

**PROGRESS REPORT TO THE FACULTY OF MEDICINE AND HEALTH SCIENCES RESEARCH ETHICS COMMITTEE (FMHS FREC)**

To be completed in typescript and submitted to [health.ethics@keele.ac.uk](mailto:health.ethics@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 MH-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 FMHS FREC 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 who have withdrawn consent.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 REC? | Choose an item. |
| **If yes,** have these issues been notified to the REC? | Choose an item. |
| ***If issues that may affect the FMHS FREC’s ethical opinion have occurred by not yet been notified to the FMHS FREC, 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 FMHS FREC*** | |

**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**

|  |  |
| --- | --- |
| Signature of Applicant: |  |
| Print name: | Click here to enter Applicant name |
| Date of submission of report: | Click here to enter a date. |