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Suspension of Recruitment to a Research Study at UCLH

UCLH procedure

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Responsible Director	Medical Director, Corporate
Policy Author	Deputy Director of Research Support
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Documents to read in conjunction with this policy	UCLH Incident Reporting Policy
Complete review by date	31/10/21

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UCLH is an NHS Foundation Trust comprising: University College Hospital (incorporating the Elizabeth Garrett Anderson Wing, the Macmillan Cancer Centre and University College Hospital at Westmoreland Street), Royal London Hospital for Integrated Medicine, Royal National Throat, Nose and Ear Hospital, National Hospital for Neurology and Neurosurgery at Queen Square and Cleveland Street, Institute of Sport, Exercise and Health, Hospital for Tropical Diseases, The Eastman Dental Hospital.

List of reviewers & contributors	Director of Research Quality & Safety (Joint Research Office) Head of Risk and Regulation (Joint Research Office) Deputy Director of Research Support (Joint Research Office) Research Quality and Safety Manager (Joint Research Office)	
Summary of main points from consultation	*Document to be updated to include current research terminology, JRO titles, groups and definitions, and references to research policy and legislation (e.g. UK Policy Framework for Health and Social Care, 3rd edition, and EU Clinical Trials Directive (2001/20/EC).* *Further clarifications needed to specify what circumstances will require a suspension to recruitment at UCLH, and the process to be followed by the Research Quality and Safety Unit.*	
Review body	Research Quality and Safety Unit	Date of meeting when policy reviewed and endorsed: 28/08/2018
Date of meeting when this version of the policy approved by PASG	27/11/18	

Review amendment log

Version No	Date amendments made	Description of change
V.4	August 2018	1. Policy template – front cover revised and guidance notes added to assist policy authors. Amendment log added. Information previously captured in policy approval form added to policy structure/template e.g. list of consultees. 2. Section 3: Introduction updated to include current terminology for research regulatory and NHS approvals. 3. Sections 3, 7 and 8 updated to include additional circumstances in which recruitment to a research study may be suspended by authorised managers. 4. Section 6: Definitions expanded to capture additional research-related terms and references, and personnel involved in set up of research. 5. Section 7: Duties and responsibilities updated to include Head of Finance (JRO) as an authorised manager. 6. Section 8 updated to reference an R&D Standard Operating Procedure, *UCLH SOP 6: Reporting and Managing Incidents and Events in Studies.* 7. Section 9 inserted, and Section 10 updated to provide further detail regarding monitoring and audit process. Section 11 also updated to include additional references. 8. Minor clarifications added, e.g. references to EU Clinical Trials Directive and U.K Policy Framework for Health and Social Care Research, minor corrections to typos, elaboration provided on types of regulatory approvals (e.g. REC, HRA, etc.). Minor reformatting throughout document.

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Table of contents **Page Numbers**

1.	Summary	1
2.	Equality Impact Assessment	1
3.	Introduction	1
4.	Objectives	2
5.	Scope	2
6.	Definitions	2
7.	Duties & responsibilities	4
8.	Procedure for Suspension of Research Studies	5
9.	Dissemination and communication	6
10.	Monitoring	6
11.	References	6

1. Summary

1.1 This document explains the procedure to be undertaken by the Research & Development Directorate (the "Joint Research Office"), for stopping and restarting (suspending) recruitment to a research study taking place at University College Hospital NHS Foundation Trust (UCLH). It explains who is authorised to make a decision to suspend recruitment to a research study, the grounds for the decision, who must be informed and the information required.

1.2 This procedure applies to all studies taking place at UCLH and to staff within the Joint Research Office (JRO). It applies to individual studies and groups of studies (e.g. within a department or research unit).

1.3 Suspension of recruitment (i.e. the suspension of the research study at UCLH, including all research-related activity) allows for the initiation of an investigation of events. It also guards against patients being placed at risk and ensures the reputation of UCLH is protected until an investigation is completed.

1.4 It does not cover circumstances where a research Sponsor makes an independent assessment to terminate a study based on safety, protocol violations or failure to reach expected recruitment targets, or circumstances where funders or regulatory bodies terminate research studies early. In such circumstances, Sponsors, funders or regulatory bodies should liaise with the Joint Research Office in the first instance.

2. Equality Impact Statement

The author of this policy has undertaken an Equality Impact Assessment (EIA) and has concluded that there is no negative impact on any of the protected equalities groups. The completed EIA form is available from the Policy Compliance Officer.

3. Introduction

3.1 In line with the current EU Clinical Trials Directive (2001/20/EC) and the UK Policy Framework for Health and Social Care Research 2017, 3rd Edition (and subsequent amendments) the JRO's Research Quality and Safety Unit needs to take action to suspend recruitment to a research study in situations where there is strong reason to believe that the conduct of a study:

- Places research participants' rights and/or wellbeing at risk;
- Jeopardises the scientific integrity of the study and its data;
- Places UCLH at reputational or financial risk;
- Is currently being investigated by Sponsors/funders/regulatory bodies/research team/UCLH/Joint Research Office;
- Is non-compliant with research legislation, regulatory requirements or ethical guidance, e.g. the Human Tissue Act, General Data Protection Regulation, Good Clinical Practice, UCLH or R&D policies, procedures and Standard Operating Procedures;
- Has significant issues determined by the Director of Research Quality and Safety (JRO).

Or

- Where the study has been initiated without the required regulatory or policy requirements. This includes the absence of regulatory approvals (e.g. Research Ethics Committee (REC) Favourable Opinion, Health Research Authority (HRA) Approval, Medicines and Healthcare products Regulatory Agency (MHRA) acceptance/no objection, and UCLH confirmation of Capacity & Capability (formerly referred to as 'R&D Approval')), or a need identified by regulatory bodies or REC for a new approval.

3.2 The suspension will allow for appropriate measures to be put in place to alleviate any risk. The Research Quality and Safety Unit's investigation may also lead to a recommendation for the permanent closure of the study (following approval of the Director of Research (or delegated nominee in the Joint Research Office).

4. Objectives

4.1 The objective of this procedure is:

- To define which practices may lead to the suspension of recruitment to a research study
- To document responsibilities
- To outline the appropriate actions to be taken to alleviate any immediate risk to participants and UCLH.

5. Scope

5.1 This procedure applies to all research studies (as defined by the UK Policy Framework for Health and Social Care Research) which recruit patients at UCLH.

6. Definitions

Research study	Studies of all methodology types: - Clinical Trials of Medicinal Products (CTIMPs) - Advanced Therapy Investigational Medicinal Products (ATIMPs) - Clinical investigation or other study of a medical device - Combined trial or an investigational medicinal product and an investigational medical device - Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice - Basic science study involving procedures with human participants - Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology - Study involving qualitative methods only

	- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only) - Study limited to working with data (specific project only) - Research tissue bank - Research database
Chief Investigator (CI)	Clinical lead/individual who is responsible for the conduct of the whole research project in the UK, and has overall oversight
Principal Investigator (PI)	Clinical lead/individual responsible for the leadership and conduct of a research study at UCLH
Joint Research Office	A partnership between UCLH and University College London (UCL), the JRO provides support to the clinical research portfolio via services such as sponsorship, feasibility, quality and safety, and contract and financial management, and issues Confirmation of Capacity and Capability (formerly 'NHS Permission') to all research conducted at UCLH.
Authorised Manager for suspensions	Manager able to make decisions or take action relating to the suspension of recruitment to a study. These managers work within the Research & Development corporate directorate
Suspension	Suspension of recruitment to active UCLH studies; formally issued to the CI/PI/Research Teams by authorised managers within the R&D directorate.
Datix	UCLH Incident Reporting system
Sponsor	The organisation that takes on ultimate responsibility for the initiation, management and financing (or arranging the financing) of the study
Funder	The funder is the organisation or group of organisations providing funding for the research project.

7. Duties and responsibilities

7.1 The following managers working within the Research and Development corporate directorate are authorised to suspend recruitment to a study:

- Director of Research Quality and Safety (JRO)
- Head of Risk and Regulation
- Director of Research
- Director of Research Support
- Deputy Director of Research Support
- Research Quality and Safety Manager
- Head of Finance and Contracts (JRO)

The Director of Research Quality and Safety (JRO) will determine if a suspension is required, and which Authorised Manager(s) will issue the suspension notice and lead the investigation. The Authorised Manager(s) will advise on lifting suspension of recruitment to studies, and on the use of data where recruitment to a study has been suspended (following consultation with the relevant UCLH Clinical Director).

7.2 Recruitment to a study may be suspended by the nominated Authorised Manager for suspensions where there is strong reason to believe that the conduct of a study:

- Places research participants' rights and/or wellbeing at risk;
- Jeopardises the scientific integrity of the study and its data;
- Places UCLH at reputational or financial risk;
- Is currently being investigated by Sponsors/funders/regulatory bodies/research team/UCLH/Joint Research Office;
- Has had significant issues flagged within service support departments, e.g. Pharmacy, Radiology, Nuclear Medicine, etc.;
- Is non-compliant with research legislation, regulatory requirements or ethical guidance, e.g. the Human Tissue Act, General Data Protection Regulation, Good Clinical Practice, UCLH or R&D policies, procedures and Standard Operating Procedures;
- Has significant issues determined by the Director of Research Quality and Safety (JRO).

Or

- Where the study has been initiated without the required regulatory or policy requirements. This can include the absence of the following regulatory approvals or NHS confirmations (where applicable):
  - NHS Research Ethics Committee (REC) Favourable Opinion
  - Health Research Authority (HRA) Approval
  - Medicines and Healthcare products Regulatory Agency (MHRA) acceptance/no objection
  - Confirmation of Capacity & Capability (formerly referred to as 'R&D Approval' or 'NHS Permission')
  - Other approvals such as Confidentiality Advisory Group (CAG) approval, Administration of
    Radioactive Substances Advisory Committee (ARSAC) approval, etc.

8. Procedure for Suspension of Research Studies

8.1 Process:

An issue may be raised to the JRO in a number of ways (i.e. via email or telephone call, Datix incident report, or other incident reporting systems accessible to the JRO). Research staff should refer to the UCLH R&D Standard Operating Procedure for reporting research incidents, *UCLH SOP 6: Reporting and Managing Incidents and Events in Studies*, for guidance.

All investigations conducted will:

- Make a detailed assessment (e.g. whether there are any financial/contractual/patient safety/research integrity/reputational implications and risks)
- State that further recruitment to the study may be suspended, or whether there is a necessity to withdraw the research intervention/treatment
- Determine whether any other current or in set up studies need to be suspended

- Inform and report outcomes to the Director of Research Quality and Safety (JRO)
- Conduct any further investigations or actions.

8.2 Where a decision is taken to halt recruitment, the investigating manager must:

A. Inform the following staff of the reasons for suspension of recruitment:

- Local clinical lead (Chief or Principal Investigator for UCLH)
- The clinical director for the clinical service recruiting patients
- The Director of Research Quality and Safety (JRO)
- The Sponsor (if required)
- If a Device Trial, the manufacturer (if deemed appropriate by the investigating manager or Director of Research Quality and Safety)
- Regulatory bodies (if required).

B. Ensure that the decision to suspend recruitment is:

- Documented within the appropriate records and study databases within the JRO Research Office (by the investigating manager)
- Documented within the study Trial Master File/Investigator Site File (by the Chief/Principal Investigator)
- Reported as a research related incident on Datix and documented internally in JRO incident reporting systems.

C. Agree an action plan with the JRO Research Quality and Safety Unit. The action plan must include:

- Allocation of an investigation lead
- An investigation into the incident which caused the suspension of the study
- Corrective actions or measures required before recruitment can recommence.

The plan should be documented appropriately within Datix/JRO incident reporting systems.

D. Upon completion of the investigation and corrective measures/actions, the JRO Research Quality and Safety Unit will either:

- Agree the actions are sufficient to lift the suspension on the study, OR
- Recommend further actions, OR
- Refer to the UCLH Quality and Safety Committee with a recommendation that the study be closed permanently.

8.3 In the case of a study where recruitment has been suspended and it is sponsored by UCL, the suspension, action plan and outcome should be reported by an Authorised Manager to the UCL Clinical Research Governance Committee or other appropriate committee appointed by the JRO Research Quality and Safety Unit.

9. Dissemination & Communication

9.1 This Policy will be made available on the Policies & Procedures page on the UCLH intranet, and the Joint Research Office website: www.ucl.ac./jro.

10. Monitoring and Audit

What in the policy is going to be monitored	Monitoring method	Who will lead the monitoring?	How often?	Where will it be reported?
Compliance with the policy (i.e. requirements for study suspension have applied and been followed, studies have been suspended by an Authorised Manager, suspension was appropriately issued and corrective actions were implemented prior to lifting of suspension.	Local Audit of studies suspended by UCLH/UCL Joint Research Office (correspondence, documents, Datix, and internal JRO incident logs)	Director of Research Quality and Safety (JRO)	Annually	UCLH Quality and Safety Committee

11. References

EU Clinical Trials Directive EU 2001/20/EC - https://ec.europa.eu/health/human-use/clinical-trials_en

Health Research Authority (REC, HRA, CAG, U.K Policy Framework for Health & Social Care Research) – www.hra.nhs.uk

Medicines & Healthcare products Regulatory Agency (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Administration of Radioactive Substances Advisory Committee (ARSAC) - https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee

UCLH/UCL Joint Research Office – www.ucl.ac.uk/jro