

University Hospitals of Leicester NHS Trust (UHL)
Index of Standard Operating Procedures for all research HOSTED by the UHL or where the UHL is a SITE
July 2017

Please note that with effect from November 2015, all SOPs and Appendices use the same Version Number. Previous versions must not be used after 1st November 2015. Originals must be obtained from the UHL Research Web Pages to ensure that the latest versions are being used. www.leicestersresearch.nhs.uk

SOP Ref	Title	Version	PGC Ref. No.	Date	Review Date	Appendix Numbers
1000 – UHL	Standard Operating Procedure for writing Standard Operating Procedures for Research & Development procedures conducted within or sponsored by University Hospitals of Leicester NHS Trust (UHL) (SOP for SOPs)	7	C6/2012	February 2017	June 2018	No Appendices
C 2001 - UHL	Informed Consent for Research where the UHL are the HOST / Research SITE	3	C39/2015	February 2017	June 2018	Appendix 1 - Delegation of Authority and Signature Log V3 Appendix 2 - Assent Signature Log V3 Appendix 3 – Procedures prior to consent proforma V3
C 2002 - UHL	UHL Processing and Reporting of Serious Adverse Events, Serious Adverse Reactions and Suspected Unexpected Serious Adverse Reactions for all Research Hosted by the University Hospitals of Leicester NHS Trust	4	C18/2013	February 2017	June 2018	Appendix 1 – Pregnancy Form V4 Appendix 2 – CTIMP Line Listing V4 Appendix 3 – Non-CTIMP Line Listing V4
C 2003 - UHL	Standard Operating Procedure for Principal Investigator Responsibilities for research HOSTED by or where University Hospitals of Leicester NHS	3	C52/2015	February 2017	June 2018	No Appendices

	Trust (UHL) is a research SITE					
C 2004 – UHL	Standard Operating Procedure for Management (Monitoring) of research HOSTED by or where the University Hospitals of Leicester NHS Trust (UHL) is a SITE.	3	C4/2016	February 2017	June 2018	No Appendices
C 2005 - UHL	Training for Staff Engaged in Research HOSTED by the University Hospitals of Leicester NHS Trust	4	C5/2016	March 2017	June 2018	No Appendices
C 2006 - UHL	Process for managing EOI, Feasibility and Site Selection for all research HOSTED by the University Hospitals of Leicester NHS Trust	5	C11/2015	February 2017	December 2017	No Appendices
C 2006a – UHL	Process for managing EOI, Feasibility and Site Selection for research hosted by UHL - Specialty process	4	C40/2015	February 2017	August 2018	No Appendices
C 2007 – UHL	Process for completion of the Operational Capability Assessment for all research HOSTED by the University Hospitals of Leicester NHS Trust	5	C12/2015	February 2017	January 2019	No Appendices
C 2007a – UHL	Process for completion of the OCA for research HOSTED by the UHL – Speciality Process	3	C41/2015	February 2017	June 2018	Appendix 1 – UHL Operational Capability Assessment (Arrange Study) V3
C 2008 - UHL	Process for gaining Trust Authorisation for all research HOSTED by the University Hospitals of Leicester NHS Trust	4	C13/2015	February 2017	June 2018	No Appendices
C 2009 – UHL	Creating and Maintaining an Investigator Site File (ISF) for studies where University Hospitals of Leicester (UHL) NHS Trust is not the Sponsor	3	C14/2016	February 2017	July 2018	Appendix 1 - UHL Trial Investigator Site File Index- Clinical Trials of Investigational Medicinal Products V3 Appendix 2 - UHL Trial Investigator Site

						File Index- NON Clinical Trials of Investigational Medicinal Products V3
C 2010 – UHL	Pre-approval of Studies Involving Genetically Modified Materials and / or Gene Therapy	4	C14/2013	February 2017	September 2018	Appendix 1 – GM Application Checklist V4 Appendix 2 – GM Committee application review V4 Appendix 3 – GM Committee application review comments V4
C 2011 – UHL	Procedure for Authorisation of amendments or additions to documents for studies already authorised where UHL are the Host Organisation or the Research Site	2	C271/2016	February 2017	August 2018	No Appendices
C 2012 - UHL	Procedure for management of contracts for research where the UHL are the Host Organisation or the Research Site.	3	C272/2016	February 2017	July 2018	Appendix 1 – Process Flow Chart V3
C 2013 – UHL	Procedure in Event of Non-Compliance in Research where the University Hospitals of Leicester are the HOST Organisation or the Research SITE.	2	C273/2016	February 2017	September 2018	No Appendices
C 2014 – UHL	Procedure for management and production of Corrective & Preventative Action Plan (CAPA) for studies where the University Hospitals of Leicester NHS Trust are the HOST organisation of the Research SITE	2	C274/2016	February 2017	September 2018	Appendix 1 – CAPA Template V2
C 2015 – UHL	Identifying and Reporting Deviations and Serious Breaches of GCP and/or the Protocol for Clinical	2	C275/2016	February 2017	September 2018	Appendix 1 – Site File Note Template V2

	Trials Hosted by the University Hospitals of Leicester NHS Trust					
C 2016 – UHL	Procedure for the Management of Suspected Fraud and Misconduct in Clinical Research within University Hospitals of Leicester NHS Trust	2	C276/2016	February 2017	September 2018	Appendix 1 – Initial Investigation Template V2 Appendix 2 – Interview Template V2 Appendix 3 – Evidence Listing Template V2
C 2017 – UHL	Archiving of essential study documents for research where the University Hospitals of Leicester NHS Trust are the HOST Organisation or Research Site.	3	C277/2016	July 2017	September 2018	No Appendices
C 2018 – UHL	Procedure for End of study reporting requirements for research where University Hospitals of Leicester are the HOST Organisation or Research Site	2	C278/2016	February 2017	September 2018	No Appendices
C 2019 – UHL	Procedure for obtaining Finance approval for research where the University Hospitals of Leicester NHS Trust are the HOST Organisation or Research Site	3	C279/2016	February 2017	July 2018	No Appendices
C 2020 – UHL	Procedure for the management of the Electronic Data Records Management system for research where the University Hospitals of Leicester NHS Trust are the HOST Organisation or Research SITE	1				Currently being authored
C 2021 – UHL	Procedure for the use and completion of the EDGE system where the University Hospitals of Leicester are the HOST Organisation or Research SITE	1				Currently being authored
C 2022 - UHL	Pandemic Plan for Research	1				Currently being authored