Standard Operating Procedures for Delegation of Roles & Responsibilities

This is a controlled document
Any printed versions of this document will be classed as uncontrolled

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Authorised by: Dr Daniel Michelson Designation: SSC Chair		29.3.21

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1.0	15 April 2021	

[1] 1

3.2 The CI must also ensure that the Principal Investigators at each participating research site undertake their duties or delegate them appropriately.

US Research Ethics, Integrity and Governance Office (REIGO)

3.3 The US Office Research Ethics, Integrity and Governance Office is responsible for ensuring this SOP is followed and the duties expected to be conducted by the department, are performed.

4.

Responsibility/Role	REIGO				

Responsibility/Role	REIGO	CTU	CI	PI	Other
Reporting of Serious Breaches & Urgent Safety Measures to REIGO (SOPRG03 and SOPRG16)			X		
Reporting of Serious Breaches & Urgent Safety Measures to MHRA & REC			X		
Reference Safety Information check			X		
End of the research study					
Notification of the end of the study to REC, Research Governance Office and MHRA when applicable (SOPRG09a)					
Submission of the clinical study report within one year of the end if study the MHRA					
Archiving of the research sites study documentation (SOPRG33)					

SOP for

Appendix 1

HRA Delegation Log Template Non-

STAFF SIGNATURE AND DELEGATION OF RESPONSIBILITIES LOG

Study Sponsor: _____

IRAS Project ID: _____

Protocol / Study Number: _____

Principal Investigator:

Keyto tasks

1. Coordinate approval communications/ submissions
2. Screen/ recruit study participants
3. Obtain informed consent
4.

STAFF SIGNATURE AND DELEGATION OF RESPONSIBILITIES LOG

Study Sponsor: