

## APPLICATION TO HEALTH RESEARCH AUTHORITY

**All studies except clinical trials of investigational medicinal products**

REC Ref: 16/LO/1154

Short Title of Study: Intraoperative Hypotension in Elder Patients (IHypE)


CI Name: Dr Daniel Martin

Sponsor: University College London

**IMPORTANT:** This checklist supports an application where supporting documentation is electronically submitted, with the application form, from IRAS to the review body.

You must attach your supporting documentation to this checklist before submitting your application.



**Instructions for attaching files:**

1. Click on the file upload symbol  in the far right hand column of the row for the document you wish to submit. This opens a pop-up window where you can select the document to upload and enter details about it.
2. Select where you want to upload the document from: *Uploading from your hard drive* - select the radio button for hard drive and then click on the button immediately below to open your computer's standard file browser window. Once you have chosen the file, simply complete the fields for document title, version number and date. Click the 'upload document' button.  
*Uploading from the IRAS document storage areas called 'My documents' or 'Project Documents'* - Click the appropriate radio button to open a window showing all the documents you have saved in that IRAS storage area. Select the document you want to use, enter a name for the document and click 'Add document' button.
3. When you have attached a document to the checklist the screen will show a summary of the details. Click on 'Close' to return to the checklist and select another document.

**Notes about attaching files:**

- The field for the type of document is pre-chosen based on the item you selected in the checklist.
- All letters must be dated. All other accompanying documents must bear version numbers and dates. These will then show in your checklist.

**Notes about documents attached to this checklist:**

- All documents listed below that are applicable to the application must be submitted so that the application clearly describes the study and is complete with all required documentation.
- If a document is not attached to the checklist please state why in the "reason not supplied" field. For example if not applicable, please enter "N/A". You can add/edit information in this field by clicking .
- The CI must send all the relevant documents and files to each PI.
- This button  allows you to add extra documents of the same type
- If any documents are revised as a result of review by any other body, the revised version must be submitted.

For information on submitting the documents and files attached to this checklist please select the "E-Submission" tab.

Document	Subtitle	Enclosed	Date	Version	Office Use	Reason not supplied
<b>Project Information: (All documents must be dated and/or have version numbers)</b>						
Covering letter on headed paper		Yes	30/05/2016			
Research protocol or project proposal		Mandatory	30/05/2016	5.3		
Summary CV for Chief Investigator (CI)		Mandatory	30/05/2016			
Participant information sheet (PIS)		Yes				

Participant consent form		No				
Letters of invitation to participant		Yes	30/05/2016	2		
GP/consultant information sheets or letters		No				
Sample diary card/patient card		No				
Interview schedules or topic guides for participants		No				
Validated questionnaire		No				
Non-validated questionnaire		No				
Referee's report or other scientific critique report		Yes	30/05/2016			
Summary, synopsis or diagram (flowchart) of protocol in non-technical language	Flow Sheet	Yes	01/06/2016	1		
Copies of advertisement materials for research participants	Poster	Yes				
<b>Finance Agreements:</b>						
Letter from sponsor		No				
Letter from funder		No				
Letter from statistician	Statistician letter	Yes	01/06/2016			
Costing template (commercial projects)		No				
Contract/Study Agreement		No				
Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only)		Yes	30/05/2016			
<b>Investigator Information:</b>						
Summary CV for student		No				
Summary CV for supervisor (student research)		No				
<b>Documents required prior to Approval being issued: (in England, HRA will work with MHRA and CAG (formerly NIGB) and other regulators to receive these documents but may be in contact with researcher should there be queries)</b>						
MHRA "Notice of No Objection" Letter (Medical Devices) and relevant correspondence		No				
Confirmation of any other regulatory approvals (e.g. CAG) and all correspondence		No				
Laboratory Manual		No				
Instructions for use of medical device		No				

Other documents						
Other (please specify)	HRA Statement of Activities	Yes	30/05/2016	1		
Other (please specify)	HRA Schedule of events	Yes	30/05/2016	1		
Other (please specify)	Patient information sheet	Yes	07/08/2016	2.2		
Other (please specify)	Response to REC committee	Yes	14/07/2016	3		