Plymouth Research and Development

NHS University Hospitals Plymouth NHS Trust

Standard Operating Procedure

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Title:	Suspension and/or discontinuation of Trust sponsored studies for unsafe or unacceptable practices		
Approver		Document No:	QA4
Name:	Chris Rollinson	Version No:	7.0
Signature:		Effective Date:	Apr-2022
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1. Purpose

To describe the procedure to be followed in response to monitoring/ audit findings, which require an option of last resort, study suspension and/ or discontinuation.

2. Scope

This Standard Operating Procedure (SOP) relates to Trust sponsored studies, excluding studies regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) where the MHRA can only suspend or terminate the study. Please refer to SOP T6 Non-Compliance Reporting.

3. Responsibilities

Chief Investigator (CI) and Principal Investigator (PI) are responsible for a study being run in line with the study protocol and applicable regulation.

Trust has responsibility for the study oversight which is done *via* the R&D Governance team.

Director of Research, R&D Operations Director, Lead Research Nurse and the Trust's Risk and Incident Team will oversee the review of study suspension and or discontinuation.

Research Governance Manager (RGM) and Deputy RGM will conduct monitoring visits or instruct suitable trained delegates.

4. Documents needed for this SOP

- Latest regulatory approved study protocol
- SOP's QA2 Monitoring
- SOP QA6 Suspected Research Fraud
- SOP T6 Non-Compliance Reporting
- SOP T8 Research Study Amendments
- SOP SC1 Study Closure

5. Related documents

- UK Policy Framework for Health and Social Care Research (2017)
- Research Ethics Committee (REC) SOP
- TRW.HGV.POL.936.5 Incident Management Policy
- Incident Management Procedure SOP

6. Acronyms

CI: Chief Investigator

ICF: Informed Consent Form

PI: Principal Investigator

PIS: Participant Information Sheet

R&D: Research and Development

RCA: Root cause Analysis

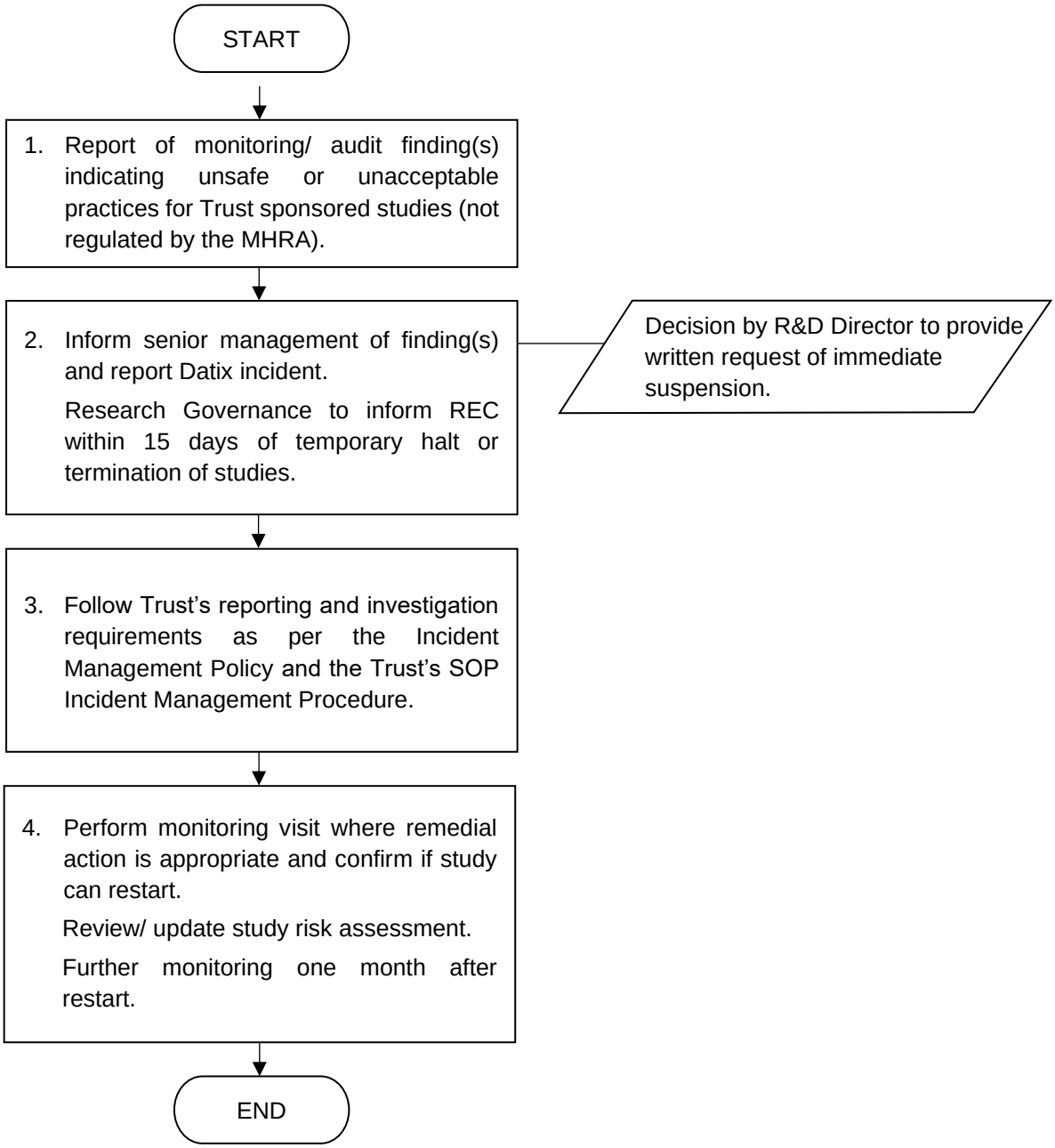
REC: Research Ethics Committee

RGF: Research Governance Framework

SOP: Standard Operating Procedure

UHP: University Hospitals Plymouth NHS Trust

7. Process map(s)/ flow chart(s)



8. Procedure

Step	Action	Responsibility
1	Suspension of a study will be immediate as a result of any of the following pre-defined audit/ monitoring finding(s) that indicate unsafe or unacceptable practices. • Absence of full ethical and R&D approvals. • Failure to consent. No evidence of signed informed consent from participants. • Major violation* from the approved protocol i.e. treatment blinding has been compromised. • Therapy given in an unsafe environment with inadequate supervision or inappropriate facilities being available for the intervention under investigation. • Failure to report serious adverse events/ reactions within the appropriate timescales. • Major administrative flaws i.e. using wrong version of the study protocol, Participant Information Sheet (PIS), Informed Consent Form (ICF) where it is likely that participant safety or data quality may be seriously compromised. **Violations are actions that impact participant's rights, safety or data integrity (in studies regulated by the MHRA this is referred to as a Serious Breach).*	Research Governance team.
2	Inform the R&D Director, R&D Operations Director, and Lead Research Nurse immediately on discovery of any one of the pre-defined findings and record as Datix incident. For suspected fraud cases, refer to SOP QA6 Suspected Research Fraud. Written request of immediate suspension to the study Investigator, if required, following the R&D Director's initial review. If appropriate, conduct triggered monitoring as needed of other studies the Investigator is responsible for and submit report to R&D Directors.	Researcher, Monitor, R&D Director, Research Governance, Trust's Risk and Incident Team
3	Decision to temporary halt or permanently terminate the studies must be submitted to the Research Ethics Committee within 15 days either through a substantial amendment or completion of an early termination form.	Research Governance

Step	Action	Responsibility
4	Follow the Trust's reporting and investigation requirements as per the Incident Management Policy and the Trust's SOP Incident Management Procedure. This may include a formal Root Cause Analysis (RCA) investigation led by Risk & Incident Team.	Research Governance and Trust's Risk and Incident Team
5	Perform a monitoring visit, where remedial action is appropriate to ensure all required process are in place. Inform REC of the intention to restart the study through a further substantial amendment requesting authorisation and a favourable ethical opinion. The investigator must wait for confirmation in writing before re-starting recruitment. Review and update the study risk assessment and monitoring schedule accordingly. If need appropriate record of Datix Risk Register. Conduct further monitoring one month after the restart of study or earlier if indicated by risk assessment.	Monitor.

9. Changes from last revision

Major revision of reporting and investigation to align with Trust procedures; Minor revisions, including re-wording of SOP title, updated to new SOP template addition of flow diagram.