**OXFORD TROPICAL RESEARCH ETHICS COMMITTEE (OxTREC)**

**ANNUAL PROGRESS REPORT**

**Continuation of ethical approval is contingent on the submission of this report.**

**Please send your signed report by email to** **oxtrec@admin.ox.ac.uk****.**

|  |
| --- |
| Full Title of Study: |
| OxTREC Reference: |
| Date OxTREC Approval Given: |
| Date Local IRB Approval Given: |
| Sponsor: |

**Details of Principal Investigator and confirmation that the listed investigators are still involved in the study**

|  |  |
| --- | --- |
| PI Name |  |
| Address |  |
| Email |  |
| 1. Name & Details |  |
| 2. Name & Details |  |
| 3. Name & Details |  |
| 4. Name & Details |  |

**Details of Study**

|  |  |
| --- | --- |
| Has the study started yet? | Yes / No |
| If yes, what was the actual start date? |  |
| Expected/Actual End Date |  |

**Are there any new/additional investigators/research assistants/nurses or sites participating in the study? (If yes, please supply details)**

|  |
| --- |
|  |

**Recruitment/Number of participants in the study**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Participants | Brought forward (from previous report) | Number recruited this year | Total to date | Number yet to be recruited | Total withdrawn to date |
| Healthy |  |  |  |  |  |
| Patients |  |  |  |  |  |
| Controls |  |  |  |  |  |
| Totals |  |  |  |  |  |

**Recruitment Process**

|  |  |
| --- | --- |
| Has there been any difficulty recruiting? |  |
| Is the recruitment process closed? |  |
| Number of self withdrawals |  |

**Have there been any significant safety issues?**

|  |
| --- |
| Please provide details of any significant safety issues along with information of the outcome: |

**Amendments**

|  |  |
| --- | --- |
| Have any amendments been made to the study during the year? | Yes / No |
| If yes, please give the date and amendment/protocol version number for each amendment |  |

**Brief project report/status of the study to date**

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|  |

**Have any publications (or other research outputs) arisen from this research so far? Please list below (providing links where appropriate).**

NB: in line with funder requirements, investigators should publish their findings, *including null and negative results*.

|  |
| --- |
| Please list all publications/research outputs and links here: |
| Please confirm that all publications:* include the clinical trial registration number (for clinical trials)
* list the funder
* are made freely available (*please supply full details of where they are available*)
 |  |
| Please confirm that data underlying the publications are accessible to other researchers, either openly or via a managed access approach, and *list where they can be accessed* |  |

**For clinical trials and interventional studies**

|  |  |
| --- | --- |
| Please provide clinical trial registry & trial registration number |  |
| Please confirm that all of the following are included in the clinical trial registration:* funder & grant reference number
* sponsor
* summary of trial (*please attach this*)
* data sharing plan (*please attach this*)[[1]](#footnote-1)
 | Please supply full details here: |

**Principal Investigator**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator**

**Name (block capitals): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. NB: in cases where there is no specific section in which to input this information in the registry, you should include this information somewhere in the registry entry, e.g. in the ‘Descriptive Information’ section on clinicaltrials.gov. [↑](#footnote-ref-1)