

London - Queen Square Research Ethics Committee

HRA NRES Centre Bristol
3rd floor, block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

16 January 2023

Professor John Dark
Professor of Cardiothoracic Surgery
Newcastle University
Faculty of Medical Sciences
Framlington Place
Newcastle Upon Tyne
NE2 4HH

Dear Professor Dark

| | |
|--------------------------|---|
| Study title: | Statins in Organ Donor Management An evaluation of the benefits of a single dose of Simvastatin given to potential organ donors declared dead by neurological criteria on outcomes in organ recipients |
| REC reference: | 21/LO/0412 |
| Protocol number: | 9691 |
| EudraCT number: | 2021-000047-44 |
| Amendment number: | Substantial Amendment 01 |
| Amendment date: | 13 December 2022 |
| IRAS project ID: | 288722 |

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|---|----------------|------------------|
| Completed Amendment Tool [09691 SIGNET Amendment Tool SA01 Protocol Change v1.0 2022 12 13] | 1.0 | 13 December 2022 |
| Covering letter on headed paper [SIGNET_ Cover letter to REC_v1.0_2022 12 13] | 1.0 | 13 December 2022 |
| Research protocol or project proposal [09691 SIGNET Protocol V2.0 2022 12 07 Clean] | 2.0 | 07 December 2022 |
| Research protocol or project proposal [SIGNET Protocol_V2.0 2022 12 07_Tracked Changes] | 2.0 | 07 December 2022 |

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities— see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

| |
|----------------------------------|
| IRAS Project ID - 288722: |
|----------------------------------|

| |
|---|
| Please quote this number on all correspondence |
|---|

Yours sincerely



On behalf of
Ms Danielle Wilson
Chair

E-mail: queensquare.rec@hra.nhs.uk

Enclosures:

List of names and professions of members who took part in the review

Copy to:

Miss Amy Evans

London - Queen Square Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 03 January 2023

Committee Members:

| <i>Name</i> | <i>Profession</i> | <i>Present</i> | <i>Notes</i> |
|----------------------------|---|----------------|--------------|
| Dr Marie E Bardsley | Director (Pharmaceutical Publication) | Yes | |
| Ms Danielle Wilson (Chair) | Centre and Research Commercialisation Manager | Yes | |

Also in attendance:

| <i>Name</i> | <i>Position (or reason for attending)</i> |
|-------------------|---|
| Miss Bethan Lilly | Approvals Administrator |