University College London Hospitals NHS
NHS Foundation Trust

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Joint Research Office

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UCL Clinical Research Insurance Registration Form for CTIMPs and non-CTIMPs

What is covered?

The insurance for all UCL studies is provided by a commercial insurer. For Clinical Trials of Investigational Medicinal Products (CTIMPs) which fall under the Medicines for Human Use (Clinical Trial) Regulations 2004, the insurance policy provides two types of cover:

- Cover for claims against UCL for negligence by research participants and others
- Cover for non negligent harm to study participants, that is compensation to participants where negligence cannot, or is not proven.

For all other studies (non-CTIMPs), cover is only usually provided for the negligence of UCL or UCL employees. In exceptional circumstances and, only where the Research Ethics Committee requires it, non negligent harm cover may be available for non-CTIMPs.

Studies where the insurer needs to be notified before cover is provided

For the majority of CTIMPS and non-CTIMPs, cover is automatic and we are required only to provide the insurer with a list of all studies covered by the policy. However, for a minority of studies, in certain categories, the insurer requires prior notifications before cover can be provided. For these studies the insurer may:

- Decide that the study can go ahead with no further conditions
- Decide that the study can go ahead with the provision of an additional payment
- Refuse to provide cover.

The purpose of this form is to identify those studies where cover is not automatic and where the insurer's approval or "a waiver" is required. For example, trials which aim to enrol pregnant women or trials where subjects are under 5 at the time of study will only be covered with the approval of the insurers. Similarly, special insurance arrangements may be required for participatory sites in CTIMPs outside the UK.

Claims arising from any condition associated with CJD, vCJD or hepatitis or Human T Cell Lymphotropic Virus Type ii, or Lymphadenopathy Associated virus or AIDS contracted in the course of the study will not be accepted by the insurers, so we also need to identify those studies where this may be a risk. Studies with subjects who already have these conditions will be covered for harm as a result of participation in the trial.

If insurance can be provided automatically, an insurance confirmation letter will be issued by UCL. If a waiver is agreed, the letter will be issued by the insurer.

Who to contact

The Joint UCLH/UCL/RFH Research Office administers the form on behalf of UCL. All queries relating to UCL insurance letters or insurers waivers should be directed to david.wilson@ucl.ac.uk in the first instance.

A cover note summarising the terms and conditions of the policy is also available from david.wilson@ucl.ac.uk .

Who should complete the form?

The Chief Investigator should complete this form, though this may be delegated to a member of the research team or departmental administrator if they fully understand the details of the clinical study or trial.

The insurer requires information in layman's terms using straightforward explanations, such as you would use when explaining a study to a participant when seeking informed consent.

Depending upon your answers in **Section 1** below, it may be necessary to ask you for further information covered in **Section 2** of this form.

SECTION 1: General information

	Question	Response (If the space in this column is insufficient please expand the table.)
1	Short title of study/trial.	Intraoperative Hypotension in the Elderly: Observational Study of Intraoperative Hypotension in Elderly Patients in UK Hospitals (iHypE)
2	Name, job title and contact details of person (other than Chief Investigator for the study/trial) completing this form.	Name: Dr Alex Wickham Position: Anaesthetic Registrar Address: Department of Anaesthetics, Harefield Hospital, Harefield, Middlesex, UB9 6JH Email: alex.wickham@nhs.net Tel: 07734819931
3	Name of Chief Investigator (CI) for the study/trial.	Dr Daniel Martin
4	Does the CI for the study/trial hold a UCL contract?	Substantive ☒ Honorary ☐ No UCL contract ☐
5	If the CI is <u>not</u> a UCL employee please give full contact details.	Employer: Address: Email: Tel:
6	**<u>For UCL Student projects only:</u>** If you are undertaking a student project as a UCL registered student, please provide name and contact details of your academic supervisor.	Name of supervisor: Dept: N/A Email: Tel:
7	Is the projected total number of volunteers / participants recruited to the study greater than 5,000?	Yes ☐ No ☒

	If yes, how many will be recruited?	_____
8	Please list: - all the participating countries - anticipated nos. of patients per country outside the UK where the study/trial will be conducted.	1. England ~2000 2. Wales ~300 3. Scotland ~150 4. Northern Ireland ~150
9	Are any of these sites in the UK private or non-NHS hospitals? If yes, which?	Yes ☐ No ☒ _____
10	Do you intend to enrol private patients in NHS hospitals?	Yes ☐ No ☒
11	a) Is your study an "intervention" trial/study? An intervention trial/study is one where the research interventions are either: - a device - an investigational drug or cellular product - a procedure which requires entry into a body cavity, or - radiation including X-rays b) Are ALL interventions in the trial/study standard of care?	Yes ☐ No ☒ Yes ☒ No ☐
12	Does your study involve the use of nanotechnology either in a device or as part of a drug delivery system?	Yes ☐ No ☒
13	Is your study a Clinical Trial of an Investigational Medicinal Product (CTIMP)? *If you are unsure about this, please email david.wilson@ucl.ac.uk with full details of the study for advice including a copy of the trial protocol.* • **IF YES to Question 11a and NO to 11b i.e. intervention studies where ALL arms are not standard care.** **OR** • **YES TO Question 13 i.e. CTIMP** **THEN you are also required to complete Section 2**	Yes ☐ No ☒

SECTION 2: STUDIES REQUIRING SPECIFIC APPROVAL FROM INSURERS

If you have answered YES to Question 11 and ALL interventions are NOT standard of care OR "Yes" to question 13, please complete this section as UCL will need to identify whether the CTIMP/interventional trial or study falls within the insurance category where we are required to notify the UCL insurer.

The insurer may

- decide the study can go ahead without any additional fee,
- impose an additional insurance fee or
- refuse to insure the study.

14	Do the inclusion criteria for the CTIMP or interventional trial include a requirement for the research subject to be pregnant? If yes, please provide brief details – including whether the trial is primarily concerned with the health of the mother, or that of the unborn child.	Yes ☐ No ☐
15	Will the trial enrol over 500 participants?	Yes ☐ No ☐
16	Will children of 5 years and under be enrolled in the trial? Is the aim of the trial prophylaxis?	Yes ☐ No ☐ Yes ☐ No ☐
17	Will the study be conducted in the USA, Canada or territories within their jurisdiction?	Yes ☐ No ☐
18	Does the study use vaccines, blood products or other materials of human origin where there may be a risk from: • CJD • HIV • Hepatitis	Yes ☐ No ☐
19	Is it the intention that the Trial will be sponsored by an institution other than UCL? *If yes*	Yes ☐ No ☐

	a) Will the Trial be sponsored by GOSH NHS Trust? b) Will UCL CTC be managing the Trial? c) Will the UCL CTU be managing the Trial? *If yes to b) or c), who is the sponsor?*	Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ _____
20	Are there **any other factors** that you think you ought to draw to the underwriters' attention, to assist in their assessment of the risk? If yes please explain. *(e.g. injections that occasionally cause anaphylactic shock, new techniques)*	Yes ☐ No ☐ _____ _____

Thank you for completing this form. Please email the completed form to david.wilson@ucl.ac.uk

Date: ___26/05/2016_____