**UCLH Principal Investigator Responsibilities**

**Terms and Conditions of UCLH Confirmation of Capacity and Capability**

**Version 1.1 (18th January 2021)**

A condition of UCLH confirmation of Capacity and Capability, is for the Principal Investigator (PI) to confirm their agreement to comply with the responsibilities outlined within this document. PI’s are requested to read and sign this document for each study submitted for Capacity and Capability at UCLH.

This document is managed by the Joint Research Office (JRO), for studies taking place at UCLH.

1. **Legislation, regulations and other requirements**

PI’s should comply with the following legislations and policies:

* Applicable JRO and UCLH (Trust and divisional) policies, processes, and Standard Operating Procedures (SOPs),
* Terms of contractual agreement(s), including site agreements, material, and financial transfer, and/or Organisation Information Document (OID) and the Schedule of Events/SoeCAT
* Applicable regulations including but not limited to:
	+ General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018); Caldicott Principles; UCLH Information Governance Policy
	+ Human Tissue Act (2004) and the HTA Codes of Practice
	+ Human Tissue Regulations 2007 (Quality and Safety for Human Application)
	+ U.K Policy Framework for Health and Social Care Research and subsequent amendments
	+ Good Clinical Practice Guidance (ICH-GCP)
* All applicable regulatory approvals, including but not limited to:
	+ NHS Research Ethics Committee Favorable Opinion
	+ HRA Approval
	+ MHRA Notice of Acceptance/No Objection
	+ Confidentiality Advisory Group Approval (CAG)
* All applicable, guidance and requirements from other UCLH governance structures, such as Information Governance, the Data Access Committee, Use of Medicines Committee, Genetic Modifications Safety Committee, Medical Devices Committee, and the Clinical Effectiveness Steering Group (CESG).
* For human tissue, the PI should ensure that once NHS REC’s ‘Notice of Favorable Opinion’ for the study has expired, they consult with the sponsor and ensure the sponsor has taken and advised on the relevant actions including:
	+ instructing the PI on the disposal of any remaining tissues in accordance with the study protocol and Human Tissue Act 2004
	+ made an application to the NHS REC for the use of remaining tissue (where applicable)
	+ provided instruction to transfer any remaining tissue to a HTA licensed tissue bank (where applicable)
* UCLH’s [*Standards of Business Conduct Policy*](https://my.uclh.nhs.uk/Interact/Pages/Content/Document.aspx?id=2999)
* UCLH infection control policies/guidance and other pandemic or major change directives, policies or guidance issued by UCLH, the UCLH clinical division or the JRO
* All other relevant UCLH Policies and training requirements
1. **Responsibilities of the PI and the Research Team:**

PIs should comply with the following responsibilities:

* Maintain oversight of all research activities
* Ensure the study is run in accordance with sponsor requirements, including the approved protocol, contracts/agreements, and other conditions
* Ensure the study is run in accordance with the division/UCLH requirements
* Ensure any change which is relevant to the transfer/ share of data and use of IP within the study are declared to the JRO
* Respond to all requests relating to the study from the sponsor and the JRO
* Prepare and maintain a UCLH Investigator Site File (ISF) which contains all relevant documentation in accordance with Sponsor and host SOPs including an up-to-date delegation log (*refer to* [*UCLH SOP 8: Essential Documents and the ISF/TMF*](https://www.ucl.ac.uk/joint-research-office/sops-and-templates/uclh-rd-sops-policies-and-templates),
* Ensure all research staff are suitably trained, qualified, and experienced to carry out their required duties (throughout the life course of the study).This includes Epic Research Add-on training and Good Clinical Practice (GCP) training (Clinical Trials of Investigational Medicinal Products), renewable every 2 years
* Follow the [*UCLH SOP: Monitors Access to UCLH EHRS (EpicCare Link UCLH)*](https://my.uclh.nhs.uk/Interact/Pages/Section/ContentListing.aspx?subsection=8025)for facilitating monitor access to UCLH EHRS including responsibility for monitors signing the ‘Monitors Code of Conduct’ document prior to accessing patient records
* Facilitate any audits or monitoring activity as required by the sponsor or the JRO.
* During periods of pandemic or local and national emergencies or local need release appropriate research staff to support urgent public health studies and/or urgent clinical care requirements at UCLH
1. **Reporting Requirements**

The PI should report the following requirements within UCLH.

***Research Events and Incidents***

PIs should report all incidents which are related to research procedures at UCLH (in accordance with the [*UCLH SOP for Reporting Research Incidents and Events*).](https://www.ucl.ac.uk/joint-research-office/sops-and-templates/uclh-rd-sops-policies-and-templates) These incidents include:

* All Serious Incidents, which should be reported immediately via Datix and concurrently emailed to the UCLH Patient Safety Team
* All incidents which cause harm to a patient whilst they are taking part in a research study – including those incidents which cause significant harm or distress and appear un-related to the study intervention itself
* All complaints from NHS patients at UCLH. Complaints should be reported in the first instance to the UCLH NHS Complaints Dept. (uclh.complaints@nhs.net) who will liaise with the JRO as applicable
* All **unexpected and related** research incidents occurring at UCLH. Such incidents should be reported via Datix immediately (marked as related to a clinical trial or research study).

***Incidental Findings in Research***

A finding that has potential health or reproductive importance, which is discovered while conducting research, but is unrelated to the aims of the study[[1]](#endnote-1).

The PI should ensure research staff follow the UCLH and departmental incidental findings policy and where required, are trained as part of initiation of the study.

The following expectations must be conveyed (by the PI) to research staff:

* immediately (within 48 hours) inform the PI of an incidental finding and any actions taken and request actions from the PI
* inform the responsible clinical care team (for the participant), and ensure an acknowledgement is received (to include appropriate referrals)

In the event an incidental finding becomes an incident (e.g., is not actioned), the incident reporting procedure should be followed.

***Study progress and changes***

The PI should instruct the research team of, and regularly monitor, the following EPIC requirements:

* Associate patients with the research studies in accordance with the EPIC ‘assigning a patient to a clinical trial’ tip sheet.
* The correct active start date, enrolment status and billing status and research study status within the study’s Epic record

In addition, the PI should send the following notifications and changes to the JRO (via uclh.randd@nhs.net):

* The early termination of a research study by the sponsor or UCLH department/authority
* Any change in PI at UCLH and/or PI halt to recruitment or follow-up activities
* Any change to the status of a study, including from active to in-follow up or to completed and the number of participants recruited at each stage
* Formal notification of end of study (REC/MHRA Declaration of End of Study to uclh.randd@nhs.net), (in line with the *UCLH SOP for Study Close Down*)
* Amendments to the study (in line with the *UCLH SOP for Reporting Amendments)* including but not limited to any changes to the study status, extensions to end dates, conduct, funding, or management arrangements
* Audit activity including:
	+ Notification of audits or inspections
	+ Audit reports (where possible, and in agreement with the Sponsor, provide a copy of the corrective and preventive actions)

Once a study has concluded, and if the PI wishes to introduce a new interventional procedure to UCLH (previously part of a research protocol), the PI should follow the [*UCLH New Interventional Procedures Policy*](https://my.uclh.nhs.uk/Interact/Pages/Content/Document.aspx?id=2885)*,* and obtain approval from the Clinical Effectiveness Steering Group (CESG). Similarly, if a PI wishes to introduce a licensed or unlicensed drug to UCLH or medical device, they must first obtain approval from the [Use of Medicines Committee (UMC)](https://my.uclh.nhs.uk/Interact/Pages/Section/Default.aspx?Section=6469) or [Medical Devices Committee](https://my.uclh.nhs.uk/Interact/Pages/Section/Default.aspx?section=6120).

Principal Investigator acknowledgement:

As Principal Investigator, I agree to conduct this research study in accordance with the protocol, regulatory approvals, applicable regulatory requirements, and the above requirements

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| --- | --- |
| Name |  |
| Study Title |  |
| IRAS Number |  |
| Signature |  |
| Date |  |

1. <https://mrc.ukri.org/documents/pdf/mrc-wellcome-trust-framework-on-the-feedback-of-health-related-findings-in-researchpdf/> [↑](#endnote-ref-1)