University of Leicester Research Governance Office

Standard Operating Procedures

SOP S-1050 UoL

Standard Operating Procedure for Research Sponsored by the University of Leicester during a Pandemic

Version 2.0 May 2024

Effective Date: July 2024

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used. For active studies there is no requirement to update appendices to the latest version.

1.0 Introduction and Scope

This Standard Operating Procedure (SOP) describes the process for the management of research sponsored by the University of Leicester (UoL) during a World Health Organisation (WHO) categorised pandemic. This SOP is designed to be generic. Responses to individual pandemics may require different approaches and as such are added as appendices. This SOP applies to all staff, and any external individuals who are involved in research that is sponsored by the University of Leicester.

A pandemic is a unique and challenging situation and will place considerable pressure on research governance arrangements. National organisations, government bodies and NHS organisations will publish guidance to ensure that best practice is maintained during the pandemic and these will be followed. As a Sponsor, the UoL has a duty to maintain and support research activities, and to balance this duty with the need to maintain staff and patient safety.

The aim of this SOP is to define the procedures for dealing with different aspects of research governance during a pandemic including but not limited to the preparation and amendment of research, the monitoring of research and deviations to the approved protocol of research sponsored by the UoL.

2.0 Preparation of Sponsorship Applications

It is important to recognise that a pandemic situation is unique and challenging and that decisions are being made rapidly as the situation changes. The normal research governance process is complex and can often take several weeks or months to complete. During a pandemic situation, there is a requirement to be flexible, adaptive and proportionate in our research governance processes; research has therefore been separated into the following categories:

- Prioritised Studies
- Expedited Studies
- Non-pandemic related studies

2.1 Prioritised Studies

Prioritised studies are those that meet Urgent Public Health Research needs. Where the University of Leicester is identified as the Sponsor for a prioritised study, the Research Governance Office will work with and in parallel to the regulatory process to ensure a rapid set up. The Chief Investigator (or their delegate) must submit their application via Infonetica. A Sponsor review will be completed and indemnity will be issued prior to the study being submitted for regulatory approvals. Submissions to all regulatory bodies and host NHS organisations may be done in parallel to avoid delay.

Where available, the host NHS Organisation's SOP for setting up prioritised studies should be consulted and followed. The appropriate teams within the Research and Enterprise Division should be consulted.

2.2 Expedited Studies

Studies that are focussed on the pandemic but have not been identified as a priority study and where the University of Leicester is identified as the sponsor will receive an expedited review by the Research Governance Office. The Research Governance Office will work with and in parallel to the regulatory process to ensure a rapid set up. This includes advanced notification to the host NHS Organisation for them to confirm that they have the Capacity and Capability to support the research. Where a host NHS Organisation deems that it cannot support the research, unless the Chief Investigator (and/or Principal Investigator) are able to demonstrate that the research requires little-to-no resources, the research will not be sponsored by the University of Leicester.

Where a host NHS Organisation confirms its Capacity and Capability to support the research, the Chief Investigator (or their delegate) must submit their application via Infonetica. A Sponsor review will be completed and indemnity will be issued prior to the study being submitted for regulatory approvals. Submissions to all regulatory bodies and host NHS organisations may be done in parallel to avoid delay.

Where available, the host NHS Organisation's SOP for setting up expedited studies should be consulted and followed.

2.3 Non-pandemic related Studies

The Research Governance Office will continue to accept applications for non-pandemic related studies during the pandemic and SOP S-1002 should be followed. Applications for non-pandemic related studies will be processed only if the Research Governance Office has the capacity in light of prioritising pandemic applications (see 3.1 and 3.2 above) and amendments (see 4.1 below). Applications should be submitted via Infonetica.

3.0 Amendments to Existing Research

The Health Research Authority guidance for amending existing research should be followed.

In addition, the Research Governance Office has issued a Risk Assessment and Site File Note which must be used to record any and all changes to the management and conduct of research sponsored by the University of Leicester during a pandemic. These documents are Appendix 1 (Risk Assessment) and 2 (File Note), respectively. This includes categorising your research based on the pandemic-specific categories provided, which will then determine how the research will be prioritised.

As and when restrictions are lifted, the Risk Assessment and Site File Note must be updated and submitted to the Research Governance Office for approval at rgosponsor@le.ac.uk.

Sponsor approval for any and all changes will be issued by email. A copy of the email(s) must be retained in the Trial Master File (TMF)/Investigator Site File (ISF) for monitoring and auditing purposes.

3.1 Adding a Pandemic Element(s)

Researchers wishing to add a pandemic related element(s) to their existing study are expected to inform the Research Governance Office by email to at rgosponsor@le.ac.uk ahead of submitting their amended documentation via Infonetica.

The Research Governance Office will seek assurance on the following aspects:

- Confirmation of Funding (existing or pending)
  - The appropriate Research and Enterprise Division Grants team should be consulted.
- That host NHS Organisation(s) have been contacted and have confirmed that they have the Capacity and Capability to the support the research
  - Where Capacity and Capability cannot be provided, unless the Chief Investigator (and/or Principal Investigator) are able to demonstrate that the research requires little-to-no resources, the amendment will not be processed by the Research Governance Office.

The Chief Investigator (or their delegate) must submit their amendment to the Research Governance Office via Infonetica. A Sponsor review will be completed and where necessary, indemnity will be (re)issued prior to the amendment being submitted for regulatory approvals. Submissions to all regulatory bodies and host NHS organisations may be done in parallel to avoid delay.

Where available, the host NHS Organisation's SOP for approving pandemic related amendments to existing hosted studies should be consulted and followed.

4.0 Procedures

Where reasonably possible, all University of Leicester Sponsor SOPs should be followed. In some cases, deviations to SOPs will be necessary to ensure the safety and integrity of staff, participants and the research.

4.1 Consent

Every effort should be made to continue to obtain informed consent in a GCP-compliant manner and according to existing SOPs. Where a change is required, for example; a paper copy cannot be retained because of biohazards, other means can be implemented. A photograph of the form can be taken and retained. Where this is a change to the current protocol it should be documented in the pandemic-specific Risk Assessment and Site File Note (Appendices 1 and 2 to this SOP, respectively).

4.2 Local Policies and SOPs

Where a host NHS Organisation has changed local policy and procedures, researchers should consider the impact of the change(s) on their research and the overarching sponsor SOPs. Change(s) that necessitate a deviation from the Sponsor SOP should be documented in the pandemic-specific Risk Assessment and Site File Note (Appendices 1 and 2 to this SOP, respectively). The process outlined in Section 4 above should be followed.

4.3 Deviations, Violations, Serious Breaches, Urgent Safety Measures, Waivers and SAEs/SUSARS

4.3.1 Deviations

Due to reduced hospital visits, self-isolation and shielding arrangements it is expected that there will be an increase in deviations. All deviations are to be recorded during this time using the current Protocol Deviation Tracking Log or, if a large number of deviations are anticipated, the Research Governance Office request that the Trial Management/research teams collect information regarding deviations and collate in one document (for example: Excel spreadsheet).

It is expected that the list of protocol deviations is provided to the Research Governance Office upon request.

4.3.2 Violations, Serious Breaches and Non-Compliance

Any violations, serious breaches and occurrences of non-compliance to the approved study protocol should be reported in-line with the SOPs S-1013 (Identifying and Reporting Deviations and Serious Breaches of GCP and/or the Protocol) and S-1016 (Procedure in the Event of Non-Compliance in Research).

4.3.3 Urgent Safety Measures

Urgent Safety Measures (USMs) that are made to studies in order to continue during the pandemic must be discussed with and reported to the Sponsor immediately and in line with SOP S-1029. These can include, but are not limited to, the deliberate/planned omission of approved protocol procedures and assessments such as safety blood collection or other outcome measures to reduce risk of contamination to both staff and participants.

4.3.4 Waivers

Prospective protocol waivers are unacceptable and should not be used to change a study due to the pandemic (for example eligibility, patient safety and/or difficulties in assessments). Chief Investigators should discuss issues with following the approved protocol with the Sponsor immediately, and should consider the implementation of an USM, temporary halt or participant discontinuation.

4.3.5 Safety Reporting

All safety reporting procedures including the reporting of Serious Adverse Events and Suspected Unexpected Serious Adverse Reactions must continue to be reported to the Sponsor immediately and in-line with the SOP S-1009 (Processing and Reporting of Serious Adverse Events, Serious Adverse Reactions and Suspected Unexpected Serious Adverse Reactions).

5.0 Risk Assessments

Risk Assessments continue to be applicable to all UoL sponsored studies. To ensure compliance with the national guidance, studies that continue to operate during the pandemic because they, “directly relates to and informs a response/solution to pandemic” and/or, “where clinical care is heavily woven into the research protocol”, a

pandemic-specific Risk Assessment should be completed and returned to the Sponsor along with the pandemic-specific Site File Note as per Section 4 above.

6.0 Monitoring Plans

After the completion of the pandemic-specific Risk Assessment and Site File Note, it may be necessary to make changes to existing monitoring plans. To reduce the administrative burden on the Sponsor and Trial Management teams, an Appendix should be added to the monitoring plan detailing the changes. Consideration should be given to a reassessment date of the appendix to decide if the changes remain applicable or it is appropriate to revert back to the original monitoring plan. Reassessment and outcomes should be documented.

Pandemic Monitoring Plan appendix pages will be completed by the Sponsor and shared with the Trial Management team for review.

7.0 Legal Liability Statement

Guidelines or Procedures issued and approved by the Sponsor are considered to represent best practice. Staff may only exceptionally depart from any relevant Sponsor guidelines or procedures and only providing the departure is confined to the specific needs of individual circumstances. In healthcare delivery, such departure shall only be undertaken where, in the judgement of the responsible healthcare professional, it is fully appropriate and justifiable – such a decision must receive Sponsor approval which will be issued by email. A copy of the email(s) must be retained in the Trial Master File (TMF)/Investigator Site File (ISF) for monitoring and auditing purposes.

8.0 Responsibilities

Responsibility	Undertaken by	Activity
Sponsor	Head of Governance Manager or their delegate	Ensure compliance with SOP and update SOP as relevant guidance changes.
Sponsor	Head of Governance Manager or their delegate	Review all pandemic-related research and amendment applications. Liaise with host NHS organisations to confirm Capacity and Capability.
Researcher	Researcher	Ensure compliance with SOP.

9.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Management and Operations Group (RSMOG)	Professor Nigel Brunskill 	14/06/2024

10.0 Review Record

This table is used to track the changes made across document revisions.

Date	Version number	Reviewed by	Description of changes (If any)
May 2024	2.0	Cat Taylor	Removal of references to specific guidance and websites in place during the COVID-19 pandemic and replacement with statements applicable to all pandemic scenarios. Removal of distribution record Removal of office address Appendix 1 – minor updates Appendix 2 – Removal of references to COVID-19