Standard Operating Procedure CCTU/SOP007

CCTU Escalation Cascade

1. Scope

This procedure covers escalation of all issues arising from activities undertaken by the CCTU.

2. Purpose

To ensure that arising issues are dealt with in a timely and appropriate manner by all members of CCTU.

3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

3.1. Definitions

Term	Definition
Cambridge Sponsored	Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH); or the University of Cambridge (UoC); or jointly by CUH and UoC or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge

3.2. Abbreviations

Abbreviation	Meaning
CCTU	Cambridge Clinical Trials Unit
CTIMPs	Clinical Trials of Investigational Medicinal Products
Non-CTIMP	Any research study that does not involve an IMP as defined by the MHRA. This may include observational, surgical or other interventional trials such as radiotherapy, but for the purpose of this SOP does not include non-CE/non-UKCA marked device trials.

4. Undertaken by

Any member of the CCTU

5. Items Required

CCTU/SOP018 Handling of Protocol and Regulatory Non-Compliance in Clinical Trials

CCTU/SOP100 Handling of Non-Compliance in CCTU led Non-CTIMPs

CCTU/SOP019 Urgent Safety Measures and Temporary Halt for CTIMPs

R&D/SOP003 Serious Breach of Protocol or GCP in CTIMPs

Trust Procedure: Raising concerns (whistle-blowing) procedure

http://merlin/Lists/DMSRecords/DispRecordTabsDoc.aspx?ID=20663&IsDlg=1&Source=/&IsDlg=1#

R&D Policy and procedure: Scientific misconduct

http://merlin/Pages/Results.aspx?k=ALL(scientific%20misconduct)

Trust Policy and Procedure: Data Protection

http://merlin/Pages/Results.aspx?k=data%20protection

6. Summary of Significant Changes

Addition of non-CTIMP reporting requirements.

Non-CTIMP reporting procedures added to section 7.1

7. Method

The following sections provide a description of the processes to be followed when implementing this document's procedures.

7.1. GCP Non Compliances

- For CTIMPs:
  - Reporting of protocol or regulatory non compliances will be according to CCTU/SOP018 Handling of Protocol and Regulatory Non-Compliance in Clinical Trials
  - Reporting of serious breach will be according to R&D/SOP003 Serious Breach of Protocol or GCP in CTIMPs
  - Reporting of urgent safety measures will be according to CCTU/SOP019 Urgent Safety Measures and Temporary Halt for CTIMPs

- For Non-CTIMPs and Non-Device Trials:
  - Reporting of protocol or GCP non-compliances, urgent safety measures and serious breaches will be according to CCTU/SOP100 Handling of Non-Compliance in CCTU led Non-CTIMPs.

7.2. Misconduct and Fraud

- Reporting of misconduct and fraud will be according to Trust R&D Policy and Procedure: Scientific misconduct

7.3. Breach of Data Protection Act

- Reporting of breach of data protection will be according to Trust Policy and Procedure: Data Protection

7.4. EPIC Use and Functionality Issues

- In the event of significant issues which affect patient safety or data integrity, these will be escalated immediately as appropriate

7.5. All other issues

- For escalation of all other issues/concerns that do not fit into the above categories, including but not limited to: complaints, staff issues, confidentiality concerns, resourcing issues
- Establish all information where possible relating to the issue to be reported
- Email or send written letter/notes, should the reporter prefer to do so anonymously, to CCTU Operations Director or delegate (Note: all issues raised will be dealt with in confidence; reports made anonymously may be more difficult to investigate depending on information made available)
- CCTU Operations Director or delegate will assess and escalate the issues/concerns as appropriate
- Refer to Trust Procedure: Raising concerns (whistleblowing)

8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring Compliance and Effectiveness

As part of routine monitoring visits, audit and inspection

b. Standards/Key Performance Indicators

This process forms part of a quality management system and is reviewed according to CCTU procedures. Standard Operating Procedures are reviewed every two years.

9. References

The Institute of Clinical Research, Abbreviations used in Clinical Trials.

MHRA, Good Clinical Practice "Grey Guide"

10. Associated Documents

- CCTU/SOP018 Handling of Protocol or Regulatory Non-Compliance
- CCTU/SOP019 Urgent Safety Measures for CTIMPs
- R&D/SOP003 Serious Breach of Protocol or GCP in CTIMPs
- CCTU/SOP100 Handling of Non-Compliance in CCTU led Non-CTIMPs

11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

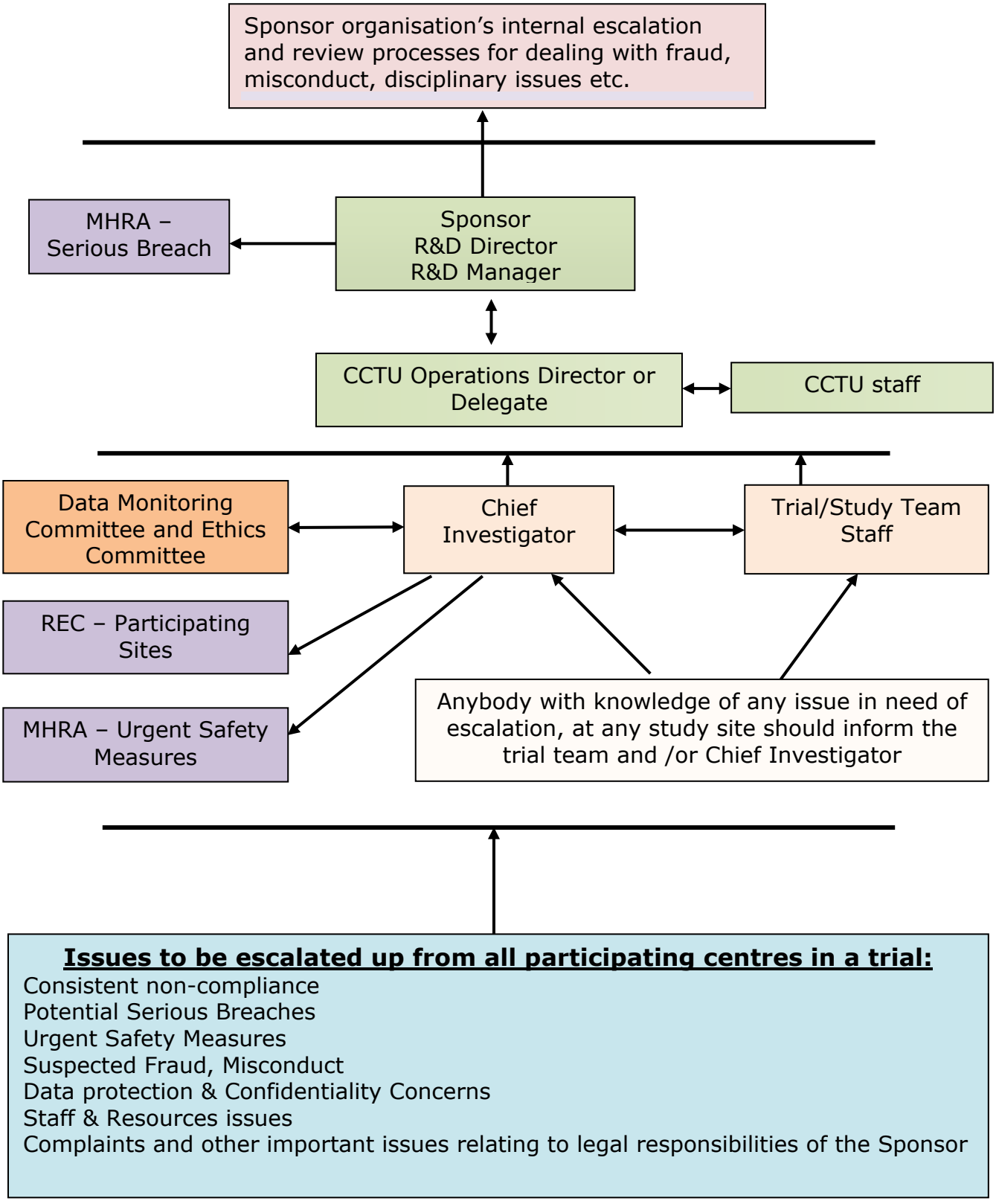
12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

Review date	2 years (or earlier in light of new evidence) from approval date
Owning department:	CCTU QA
Supersedes:	CCTU/SOP007 V4
Local reference:	CCTU/SOP007 v5

Escalation pathway

Associated with the following SOPs: CCTU/SOP007, CCTU/SOP018, CCTU/SOP019, CCTU/SOP100 and R&D/SOP003



<u>Issues to be escalated up from all participating centres in a trial:</u>

Consistent non-compliance
Potential Serious Breaches
Urgent Safety Measures
Suspected Fraud, Misconduct
Data protection & Confidentiality Concerns
Staff & Resources issues
Complaints and other important issues relating to legal responsibilities of the Sponsor