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28 June 2021

Dear Professor Dark

HRA and Health and Care Research Wales (HCRW) Approval Letter

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**
IRAS project ID:	**288722**
Protocol number:	**9691**
REC reference:	**21/LO/0412**
Sponsor	**Newcastle Upon Tyne Hospitals NHS Foundation Trust**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **288722**. Please quote this on all correspondence.

Yours sincerely,

Kevin Ahmed
Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Miss Amy Evans*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [Model Agreement for Non-Commercial Research (all other sites)]	N/A	07 May 2021
Contract/Study Agreement template [Model Agreement for Non-Commercial Research (NUTH)]	N/A	07 May 2021
Covering letter on headed paper [Cover Letter]	1.0	30 April 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Newcastle University Insurance 2020-2021]		01 July 2020
IRAS Application Form [IRAS_Form_07052021]		07 May 2021
Letter from funder [Letter From Funder]		17 September 2020
MHRA Notice of No Objection Letter (Medical Devices) and relevant correspondence [MHRA Email Confirmation SIGNET Non-CTIMP]	N/A	01 March 2021
Organisation Information Document [09196 Organisation Information Document]	1.0	14 April 2021
Other [09691 Recipient Parent/Guardian Letter]	1.0	12 April 2021
Other [List of Collaborating sites to date 2021 06 14]		14 June 2021
Other [SIGNET Response to Provisional Opinion]	1.0	14 June 2021
Other [Dan Harvey Signed CV]	N/A	15 April 2021
Other [09691 Recipient Information Sheet]	1.0	12 April 2021
Other [09691 Recipient letter]	1.0	12 April 2021
Participant consent form [09691 Consent Sticker]	1.1	11 June 2021
Participant information sheet (PIS) [09691 Donor Family Information Sheet]	1.1	11 June 2021
Research protocol or project proposal [09691 SIGNET Protocol]	1.0	12 April 2021
Schedule of Events or SoECAT [Validated SoECAT]		17 September 2020
Summary CV for Chief Investigator (CI) [John Dark Signed CV]		01 January 2021

IRAS project ID	288722

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
All sites will perform the same research activities therefore there is only one site type.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is intending to use a model non-commercial agreement with sites	No study funding will be provided to sites as per the Organisation Information Document	A Principal Investigator should be appointed at study sites	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.