

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

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21 September 2021

Dr Claire Swarbrick
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Trainee Lead and PhD student
Royal Devon and Exeter Hospital NHS Trust
Anaesthetics Department
Royal Devon and Exeter Hospital (Wonford)
Barrack Road
EX2 4EQ

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/SS/0051**

Protocol number: **21002**

IRAS project ID: **302033**

Thank you for your letter of 09/09/2021. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 05 August 2021

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Other [Cover Letter to the Scotland A REC]		9 th September 2021
Participant consent form [Personal Legal Representative Consent Form Scotland]	1.2	9 th September 2021
Participant consent form [Personal Legal Representative Consent Form Scotland Clean Copy]	1.2	9 th September 2021
Participant consent form [Telephone Personal Legal Representative Consent Form Scotland]	1.2	9 th September 2021
Participant consent form [Telephone Personal Legal Representative Consent Researcher Information]	1.2	9 th September 2021
Participant consent form [Telephone Personal Legal Representative Consent Researcher Information Clean Copy]	1,2	9 th September 2021
Participant information sheet (PIS) [Personal Legal	1.2	9 th September 2021

Representative Clean Copy]		
Participant information sheet (PIS) [Personal Legal Representative]	1.2	9 th September 2021
Participant information sheet (PIS) [Telephone Personal Legal Representative Information Sheet Scotland]	1.2	9 th September 2021
Participant information sheet (PIS) [Telephone Personal Legal Representative Information Sheet Scotland Clean Copy]	1.2	9 th September 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_02072021]		02 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
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 6 Highest Education Level]	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 [Delegation Log]	1.0	
Other [Royal College of Anaesthetists Funding Letter]	1.0	03 June 2021
Other [Professional indemnity cover letter]	1.0	20 July 2020
Other [Initial Assessment Letter HRA]		08 June 2021
Other [Wales REC 7 FOWC Letter]		28 June 2021
Other [REC Favourable Opinion Letter]		06 July 2021
Other [HRA Approval Letter]		06 July 2021
Other [Response to FOWC From Wales REC 7]		01 July 2021
Other [Cover Letter to the Scotland A REC]		09 September 2021
Participant consent form [Consent form, England & Wales]	1.0	28 May 2021
Participant consent form [Consent form, Northern Ireland]	1.0	28 May 2021

Participant consent form [Patient facing information matrix per country]	1.0	28 May 2021
Participant consent form [Consent Form Scotland]	1.1	24 June 2021
Participant consent form [Personal Legal Representative Consent Form Scotland]	1.2	09 September 2021
Participant consent form [Personal Legal Representative Consent Form Scotland Clean Copy]	1.2	09 September 2021
Participant consent form [Telephone Personal Legal Representative Consent Form Scotland]	1.2	09 September 2021
Participant consent form [Telephone Personal Legal Representative Consent Researcher Information Clean Copy]	1.2	09 September 2021
Participant consent form [Telephone Personal Legal Representative Consent Researcher Information]	1.2	09 September 2021
Participant information sheet (PIS) [Participant Information Sheet England & Wales]	1.0	28 May 2021
Participant information sheet (PIS) [Participant Information Sheet Northern Ireland]	1.0	28 May 2021
Participant information sheet (PIS) [Summary Participant Information Sheet England, Northern Ireland, Scotland and Wales]	1.0	28 May 2021
Participant information sheet (PIS) [Participant Information Sheet Scotland]	1.1	24 June 2021
Participant information sheet (PIS) [Regaining Capacity Participant Information Sheet Scotland]	1.1	24 June 2021
Participant information sheet (PIS) [Personal Legal Representative Clean Copy]	1.2	09 September 2021
Participant information sheet (PIS) [Personal Legal Representative]	1.2	09 September 2021
Participant information sheet (PIS) [Telephone Personal Legal Representative Information Sheet Scotland]	1.2	09 September 2021
Participant information sheet (PIS) [Telephone Personal Legal Representative Information Sheet Scotland Clean Copy]	1.2	09 September 2021
Referee's report or other scientific critique report [Scientific Critique Email Thread BGS]		28 May 2021
Research protocol or project proposal [SNAP 3 Protocol]	1.0	28 May 2021
Summary CV for Chief Investigator (CI) [Iain Moppett CV]		28 May 2021
Summary CV for student [CV for Claire Swarbrick]		28 May 2021
Summary CV for supervisor (student research) [CV for Judith Partridge]		06 July 2021
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Lay Summary]	1.0	24 June 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 (CFS)]		

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: 302033	Please quote this number on all correspondence
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Yours sincerely

Manx Neill

Manx Neill
Scotland A/B REC Manager

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Copy to: Lead Nation: England: approvals@hra.nhs.uk