University College London Hospitals
NHS Foundation Trust

Suspension of a Research study at UCLH

UCLH policy & procedure

Policy number	013/CLN/T
Issue number	5
Issue date	08/02/2022
Approved by	SDT policy approval sub group (PASG)
Responsible Director	UCLH Director of Research
Policy Author	Head of Clinical research Governance and Compliance, Joint Research Office (JRO)
Review Body	Clinical Research Board
Documents to read in conjunction with this policy	UCLH Incident Reporting Policy Scientific Fraud and Research Misconduct–the reporting and investigation of allegations of scientific fraud and research misconduct
Complete review by date	31/01/2025

If reading a printed copy, always check that it is the most recent approved version. This can be found on the Policies & Procedures page on the intranet.

List of reviewers & contributors	Clinical Director of Sponsorship and Governance Deputy Director of Research Support (JRO) Head of Finance (JRO)	
Summary of main points from consultation		
Review body	Clinical Research Board, Research Directorate	Date of meeting when policy reviewed and endorsed: 17/12/2021
Date of meeting when this version of the policy approved by PASG	18/01/22	

Review amendment log

Version No	Date amendments made	Description of change
V.5	December 2021	1. Clarification that this policy covers not just suspension of recruitment but extends to suspension of all areas of research activity of a hosted study. 2. Role titles and authorised list in 7.1 updated. 3. Duplication in 3.1 removed (remains in 7.2). 4. Contractual and funding authorisations added to 7.2 as additional reasons for suspension. 5. Further details of the procedure added, with a form and summary flow chart attached as appendices.
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.

Environmental

Do you really need to print this document? Please consider the environment before you print this document and where possible copies should be printed double-sided. Please also consider setting the Page range in the Print properties to avoid printing the policy in its entirety.

Table of contents **Page Numbers**

1. Summary

1.1 This document explains the procedure to be undertaken by the Research Directorate (specifically the "Joint Research Office"), for stopping and restarting (suspending) a research study taking place at University College Hospitals NHS Foundation Trust (UCLH) as a host site. Suspension could be in the form of suspending any new recruitment or suspending any associated on-going research activity if deemed necessary and safe to do so. It explains who is authorised to make a decision to suspend a research study, the grounds for the decision, who must be informed, and the information required.

1.2 This procedure applies to all hosted studies taking place at UCLH, irrespective of Sponsor. It applies to individual studies and groups of studies (e.g. within a department or research unit).

1.3 Suspension of the research study at UCLH, (including recruitment and other 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. A suspension may lead to termination of a study at UCLH as a host site on conclusion of an investigation.

1.4 This document does not cover circumstances where a research Sponsor, Funder or regulatory body makes an independent assessment to terminate a study based on safety, protocol violations or failure to reach expected recruitment targets, or any other circumstances where such bodies terminate research studies early. In such circumstances, the investigator, Sponsors, funders or regulatory bodies should liaise with the JRO in the first instance.

1.5 This document does not cover circumstances where UCLH may have to suspend studies due to unexpected, extenuating circumstances such as a pandemic or national emergency. In such circumstances, the process and mechanism to follow will be overseen and communicated by the JRO.

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

In line with the current UK Clinical Trials Regulations and the UK Policy Framework for Health and Social Care Research 2017, 3rd Edition (and subsequent amendments) the JRO, acting as the UCLH host organisation R&D Office, may need to take action to suspend a hosted research study in situations where there is strong reason to believe that the conduct of a study places participants, the study integrity or the organisation at risk or where there has been non-compliance with internal or external policies, procedures and regulations.

4. Objectives

The objective of this procedure is:

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

5. Scope

This procedure applies to all hosted research studies (as defined by the UK Policy Framework for Health and Social Care Research) which involve patients, their data or tissue or staff 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) - Study limited to working with data (specific data only project) - Research tissue bank - Research database
Chief Investigator (CI)	Clinical lead/individual who is responsible for the conduct of the whole research project at all sites 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 (PI could be the same person)
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, QA, compliance, 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 a study. These managers work within the UCLH Research Directorate
Suspension	Suspension of recruitment to active UCLH studies; formally issued to the CI/PI/Research Teams by authorised managers within the Research Directorate.
Datix	UCLH Incident Reporting system
Sponsor	The organisation that takes ultimate responsibility for the initiation, management and financing (or arranging the financing) of the study
Funder	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 Directorate are authorised to suspend a study:

- Director of Research (UCLH)
- Managing Director of Research
- Clinical Director of Sponsorship and Governance
- Deputy Director of Research Support
- Head of Clinical Research Governance and Compliance
- Head of Finance (for financial and contractual matters)

7.2 A hosted study may be suspended at UCLH where there is strong reason to believe that the study:

- Places research participants' health, 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/JRO;
- Has had significant issues flagged within service support departments, e.g. Pharmacy, Radiology, Nuclear Medicine, etc., 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;
- Is at risk due to a serious complaint or allegation of potential misconduct having been received
- Is at risk due to the PI or a member of the research team being suspended or being under investigation

Or

- Where the study has been initiated without the required regulatory or policy requirements being adhered to. 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
  - Formal confirmation of Decision to Deliver/Capacity & Capability
  - Other approvals such as (but not restricted to) Confidentiality Advisory Group (CAG) approval, Administration of Radioactive Substances Advisory Committee (ARSAC) approval, etc.

Or

- Where the study has been initiated without the appropriate funding or contractual authorisations being in place

8. Procedure for Suspension of Research Studies

Appendix A provides a flow of the procedure for Suspension of Research Studies.

8.1 Raising an issue or concern

Issues with hosted research studies must be raised with the JRO and may be presented in a number of ways (i.e. via email or telephone call, Datix incident report, or other incident reporting systems accessible to the JRO). For guidance, research staff should refer to the following documents:

- UCLH R&D Standard Operating Procedure for reporting research incidents, *UCLH SOP 6: Reporting and Managing Incidents and Events in Studies*.
- UCLH Policy and Procedure on Scientific Fraud and Research Misconduct–the reporting and investigation of allegations of scientific fraud and research misconduct

An authorising manager, as listed in 7.1 above, should consider whether the issue raised, falls into one of the categories listed in 7.2 above. Where necessary, this will be done in discussion with the relevant Research Directorate Director(s) and be logged on Datix as a research incident.

8.2 Determining if suspension is required

If a concern is identified as potentially requiring suspension of research activity, an initial assessment should be documented (see Appendix B) to be held by the JRO QA unit. The written assessment will include:

- Details on any patient safety/research integrity/financial/contractual/reputational implications and risks that have been identified
- Where there is a clinical safety concern, a determination made by the Clinical Director of Sponsorship and Governance on whether further recruitment to the study should be suspended, whether it is safe for patients already on the study to continue or whether there is a necessity to withdraw the research intervention/treatment

- A determination on whether any other research activities associated with the study can continue or should be suspended including data collection/data analysis
- A determination whether any other current or in set up studies need to be suspended

The assessment should detail how each determination was reached including the persons involved in any discussions/decision making. A decision to suspend must be agreed with the relevant Research Directorate Director(s) or another member of the JRO senior leadership team.

In all cases, the Director of Research must be notified, and approve the suspension on the assessment form.

A copy of the assessment form must be provided to the JRO QA unit for recording purposes.

8.2 Actioning a suspension

The suspension of a study allows for an independent investigation to take place and for appropriate measures to be agreed and actioned where required. The investigation may also lead to a recommendation for the permanent closure (termination) of the study, to be actioned following approval from the Director of Research (or delegated nominee in the JRO).

Where a decision is taken to suspend recruitment (or any other aspect of the research activity) whilst an investigation is initiated, the investigating manager must:

A. Inform the following staff of the activities that need to be suspended and the reasons for suspension:

- Local clinical lead (Chief or Principal Investigator for UCLH)
- The clinical director for the clinical service recruiting patients
- The Clinical Director of Sponsorship and Governance
- The Sponsor
- If a Device Trial, the manufacturer (if deemed appropriate by the investigating manager or Director of Research Quality and Safety)
- Regulatory bodies e.g. NHS REC/HRA/MHRA (where required).

B. Ensure that the decision to suspend is:

- Documented within the appropriate study records and study databases within the JRO (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. The authorised manager must put in place an action plan, agreed with the relevant Research Directorate Director(s) or another member of the JRO senior leadership team to include:

- Allocation of an investigation lead
- Details of the investigation into the incident which caused the suspension of the study
- Corrective actions or measures required before recruitment can recommence
- External notification requirements (e.g. Sponsor, NHS REC, participants etc).

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

D. Upon completion of the investigation and corrective measures/actions, the authorising manager will recommend to the relevant Research Directorate director:

- That the actions have been satisfactorily completed to lift the suspension on the study, OR
- Where the investigation deems no corrective actions can rectify the situation or where the corrective actions have not been satisfactorily completed that either
    - Further actions should be taken, OR
    - the study be closed permanently.

8.4 Lifting a suspension

Where all the corrective and preventative actions have been completed satisfactorily, and a decision to lift the suspension is recommended, the following actions will be taken by the authorising manager:

- The Director of Research is notified and approves the lifting of the suspension on the assessment form.
- Inform the persons listed in 8.3A above, that the suspension has been lifted.
- Ensure the decision to lift the suspension is documented within the appropriate study records and study databases within the JRO.
- The lifting of the suspension is entered on the Datix incident record.
- The assessment form (Appendix B) is updated with details of the decision to lift the suspension.

8.5 Further actions or permanently closing a hosted study

Where the corrective actions have not been satisfactorily completed, further actions may be considered, such as extending the time to enable the actions to be completed or identifying further resources to enable the study to re-start. Any decision to continue suspension with further actions in place, must repeat steps 8.3 A-C with all relevant documentation being updated with the additional details.

Where the investigation deems no corrective actions can rectify the situation and the recommendation is to close the study permanently at UCLH as a host site, the following actions will be taken by the authorising manager:

- The Director of Research is notified and approves the permanent closure of the study on the assessment form.
- Inform the relevant persons (as listed in 8.3A) above of the decision to permanently close the study.
- Ensure the decision to close the study and any associated actions to ensure safe closure at site are documented within the appropriate study records and study databases within the JRO.
- The decision to close the study and any associated actions to ensure safe closure are entered on the Datix incident record.
- The assessment form (Appendix B) is updated with details of the decision to close the study.

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)	Head of Clinical Research Governance and Compliance	Annually	Clinical Research Board (CRB) UCLH Quality and Safety Committee

11. References

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

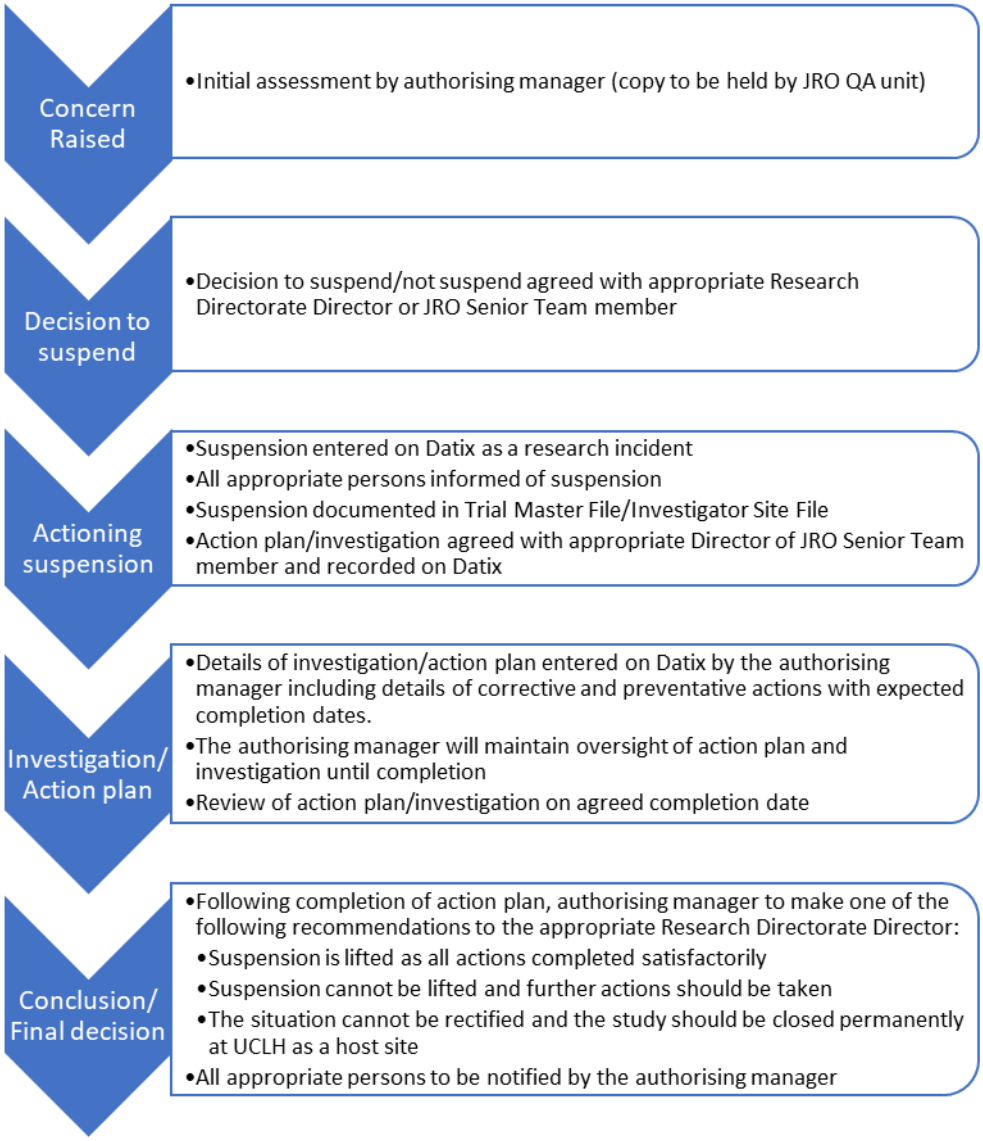
UK Clinical Trials Regulations – http://www.legislation.gov.uk/2004-*?title=Clinical%20Trials%20Regulations

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

Appendix A: Flow of the procedure for Suspension of Research Studies.



Appendix B: Assessment Form for documenting decision for suspension

1. Details of issue

Research Directorate authorised manager:
Date Raised:
Name of Reporter:
Study Ref (NHS REC/EDGE):
Sponsor:
Name of Study:
Description of issue:

2. Initial assessment

Potential reason for suspension (select from list in 7.1 of Procedure):

Details of any meetings/discussions (name/date/detail and conclusion of discussion):

3. Details of determinations made

i. **Details on any patient safety/research integrity/financial/contractual/reputational implications and risks that have been identified (state *none* if none identified)**:

ii. **Where there is a clinical safety concern, enter the determination made by the Clinical Director of Sponsorship and Governance on whether further recruitment to the study should be suspended, whether it is safe for patients already on the study to continue or whether there is a necessity to withdraw the research intervention/treatment**:

iii. **Research activities associated with the study that can continue or should be suspended including data collection/data analysis**:

iv. **Details on any other current or in set up studies that may need to be suspended**:

4. Decision to suspend

Name of Research Directorate Director/JRO Senior Team member providing agreement with decision:

Date of suspension:

Approval by Director of Research:

5. Actioning suspension

Date incident and action plan entered on Datix:

Persons/bodies notified:

6. Action Plan/details of investigation:

Action point	Timeframe	Person Responsible	Due Date	Date Completed

7. Final decision (choose one, delete those not applicable):

- **Suspension is lifted as all actions completed satisfactorily**
- **Suspension cannot be lifted and further actions should be taken** (If further actions are required, this must be detailed in section 5 above)
- **The situation cannot be rectified and the study should be closed permanently at UCLH as a host site** (this must be agreed with the Director of Research before actioning)

Name of Research Directorate Director/JRO Senior Team member agreement with decision:

Date of decision:

Approval by Director of Research:

8. **Details of actions to be taken following final decision**:

Action point	Timeframe	Person Responsible	Due Date	Date Completed