# Appendix 5

## Workflows - Responsibilities

| Name of Workflow - GREEN to be added to PROJECT LEVEL. RED to be added to SITE LEVEL | What is the purpose | When must it be used | Who completes it? |
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| Amendment Effective 01/04/19 | To be added every time an amendment requires R&I Approval/Acknowledgement. This includes substantial and non-substantial amendments, regardless of Categorisation. | To be added every time an amendment requires R&I Approval/Acknowledgement. Substantial and Non Substantial Amendments | TBC |
| Antimicrobial Agent or Process | To identify Antimicrobial Agent or processes in use | This must be completed whenever it is identified that an Antimicrobial Agent or process is being used within the study & where the Attribute in Mandatory 1 has been ticked as 'YES'. The best individual to make the call will be a member of either the clinical team or pharmacy | Specialty Staff with liaison from Pharmacy |
| Archiving Arrangements | To track Archiving Arrangements | Every single study - in addition Mandatory Category 3 Attribute must be added | Corporate R&I |
| Audiology Approval | To facilitate Audiology approval | For every study where Audiology is required to deliver the study | Any staff facilitating Audiology Approval - Speciality Staff |

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| **Bid / Grant process - Lead Organisation** | To track Bids / Grants | Every Bid / Grant. In addition the Bids & Grants Attribute must be added | Corporate R&I |
| **Capacity / Capability Confirmation NOT REQUIRED** | This workflow must be added to a study where there is no expectation for a formal acceptance of Capacity or Capability. | | TBC |
| **Cardiac Investigations** | To be used by Cardiac Investigations & completed by authorised personnel within Cardiac Investigations. Marian Campton | This workflow is to be used when Cardiac Investigations are required for studies. The workflow must be completed by authorised individuals within Cardiac Investigations. | Cardiac Investigations Team Only |
| **CMG Approval - CHUGGS** | To manage the CMG / Speciality approval process | To be added where the Cancer, Haematology, Urology, Gastroenterology & General Surgery CMG have involvement in the study either as a primary or secondary CMG | Any staff facilitating CHUGGS CMG Approval - Speciality Team |
| **CMG Approval - Corporate** | To manage the CMG / Speciality approval process | To be added where the Corporate CMG have involvement in the study either as a primary or secondary CMG | Any staff facilitating Corporate CMG Approval - Speciality Team |
| **CMG Approval - CSI** | To manage the CMG / Speciality approval process | To be added where the Clinical Services CMG have involvement in the study either as a primary or secondary CMG. This is separate and different to where CSI is involved with Support Services / Departments - it relates to when the CI/PI or collaborators are leading the study | Any staff facilitating CSI CMG Approval - Speciality Team |

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| **CMG Approval - ED & Specialist Meds** | To manage the CMG / Speciality approval process | To be added where the Emergency Department or one of Specialist Medicines CMG have involvement in the study either as a primary or secondary CMG | Any staff facilitating EDSM CMG Approval - Speciality Team |
| **CMG Approval - ITAPS** | To manage the CMG / Speciality approval process | To be added where the Intensive Care, Theatres, Anaesthesia, Sleep & Pain CMG have involvement in the study either as a primary or secondary CMG | Any staff facilitating ITAPS CMG Approval - Speciality Team |
| **CMG Approval - MSK & Specialist Surgery** | To manage the CMG / Speciality approval process | To be added where the Musculoskeletal & Specialist Surgery CMG have involvement in the study either as a primary or secondary CMG | Any staff facilitating MSK SS CMG Approval - Speciality Team |
| **CMG Approval - RRCV** | To manage the CMG / Speciality approval process | To be added where the Respiratory, Renal, Cardiac and Vascular CMG have involvement in the study either as a primary or secondary CMG | Any staff facilitating RRCV CMG Approval - Speciality Team |
| **CMG Approval - Womens & Childrens** | To manage the CMG / Speciality approval process | To be added where the Women's & Children's CMG have involvement in the study either as a primary or secondary CMG | Any staff facilitating Womens & Childrens CMG Approval - Speciality Team |
| **Collaborations Confirmed - Multi Centre** | This Workflow must be added to all Multi-centre studies to confirm that the sites are added as collaborators with UHL and vice versa. Where the study is on the Portfolio the CRNEM must also be added as a collaborator with each site too! | | TBC |

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| **Confidentiality Disclosure Agreement Process** | This is the workflow to use when processing a CDA for a prospective study / Expression of Interest or Capability. The CDA process is the same for any study. | | Corporate R&I |
| **Confirm process Stage 3 (R&I Authorisation)** | To track the authorisation process for UHL R&I | Every single study. In addition Mandatory Category 4 must be added | Head of Research Operations, Deputy Dir R&I or R&I Manager only |
| **Contract process** | To track the progress of contracts | Every single study where a contract is required except for CDAs. In addition the Contracts Attribute must be addded | Corporate R&I |
| **DSUR - SOP S-1004 UHL** | To be completed for studies where a DSUR is due to be sent to regulatory authorities. | | Corporate R&I |
| **Final Contract Pre-sign Checks (HRA Only)** | To check the final stages of Assess, Arrange, Confirm before Contract is signed | This workflow to be completed when the study has been processed through the HRA. | Corporate R&I |
| **Imaging Approval** | To be completed by Imaging - authorised signatory - Bruno Morgan | Provides Imaging authorisation confirmation for each study where Imaging is required | Imaging Staff Only |
| **Imaging Post-Approval Check** | To be completed by Imaging once approval of a study has been confirmed | To be completed by Imaging | Imaging Staff Only |
| **Laboratory Services Approval** | To faciliate Laboratory Services approval | For every study where Laboratory Services is required to deliver the study and where it is identifed in Mandatory Category 1 that Laboratory Services are required | Any staff facilitating study set up - Speciality Team |

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| **LCBRU Internal Authorisations Complete** | To facilitate internal Leicester Cardiac BRU Processes | For every study where the LCBRU is involved | LCBRU Staff Only |
| **Medical Illustration** | To faciliate Medical Illustration approval | For every study where Medical Illustration is required to deliver the study and where it is identified in Mandatory Category 1 that Medical Illustration are required | Any staff facilitating study set up - Speciality Team |
| **Medical Physics Approval** | To facilitate Medical Physics approval | For every study where Medical Physics is required to deliver the study and where it is identified in Mandatory Category 1 that Medical Physics are required | Any staff facilitating study set up - Speciality Team |
| **Musketeers Memorandum Studies Workflow** | To facilitate MM studies process | For every study where MM is the Process to be followed | Corporate R&I |
| **NOT YET IN USE UHL Pharmacy Set Up** | To facilitate Pharmacy Set Up | For every study where Pharmacy is involved | Pharmacy Staff Only |
| **Nuclear Medicine Approval** | To facilitate Nuclear Medicine Approval | For every study where Nuclear Medicine is required to deliver the study and where it is identified in Mandatory Category 1 that Nuclear Medicine are required | Any staff facilitating study set up - Speciality Team |
| **Opthalmology Approval** | To facilitate Opthalmology Approval | For every study where Opthalmology is required to deliver the study and where it is identified in Mandatory Category 1 that Opthalmology are required | Any staff facilitating study set up - Speciality Team |

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| **Orthodontics** | To faciliate Orthodontics approval | For every study where Orthodontics is required to deliver the study and where it is identified in Mandatory Category 1 that Orthodontics are required | Any staff facilitating study set up - Speciality Team |
| **Pandemic Studies Annual Review** | This workflow is to be used to check that all potential pandemic studies that could be launched at UHL are as ready as possible without actually hitting 'go'. | | TBC |
| **Pandemic Studies Hard Launch** | This workflow is to be used when a pandemic has been declared. | | TBC |
| **Partial Authorisation Workflow** | To track the progress of a study that was initially given Partial authorisation then progresses to Full Authorisation | Every study initially given Partial authorisation. In addition Partial to Full authorisation attribute must be added | Head of Research Operations, Deputy Dir R&I or R&I Manager only |
| **R&I Finance Approval** | To faciliate Finance approval | For every study | Corporate R&I |
| **Recall from Archive** | To be added to all studies along with Mandatory Category 3. Details that the Archiving Arrangements have been discussed with the Sponsor before the study commences. | | Corporate R&I |
| **Research Passport, NHS to NHS & H/C** | To track the progress of Research Passport applications | Every time a HRC/letter of access is required. A workflow must be added for each individual - cloned and renamed accordingly | Speciality Team and Corporate R&I |

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| **Respiratory Services** | To facilitate Respiratory Services Approval | For every study where Respiratory Services is required to deliver the study and where it is identified in Mandatory Category 1 that Respiratory Services are required | Any staff facilitating study set up - Speciality Team |
| **SPONSOR 01 Initial Review No Risk Assessment** | See SOP S-1003 UHL Appendix 4 to determine whether or not a Risk Assessment is required. | | Corporate R&I |
| **SPONSOR 05 Review Risk Assessed -Multi Centre** | Please see SOP S-1003 UHL Appendix 4 to determine whether a risk assessment is required. If a Risk Assessment is required then please use this Workflow. If not please use NO RISK ASSESSMENT. | | Corporate R&I |
| **SPONSOR 06 Review Risk Assessed -Single Centre** | If a Risk Assessment is NOT required then please use this Workflow. If one IS required please use the RISK ASSESSMENT workflow. | | Corporate R&I |
| **SPONSOR 07 Safety Reporting - Multi Centre** | This Workflow must be added for each study where UHL is the Sponsor for a Single Centre Study | | Corporate R&I |
| **SPONSOR 08 Safety Reporting - Single Centre** | This Workflow must be added for each study where UHL is the Sponsor for a Single Centre Study | | Corporate R&I |
| **SPONSOR 10 Study Training - Single Centre** | Add this Workflow for all studies where UHL is the Sponsor - Single Centre | | Corporate R&I |

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| **SPONSOR 11 DSUR** | This workflow must be added to every study where a DSUR will be required in accordance with SOP S-1004 UHL | | Corporate R&I |
| **SPONSOR 12 Finance Approval** | This workflow is to be used to show the Finance Approval for all Studies that UHL Sponsor. | | Corporate R&I |
| **SPONSOR 13 General Workflow** | This workflow must be added to every study where UHL is the Sponsor. | | Corporate R&I |
| **SPONSOR 15 PIS / ICF Review** | The workflow to be used when reviewing PIS / ICF for studies Sponsored by UHL | | Corporate R&I |
| **SPONSOR 16 Site Audits** | This workflow must be added for each study that is Sponsored by UHL and where a Site Initiation is required as stated in SOP S-1011 UHL. | | Corporate R&I |
| **SPONSOR 17 Site Close Down** | This workflow must be added for each study that is Sponsored by UHL and where a Site Initiation is required as stated in SOP S-1011 UHL. | | Corporate R&I |
| **SPONSOR 21 Annual Reports** | To be completed for studies where a DSUR is due to be sent to regulatory authorities. | | Corporate R&I |

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| **SPONSOR 22 Multi Centre Amendment** | To be added every time an amendment requires R&I Approval/Acknowledgement. This includes substantial and non-substantial amendments, regardless of Categorisation. The Amendment Type/Number/Date must be included in the workflow comment. | | Corporate R&I |
| **SPONSOR 23 Urgent Safety Measures (Single Centre)** | This workflow should be completed when an USM has been implemented for a Single Centre Study | | Corporate R&I |
| **SPONSOR 24 3rd Party Vendors** | To be added where external / 3rd party vendors are to be contracted to deliver aspects of a research study where UHL is the Sponsor | | Corporate R&I |
| **SPONSOR 25 Contracts Process** | To be added to studies were UHL is Sponsor and contracts are to be negotiated | | Corporate R&I |
| **SPONSOR 26 Substantial Amendment Review** | To be added every time a Substantial amendment requires Sponsor authorisation. The Amendment Type/Number/Date must be included in the workflow comment. | | Corporate R&I |
| **SPONSOR 27 NON Substantial Amendment Review** | To be added every time a Non Substantial amendment requires Sponsor authorisation. The Amendment Type/Number/Date must be included in the workflow comment. | | Corporate R&I |

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| **SPONSOR 34 Site Pharmacy Close Down** | This workflow must be added for each study that is Sponsored by UHL and where a Site Initiation is required as stated in SOP S-1011 UHL. | | Corporate R&I |
| **Study Staff Added** | To verify that all staff have been added to EDGE appropriately That all training & certificates have been uploaded and relevant contracts obtained. | For Every Study | Any staff facilitating study set up - Speciality Team |