

Dr Louise Savic
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Email: hra.approval@nhs.net

30 January 2018

Dear Dr Savic

Letter of HRA Approval

| | |
|-------------------------|---|
| Study title: | What is the prevalence, accuracy and impact of drug allergy labelling in the elective surgical population, and how do anaesthetists respond to these labels? |
| IRAS project ID: | 232512 |
| REC reference: | 17/LO/2106 |
| Sponsor | Research and Innovation Centre, Leeds Teaching Hospitals Trust |

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from the [HRA website](#).

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The 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.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the [HRA website](#), and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the [HRA website](#).

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found through [IRAS](#).

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the [HRA website](#).

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details on the [HRA website](#).

Your IRAS project ID is **232512**. Please quote this on all correspondence.

Yours sincerely

Maeve Ip Groot Bluemink
Assessor

Email: hra.approval@nhs.net

Copy to: Anne Gowing, Leeds Teaching Hospitals Trust – Sponsor & Lead R&D Contact

Appendix A - List of Documents

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

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|--|----------------|-------------------|
| Copies of advertisement materials for research participants [Advertising poster] | 2.0 | 21 November 2017 |
| Covering letter on headed paper [Cover letter] | 1 | 23 November 2017 |
| IRAS Application Form [IRAS_Form_23112017] | | 23 November 2017 |
| Other [PIL - Healthy Controls] | 2 | 18 December 2017 |
| Other [Schedule of Events] | 1 (HRA final) | 30 January 2018 |
| Other [Statement of Activities] | 1 (HRA final) | 25 January 2018 |
| Other [DALES Info] | 1.0 | 20 December 2017 |
| Other [Anaesthetist Survey] | | 17 December 2017 |
| Other [Antibiotic Follow Up] | | 17 December 2017 |
| Other [Opioid Analgesia Follow Up] | | 17 December 2017 |
| Other [Patient Survey -Online] | | 17 December 2017 |
| Research protocol or project proposal [Protocol] | 3.3 | 21 November 2017 |
| Summary CV for Chief Investigator (CI) [CV] | 1 | 18 September 2017 |

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability and Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Anne Gowing

Tel: 01132060469

Email: anne.gowing@nhs.net

HRA assessment criteria

| Section | HRA Assessment Criteria | Compliant with Standards | Comments |
|---------|---|--------------------------|--|
| 1.1 | IRAS application completed correctly | Yes | No comments |
| 2.1 | Participant information/consent documents and consent process | Yes | The Applicant confirmed that a separate staff PIS will not be used. The Applicant confirmed that the research team is also considered part of the direct care team. |
| 3.1 | Protocol assessment | Yes | No comments |
| 4.1 | Allocation of responsibilities and rights are agreed and documented | Yes | A Statement of Activities has been submitted and it is intended for this to be used as the contract between the Sponsor and NHS sites. |
| 4.2 | Insurance/indemnity arrangements assessed | Yes | NHS indemnity will apply for the design and management of the study as well as for the conduct of the study while on NHS premises/under the duty of care of |

| Section | HRA Assessment Criteria | Compliant with Standards | Comments |
|---------|--|--------------------------|--|
| | | | the NHS. Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study |
| 4.3 | Financial arrangements assessed | Yes | External funding has been secured from the National Institute of Academic Anaesthesia There will be no financial provisions to the sites. |
| 5.1 | Compliance with the Data Protection Act and data security issues assessed | Yes | The Applicant confirmed that even though some questions in the questionnaires related to very rare allergies, no patient should be identifiable after anonymisation. |
| 5.2 | CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed | Not Applicable | No comments |
| 5.3 | Compliance with any applicable laws or regulations | Yes | No comments |
| 6.1 | NHS Research Ethics Committee favourable opinion received for applicable studies | Yes | REC Favourable Opinion was issued by the London - Hampstead REC. |
| 6.2 | CTIMPS – Clinical Trials Authorisation (CTA) letter received | Not Applicable | No comments |
| 6.3 | Devices – MHRA notice of no objection received | Not Applicable | No comments |
| 6.4 | Other regulatory approvals and authorisations received | Not Applicable | No comments |

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There is one type of participating NHS organisation in England; therefore, there is only one site type.

The Applicant confirmed that circa 200 NHS/HSC organisations from England, Northern Ireland, Scotland and Wales will be invited to participate. These are yet to be identified and will be submitted as an amendment.

The following organisations have currently been confirmed:

- 1) Leeds Teaching Hospitals Trust
- 2) Bradford Teaching Hospitals Trust
- 3) Huddersfield and Halifax NHS Trust
- 4) East Cheshire NHS Trust
- 5) Mid Cheshire Hospitals NHS Foundation Trust
- 6) Southport and Ormskirk Hospital NHS Trust
- 7) Warrington and Halton Hospitals NHS Foundation Trust
- 8) Countess of Chester Hospital NHS Foundation Trust
- 9) Wirral University Teaching Hospital NHS Foundation Trust
- 10) St Helens and Knowsley Hospitals NHS Trust
- 11) Royal Liverpool and Broadgreen University Hospitals NHS Trust
- 12) Aintree University Hospital NHS Foundation Trust
- 13) United Lincolnshire Hospitals NHS Trust
- 14) Derby Teaching Hospitals NHS Foundation Trust
- 15) Nottingham University Hospitals NHS Trust
- 16) Sherwood Forest Hospitals NHS Trust
- 17) Chesterfield Royal Hospital NHS Foundation Trust
- 18) Kettering General Hospital NHS Foundation Trust
- 19) University Hospitals of Leicester NHS Trust

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England **will be expected to formally confirm their capacity**

and capability to host this research.

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
- The [Assessing, Arranging, and Confirming](#) document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

Principal Investigators (PIs) are expected for this type of study. Support has been requested to identify PIs at sites.

Local staff will be provided with a study guide and are expected to have undertaken GCP training.

GCP training is not a generic training expectation, in line with the [HRA/MHRA statement on training expectations](#).

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

Use of identifiable patient records held by an NHS organisation to identify potential participants without their prior consent should be undertaken by a member of the direct care team for the patient, so it would not normally be acceptable for this to be done by staff not employed by that organisation.

The activities at the participating NHS organisation will be undertaken by local staff therefore it is expected that adequate contractual relationship with the host organisation are already in place.

Where contractual arrangements are not already in place, network/external staff (or similar) undertaking research activities would be expected to obtain Honorary Research Contracts on the basis of a Research Passport (if university employed) or a Letter of Access on the basis of an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). Standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.

Further to the submission of the IRAS Form, the Applicant has confirmed via email that they intend to apply for inclusion on the NIHR CRN Portfolio