

Policy for the Organisation and Governance of Medical Training Courses Comprising Interventional Procedures Involving Patients

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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

This policy will be reviewed every 3 years.

KEY WORDS

Medical training courses comprising interventional procedures, Governance, Honorary Contracts.

1 INTRODUCTION

- 1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy and Procedures for the optimal organisation and robust governance of medical training courses comprising interventional procedures involving patients. As a teaching Hospital UHL has the role in terms of training clinicians in innovative procedures. For clarity of the process a flow diagram is attached in Appendix A.
- 12 Background: There are no written GMC guidelines or UHL policies as regards medical clinical interventional training courses.

2 POLICY AIMS

- 21 The aim of this document is to provide clear and concise guidelines with regards to the organisation and governance of medical training courses comprising interventional procedures.
- 22 Participation in the course is not expected to alter the standards of care for patients. A number of other doctors, and/or nurses and possibly other healthcare professionals are expected to be present in the clinical area of treatment. These individuals are not there for the purpose of diagnosis and treatment, but for the purpose of being trained or providing training to others. On occasions a number of these individuals may take active part in diagnostic and/or therapeutic procedures, under the supervision of the organising consultant(s).

3 POLICY SCOPE

- 31 The staff groups and professionals this policy applies to, includes:
- Organising medical staff (consultants who organise the course, doctors who assist in the organisation of the medical training course and/or participate in the teaching sessions of the course).
 - Participating medical and non-medical staff (consultants, doctors, nurses, health care and other professionals who participate in the course).
 - Managers who are responsible for the clinical area(s) where the course is taking place.
 - Nursing staff of the clinical area(s) where the course is taking place.
 - Human resources staff that will be responsible for issuing Letters of Authority
 - Staff in the Clinical Education Centres.
- 32 This policy does not cover medical students or medical trainees who will be subject to existing governance processes as part of their training programme.
- 33 The group of patients covered by this document are all patients included in medical training courses comprising interventional procedures, where interventional procedures are used.
- 34 The Clinical Management Groups (CMG) role will be to advertise and promote other aspects of course organisation.

- 35 The processes included in this policy document are applicable to course participants who are currently employed within an NHS Trust. Additional advice must be sought, from HR Employee Services, for applicants from overseas or those who are not in current NHS employment

4. DEFINITIONS

- 4.1 A medical training course comprising interventional procedures is a teaching / training course which involves patients. For the purpose of this policy, an interventional procedure is defined as any procedure used for the diagnosis or treatment that involves incision, puncture, entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy.

5 ROLES AND RESPONSIBILITIES

5.1 Medical Director

The Medical Director is the Executive Lead for this policy.

The Medical Director and the Medical Director's Deputies will have responsibility for giving final approval for a medical training course comprising interventional procedures involving patients to proceed. This responsibility is currently delegated to the Director of Clinical Education/Associate Medical Director.

5.2 Directorate of Medical Education

Oversight for the governance process of medical training courses comprising interventional procedures involving patients will be through the Department of Medical Education who will have responsibility for keeping a register of such courses.

5.3 CMG Clinical Director

The responsibility of the CMG Clinical Director is to ensure that robust clinical and financial governance processes are in place across their CMG to ensure that the medical training course comprising interventional procedures is conducted in a way to ensure that patient safety and quality remain paramount. Whilst the Clinical Director, may delegate this to another individual, for example the Courses Director, he/she will remain responsible for ensuring the process is followed, this will include.

- A. Ensuring that all external participants have a Letter of Authority or Honorary Contract in place issued by HR Employee Services, before commencing in any clinical course or patient contact. Participants will not be allowed to participate without this
- B. Ensuring that the NHS to NHS proforma form and authorisation form (attached at Appendix C and D) are completed and are sent to HR Employee services at least 6 weeks prior to the course commencement date.
- C. Examining that the CV's of the participants, ensuring that they all possess the appropriate basic qualifications and competences in relation to the training course requirements.

- D. Signing off the 'proposal of medical clinical interventional training courses' application form (attached at Appendix B) prior to this being forwarded to the Medical Director for approval.
- E. Ensuring that appropriate patient selection for the medical clinical training course has taken place which may include discussion at a Multi-Disciplinary Team (MDT).
- F. Ensuring that an appropriate Patient Information Leaflet is provided to patients participating in the medical training course comprising interventional procedures.
- G. Ensuring that valid informed consent is obtained from all patients included in the medical clinical interventional training course. This will be consistent with UHL policies on Consent to Examination or Treatment Policy Ref: A16/2002 and Delegated Consent policy Ref: B10/2013. This includes the need to inform the patient of the risks and benefits of the procedure.
- H. Ensuring that patients provide explicit documented consent to participate in the medical training course comprising interventional procedures, including informing the patient that should they decline to participate in the medical training course, this will have no detriment to their on-going care.
- I. Ensuring that all course participants are appropriately supervised and that the supervisor understands their responsibility to intervene where appropriate, in order to ensure patient safety is maintained.
- J. Ensuring that any adverse events are reported promptly according to the Incident and Accident Reporting Policy (Including the investigation of serious RIDDOR and Security incidents) Ref:A10/2002. Reference should be made in the incident report that the Patient is participating in a medical training course comprising interventional procedures.
- K. Ensuring that adverse events within the medical clinical interventional training course are acted upon promptly and effectively.
- L. Ensuring that the financial and operational implications of the course are considered.
- M. Ensuring that any commercial sponsorship (if applicable) is appropriate and in line with UHL standing financial instructions and that Declarations of Interest have been registered.
- N. Ensuring that a Lead Clinician is appointed for every patient on the course who shall be responsible for (1) ensuring that the operative notes are written up appropriately (2) where more than one surgeon operates on the patient that this is clear from the operative notes which also shall detail which elements of the surgery were undertaken by which surgeon and (3) production of a list of all course attendees who were present in the theatre at any time during the procedure.
- O. Ensuring that the CMG Quality Board has a mechanism for monitoring the outcomes of patients who participate in the medical training course comprising interventional procedures through review of audit information.

54 HR Employee Services Department

The HR Employee Services department has a responsibility for:

- A. Determining whether a Letter of Authority is necessary and/or appropriate.

- B. Where applicable, administering the Letter of Authority process upon receipt of a fully completed NHS to NHS proforma.
- C. Providing advice and guidance on the policy and process for completing the application form.
- D. Ensuring that all appropriate pre-engagement checks are completed prior to commencement, including occupational health clearance. This will also include ensuring the Doctor is a suitably qualified Doctor to work in the UK i.e. GMC registered.
- E. Any participant introduced by a third party has satisfactory clearances in place prior to being issued with a Letter of Authority.
- F. Issuing the Letter of Authority to the CMG Clinical Director for signing by the person undertaking the honorary placement.
- G. Maintaining records of Letters of Authority holders and retaining records for 2 years once the placement has ended.
- H. Informing the CMG Clinical Director of any placements that are due to commence without a Letter of Authority or without all satisfactory clearances in place.

55 **Lead Clinician**

The Lead Clinician (as appointed by the CMG Clinical Director or Course Director is responsible for

- A. Ensuring that the operative notes are written up appropriately
- B. Where more than one surgeon operates on the patient that this is clear from the operative notes which also shall detail which elements of the surgery were undertaken by which surgeon
- C. Production of a list of all course attendees who were present in the theatre at any time during the procedure.
- D. Ensuring relevant UHL policies and procedures followed
- E. Compliance with current UHL COVID infection prevention guidance on testing and mask wearing.

56 **All Staff**

All staff have a responsibility to challenge the appropriateness of actions by course participants if they have concerns. Furthermore, all staff have the responsibility to immediately report any issue of concern and adverse events to their line manager.

6 **POLICY STATEMENTS**

6.1 Responsibilities of and communication with stakeholders

All patients must be provided with a patient information leaflet (PIL) and have agreed to participate by signing a consent form. The PIL and the consent form must be filed in the clinical notes.

6.2 Appendix A outlines the process that the CMG Clinical Director needs to undertake in

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applying for a Letter of Authority for external staff that require this. The relevant form needs to be submitted to HR Employee Services 6 weeks prior to course commencement.

- 6.3 Once the Letter of Authority has been issued the CMG Clinical Director will submit Appendix B to the Medical Director for final approval that the course can commence. One week should be allowed for the Medical Director to review and authorise the application.

7 EDUCATION AND TRAINING REQUIREMENTS

- 7.1 Since medical training courses comprising interventional procedures focus on experienced health-care professionals, it is expected that they have achieved the basic qualifications and competence deemed necessary for the course. This must be assessed as part of the application process.
- 7.2 Course participants also need to familiarise and abide by relevant Trust policies, guidance and standing operating procedures for the relevant area including infection prevention, radiation protection and health and safety requirements.

8 PROCESS FOR MONITORING COMPLIANCE

- 8.1 On a biannual basis, the Directorate of Medical Education will seek assurance from CMG Clinical Directors and CMG Education Leads as to whether any Interventional Procedures Involving Patients as part of a Training Course have been undertaken.
- 8.2 This information will then be cross referenced with the corporately held Register of Courses and any incidents or complaints reported on Datix.

POLICY MONITORING TABLE

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements Who or what committee will the completed report go to.
Register of Clinical Courses	Conference Manager	Conference Service records. Information from Clinical Directors, CMG Education Leads and MD office	Bi-annual	Medical Director at the Corporate Medical Operations Meeting
Incidents related to Clinical Courses	Deputy Ops Mgr, Dept of	Datix	Bi annual	Medical Director at the Corporate Medical Operations Meeting

	Clinical Education			
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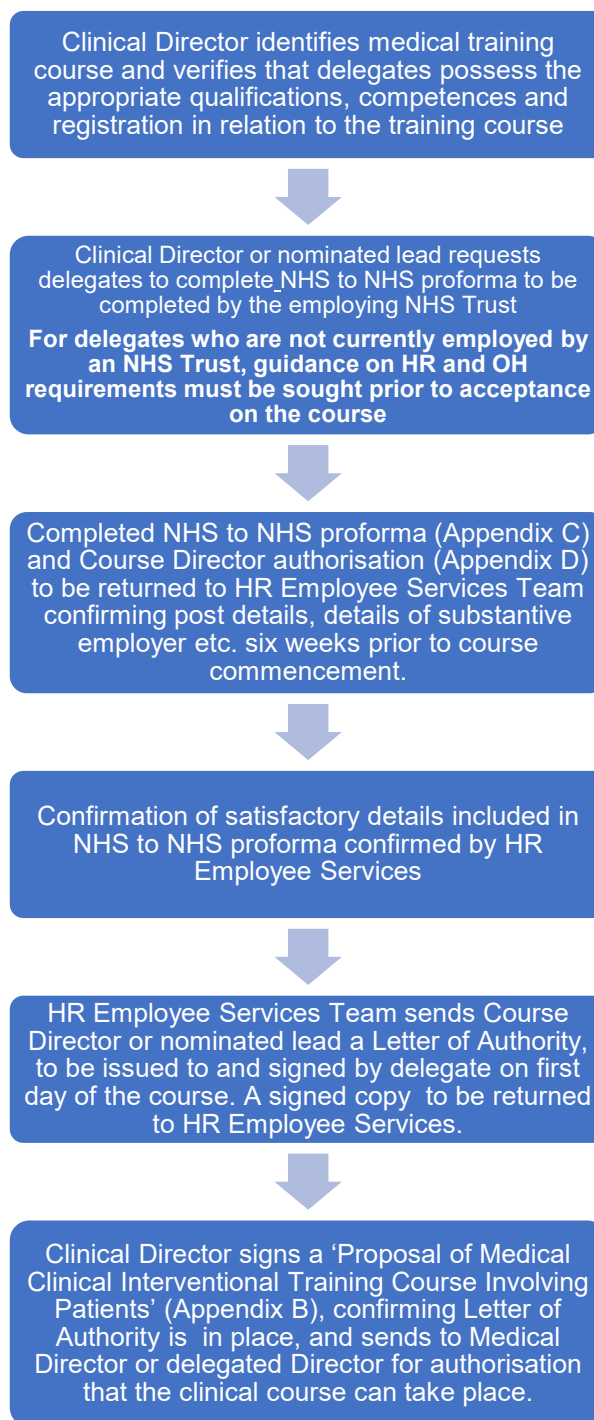
9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

9.1 The following are UHL related policies: -

- A. Delegated Consent policy, Trust Reference: B10/2013
- B. Consent to Examination or Treatment policy, Trust Reference: A16/2002
- C. UHL Incident and Accident Reporting Policy (Including the investigation of serious RIDDOR and Security incidents) Trust Reference: A10/2002

**Process for Medical Training Courses Comprising Interventional
Procedures Involving Patients**

Definitions of Clinical Training Course - A medical training course comprising interventional procedures is a teaching / training course which involves patients. For the purpose of this policy an interventional procedure is defined as any procedure used for the diagnosis of treatment that involves incision, puncture, entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy.



University Hospitals of Leicester NHS Trust
PROPOSAL FOR MEDICAL INTERVENTIONAL TRAINING COURSES INVOLVING
PATIENTS

Name of medical clinical Interventional training course:	Medical Director's Office Use Only
Name of lead (UHL) clinician:	Reference Number:

Description and indication for medical clinical training course:

Intended benefits for those being trained:

Intended benefits for patients:

Possible complications for patients:

Proposed start date of course:	Proposed finish date of course:
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Please list UHL colleagues who have assessed these Patients as being suitable for the course including if this decision was subject to MDT discussion:

Please list any external clinicians who will be involved in this Medical clinical Interventional training course and give details of relevant training:

Declaration by Clinical Director:

I have assessed the potential value of this medical clinical interventional course and am satisfied that appropriate

governance is in place namely:	
External colleagues have been issued a Letter of Authority	Yes <input type="checkbox"/> No <input type="checkbox"/>
The CVs of External Colleagues have been reviewed.	Yes <input type="checkbox"/> No <input type="checkbox"/>
External colleagues have appropriate GMC registration.	Yes <input type="checkbox"/> No <input type="checkbox"/>
External colleagues have been made aware of the relevant UHL policies, procedures and standing operating procedures including infection prevention and radiation protection.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Any commercial sponsorship (if applicable) is appropriate and in line with UHL standards.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Any adverse events that occur during the course will be reported.	Yes <input type="checkbox"/> No <input type="checkbox"/>
The CMG Quality and Safety Board will monitor the outcomes from the proposed medical clinical training course through existing morbidity and mortality processes and the clinical audit programme.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Appropriate consent procedures are in place including the use of a patient information leaflet.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Patients selected are aware that they are participating in a medical clinical interventional course and have provided explicit consent.	Yes <input type="checkbox"/> No <input type="checkbox"/>

CLINICAL DIRECTOR (person submitting proposal)	Name: CMG: e-mail: Telephone:
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Advisor: Who from your specialist society would be able and willing to advise the Medical Director if necessary. Name/Position held	
Telephone :	Email:

Once completed, this Notification should, sent to the Director of Clinical Education/Associate Medical Director, c/o Senior Adminstrator, Department of Clinical Education, Jarvis Building, LRI.
 Electronic copies should also be sent via email to khadijah.osman@uhl-tr.nhs.uk

NHS TO NHS Proforma - Confirmation of pre-employment checks

CONFIDENTIAL

Details of Applicant
Applicants Name:
Job Title:
Workplace and postal address:

As the representative of the NHS employer of the above-named person, I can confirm that s/he is employed by this organisation. I understand that the responsibility for ensuring that the appropriate pre-engagement checks have been undertaken rests with us as the individual's substantive employer. I can confirm that the appropriate pre-engagement checks have been completed, in line with NHS employment checks standards

1. Verification of Identity

A combination of photographic personal identification and documents confirming address

2. Right to Work

A) UK or EU Passport.

B) Passport of Non-UK National containing a visa or a UK residence permit, Biometric Card or Share code

3. Professional Registration & Qualifications

Evidence obtained on appointment to post

Yes/ No (please circle)

4. Employment History & Reference Checks

Satisfactory references obtained on appointment to post

Yes/No (please circle)

5. DBS

Level: _____

Issue Date: _____

Disclosure Number (if available): _____

6. Occupational Health

Health Cleared: **Yes/No (please circle)**

EPP Cleared (where applicable) **Yes/No (please circle)**

Clearance Date: _____

Name of employer's representative:

Job Title:

Workplace address:

Telephone:

Official Stamp of Employing Organisation:

- a. **Ethics committee reference number (if known)** – This is the number allocated to the research project(s) by the ethics committee.
 - b. **Study Title:** - The full title of the research project(s) you are working on.
2. **The date your involvement in the course will commence and the date your involvement will cease:** If you do not know when you are likely to finish your course here at University Hospitals of Leicester NHS Trust, please add in a review date. We can always extend the contract, but we must have a date by which to do this.
3. **Number of hours / sessions to be undertaken at the UHL.**
4. **Supervisors Details:** Please provide Name, Address and Telephone Number. This is the person who is supervising your work on a day-to-day basis. This may be your university supervisor or an employee at University Hospitals of Leicester NHS Trust.
5. **Authorisation and Accountability:**
- a. Authorisation must be obtained in order for a contract to be issued. (An application will not be considered without this). The authorising signatory must be a University Hospitals of Leicester NHS Trust employee and be willing to take on the responsibilities as detailed in the declaration, appendix D.
 - b. Please note the guidance notes should be read and the application form completed in all circumstances where an honorary contract is required.
6. **Applicant's signature and date:**

Once issued with an Honorary Contract, a signed copy must be returned to the department of HR Recruitment Services before you commence. If our records show that you have not been issued with an honorary contract, the Trust has the right to ask you to cease your work/placement until the appropriate documentation has been issued.