

06 July 2021

Dr Claire Swarbrick
Co-investigator, HSRC Research Fellow and Specialty Trainee in Anaesthesia, Trainee Lead
and PhD student
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Dear Dr Swarbrick

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

Thank you for your email of 1 July 2021. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 28 June 2021

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
IRAS Checklist XML [Checklist_01072021]		01 July 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 [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 [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

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
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
IRAS Checklist XML [Checklist_01072021]		01 July 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
Other [Appendix 6 Highest Education Level]	2	19 February 2021
Other [Delegation Log]	1.0	
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
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
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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
Response to Additional Conditions Met		01 July 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]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

IRAS Project ID: 294618

Please quote this number on all correspondence

Yours sincerely



Sue Byng
Approvals Specialist

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Copy to: Dr Claire Swarbrick, Royal Devon and Exeter Hospital NHS Trust

Lead Nation
England: approvals@hra.nhs.uk