**Application for Full Committee Review**

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| **Section A** |
| **Full Study Title:** |  |
| **Short Title:** |  |
| **Principal Investigator:**  |  |
| **Sponsor:**  |  |
| **Funding Source:**  |  |
| **Countries Involved:** |  |
| **Organizations Involved and Locations:** |  |
| **Anticipated Start Date:** |  |
| **Anticipated End Date:** |  |

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| **Applicant Details:** |
| **Principal Investigator:** |  |
| **PI Job Title:** |  |
| **PI Employer:**  |  |
| **PI Address:** |  |
| **Phone:**  |  |
| **Email:**  |  |
| **Primary Contact:** |  |
| **Post:** |  |
| **Employer:** |  |
| **Address:** |  |
| **Email:** |  |
| **What planned or completed training on research skills has the applicant received/will receive, e.g. GCP training, online training in ethics/human subject protection etc.** |  |

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| **Funding Details and Conflict of Interest** |
| **How will this research be funded?** **List:*** **Funding organization**
* **Amount secured**
* **Support to be provided**
* **Duration of grant/contract**
 |  |
| **Is the study funded by the US National Institutes of Health (NIH) or any other US federal funding agency? If so, complete the form for NIH funded studies.** [**https://researchsupport.admin.ox.ac.uk/files/form-nih-funded-studies**](https://researchsupport.admin.ox.ac.uk/files/form-nih-funded-studies) |  |
| **If the research sponsor is other than the University of Oxford, have they agreed to provide indemnity for the study? If not, specify the alternative arrangements.** |  |
| **Will individual researchers receive any personal payment or other benefits for undertaking this research? If so provide full details. Are there any conflicts of interest?** |  |

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| **Researchers (Add more rows as needed):** |
| Name |  |
| Job Title |  |
| Employer |  |
| Address |  |
| Email |  |

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| **Section B: Description** |
| **1. Brief Scientific Background and Rationale****DO NOT EXCEED 500-word limit** |  |
| **2. What is the primary objective of the study?** |  |
| **3. What is the primary endpoint or outcome measure?** |  |
| **4. What are the secondary objectives?** |  |
| **5. What are the secondary endpoints or outcome measures?** |  |

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| **Section C: Study Design & Methodology**  |
| **1. Please summarize the design and methodology of the planned research:** (define abbreviations) **DO NOT EXCEED** 500-word limit |  |
| **2. How many participants will be recruited?** Give the total sample size. |  |
| **3.** **Describe participant groups and numbers per group:** |  |
| **4.** **How was the number of participants decided?** Provide sufficient detail of the calculation to allow replication**.** |  |
| **5. Has statistical advice been sought?** Give details of the statistical analysis methods. |  |
| **6. Is this a clinical trial?**  |  |
| **7. If yes, on which clinical trial registration site has the trial been registered? Provide the trial registration number.** |  |
| **8. What is your intervention?** e.g. use of a new medical product or device, a surgical procedure, a therapy or a test. |  |
| **9. Is a medical product being tested outside its local terms of licence?** |  |
| **10. Does your trial need a Data and Safety Monitoring Board (DSMB)?**  |  |
| **11. List all other procedures that are part of the trial, e.g. blood and other samples taken, tests performed, questionnaires etc.** |  |
| **12. Give the total volume of blood to be taken for research, and over what time period:** |  |
| **13. Give an estimate of the quantity of blood which will be taken for clinical investigations not related to the research:** |  |
| **14. Will participants' genetic material be analyzed?** This does not include routine tests (e.g. for G6PD and Hb electrophoresis). **If yes, is permission for genetic testing requested in the consent form?** (Ensure future use covered with a separate tick box on consent form) |  |

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| **Section D: Screening Process**  |
| **1. What are the inclusion criteria of the study?** |  |
| **2. What are the exclusion criteria of the study?** |  |
| **3. Will participants be recruited from any of the following groups? Specify and describe the vulnerable groups:** |
| **Pregnancy:**  |  |
| **Children under 18:**  |  |
| **People with learning difficulties:**  |  |
| **Unconscious or severely ill:**  |  |
| **Other Vulnerable groups:**  |  |
| **4: Identify any potential safeguarding issues** (concerns regarding the protection and welfare of individuals participating in the study, such as risks to privacy and participant confidentiality, physical or psychological harm, sexual harassment, or any other factors that may compromise well-being that may arise (for participants and study staff). **Explain how these will be addressed by providing a detailed explanation of the specific steps, protocols, and measures that will be implemented to mitigate and address these concerns, ensuring the safety and protection of individuals throughout the research study.** Your attention is drawn to the University's Safeguarding Code of Practice and its implications for researchers involving children or adults at risk, including the need for the work to be risk assessed and for researchers to undertake related training. |  |
| **5. Identify any racial, ethnic or gender group(s) which will be specifically excluded from participation in this research study and justify such exclusion.** |  |
| **6. How will the potential participants be identified and approached?** |  |
| **7. How long will you allow potential participants to decide whether or not to take part?** |  |
| **8. Describe the consent process, including who will take consent and how it will be done. Provide copies of consent materials (e.g. participant information sheet (PIS), videos or interactive material).** The PIS should include: a short/lay title for the study;details of whether interventions are approved/tested in humans; clear and simple explanation of the risks and benefits of taking part; explanation of what procedures additional to normal clinical practice are involved. |  |
| **9. Are there any issues that might affect consent? (e.g. ongoing trials in the same population, or participants are very unwell). How would these be addressed?** |  |
| **10. Will there be advertising for recruitment e.g. posters, flyers, emails? If so, provide copies.** |  |

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| **Section E: Risks & Benefits**  |
| **1. What are the potential adverse effects, pain, distress, inconvenience, risks or hazards for participants from the research procedures, or changes to life style for participants?** These may include tests, procedures, treatments and questionnaires.  |  |
| **2. Are there any potential benefits to participants?** |  |
| **3. Are there any risks or benefits to the community?**  |  |
| **4. Does your research raise issues relevant to the Counter-Terrorism and Security Act (the Prevent duty), which seeks to prevent people from being drawn into terrorism?** If yes, please say how you plan to address any related risks. |  |

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| **Section F: Ethical Issues** |
| **1. Summarize the main ethical issues from the participants' and researchers' point of view and say how you propose to address them:** **DO NOT EXCEED 1000 words** |  |

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| **Section G: Data Management & Sample Storage** |

In this section, ["personal data"](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#P) means any data relating to a participant who could potentially be identified. It includes [pseudonymized](https://researchsupport.admin.ox.ac.uk/policy/data/scope#collapse461586) data capable of being linked to a participant through a unique code number.

Management of [personal data](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#P) of human participants, either directly or via a third party, will need to 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 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. For advice on research data management and security, please consult with the University’s Research Data Team (researchdata@ox.ac.uk) and/or your local IT department and the University's [web pages on research data management](http://researchdata.ox.ac.uk/)

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| **1. Will your research involve any of the following activities?** |
| **Collecting records of consent:**  |  |
| **Access to medical records:**  |  |
| **Electronic transfer of data by email, computer network or other means:**  |  |
| **Sharing of personal data with other organizations**  |  |
| **Use and/or storage of personal addresses, email addresses, or telephone numbers:**  |  |
| **Access to mobile phone data:**  |  |
| **Publication of direct quotations from participants:**  |  |
| **Publication of data that might allow identification of participants:**  |  |
| **Use of audio-visual recording devices (e.g. voice recorder, video recorder, camera):**  |  |
| **Transcription of audio/video recordings:**  |  |
| **2. Will your research involve storage of personal data on any of the following?** |
| **Manual files (paper or film):**  |  |
| **Home or personal computers:**  |  |
| **University of Oxford computers:**  |  |
| **Hospital computers:**  |  |
| **Other university computers:**  |  |
| **Private company computers:**  |  |
| **Laptop computers:** |  |
| **3. For each type of personal data collected during the study, please state how it will be physically transferred from where it is collected to a secure local storage site (and backed up as necessary).** This includes both paper records and data captured electronically. |  |
| **4. Where will the personal data be stored during the study?** |  |
| **5. Describe the physical security arrangements for storage of personal data during the study.** |  |
| **6. How will you ensure the confidentiality of personal data? Provide a general statement of the procedures for ensuring confidentiality, e.g. anonymization or pseudonymization of the data.** |  |
| **7. Will identifiers be held in the same database as the clinical data, or in a separate database and linked through a unique study number?** |  |
| **8. If identifiers will be held separately, please specify how and at what point the separation will occur?** |  |
| **9. If identifiers will be held in the same database, will the identifiers be encrypted?** |  |
| **10. If the identifiers will be encrypted, what will be encrypted and who will have access?** |  |
| **11. Who will have access to participants’ personal data during the study?** |  |
| **12. How long will personal data be stored or accessed after the study has ended?** |  |
| **13. Where will the research data generated by the study be analyzed and by whom?** |  |
| **14. Who will have control of, and act as custodian for, the research data generated by the study?** |  |
| **15. For how long will you store other research data generated by the study?** Provide details of the long-term arrangements for storage of research data after the study has ended: |  |
| **16. Where will the research data be stored?** |  |
| **17. Who will have access to the research data?** |  |
| **18. What arrangements will be in place to ensure security of the research data?** |  |
| **19. What are the arrangements for storage and disposal of the biological samples (if applicable)?** |  |
| **20. Will the study involve exporting any human tissue/fluid samples to Oxford and storing them there?** If so, provide details of exactly what samples will be sent to Oxford and where in Oxford they will be stored. |  |

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| **Section H: Payments & Incentives** |
| **1. Will participants receive reimbursement of expenses? If yes, state how much. Convert to GB pounds or US dollars and relate to average daily wage if appropriate.** |  |
| **2. Will individual participants receive any payment or gifts for taking part in the research? If yes state how much and how this has been decided upon.** |  |
| **3. Will the cost of routine care be reimbursed?**  |  |
| **4. Does participation in the study require the use of contraceptives? If so, confirm that the cost of the contraceptives will be covered by the study.** |  |

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| **Section I: Management of the Research** |
| **1. Has the proposed study had an independent peer review? If so, attach a copy including your response to comments.**  |  |
| **2. Give details of the local ethics committee to whom you have applied. If there is no appropriate local committee provide an explanation.** |  |
| **3. Has this, or a related proposal, been submitted to OxTREC or any other ethics committee for review in the past year?** If so, provide brief details. |  |
| **4. Give details of the competent authority (if any) e.g. regulatory agencies that will approve the study.** |  |
| **5. Will you inform any other health professional responsible for the participants' care that they are taking part in the study? If yes explain how, if no justify.** |  |
| **6. What demand will this research place on local health services? How will the design of the project take these demands into account?** |  |

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| **Section J: Community Engagement**  |
| **1. In which aspects of the research process have you actively involved/engaged, or will you actively involve/engage, any of the following stakeholder groups?** In the table below, indicate which groups will be involved (Column A), and the broad area(s) (Column B) and approaches/timing for their involvement (Column C). If there are no plans for stakeholder involvement/engagement, explain why this is not needed in section 2.Examples of areas of involvement: design of research; management of research; undertaking research; analysis of results; dissemination of findings; other (specify)Examples of approach to involvement/activity: One-on-one meetings; group discussions; radio broadcasts; distribution of leaflets/posters, etc.; participatory research methods; other (specify) AND timing (before, during, after the research) |
| **A. Stakeholder group(s) involved (add rows as needed)** | **B. Areas of involvement** | **C. Approaches to involvement including timing** |
| Potential study participants and/or their legal guardians |  |  |
| Local residents in areas or users of facilities where study will be conducted |  |  |
| Members of the wider public in the research setting |  |  |
| Health policy/service managers/providers in facilities involved in the research |  |  |
| Other: please specify |  |  |
| **2. If no stakeholder involvement/engagement is planned, explain why this is not needed.** |  |
| **3. How do you intend to report and disseminate the results of the study?** |  |
| **4. Will you inform participants of the results?** |  |

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| **Additional information for the committee** |
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**Document checklist**

**Please complete this checklist and ensure you have enclosed the relevant documents.**

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| **Document**  | **Version** | **Date** | **Indicate (X) if included**  |
| Completed Application Form |  |  |  |
| Protocol |  |  |  |
| Investigator Brochure or Summary of Product Characteristics (SmPC) |  |  |  |
| PI Signature Page |  |  |  |
| Participant Information Sheet (PIS) |  |  |  |
| Participant Consent Form (CF) |  |  |  |
| Invitation to participants |  |  |  |
| Advert for participants |  |  |  |
| Approval Letter from local ethics committee |  |  |  |
| Sponsor Letter |  |  |  |
| Participant Questionnaire |  |  |  |
| Peers' reviews of study |  |  |  |

**(add rows as needed)**