Research Governance Office Sponsorship Standard Operating Procedures

Pandemic Adaptations for Trials

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1.0 Introduction and Scope

This Standard Operating Procedure (SOP) describes the process for the management of research (referred to as 'trial' hereafter) 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 will be added as appendices. This SOP applies to all staff, and any external individuals who are involved in trials sponsored by the UoL.

A pandemic is a unique and challenging situation and will place considerable pressure on trial 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 trial 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 modification of trials, the monitoring of trials and deviations to the approved protocol of trials.

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 trials
- Expedited trials
- Non-pandemic related trials

2.1 Prioritised trials

Prioritised trials are those that meet Urgent Public Health Research needs. Where the UoL is identified as the Sponsor for a prioritised trial, the Research Governance Office (RGO) 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 trial 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 trials should be consulted and followed. The appropriate teams within the Research and Enterprise Division should be consulted.

2.2 Expedited Trials

Trials that are focussed on the pandemic but have not been identified as a priority trial and where the UoL is identified as the sponsor will receive an expedited review by the RGO. The RGO 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 UoL.

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 trial 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 trials should be consulted and followed.

2.3 Non-pandemic related Studies

The RGO will continue to accept applications for non-pandemic related trials during a pandemic and SOP S-1002 should be followed. Applications for non-pandemic related trials will be processed only if the RGO has the capacity in light of prioritising pandemic applications (see sections above) and modifications (see section below). Applications should be submitted via Infonetica.

3.0 Modifications to Existing Research

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

In addition, the RGO 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 trials sponsored by the UoL during a pandemic. These documents are Appendix 1 (Risk Assessment) and 2 (File Note), respectively. This includes categorising your trial based on the pandemic-specific categories provided, which will then determine how the trial will be prioritised.

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

Sponsor approval for any and all changes will be issued by Infonetica. A copy of the correspondence must be retained in the Trial Master File (TMF) and 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 trial are expected to inform the RGO via rgosponsor@le.ac.uk ahead of submitting their modified documentation via Infonetica.

The RGO 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 modification to the RGO via Infonetica. A Sponsor review will be completed and where necessary, indemnity will be (re)issued prior to the modification 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 modifications 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 trial.

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).

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

4.3.1 Deviations

Due to the potential for 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 (See SOP S-1013) or, if a large number of deviations are anticipated, the RGO 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 RGO 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 SOP S-1013 and/or S-1016.

4.3.3 Urgent Safety Measures

Urgent Safety Measures (USMs) that are made to studies in order to continue during a pandemic must be discussed with and reported to the RGO 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 a 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.

5.0 Risk Assessments

Risk Assessments continue to be applicable to all UoL sponsored studies. To ensure compliance with the national guidance, trials that continue to operate during a pandemic because they, “directly relate to and inform a response/solution to the 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) and Investigator Site File (ISF) for monitoring and auditing purposes.

8.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Version number	Description of changes
April 2026	3.0	• Minor updates to wording throughout • Removal of responsibilities table as responsibilities are laid out within the body of the SOP. • Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive. • Appendix 1 & 2 - Minor updates to wording