

**PROGRESS REPORT TO THE CENTRAL RESEARCH ETHICS COMMITTEE**

To be completed in typescript and submitted to [research.governance@keele.ac.uk](file:///\\ufs.uso.keele.ac.uk\busdev\Academic%20Legal%20Services\PARI\QMS%20Documents\UREC\UREC%20QMS%20-%20Documents\PH%20UREC-QCD-10%20-%20Annual%20Progress%20Report\research.governance@keele.ac.uk) by the Applicant.

**1. Details of study**

|  |  |
| --- | --- |
| Applicant name: | Click here to name. |
| Full title of study: | Click here to enter study title. |
| REC reference number: | Click here to enter REC ref in format CR-yy####. |

#### 2. Commencement and termination dates

|  |  |
| --- | --- |
| Has the study started? | Choose an item. |
| ***If yes,*** *what was the actual start date?* | Click here to enter a date. |
| ***If no****, What is the expected start date?* | Click here to enter a date. |
| *What are the reasons for the study not commencing?* | Click here to enter reasons. |
| Has the study finished? | Choose an item. |
| ***If yes, complete and submit “Declaration of end of study” form.*** | |
| ***If no,*** *what is the expected completion date?* | Click here to enter a date. |
| If you expect the study to overrun the planned completion date this should be notified to the CREC for information. Enter details. | Click here to enter details. |
| *If you do not expect the study to be completed, give reason(s)* | Click here to enter reasons. |

**3. 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: | Click here proposed no. of participants. |
| *Actual number recruited to date:* | Click here to no. recruited. |
| Number of participants completed to date: | Click here to enter no. completed. |
| Number of withdrawals from study to date due to: |  |
| 1. *withdrawal of consent:* | Click here to enter no. who have withdrawn consent. |
| 1. *loss to follow-up:* | Click here to enter no. lost to follow-up |
| *Total study withdrawals:* | Click here to enter total no. withdrawals. |
| Have there been any serious difficulties in recruiting participants? | Choose an item. |
| ***If Yes,*** *give details:* | Click here to enter details. |
| Do you plan to increase the planned recruitment of participants into the study? | Choose an item. |
| ***Any increase in planned recruitment may require a substantial amendment in in accordance with the conditions of the favourable ethical opinion or as directed by the REC.*** | |

**4. Ethical Issues**

|  |  |
| --- | --- |
| Have there been any issues during this study that may affect the ethical opinion of the CREC? | Choose an item. |
| **If yes,** have these issues been notified to the CREC? | Choose an item. |
| ***If issues that may affect the CREC’s ethical opinion have occurred by not yet been notified to the CREC, please submit details with this report and give reasons for delayed notification.*** | |
| Have any concerns arisen about the safety/wellbeing of participants in this study? | Choose an item. |
| ***If yes,*** *give details and say how the concerns have been addressed.* | Click here to enter details. |

**5. Amendments**

|  |  |
| --- | --- |
| Have any substantial amendments been made to the project during the year? | Choose an item. |
| ***If yes,*** *please give the date and amendment number for each substantial amendment made.* | Click here to enter reference codes. |

**6. Serious non-compliances or issues which may impact on ethical opinion**

|  |  |
| --- | --- |
| Have any events occurred which may impact on the ethical opinion of the project during the year? | Choose an item. |
| ***If Yes, please enclose a report of any serious issues not already notified to the CREC*** | |

**7. Other issues**

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

**8. Declaration**

|  |  |
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| Signature of Applicant: *(electronic signatures are acceptable)* |  |
| Print name: | Click here to enter Applicant name |
| Date of submission of report: | Click here to enter a date. |