# Annual Progress Report to Research Ethics Committee

## For all studies except clinical trials of investigational medicinal products

**To be completed and submitted by the Chief Investigator or sponsor. Please email this report to the REC. For questions with Yes/No answer options, please indicate your answer in bold type.**

### Details of the Chief Investigator

|  |  |
| --- | --- |
| Name: |  |
| Address: |  |
| Telephone: |  |
| E-mail: |  |

1. **Details of study**

|  |  |
| --- | --- |
| Full title of study: |  |
| IRAS ID: |  |
| Name of REC: |  |
| REC reference number: |  |
| Date of favourable ethical opinion: |  |
| Sponsor: |  |

1. **Commencement and termination dates**

|  |  |
| --- | --- |
| Has the study started? | Yes / No |
| 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?  Please note, if the study will not start within 24 months of the REC Favourable Opinion date the REC may review its’ opinion. |  |
| Has the study finished?  If yes, complete and submit ‘Declaration of the end of a study’ form, available on the [HRA website](https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/). | Yes / No |
| If no, what is the expected completion date?  If you expect the study to overrun the planned completion date, what are the reasons for this? |  |
| If you do not expect the study to be completed, give reason(s). |  |

1. **Registration**

|  |  |
| --- | --- |
| Is the study a ‘clinical trial’? (Defined as the first 4 categories on the IRAS filter page)  (For CTIMPs, please use CTIMP progress reporting template) | Yes / No |
| Is the study registered on a publicly accessible database? (Registration of clinical trials is a condition of approval for studies approved after 30 September 2013) | Yes / No |
| If yes, please provide the name of the publicly accessible database and the registration number | Registration number: |
| If no: | 1. What is the reason for non-registration? 2. What are your intentions for registration? |

1. **Recruitment of participants**

In this section, ‘participants’ includes those who will not be approached but whose samples/data will be studied.

|  |  |
| --- | --- |
| Number of participants recruited: | Proposed in original application:  Actual number recruited to date: |
| Number of participants completing the study: | Actual number completed to date: |
| Number of withdrawals from study to date due to:  Total study withdrawals: | 1. withdrawal of consent: 2. loss to follow-up 3. death (where not the primary outcome) |
| \*Number of treatment failures to date (prior to reaching primary outcome) due to:  Total treatment failures:  \*Applies to studies involving clinical treatment only | 1. adverse events 2. lack of efficacy |
| Have there been any serious difficulties in recruiting participants? | Yes / No |
| If yes, give details: |  |
| Do you plan to increase the planned recruitment of participants into the study?  Please note, any significant increase in planned recruitment or changes to the recruitment methodology should be notified to the REC as a substantial amendment for ethical review. | Yes / No |

### Safety of participants

|  |  |
| --- | --- |
| Have there been any related and unexpected serious adverse events (SAEs) in this study? | Yes / No |
| Have these SAEs been notified to the Committee?  If no, please submit details with this report and give reasons for late notification. | Yes / No /Not applicable |
| Have any concerns arisen about the safety of participants in this study?  If yes, give details and say how the concerns have been addressed. This information may be considered by the Committee when reviewing the report. | Yes / No |

1. **Amendments**

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

1. **Serious Breaches of the Protocol**

|  |  |
| --- | --- |
| Have any serious breaches of the protocol occurred during the year?  If yes, please enclose a report of any serious breaches not already notified to the REC. | Yes / No  Yes / No |

1. **Other issues**

|  |  |
| --- | --- |
| Are there any other developments in the study that you wish to report to the Committee? | Yes / No  Yes / No |

1. **Declaration**

|  |  |
| --- | --- |
| \*Signature/Electronic Signature of Chief Investigator or Sponsor representative:  \*Please print name below and insert electronic signature, if possible |  |
| Print name: |  |
| Date of submission: |  |