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University Hospitals of Leicester NHS Trust (UHL)
Index of Standard Operating Procedures for all research Sponsored by the UHL
Dec 2021

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

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1000 – UHL	Standard Operating Procedure for writing Standard Operating Procedures for Research & Development procedures conducted within or sponsored by University Hospitals of	10	C6/2012	March 2020	March 2022	No Appendices								

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	Leicester NHS Trust (UHL) (SOP for SOPs)													
S 1001 = UHL	OBSELETE: Sponsor category confirmation for research sponsored by University Hospitals of Leicester NHS Trust (UHL)	3.0	C7/2012	March 2015	March 2017	No Appendices								
S 1002 – UHL	Documentation review process for research sponsored by University Hospitals of Leicester NHS Trust (UHL)	10	C8/2012	February 2021	February 2023	Appendix 1 – Sponsor Request Form V8-Obsolete Appendix 2 – Peer Review Form V10 February 2021 Appendix 3 – Data & CRF Information Form V3-Obsolete Dec 2016 Appendix 3 – Sponsor guidance								

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						form V10 February 2021									
S 1003 – UHL	Sponsor risk assessment and management of research sponsored by University Hospitals of Leicester NHS Trust (UHL)	9	C9/2012	March 2020	March 2022	Appendix 1 – Risk Matrix V8 Appendix 2 – Risk Assessment Form V8 – OBSOLETE Oct 17 Replaced by EDGE Locations Doc Appendix 3 – Risk Summary Table V4 – OBSOLETE Dec 16 Appendix 4 – Risk Assessment Flow Chart V8 Appendix 5 – Sponsor review checklist for studies not requiring Risk Assessment V6 Replaced by EDGE Locations Doc OBSOLETE Oct 17 Appendix 6 – Sponsor review checklist for studies that do									

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						require Risk Assessment V6 OBSOLETE Oct 17 Appendix 7 – Sponsor review document V6 OBSOLETE Oct 17								
S 1004 – UHL	Development Safety Update Report for Clinical Trials of Investigational Medicinal Product Studies Sponsored by University Hospitals of Leicester NHS Trust (UHL)	10	C20/2013	February 2021	February 2023	Appendix 1 - Development Safety Update Report Template. V10 Appendix 2 –DSUR Reporting Timeframe Guidance Document V10 Appendix 3 – DSUR Timeframe flowchart V10								
S 1005 – UHL	Management of contracts for research sponsored by University	7	C4/2014	May 2020	May 2022	Appendix 1 – Contract & Review process V6								

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	Hospitals of Leicester NHS Trust (UHL)													
S 1006 – UHL	Informed Consent for Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	1	C11/2014	November 2020	November 2022	Appendix 1 – Delegation of Authority & Signature Log V10 Appendix 2 – Assent Signature Log V10 Appendix 3 – Assent/Consent Log V10 Appendix 4 – Witness Consent Form Template V10 Appendix 5 – Consent Witness Statement V10 Appendix 6 – Pre-Consent Proforma Template V10 Appendix 7 – EDGE eDOA Signature Log V10		Has been redone to include e consent						

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S-1007 UHL	Management (Monitoring) for research sponsored by the University Hospitals of Leicester NHS Trust (UHL)	11	C16/2013	April 2020	April 2022	Appendix 1 – Monitoring Plan V10 Appendix 1a – Monitoring Plan Medical Devices V10 Appendix 2 – Risk Based Monitoring Strategy V10 Appendix 3 – Contact Monitoring Log V10 Appendix 4 - Monitoring Visit Log V10 Appendix 5 – Schedule of Source Data – V10 Appendix 6 - Monitoring Visit Report Form V10 Appendix 6a – Monitoring Visit Report Form Non CE Marked Medical Devices V10 Appendix 7 – Pharmacy Visit report Form V10								
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						Appendix 8 – Non-CTIMP Monitoring Visit report V10 Appendix 8a – CE Marked Device interim site Audit Checklist V10								
S-1008 UHL	Training for Staff Engaged in Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	10	C12/2014	February 2021	February 2023	Appendix 1 – SOP Read Log V8 Appendix 2 – Protocol Training Log V8 Appendix 3 – CTIMP Generic SOP List V8 Appendix 4 – Non-CTIMP Generic SOP List V8								
S-1009 UHL	Processing and Reporting of Serious Adverse Events, Serious Adverse Reactions and Suspected Unexpected	11	C10/2014	November 2020	November 2022	FORM A – CTIMP Reporting Form V10 FORM B – NON-CTIMP Reporting Form V10 Appendix 1 – Pregnancy Form V10 Appendix 2 –								

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	Serious Adverse Reactions for all Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)					Multi-centre site listings table V10 Appendix 3 – AR/AE/SAE Log V10 Appendix 4 - Flow Chart V10 Appendix 5 – SAE amendment request V10 Appendix 6 – Multi-Centre line listing template for CTIMPs V10 Appendix 7 – e-SUSAR Walk through V10 Appendix 8 – UHL SUSAR Process Flowchart v10 Appendix 9 – Expedited SUSAR Template email V10 Appendix 10 – SUSAR unblinding process flowchart V10									
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S-1010 UHL	Chief Investigator Responsibilities for Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	9	C22/2013	February 2017	November 2018	Appendix 1 – Roles & Responsibilities of CI document V9								
S-1011 UHL	Site Initiation for Clinical Trials of Investigational Medicinal Products Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	10	C17/2013	February 2021	February 2023	Appendix 1 – Site Initiation Check List V10 Appendix 2 – Pharmacy Check List V9 Appendix 3 - SOP Read Log V9 Appendix 4 – Subject Screening Log V9 Appendix 5 – Subject Enrolment Log V9 Appendix 6 – Site Initiation Checklist Non-CTIMP V9 Appendix 7 – Site Initiation Checklist								

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						Non-CTIMP Guidance V9								
S-1012 UHL	Management and Production of Corrective And Preventative Action plan (CAPA) for Studies Sponsored by University Hospitals of Leicester (UHL)	9	C13/2014	November 2020	November 2022	Appendix 1 – UHL CAPA Form V8 Appendix 2 – UHL CAPA Tracking Log V8-OBSOLETE Jan 19								
S-1013 UHL	Identifying and Reporting Deviations and	9	C16/2014	April 2020	April 2022	Appendix 1 – Serious Breach notification form								

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	Serious Breaches of GCP and/or the Protocol for Clinical trials Sponsored by the University Hospitals of Leicester NHS Trust (UHL)					V8 Appendix 2 – File note template V8 Appendix 3 – Protocol Deviation Log V8								
S-1014 UHL	Green Light Process for Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	12	C17/2014	March 2020	March 2022	Appendix 1 – Green Light Process – First Site V11 Appendix 2 – Green Light Process – Multi Site V11 Appendix 3 – Green Light Process – Agreements V11								
S-1015 UHL	Management of Essential Documents and Trial Filing for Research	10	C18/2014	April 2020	April 2022	Appendix 1 – TMF / ISF Contents CTIMP V8 Appendix 2 – TMF / ISF Contents Non-								

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	Sponsored by University Hospitals of Leicester NHS Trust (UHL)					CTIMP V8 Appendix 3 – Version Control Doc. V8 Appendix 4 – Archiving Timetable V8								
S-1016 UHL	Procedure in the Event of Non-Compliance in Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	8	C19/2014	April 2020	April 2022	No Appendices								
S-1017 UHL	Green Light Process for Amendments to research Sponsored by University Hospitals of	8	C35/2013	March 2020	March 2022	Appendix 1 – Amendments requiring MHRA only V7 Appendix 2 – Amendments requiring MHRA & REC authorisation								

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	Leicester NHS Trust (UHL)					V7 Appendix 3 – Amendments requiring REC opinion V7 Appendix 4 – Amendments not requiring notification V7 Appendix 5 – Multi-Centre Sponsor Amendment Green Light Process V7 OBSOLETE JAN 19 Appendix 6 – First / Single Site vSponsor Amendment Green Light Process V5 OBSOLETE JAN 19								
S-1018 UHL	Approval of Amendments or Additions to Documents for Studies	4	G20/2014	February 2017	November 2018	No Appendices Duplicates wording in S-1017 UHL SOP S-1018 no longer required.								

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	Sponsored by University Hospitals of Leicester NHS Trust (UHL)													
S-1019 UHL	Procedure for the Management of Fraud and Misconduct in Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	6	C24/2015	November 2020	November 2022	Appendix 1 – Suspected Fraud or Misconduct Initial Investigation Template V5 Appendix 2 – Suspected Fraud and Misconduct Interview Template V5 Appendix 3 – Evidence Listing Template V5								
S-1020 UHL	Process for Assessing Site Feasibility for Research Sponsored by University Hospitals of Leicester NHS	6	C32/2014	February 2021	February 2023	Appendix 1 – Site Feasibility Assessment (SFA) V45 Appendix 2 – Pharmacy Site Feasibility Assessment V5								

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	Trust (UHL)													
S-1021 UHL	Process for Writing Study Protocols for Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	7	C33/2014	February 2021	February 2023	Appendix 1 – CTIMP Protocol Template V3 OBSOLETE w/e Jan 2017 Appendix 2 – Non-CTIMP Protocol Template V4 - OBSOLETE w/e Jan 2017 Appendix 3 – Protocol Training Log V6								
S-1022 UHL	Process for Submission of Annual Progress Reports for Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	6	C34/2014	February 2021	February 2023	No Appendices								
S-1023	Process for the IB / SPC	6	C35/2014	October	October	Appendix 1 – IB Template V5								

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UHL	Preparation, Review, Approval and Amendment for Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)			2018	2020	OBSOLETE From August 2020 Appendix 2 – IB Review Template V5								
S-1024 UHL	Process for Study Close Down for Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)		C27/2014	February 2021	February 2023	Appendix 1 – Site Closedown Report V5 Appendix 1a – Site Closedown Report – Non CEMarked devices V5 Appendix 2 – Site Closedown visit log V5 Appendix 3 – Site Closedown Checklist – Non CTIMP V5 Appendix 3a – Site Closedown Checklist – CE Marked devices V5								

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S-1025 UHL	SOP for Convening a Data Safety Monitoring Committee for Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	5	C28/2014	February 2019	February 2022	Appendix 1 – DSMC Charter Template V5								
S-1026 UHL	Urgent Safety Measures SOP for Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	7	C29/2014	February 2021	February 2023	Appendix 1 – Urgent Safety measures Template V6								
S-1027 UHL	Creating a Statistical Analysis Plan for Research Sponsored by University Hospitals of	6	C30/2014	November 2020	November 2022	No Appendices								

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	Leicester NHS Trust (UHL)													
S-1028 UHL	Amendments to Contracts for Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	6	C31/2014	February 2021	February 2023	Appendix 1 risk assessment								
S-1029 UHL	Archiving of Essential documents for Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	8	C37/2014	November 2020	November 2022	Appendix 1 – Archiving Assessment Check List V6 Appendix 2 – Archiving Electronic Aspects of TMF V6 Appendix 3 – Pre-Archiving Check List V6 Appendix 4 – Archiving Process								

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						flowchart V6 Appendix 5 – Retrieval process flowchart V6 Appendix 6 – Archiving Timeline Guidance V6 FORM A – V6 FORM B – V6 FORM C – V6 FORM D – V6								
S-1030 UHL	End of Study and study reporting for Research Sponsored by University Hospitals of Leicester NHS Trust (UHL)	7	C38/2014	February 2021	February 2023	No Appendices								
S-1031 UHL	Data Management process for Research Sponsored by University Hospitals of	6	C39/2014	February 2021	February 2023	No Appendices								

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	Leicester NHS Trust (UHL)													
S-1032 UHL	Process for Identifying and engaging the services of an external Vendor to provide services for research sponsored by University Hospitals of Leicester NHS Trust (UHL)	4	C2/2017	November 2020	November 2022	No Appendices								
S-1033 UHL	Randomisation and Blinding for Research Studies sponsored by the University Hospitals of Leicester NHS Trust (UHL)	6	C40/2014	February 2021	February 2023	No Appendices								

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S-1034 UHL	Finance approval process for Research sponsored by University Hospitals of Leicester NHS Trust (UHL)	5	C48/2015	February 2021	February 2023	No Appendices								
S-1035 UHL	Case Report Form production for research sponsored by the University Hospitals of Leicester NHS Trust (UHL)	7	C41/2014	February 2021	February 2023	Appendix 1 – Case Report Form Template V6 Appendix 2 – Guide to completing CRF V6								
S-1036 UHL	Quality Assurance (Audit) of Research Sponsored by the University Hospitals of Leicester NHS	4	C6/2017	February 2021	February 2023	No Appendices								

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	Trust (UHL)													
S-1037 UHL	Healthy Volunteers for Research sponsored by University Hospitals of Leicester NHS Trust (UHL)	6	C1/2015	February 2021	February 2023	Appendix 1 – Template TOPs Consent Form V5								
S-1038 UHL	OBSOLETE													
S-1039 UHL	SOP S-1039 Sample management for research studies sponsored by UHL	2	C72/2017	February 2021	February 2023	Appendix 1a Fridge Temperature Log V2 Appendix 1b Freezer Temperature Log V2 Appendix 1c Nitrogen Vessel Storage Log V2 Appendix 2 Sample								

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						Tracking Log V2 Appendix 3 Sample End of Study Notification Form V12 Appendix 4 Shipping Instructions for Biological Samples V2 Appendix 5 Human Tissue Disposal Form V2								
S-1040 UHL	Processing and Reporting Serious Adverse Events, Serious Adverse Device	1		March 2019	March 2021	Appendix 1 – Event categorisation flowchart V1 March 2019 Appendix 2 - Adverse event Adverse Effect								

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	Effects and Unexpected Serious Adverse Device Effects for Non CE Marked Medical Device Studies (requiring MHRA approval) Sponsor by the University Hospitals of Leicester NHS Trust					record V1 March 2019 Appendix 3 - SAE Report Form C V1 March 2019 Appendix 4 - SAE Form C Completion Guidance Document V1 March 2019 Appendix 5 - Medical Device Sponsor Process Flowchart V1 March 2019 Appendix 6 - Template SAE SADE Follow Up Information Request Email V1 March 2019 Appendix 7 - Device Deficiency form V1 March 2019									
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S-1041 UHL	Processing and Reporting Serious Adverse Events, Serious Adverse Device Effects and Unexpected Serious Adverse Device Effects for CE Marked Medical Device Studies (Not requiring MHRA approval) Sponsor by the University Hospitals of Leicester NHS Trust	1		March 2019	March 2021	Appendix 1 – Event categorisation flowchart V1 March 2019 Appendix 2 - Adverse event Adverse Effect record V1 March 2019 Appendix 3 - SAE Report Form C V1 March 2019 Appendix 4 - SAE Form C Completion Guidance Document V1 March 2019 Appendix 5 - Multicentre line listing V1 March 2019 Appendix 6 Medical Device Sponsor Process Flowchart V1								
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						March 2019 Appendix 7 - Template SAE SADE Follow Up Information Request Email V1 March 2019 Appendix 8 - Device Deficiency form								
S-1042 UHL	Standard Operating Procedure for the Use and completion of the EDGE system where University Hospitals of Leicester NHS Trust (UHL) Is the SPONSOR	2		March 2019	March 2021	No appendices								

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	Organisation.													
S-1043 UHL	Standard Operating Procedure for Research Transparency for all research sponsored by University Hospitals of Leicester NHS Trust (UHL)	2		November 2019	November 2021	No appendices								
S-1045 UHL	Standard Operating Procedure for End of Sponsor Green Light Process for all research sponsored by	1		November 2019	November 2021	Appendix 1 – Checklist 1 November 2019 Appendix 2 – 6 month email, reminder V1 November 2019 Appendix 3 – 9 month email,								

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	University Hospitals of Leicester NHS Trust (UHL)					reminder V1 November 2019 Appendix 4 – 10 month email, reminder V1 November 2019 Appendix 5 – 11 month email, reminder V1 November 2019 Appendix 6 – Receipt of completed Sponsor green light checklist V1 November 2019								
S-1047	Procedure for process to open or re-open non-pandemic research	V1	TBC	May 2020	May 2022	Appendix 1 V1 May 2020								
S-2027	Process to open or re-open non	V2	TBC	May 2020	May 2022	Appendix 1 V2 May 2020								

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	<p>pandemic research</p>													
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