Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Drug Allergy Labels in the Elective Surgical Population

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

(●) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

[x] England
[x] Scotland

- [x] Wales
- [ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

- [x] IRAS Form
- [ ] Confidentiality Advisory Group (CAG)
- [ ] Her Majesty's Prison and Probation Service (HMPPS)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

( ) Yes (•) No

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

( ) Yes (•) No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

( ) Yes (•) No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Drug Allergy Labels in the Elective Surgical Population

Please complete these details after you have booked the REC application for review.

REC Name:
London-Bloomsbury REC

REC Reference Number:
17/LO/2016

Submission date:
23/11/2017

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

What is the prevalence, accuracy and impact of drug allergy labelling in the elective surgical population, and how do anaesthetists respond to these labels?

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Louise	Savic
Post	Consultant Anaesthetist		
Qualifications	MBBS, MRCP, FRCA		
ORCID ID			
Employer	Leeds Teaching Hospitals Trust		
Work Address	St James' University Hospital		
	Beckett Street		
	Leeds		
Post Code	LS9 7TF		
Work E-mail	louise.savic@nhs.net		
* Personal E-mail	louise.savic@nhs.net		

Work Telephone

* Personal Telephone/Mobile 07967316967

Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
		Anne	Gowing
Address	Research and Innovation Department		
	Research and Innovation Centre		
	St James' University Hospital, Leeds		
Post Code	LS9 7TF		
E-mail	anne.gowing@nhs.net		
Telephone	01132060483		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):

Sponsor's/protocol number:

Protocol Version:

Protocol Date:

Funder's reference number:

Project website:

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Self-reported drug allergies are common in the surgical population. Allergy labels are of particular concern for anaesthetists, whose patients are exposed to a wide range of drugs during the peri-operative period. Unfortunately, many of these labels are based on reactions not indicative of true allergy, but rather of side effects or other non-allergic phenomena. Allergy labels must be interpreted on the day of surgery, and may significantly influence peri-operative drug prescribing.

The avoidance of drugs due to an allergy label is potentially harmful, with important drugs unnecessarily avoided, and alternatives given which may be less effective and more toxic. A good example is the 'penicillin allergy' label. Around 10% of the population report penicillin allergy, but fewer than 5% of these will actually be allergic. Use of broad spectrum alternatives is detrimental to patients and healthcare services. Other examples relevant to anaesthesia include spurious allergy labels for opiates and non-steroidal pain killers; the impact of these has not been assessed previously.

We aim to define the prevalence of drug allergy labelling in the UK surgical population, and to determine the proportion of these labels which are likely to reflect true allergy. For a sub-set of allergy labels, we will study their impact on peri-operative prescribing. We will also conduct an attitude and knowledge-based survey of anaesthetists, to explore understanding of drug allergies, the effect of allergy labels on prescribing habits, and ideas to help reduce the burden of inaccurate labelling in the future.

This study will consist of a patient questionnaire administered on the day of surgery, for three consecutive days, and a survey for all anaesthetists to complete. We hope to offer participation in the study to 18,000 patients from over 200 UK NHS sites, and more than 1000 anaesthetists.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

This study will pose minimal inconvenience, and no risk, for participants. We will be collecting information which is routinely collected on the day of surgery, but then using this information in a different way. To reflect this, we plan to implement an electronically-enhanced form of verbal consent. This will minimise the time and inconvenience for patients wishing to take part, whilst providing specific safeguards to ensure that investigators explicitly gain patient consent before proceeding to the questionnaire.

All precautions will be taken to safeguard patient data and ensure confidentiality. There is no follow-up beyond the day of data collection, and all data will be pseudo-anonymised on a secure electronic database. Whilst individual sites will have local data returned to them at the end of the study, this will not include patient level identifiers, and will only consist of an executive summary for the site and for the study as a whole without any patient-level identifiers.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis

- [x] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [ ] Qualitative research
- [x] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

1. What is the prevalence of self-reported drug allergies in the UK elective surgical population?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

Secondary questions are:

1. What proportion of drug allergy labels represent

a) probable drug allergy

b)probable side-effects or other non-allergic phenomena

c)non-drug allergies?

2. What is the effect of opioid and penicillin allergy labels on peri-operative prescribing of these drugs by anaesthetists?

3. What are the knowledge and attitudes of anaesthetists towards drug allergy, and drug allergy labelling?

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Drug allergy labels are of particular interest to anaesthetists, given the wide range of drugs which a patient may require or be exposed to during the peri-operative period. It is widely accepted that many allergy label are inaccurate, with side effects or other non-allergic phenomena mis-attributed to allergy. These inaccurate labels can themselves cause harm through unnecessary avoidance of drugs and use of alternatives. Penicillin allergy labels are an example of this - with 90-98% labels being incorrect, and the label itself associated with increased risk of Clostridium difficile, MRSA, longer hospital stay and other poor outcomes.

The prevalence of drug allergy labels has not been studied in the UK elective surgical population. Prevalence in the worldwide literature varies widely; In Canada a study of 1818 adult and paediatric patients interviewed found that 28.1% claimed to have one or more drug allergies. More women than men claimed to have drug allergies (60.3% vs 39.7%) and there was a positive correlation between age, number of medications and reported drug allergies. Antibiotics (50%), opioids (27%), non-steroidal anti-inflammatory agents (10%), and sedatives (5%) accounted for 92% of all claimed drug allergies. Overall, 50% of claimed allergies had a high probability of true allergic reactions. In Spain a prospective study of 1439 surgical patients reported drug allergies in 8.3% (119/1439); 3.6% considered themselves allergic to β-lactams and 2.4% to non-steroidal anti-inflammatory drugs. In Serbia, a study of 1126 surgical patients demonstrated q 38% drug allergy prevalence; the most common allergens were antibiotics (68%), nonsteroidal anti-inflammatory drugs (16.4%) and iodine (3.9%). Women, urban residents and herbal drug consumers were more likely to state an allergy. Retrospective chart review revealed that 26 (6%) patients were administered the drug to which they had reported allergic reaction in the past, with no adverse effects.

In this study we aim to identify the prevalence of drug allergy labels (including those labels applied for non-drug allergy problems, as are frequently seen in clinical practise), and to catagorise these reactions on the basis of reported symptoms, into high or low likelihood of true allergy. This is the first time this has been studied in the UK, to the investigators' knowledge. We will also assess the impact of specific allergy labels on peri-operative prescribing;

opiate allergy and penicillin allergy patients will be followed up on the day of surgery to determine which (if any) alternative opiates and antibiotics are used. In addition, the knowledge and attitudes of anaesthetists will be explored; in particular the effect of drug allergy labelling on prescribing habits, and views on how to reduce the burden of inaccurate drug allergy labelling.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Adult patients attending for elective surgery on 3 consecutive days across all participating sites will be considered for inclusion. All patients will be given a patient information leaflet about the study when they arrive in hospital; this will generally be given in the pre-surgical waiting area where they wait to be seen by the surgeon and anaesthetist.

1. Patients will be approached by a member of the study team, who will be an anaesthetic trainee. They will be asked if they have any allergies.

2. If the answer is no, and the wristband confirm this, there will be no further interaction.

3.If they answer 'yes' they will be asked of they have read the PIL, if they are happy to take part, and if they have any questions.

4. If they answer 'no', but have a drug allergy label applied to their wrist, they will be treated as for patients in Q3 above.

4. Verbal consent will then be taken by the anaesthetist. The patient confirm this electronically on the handheld device used by the trainee conducting the survey.

5. The patient will then be asked detailed questions about each of their listed allergies. For most patients, this will take less than 10 minutes. Patients will be given the same degree of privacy while completing the questionnaire as is afforded them during the routine surgical and anaesthetic review required before surgery; i.e. curtains drawn where possible, or side room used if patient already in one.

6. Once the questionnaire is complete, no further participation is required. For a subgroup of patients, follow up on the day of surgery will be completed by examining the anaesthetic chart and post operative care record; this will not require further interaction with the patient.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
We have involved the Health Services Research Council's (HSRC) Patient, Carer and Public Involvement and Engagement (PCPIE) group to assist us in lay representation in the project. This has been done through the HSRC board meeting where DALES was presented and also in an additional presentation to the PCPIE biannual education day. Both the lay representative present at the HSRC meeting and those present the PCPIE meeting were very positive and supportive of the project and they have offered to be involved in the reviewing the questionnaire and information sheets in more detail, for which we are very grateful. We will continue to work with PCPIE to ensure an ongoing lay perspective into the project.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [x] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [x] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [x] Musculoskeletal
- [x] Neurological
- [x] Oral and Gastrointestinal
- [ ] Paediatrics
- [x] Renal and Urogenital
- [x] Reproductive Health and Childbirth
- [x] Respiratory
- [x] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit:	Years
Upper age limit:	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

1. Adult >18 years of age undergoing planned (elective) surgery
2. Able to consent
3. Willing to participate
4. Patients reports having allergies.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

1. Age <18 years
2. Unable to consent
3. Unwilling to participate
4. Patients currently being held as prisoners

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Consent	1	0	<5mins	Member of the study team, in surgical waiting area
Questionnaire	1	0	10 mins	Member of the study team, in surgical waiting area

A21. How long do you expect each participant to be in the study in total?

All data collection, including the follow up aspects of the study, will be completed in one day. Once participants have completed the questionnaire in the surgical waiting area, no further interaction with the study team will take place.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Participants will be approached on the day of surgery, and asked questions about their drug allergies. This represents a degree of inconvenience, during a potentially stressful time. However these are questions which would be routinely asked on the day of surgery, by members of their own healthcare team and are not stressful or difficult to answer.
In order to minimise the burden to participants whilst also ensuring a robust consent process, we have chosen to implement an electronically-enhanced form of verbal consent. Specific checks and safeguards are in place in the online form to ensure that a named investigator must explicitly gain patient consent to proceed to the survey. We believe this represents a proportionate, pragmatic approach for data collection in this study, preventing a more lengthy written consent process which would be overly cumbersome for both patient and participant. This is in line with recent HRA guidance on proportionate consent processes.
These are no risks to the patient from taking part in this study, and no change to standard care.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

○ Yes ◉ No

A24. What is the potential for benefit to research participants?

There are no benefits for participants in taking part in this study.

A26. What are the potential risks for the researchers themselves? *(if any)*

None.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

This is an opportunistic study, studying the population of patients attending for elective surgery on the data collection days. There will be no attempt to identify participants prior to this.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

A poster advertising the study will be displayed in the surgical waiting area.

A29. How and by whom will potential participants first be approached?

Potential participants will be approached by a member of the study team on the day of surgery.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

For eligible participants, verbal consent (with electronic recording and safeguards) will be taken by a member of the study team on the day of surgery. Participants are given a patient information leaflet prior to being approached by the study team, and will be asked if they have any questions about the study. Patients requiring interpreting services will be be included if an interpreter or language line service is available.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

○ Yes ◉ No

If No, how will it be recorded?

Verbal consent will be confirmed by the participant ticking the appropriate box on the electronic hand held device which the study team member is using to complete the questionnaire.

A31. How long will you allow potential participants to decide whether or not to take part?

Due to the opportunistic nature of recruitment (a snapshot of surgical patients over 3 days), there is limited time for

participants to decide whether to take part. A 20 minute minimum will be applied from giving the patient the patient information leaflet to approaching them to ask if they are happy to take part. However this reflects the low burden for the patient in terms of intervention and risk, from participating.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Where participants lack sufficient language skills to take part, an interpreter will be used. This is generally available anyway for such patients, who need to give surgical and anaesthetic consent on the day of surgery. Where this facility is not practicable, patients will be considered ineligible for inclusion.
Patients who lack capacity to consent will not be eligible for inclusion.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

Participating sites in Wales will provide the PIL in Welsh.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☐ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals

- [ ] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [ ] Manual files (includes paper or film)
  - [x] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [ ] University computers
  - [ ] Private company computers
  - [x] Laptop computers

Further details:
All data will be collected via a web browser, used on secure handheld devices. 'Secure' includes any device deemed secure enough to access NHS emails. Access is via encrypted webpages, with no information stored on the device in question, but rather information going directly to a secure NHS server. Data access is one-way for local level investigators.

A37. Please describe the physical security arrangements for storage of personal data during the study?

All data collection is electronic, with data pseudoanonymised before upload via an encrypted web browser connection directly to a secure NHS server. Notably no data is stored on the device with which it was originally collected; front-line data collectors also have no access to the master data set.

Pseudoanonymised data submitted to the cebtral research team via the encrypted online portal REDCap will be stored on NHS National Services Scotland (NSS) secure SHOW (Scottish Health On the Web) network servers. These are protected both physically and electronically. After collation at NSS SHOW, the data will be transferred to the host site (Leeds) for final analysis and data storage.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

All data will be pseudo-anonymised and no identifiable data will be accessed by anyone outside of the study team. All data collectors have completed GMP training.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Only local investigators will have access to participants personal data.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Members of the study team, including a statistical, will have access to the data after the study, for the purposes of analysis. All data will be anonymised.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Louise	Savic
Post		Anaesthetic Consultant	

Qualifications	MBBS, MCRP, FRCA
Work Address	St James'University Hospital
Post Code	LS97TF
Work Email	louise.savic@nhs.net
Work Telephone	07967316967
Fax	

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ◉ 6 – 12 months
- ○ 12 months – 3 years
- ○ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 10
Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended.*Say where data will be stored, who will have access and the arrangements to ensure security.*

The final anonymised patient dataset will be stored electronically on a secure computer at the host organisation (Leeds Teaching Hospitals NHS Trust). The study team and R & D sponsor will have access to this dataset.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◉ Yes ○ No

Please give details, or justify if not registering the research.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study?*Tick as appropriate:*

☑ Peer reviewed scientific journals
☑ Internal report
☑ Conference presentation
☑ Publication on website
☑ Other publication
☐ Submission to regulatory authorities
☑ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
☐ No plans to report or disseminate the results
☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

No identifiable personal data will be used for the study. Where patients state they have a penicillin or opioid allergy, they will be pseudo-anonymised for the purposes of same-day follow up by a member of the study team.

A53. Will you inform participants of the results?

○ Yes ◉ No

Please give details of how you will inform participants or justify if not doing so.
The scale of the study precludes dissemination of results to individual participants.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed?*Tick as appropriate:*

☑ Independent external review

☐ Review within a company

☑ Review within a multi−centre research group

☑ Review within the Chief Investigator's institution or host organisation

☑ Review within the research team

☐ Review by educational supervisor

☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
This project has developed by an expert steering committee, which includes both internal and external expertise in the field of drug allergy and microbiology. The study aims and objectives have been extensively reviewed and modified following presentation in national forums including the Health Science Research Centre, and have been peer viewed by the networks who will perform the data collection.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed?*Tick as appropriate:*

☐ Review by independent statistician commissioned by funder or sponsor

☐ Other review by independent statistician

☐ Review by company statistician

☐ Review by a statistician within the Chief Investigator's institution

☐ Review by a statistician within the research team or multi−centre group

☐ Review by educational supervisor

☐ Other review by individual with relevant statistical expertise

☑ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

Title Forename/Initials Surname

Department
Institution
Work Address

Post Code
Telephone
Fax
Mobile
E-mail

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

To determine the prevalence of drug allergy labels in elective surgical patients.

A58. What are the secondary outcome measures?*(if any)*

1. To determine the proportion of drug allergy labels that are likely to represent true allergy

2. To determine the impact of a penicillin allergy label on peri-operative antibiotic prescribing of antibiotics

3. To determine the impact of opioid allergy labels on peri-operative prescribing of opioids

4. To explore the understanding and attitudes around drug allergy labels among anaesthetists, and the impact of such labels on prescribing habits peri-operatively.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 20000
Total international sample size (including UK):
Total in European Economic Area:

Further details:
Based on previous studies by the RAFT network, we anticipate approaching 18,000 patients on the day of surgery, around 4,500 anaesthetists.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

This is an opportunistic, snap-shot study. Estimated sample size is based on previous experience with the group facilitating data collection.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Simple statistical analysis of proportions and incidence.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Beverley	Parker
Post	Anaesthetic registrar		
Qualifications	FRCA		
Employer	Leeds Teaching Hospitals NHS Trust		
Work Address	St James' University Hospital		
	Beckett Street		
	Leeds		

Post Code	LS97TF
Telephone	
Fax	
Mobile	07525153688
Work Email	bevp@doctors.net.uk

Title	Forename/Initials	Surname
Dr	Caroline	Thomas

Post	Anaesthetic Consultant
Qualifications	FCRA
Employer	Leeds Teaching Hospitals NHS Trust
Work Address	St James' University Hospital, Beckett Street Leeds
Post Code	LS9 7TF
Telephone	
Fax	
Mobile	07930651918
Work Email	caroline.thomas27@nhs.net

Title	Forename/Initials	Surname
Dr	David	Fallaha

Post	Anaesthetic Consultant
Qualifications	MBChB, BSc, MRCP, FRCA, FFICM
Employer	Golden Jubilee National Hospital
Work Address	Agamemnon Street Clydebank
Post Code	G81 4DY
Telephone	
Fax	
Mobile	07736438544
Work Email	david.fallaha@nhs.net

Title	Forename/Initials	Surname
Dr	Sam	Clark

Post	Anaesthetic trainee
Qualifications	BSc, FRCA, FFICM
Employer	Oxford University Hospitals Foundation Trust
Work Address	John Radcliffe Hospital, Headley Way Oxford
Post Code	
Telephone	
Fax	
Mobile	07921237431
Work Email	samhclark@aol.com

	Title	Forename/Initials	Surname
	Dr	Sinisa	Savic
Post	Immunology Consultant		
Qualifications	MRCP, FRC(Path)		
Employer	Leeds Teaching Hospitals NHS Trust		
Work Address	St James University Hospital		
	Beckett Street		
	Leeds		
Post Code	LS97TF		
Telephone			
Fax			
Mobile	07900224489		
Work Email	sinisa.savic@nhs.net		

	Title	Forename/Initials	Surname
	Professor	Philip	Hopkins
Post	Professor of Anaesthesia		
Qualifications	FRCA, MD		
Employer	Leeds Teaching Hospitals NHS Trust		
Work Address	Leeds Teaching Hospital		
	Beckett street		
	Leeds		
Post Code	LS97TF		
Telephone			
Fax			
Mobile			
Work Email	p.m.hopkins@leeds.AC.UK		

	Title	Forename/Initials	Surname
	Dr	Jonathon	Sand
Post	Medical Microbiologist and Associate Clinical Professor		
Qualifications	MB Ch B, FRC(Path), PhD		
Employer	Leeds Teaching Hospitals NHS Trust		
Work Address	Leeds Teaching Hospitals NHS Trust		
	Beckett Street		
	Leeds		
Post Code	LS97TF		
Telephone			
Fax			
Mobile			
Work Email	jonathon.sandoe@nhs.net		

	Title	Forename/Initials	Surname
	Dr	Chris	Rutkowski
Post	Consultant Allergist		
Qualifications	MD, MRCP		
Employer	Guys and St Thomas' NHS Foundation Trust		
Work Address	St Thomas' Hospital		
	Westminster Bridge Road		
	London		

Post Code	SE17EH
Telephone	
Fax	
Mobile	
Work Email	chris.rutkowski@gstt.nhs.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- (●) NHS or HSC care organisation
- ( ) Academic
- ( ) Pharmaceutical industry
- ( ) Medical device industry
- ( ) Local Authority
- ( ) Other social care provider (including voluntary sector or private organisation)
- ( ) Other

Commercial status:

If Other, please specify:

Contact person

Name of organisation	Research and Innovation Centre
Given name	Anne
Family name	Gowing
Address	St James' University Hospital
Town/city	Leeds
Post code	LS97TF
Country	
Telephone	01132060469
Fax	
E-mail	anne.gowing@nhs.net

Is the sponsor based outside the UK?

( ) Yes (●) No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☐ Funding secured from one or more funders

☑ External funding application to one or more funders in progress

☐ No application for external funding will be made

What type of research project is this?

◉ Standalone project

○ Project that is part of a programme grant

○ Project that is part of a Centre grant

○ Project that is part of a fellowship/ personal award/ research training award

○ Other

Other – please state:

Please give details of funding applications.

Organisation	National Institute of Academic Anaesthesia
Address	Churchill House 35 Red Lion Square
Post Code	WC1R 4SG
Telephone	02070921677
Fax	
Mobile	
Email	

Funding Application Status: ○ Secured ◉ In progress

Date Funding decision expected: 31/12/2017

Amount: £10,000

Duration

Years: 1

Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

Patient safety and clinical outcomes are the 2 priority areas met by this project.

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

○ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the

reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
		Anne	Gowing
Organisation	Research and Innovation Department		
Address	Research and Innovation Centre		
	Leeds Teaching Hospitals NHS Trust		
	Beckett Street, Leeds		
Post Code	LS97TF		
Work Email	anne.gowing@nhs.net		
Telephone	01132060469		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/01/2018
Planned end date: 01/01/2019
Total duration:
Years: 1 Months: 0 Days: 1

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☑ Scotland
- ☑ Wales
- ☑ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 200

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

- ☑ NHS organisations in England
- ☑ NHS organisations in Wales
- ☑ NHS organisations in Scotland

- [x] HSC organisations in Northern Ireland
- [ ] GP practices in England
- [ ] GP practices in Wales
- [ ] GP practices in Scotland
- [ ] GP practices in Northern Ireland
- [ ] Joint health and social care agencies (eg community mental health teams)
- [ ] Local authorities
- [ ] Phase 1 trial units
- [ ] Prison establishments
- [ ] Probation areas
- [ ] Independent (private or voluntary sector) organisations
- [ ] Educational establishments
- [ ] Independent research units
- [ ] Other (give details)

Total UK sites in study: 0

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The study will be subject to routine monitoring by the Joint University/Trust Quality Assurance Team.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:* in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland**

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- [x] NHS indemnity scheme will apply (NHS sponsors only)
- [ ] Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- [x] NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- [ ] Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- [x] NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- [ ] Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ◉ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site	Investigator Name	
IN1	(●) NHS site ( ) Non-NHS site	Forename	louise
		Middle name	
		Family name	savic
	Country: England	Email	louise.savic@nhs.net
		Qualification (MD...)	MBBS, MRCP, FRCA
		Country	UNITED KINGDOM
	Organisation name		
	Address		
	Post Code		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

◯ Chief Investigator

- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr Louise Savic on 23/11/2017 14:17.

Job Title/Post:

Organisation:

Email: louise.savic@nhs.net

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Mrs Anne Gowing on 23/11/2017 14:18.

Job Title/Post:	Research Governance Manager
Organisation:	Leeds Teaching Hospitals NHS Trust
Email:	anne.gowing@nhs.net