University Hospitals of Leicester NHS
NHS Trust

Policy for Nurses, Allied Health Professionals and Non-Medical Staff obtaining informed participant consent for clinical research studies undertaken within UHL NHS Trust

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REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
Jun 2022	V7	J James, Carolyn Maloney	Section 10 Change to Lead job title Change of Consent training provider Change of meting that audit/monitoring reports are presented.

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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

This policy has been reviewed and updated to reflect current Sponsor and Host Organisation Standard Operating Procedures. University Hospitals of Leicester NHS Trust acts a Sponsor and also a Host of research.

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KEY WORDS

List of words, phrases that may be used by staff searching for the Policy in PAGL

Informed Consent

Research Studies

Vulnerable Groups

Minors

Incapacity

Training

1 INTRODUCTION AND OVERVIEW

1.1 It is the UHL Trust policy to encourage nurses, non- medics and allied health professionals to obtain consent. UHL allows non-medics to obtain consent for research, if authorised to do so by the Sponsor, Chief Investigator (CI) & Principal Investigator (PI) However, delegation of this task will need to be approved by the Health Research Authority and detailed in the application to the Research Ethics Committee.

This policy gives directives for staff on training requirements, consent processes and procedures for all subjects being enrolled into a research study, ensuring that participants receive the best possible care.

This policy also applies to vulnerable groups, including minors and those subjects who are either temporarily or permanently incapacitated.

Informed consent is fundamental to research and written informed consent must be given prior to the conduct of **ANY** study related procedure

2 POLICY SCOPE

2.1 This policy applies to Nurses, Midwives and Allied Health Professional and Non-Medical staff involved in any research, either Sponsored or Hosted by UHL or where UHL is a research site.

3 DEFINITIONS AND ABBREVIATIONS

Allied Health Professional

Allied Health is a term used to describe the broad range of health professionals who are not doctors, dentists or nurses

Informed consent

Means that “the decision to take part in the trial is given freely after the subject(or person with parental responsibility or a legal representative) has been informed of the nature, significance and risks of the trial” European Medicines Agency- ICH Topic E6(RI) Guidelines for Good Clinical Practice – Section 4.8

Capacity

Capacity refers to the everyday ability that individuals possess to make decisions or to take actions that affect them, from simple decisions such as what to have for breakfast to far-reaching decisions about serious medical treatment or financial affairs.

A person lacks capacity if he or she is unable to make or communicate a decision about a particular matter because of an impairment of, or a disturbance in, the mind or the brain.

This may be the result of a variety of conditions, including:

- dementia
- mental illness
- learning disability
- brain damage
- intoxication
- any other condition causing confusion, drowsiness or loss of consciousness (e.g. concussion, stroke, heart attack, epileptic fit, serious accident, delirium).

Legal Representative

Means a person who makes a decision on behalf of an incapacitated person.

- Personal legal representative

  A person not connected with the conduct of the trial who is suitable to act as a legal representative by virtue of their relationship with the adult and available and willing to do so.

- Professional legal representative

  A person not connected with the conduct of the trial who is the doctor primarily responsible for the adult's medical treatment or a person nominated by the relevant health care provider (e.g. an acute NHS Trust)

4 ROLES

4.1 Responsibilities within the Organisation

a) The Board Director Lead for Research and Innovation is the Medical Director

b) The Non-Executive Director

The Director of Research and Innovation or their delegate is responsible for the oversight of the consent process for all studies sponsored or hosted by UHL

c) Chief Investigator(CI)/Principal Investigator(PI)

Research guidelines, Good clinical Practice (ICH-GCP) confirm that the Chief Investigator (CI) has overall responsibility to ensure that all consent processes are undertaken by suitably qualified and trained professionals. Additionally, the PI has the responsibility for the consent process at their individual site. However, the PI may delegate this task to suitably qualified sub-investigators or other suitably trained professionals. It is important to remember that the CI and PI remain ultimately responsible even when the tasks are delegated.

To have read the relevant UHL Sponsor or Host informed consent for Research and training for staff engaged in research standard operation procedures. In addition where appropriate they must read the policy: Trial entry for incapacitated subjects in clinical research involving medicinal products.

They must therefore assure themselves that those delegated with the responsibility are fully trained and competent.

d) All staff

All staff involved in research studies has a responsibility to be aware of the policies and standard operating procedures relevant to obtaining informed consent. To have read the relevant UHL Sponsor or Host informed consent for research and training for staff engaged in research standard operating procedures. In addition, where appropriate, they must have read the policy for trial entry for incapacitated subject in clinical research involving medicinal products. They must ensure that the interests of the subject always prevail over those of science and society.

5. POLICY IMPLEMENTATION

5.1 Process and procedures

Informed consent for research must be undertaken as per Research and Innovation(R&I) Standard Operating Procedures S-1006 UHL - Standard Operating Procedure for Informed Consent for Research sponsored by University Hospitals of Leicester (NHS) Trust for UHL Sponsored studies or C-2001 UHL Standard Operating Procedure for Informed Consent for Research where the University Hospitals of Leicester NHS Trust (UHL) are the HOST Organisation / Research SITE.

These Standard Operating Procedures (SOPs) document the organisational/regulatory and training requirements and the process of obtaining and recording informed consent for ALL research undertaken within UHL.

For clinical trials of Investigational products (CTIMP) utilising professional legal representatives, process and procedures are documented within the Policy for trial entry for incapacitated subjects in clinical research involving investigational medicinal products UHL NHS Trust B6/2014.

6 EDUCATION AND TRAINING REQUIREMENTS

To ensure that subjects receive the best possible care, it is vital that where appropriate, researchers receive specific training on the process of informed consent. It is accepted

that all professionals undertaking clinical research must be compliant with relevant legislation and local policies.

This policy is supported by the following processes / procedures / standards found in the associated documents as detailed below, which must be used in conjunction with this policy. The current version of these standard operating procedures can be obtained on the R&I website: http://www.leicestersresearch.nhs.uk/

Procedure / Process / Standard
SOP S-1006 UHL Procedure for Informed Consent for Research Sponsored by University Hospitals of Leicester NHS Trust C11/2014
SOP C-2001 UHL Procedure for Informed Consent for Research where University Hospitals of Leicester are the Host/Research Site C39/2015
SOP S-1008 UHL Training for staff engaged in research sponsored by University Hospitals of Leicester NHS Trust C12/2014
SOP C-2005 UHL Training for staff engaged in research hosted by UHL C5/2016
Policy for trial entry for incapacitated subjects in clinical research involving investigational medicinal products within UHL NHS Trust B6/2014
European Medicine Agency Guideline for Good Clinical Practice E6(R2) 01.12.16

7 PROCESS FOR MONITORING COMPLIANCE

7.1 It is the Chief Investigator/Principal Investigator's responsibility to ensure that they and all individuals delegated to obtain informed consent have undertaken the appropriate training and subsequent training updates.

7.2. Compliance with this policy and associated Standard Operating Procedures will be established through inspection of associated documentation in the process of Audit, monitoring and/or inspection by the Regulatory Agencies.

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

Policy for trial entry for incapacitated subjects in clinical research involving investigational medicinal products B6/2014 within UHL NHS Trust.

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

This document will be reviewed by the author or a delegate associate in two years from the date of publication or sooner if changes to any articles described in the policy are subject to change.

The updated version of the Policy will then be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system

POLICY MONITORING TABLE

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements Who or what committee will the completed report go to.
Investigator team training records and delegation of authority logs Investigator compliance with UHL consent policy and all related policies and standard operating procedures	Carolyn Maloney, Research & Innovation Deputy Chief Operating Officer / Julie James Clinical Trial Monitor and Trainer	The NIHR provide face to face/virtual consent training. Refresher consent training is available via UHL HELM. The Chief Investigator/Principal Investigator of the study is responsible for ensuring that all research staff undertaking consent are adequately qualified and trained to	Monitoring will occur on a risk assessed on-going basis and where issues are identified.	Reports for all audits/monitoring are presented to the Research & Innovation Deputy Chief Operating Officer at the monthly Research Governance Meeting

		undertake this task. Individual researchers are required to retain training records and ensure a copy is filed in all relevant Investigator Site File(s) Detailsof training are recorded on the Edge Database. UHL as a Sponsor has an established audit/monitoring programme in place where compliance with the policy and associated policies/SOPs will be undertaken for UHL sponsored studies. Hosted studies can also be reviewed as part of the audit programme. Where consent issues are identified R&I will organise a consent review and where applicable request further training.		