and storing them there? If so, please provide details of exactly what samples will be sent to Oxford and where in Oxford they will be stored. |
|  |

|  |
| --- |
| **SECTION G: MANAGEMENT OF THE RESEARCH** |
| 1. Give details of the local ethics committee(s) to which you have applied.(Guidance is also available in [Best Practice Guidance 16: Social science research conducted outside the UK](https://researchsupport.admin.ox.ac.uk/files/bpg16ethicalreviewofsocial-sciencebasedresearchoverseasv10pdf)) |
|  |
| 2. Please indicate what training in research ethics those working on this study have received, e.g. GCP training. (Online training is available at <http://researchsupport.admin.ox.ac.uk/support/training/ethics>.) NB: some form of training in research ethics is compulsory. |
|  |
| 3. Please list any stakeholder or community engagement that has been/will be undertaken in relation to the research (e.g. with potential participants, the local community, health policy managers/service providers, etc.). |
|  |
| 4. How do you intend to report and disseminate the results of the study? |
|  |
| 5. If this study is funded by the US National Institutes of Health (NIH) or another US federal funding agency, please complete the form for NIH funded studies available on the [OxTREC application process page](https://researchsupport.admin.ox.ac.uk/governance/ethics/apply/oxtrec#collapse404371) and submit it with your application. |
|  |
| 6. Is there any additional information that you consider relevant for the purposes of ethical review? |
|  |

|  |
| --- |
| **SECTION H: SIGNATURES** |
| Signatures will be accepted in either of the two following ways:Option 1: Handwritten (wet-ink) signatures. These should be scanned with the rest of the form pages to create a single PDF document.Option 2: Email confirmations sent from a University of Oxford email address can be accepted. Separate emails should be sent by each of the relevant signatories as outlined below, indicating acceptance of their responsibilities. |
| 1. Principal investigator/student researcher signature (**for all projects**) |
| I understand my responsibilities as [**principal investigator**](http://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#P) as outlined in the CUREC glossary and guidance on the CUREC website. I declare that the answers above accurately describe my research as presently designed and that I will submit an amendment should the design of my research change in any way. I will inform OxTREC if I cease to be the principal investigator on this project and supply the name and contact details of my successor if appropriate.**Signed by principal investigator/student researcher:**…………………………………………………….**Date:**…………………**Print name** (block capitals)……………………………………………………………………………………… |
| 2. Supervisor signature (**for student research projects only**) |
| I confirm that the above particulars are correct.**Signed by supervisor:**………………………………………………………………………………………….**Date:**…………………**Print name** (block capitals)……………………………………………………………………………………… |
| 3. Departmental endorsement signature (**for all projects**) |
| On the basis of the information available to me, I confirm that:1. I am aware of the research proposed and have read this application;
2. to the best of my knowledge, the proposed design and scientific methodology do not raise concerns;
3. I support this research in principle, subject to ethical and other necessary reviews.

**Signed by Head of Department or nominee** (example nominees for student research include the Director of Graduate Studies/Director of Undergraduate Studies):**Signature**…………………………………………………………………………………………………………**Date**…………………**Print name** (block capitals)………………………………………………………………………………………**Position held** (block capitals)…………………………………………………………………………………… |

|  |
| --- |
| **Please send your application form by email to** **oxtrec@admin.ox.ac.uk****.****Please include other supporting documents, if appropriate (e.g. participant information sheet, consent form, questionnaire, interview guide, recruitment material, evidence of approval from local ethics committee, peer review and response).** |