Application for inclusion of a research project

All sections must be completed before submitting this form to the data protection team.

All research projects using personal data must be registered with the UCL Data Protection Officer **before the data is collected.** This includes projects approved by the Joint Research Office.

It is rarely necessary to store electronic personal data on portable devices such as laptops, USB flash drives, portable hard drives, CDs, DVDs, or any computer not owned by UCL. Similarly, manual personal data should not be regularly removed from UCL premises. In the case of electronic data, to minimise the risk of loss or disclosure, a secure remote connection to UCL should be used wherever possible.

The UCL Computer Security Team has published guidance on the storage of sensitive data on portable devices and media which is available at http://www.ucl.ac.uk/cert/GuidanceStorageSensitiveData.html .

If storing sensitive data on portable devices or media all data must be strongly encrypted. ADS general encryption guidance is available at http://www.ucl.ac.uk/isd/staff/ads/help/guides/encryption .

Manual personal data and portable electronic devices should be stored in locked units, and they should not be left on desks overnight or in view of third parties.

Anonymised data Projects using anonymised data do not have to be registered with the Data Protection Team and you do not have to worry about compliance with the Act.

Data is only truly anonymised if it is impossible to identify subjects from that information and, if relevant, any other information that UCL holds. For example, if you have a list of research subjects and anonymise it by giving each one a number, but keep a list of the numbers with the names of the subjects, the information has not been anonymised. In this case, it is personal data, and the project must be registered with the Data Protection Team.

Approval We may have some questions about the information you provide, but you will normally be provided with a registration number within a week of submitting the form. However, the period leading up to meetings of the Ethics Committee is always very busy, and you should allow more time for your application to be processed. It is therefore very important to check in good time whether you need to register your project.

Please note that Data Protection Registration numbers will **NOT** be issued when you submit an application form in person to the Data Protection Team.

Please submit this form electronically and send to data-protection@ucl.ac.uk with copies of any information sheets and consent forms that you are using.

UCL Data Protection website

http://www.ucl.ac.uk/finance/legal_services/data_protection/data_protection.php

Any queries regarding this form please contact 020 3108 3128 (internal extension 53128)

This form will be returned to you with the appropriate registration number, which you may quote on your Ethics Application Form, or any other related forms.

Finance and Business Affairs
Legal Services
6th Floor, 1-19 Torrington Place
London WC1E 7HB

January 2012

Application for inclusion of a research project Form 9

A. APPLICATION DETAILS

A1	**Project Title:** **Intraoperative Hypotension in Elder Patients (IHypE)**	
	Date of Submission:	Proposed Start Date: 01/10/2016
	UCL Ethics Project ID Number: 15/0970	Proposed End Date: 02/11/2016

A2	**Principal Researcher** *(Please note that a student – undergraduate, postgraduate or research postgraduate cannot be the Principal Researcher for Ethics purposes).*	
	Full Name: Dr Daniel Martin	
	Position Held: Consultant in Anaesthesia and Critical Care, Senior Lecturer, UCL Division of Surgery and Interventional Science	
	Address: Royal Free London NHS Foundation Trust, Department of Anaesthesia, Royal Free Hospital, London, NW3 2QG	
		Email: daniel.martin@ucl.ac.uk
		Telephone: 020 3447 2838

A3	**Data Collector(s) Details** *(if Applicant is not the Principal Researcher e.g. student details)***:**	
	Full Name: Dr Alex Wickham	
	Position Held: Trainee lead	
	Address: 21 Isis Close, London, SW15 6JY	
		Email: alex.wickham@nhs.net
		Telephone: 07734819931

B. DETAILS OF THE PROJECT

B1 Please provide a brief summary of the project

Background:
Low blood pressure during surgery (also known as intraoperative hypotension or IOH) is thought to be a common occurrence. It happens as a side effect of the medicines used during an anaesthetic. In patients aged over 65 years this may lead to an increased risk heart attack, stroke, kidney failure and death following surgery. This risk increases as the degree and duration of low blood pressure increases. Patients aged over 65 years are at increased risk because their body is less able to cope with low blood pressure. Quantifying the prevalence of IOH has been problematic as it lacks a clear and universally accepted definition.

Objectives:
We aim to determine how often IOH occurs in patients aged 65 years and over throughout the UK. We also aim to discover what blood pressure anaesthetists consider to be too low, how they subsequently treat this low blood pressure and their perceptions of its overall importance. We can use this information to describe what practicing UK anaesthetists think constitutes IOH. We will also identify any patients

suffering a stroke, heart problem, kidney injury or death after surgery to identify the risk level of the older surgical population.

Design:
Using an already established national audit and research network, we will conduct this study across multiple hospitals simultaneously throughout the UK. We will review the paper or electronic anaesthetic charts of patients undergoing surgery and record instances of IOH, its magnitude and duration. Other key medical and demographic information will be recorded for each patient. Data will be collected for a total of 48 hours at each hospital. Patients included in the study will be followed up to assess their postoperative course up to 30 days after surgery. All information will be obtained from patient records rather than face-to-face encounters. As all data collected will be anonymized and already documented as part of routine care we do not anticipate consent from participants will be necessary. All data will be entered into a common database in order for it to be analysed nationally.
The other component of the study involves giving a questionnaire to anaesthetists in participating hospitals. The questionnaire will ask about individual practice in relation to the treatment of low blood pressure during surgery. The anonymised responses will be collected and assessed to determine national consensus on this topic.

Expected outcomes:
We hope to be able to quantify the prevalence of IOH across the UK. The coordinated efforts of the network should produce a comprehensive description of the extent of IOH today, its association with important clinical complications and the view of anaesthetists on when and how to treat it.

Anticipated benefits:
Defining and quantifying this important problem will provide anaesthetists with a clear picture of its extent in the UK. This will enable quality improvement programmes to reduce IOH and the harm associated with it. Furthermore, information from this study may help to unify the definition of IOH in order for anaesthetists to more easily identify and report it.

C. DETAILS OF PARTICIPANTS

C1 **Data subjects**
Who will the personal data be collected from?

Patients aged ≥65 years old who underwent general anaesthesia or regional anaesthesia either alone or in combination for emergency or elective surgery on the study dates.

C2 **What data will be collected**
Please provide details of the type of personal data to be collected

The data being collected is already documented as part of routine care and will be anonymised prior to transfer from the hospitals where the patient is treated.

Data will be collected from paper anaesthetic charts or electronic anaesthetic records as available. All efforts will be made to gather electronically recorded data where feasible.
• Patient characteristics: age group, gender, presence of cardiovascular disease, anti-hypertensive medications.
• Blood pressure: invasive or non-invasive monitoring, preoperative, pre-induction and intraoperative minimum, treatment threshold, defined as the blood pressure prior to vasopressor administration.
• Surgery: urgency and severity, cancer surgery and surgical speciality.
• Anaesthesia: seniority of Anaesthetist, mode of anaesthesia, use of regional anaesthesia.
• Outcomes: in hospital 30-day mortality, troponin (if tested; joint ESC/ AHA definition), kidney injury

(KDIGO criteria) or CT reported ischaemic stroke within 7 days of surgery. This information will be obtained from electronic hospital records by the local investigator.

The personal data that will be collected is gender and hospital number:
- Hospital number is being collected to allow follow-up of outcomes at 30 days and will not leave the local hospital.
- Gender is being collected to define the population studied and will be held in the same database as the clinical data.

C3 **Disclosure**
Who will the results of your project be disclosed to?

Individual patient data or results will not be disclosed outside of the local anaesthesia care team. Local investigators will collect data from the anaesthesia care record. This information will be entered onto our database (hosted on NHS Scotland servers) via a secure web-based programme (Project REDCap) from password protected NHS desktop computers. The data will be stored securely on NHS servers. Patient hospital number is being collected for use when collecting outcomes information. No personal identifiable information will be transferred outside the local hospital, meaning only the local NHS staff will have access this information. The central research team will not have access any patient identifiable information beyond gender. At local sites, all data will be disposed of securely following NHS code of confidentiality, centrally, non-identifiable data will be stored on secure servers in Scotland.

D. CONSENT

D1 **Consent**
Please include the information sheet and consent forms you will be using for this project, and or protocol

If you are not including an information sheet and consent form, please explain why:

We anticipate that patient consent will not be required for this study as the dataset will only include information already recorded as part of routine clinical care, all data will be anonymised and no identifiable information (apart from gender) will be shared outside of the individual hospital where the patient is treated.
By taking consent for inclusion, we could bias the results by excluding sicker and frailer patients whose blood pressure and outcomes data is potentially the most interesting, and who, in future, would benefit most from this study's findings. Identifiable patient data (apart from gender) will not leave the hospital where each individual patient is treated. The data being collected is not sensitive or embarrassing. No additional tests or interventions are being made and no changes will be made to patient care. The clinicians collecting the data will be part of the anaesthetic department in the NHS hospital in which the patient is being treated and can therefore be considered part of the normal care team. Additionally, asking for consent would be impractical as we anticipate recruiting approximately 2000-3000 patients; in taking consent we would limit the number of patients recruited, limiting the generalisability and usefulness of the findings.
Study information will be displayed in patient areas within operating theatre departments of participating hospitals to ensure that patients can register dissent in relation to the research activity. Patients will be able to decline participation or withdraw at any time without providing a reason.
Similarly, the survey of anaesthetists (see protocol appendix 2) asks no sensitive questions and collects no anaesthetist or patient identifiable data. Information will be provided about the study for the anaesthetists.
Completion of the proforma will be considered as the anaesthetist providing their consent to be included in the study.

E. INTERNATIONAL TRANSFER

E1

International Transfer

The eighth principle of the Data Protection Act 1998 prohibits the transfer of personal data to countries or territories outside the European Economic Area (which consists of the 27 EU member states, Iceland, Liechtenstein and Norway).

At the time of writing the following countries have also been deemed adequate for the purposes of the 8th principle Argentina, Canada, Guernsey, Isle of Man, Jersey and Switzerland.

If you intend to transfer data to a country not mentioned above, please supply details of adequate safeguards below:

We will not transfer the data outside of the UK.

F. PUBLICATION

Will the results of your research be published in an academic journal or other publication? **YES** / ~~**NO**~~

Please note that published results must not contain data by which an individual can be identified.

G. NOTIFICATION

G1

Notification
(*Please note that notification is a prerequisite for registration)*

Have you informed your department's Data Protection Coordinator about your project?
YES/~~**NO**~~

In progress

G2

Notification
(*Please note that notification is a prerequisite for registration)*

Have you informed your department's computer representative about your project?
YES/~~**NO**~~

In progress

H. ETHICS

H1 Are you applying to the Joint Research Office?

	YES/~~NO~~ Date of Ethics meeting: London-West London GTAC 15/6/16 proportionate review

I. REGISTRATION

I1	**Registration:** *Office use only:*	
	UCL Data Protection Registration Number: Z6364106/2016/06/46	Data issued: 2016/06/13

Further information

For more information and guidance on the Joint Research Office, please visit http://www.ucl.ac.uk/jro/.
When all essential documents are ready to archive, contact the UCL Records Office by email at records.office@ucl.ac.uk to arrange ongoing secure storage of your research records unless you have made specific alternative arrangements with your department, or funder.

For information on the UCL Records Management Service, please visit
http://www.ucl.ac.uk/efd/recordsoffice/policy/records-transfer