# ANNUAL PROGRESS REPORT TO ICREC-SETREC

For use in all research previously approved by Imperial College Research Ethics Committee or Science (ICREC), Science, Engineering and Technology Research Ethics Committee (SETREC).

To be completed by the Principal Investigator and submitted to the [ethics and research governance coordinator](mailto:rgitcoordinator@imperial.ac.uk) within 30 days of the yearly anniversary of the ethical approval until the completion of the study.

*(For questions with Yes/No delete as appropriate)*

Details of Principal Investigator and Study

|  |  |
| --- | --- |
| Name |  |
| Department and Faculty |  |
| Email |  |
| Full title of study |  |
| ICREC/SETREC reference number: |  |

## Section One

### Commencement and termination dates

|  |  |
| --- | --- |
| Date of favourable ethical opinion: |  |
| Has the study started? |  |
| If yes, what was the actual start date? |  |
| If no, what are the reasons for the study not commencing?  What is the expected start date? |  |
| Has the study finished? | Yes/No |
| If yes, complete and submit [Declaration of end of study form.](https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/imperial-college-research-ethics-committee/public/7.-End-of-Study-Notification.docx) |

|  |  |
| --- | --- |
| If no, what is the expected completion date?  If you expect the study to overrun the planned completion date this should be notified to ICREC/SETREC as a substantial amendment for ethical review. Please fill in the [*amendment form*](https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/imperial-college-research-ethics-committee/public/5.-Notice-of-Amendment.docx)*.* |  |
| If you do not expect the study to be completed, give reason(s) |  |

## Section TWO

### Recruitment of participants

*\* In the case of international studies, please provide separate figures for UK and non-UK participants.*

|  |  |
| --- | --- |
| \*Number of participants recruited |  |
| \*Number of participants that have completed study |  |

### Total number of withdrawals

*\* In the case of international studies, please provide separate figures for UK and non-UK participants.*

|  |  |
| --- | --- |
| \*Give reasons for withdrawals and number of participants withdrawing for these reasons: |  |
| Have there been any serious difficulties in recruiting participants? |  |
| If Yes, give details: |  |
| Do you plan to increase the planned recruitment of participants into the study? |  |
| Any increase in planned recruitment should be notified to ICREC/SETREC as a substantial amendment for ethical review. Please fill in the [notice of amendment form](https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/imperial-college-research-ethics-committee/public/5.-Notice-of-Amendment.docx). | |

## Section Three

### SAE’s and Safety of participants

|  |  |
| --- | --- |
| Have there been any Serious Adverse Events (SAEs) in this study? |  |
| Have there been any Unexpected and Related SAEs in this study |  |
| Have any concerns arisen about the safety of participants in this study? |  |
| *If yes and these SAEs or concerns have not previously been reported to the RGIT then please submit the* [*SAE form*](https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/imperial-college-research-ethics-committee/public/Report-of-Serious-Adverse-Event-Form.docx) *and a detail as to why the late submission or for concerns regarding participant safety give details on a separate sheet and say how the concerns have been addressed.* | |

## Section Four

### Amendments

|  |  |
| --- | --- |
| Have any substantial amendments been made to the trial during the year? |  |
| If yes, please give the date and amendment number for each substantial amendment made.  *Any substantial amendment should be notified to ICREC/SETREC for ethical review. Please fill in the* [*amendment form*](https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/imperial-college-research-ethics-committee/public/5.-Notice-of-Amendment.docx)*.* | |

## Section Five

### Other issues

|  |  |
| --- | --- |
| Are there any other developments in the study that you wish to report to the Committee? |  |
| Are there any ethical issues on which further advice is required? |  |
| *If yes to either, please attach separate statement with details.* | |

## Section Six - Declaration

|  |  |
| --- | --- |
| Signature of Principal Investigator: |  |
| Print name: |  |
| Date: |  |