Professor Iain Moppett
Anaesthesia and Critical Care
Queen's Medical Centre
Nottingham
NG7 2UH

Email:
HCRW.approvals@wales.nhs.uk

06 July 2021

Dear Professor Moppett

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

Study title:	**Sprint National Anaesthesia Project 3: an observational study of frailty, multimorbidity and delirium in older people in the perioperative period**
IRAS project ID:	**294618**
Protocol number:	**21002**
REC reference:	**21/WA/0203**
Sponsor	**University of Nottingham**

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 **294618**. Please quote this on all correspondence.

Yours sincerely,

Sue Byng

Approvals Specialist

Email: HCRW.approvals@wales.nhs.uk

Copy to: *Mrs Angela Shone*

List of Documents

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

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Poster for Participants]	1.0	28 May 2021
Covering letter on headed paper [IRAS Cover Letter]		28 May 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance letter]		14 September 2020
IRAS Application Form [IRAS_Form_08062021]		08 June 2021
Letter from funder [Letter from Frances & Augustus Newman Foundation Funder]		28 May 2021
Letter from sponsor [Sponsor letter from University of Nottingham]		08 June 2021
Non-validated questionnaire [Appendix 11 Delirium Trigger Words]	1.0	28 May 2021
Non-validated questionnaire [Appendix 2 Comorbidities]	1.0	28 May 2021
Organisation Information Document [Organisation Information Document]	1.0	28 May 2021
Other [Appendix 1 Procedures Included and Excluded]	1.0	28 May 2021
Other [Appendix 5 Source of Admission and Discharge]	1.0	28 May 2021
Other [Appendix 12 Data Linkage]	1.0	28 May 2021
Other [Appendix 3 Laboratory Results]	1.0	28 May 2021
Other [Royal College of Anaesthetists Funding Letter]		03 June 2021
Other [Professional indemnity cover letter]	1.0	20 July 2020
Other [Appendix 6 Highest Education Level]	2	19 February 2021
Other [Delegation Log]	1.0	
Participant consent form [Consent Form, England & Wales]	1.1	01 July 2021
Participant consent form [Consent form, Northern Ireland]	1.1	01 July 2021
Participant consent form [Consent Form, Scotland]	1.1	24 June 2021
Participant consent form [Consultee Declaration Form, England, Wales & Northern Ireland]	1.1	01 July 2021
Participant consent form [Personal Legal Representative Consent Form, Scotland]	1.1	24 June 2021
Participant consent form [Telephone Consultee Advice England, Northern Ireland & Wales]	1.1	01 July 2021
Participant consent form [Telephone Personal Legal Representative Consent Form]	1.1	24 June 2021
Participant consent form [Telephone Consultee Declaration, Researcher Information, England, Northern Ireland and Wales]	1.1	01 July 2021
Participant consent form [Telephone Personal Legal Representative Consent, Researcher Information, Scotland]	1.1	24 June 2021
Participant consent form [Patient facing matrix per country]		
Participant information sheet (PIS) [Consultee Information Sheet England, Northern Ireland and Wales]	1.1	01 July 2021
Participant information sheet (PIS) [Participant Information Sheet England and Wales]	1.1	01 July 2021
Participant information sheet (PIS) [Participant Information Sheet Northern Ireland]	1.1	01 July 2021
Participant information sheet (PIS) [Participant Information Sheet Scotland]	1.1	24 June 2021
Participant information sheet (PIS) [Personal Legal Representative Information Sheet Scotland]	1.1	24 June 2021

Participant information sheet (PIS) [Participant Information Sheet for those Regaining Capacity England, Wales and Northern Ireland]	1.1	01 July 2021
Participant information sheet (PIS) [Participant Information Sheet for those Regaining Capacity Scotland]	1.1	24 June 2021
Participant information sheet (PIS) [Summary Participant Information Sheet England, Northern Ireland, Scotland and Wales]	1.1	01 July 2021
Participant information sheet (PIS) [Telephone Consultee Information Sheet England, Northern Ireland and Wales]	1.1	01 July 2021
Participant information sheet (PIS) [Telephone Personal Legal Representative Information Sheet Scotland]	1.1	24 June 2021
Referee's report or other scientific critique report [Scientific Critique Email Thread British Geriatrics Society]		28 May 2021
Research protocol or project proposal [Protocol Final]	1.0	28 May 2021
Schedule of Events or SoECAT [Schedule of Events validated]	1	08 June 2021
Summary CV for Chief Investigator (CI) [CV Iain Moppett]		25 May 2021
Summary CV for student [CV for Claire Swarbrick]		31 March 2021
Summary CV for supervisor (student research) [CV for Iain Moppett]		25 May 2021
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Lay Summary]	1.0	28 May 2021
Validated questionnaire [Appendix 10 4AT Delirium Assessment Tool]		
Validated questionnaire [Appendix 13 EQ-5D-5L]		
Validated questionnaire [Appendix 4 Generic and Surgery Risk Scores]		
Validated questionnaire [Appendix 9 Postoperative Morbidity Survey (POMS)]		
Validated questionnaire [Appendix 8 Reported Edmonton Frail Scale (rEFS)]		
Validated questionnaire [Appendix 14 CAM-ICU]		
Validated questionnaire [Appendix 7 Clinical Frailty Scale]		

IRAS project ID	294618

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 not requesting and does not expect any other site agreement to be used.	No study funding will be provided to sites as per the Organisational Information Document	**A Principal Investigator**should be appointed at study sites of this type.	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 a Letter of Access based on standard DBS 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.