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JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

UoL Research Governance Office
SOP S-1050 v1.0 April 2020

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

OFFICE BASE

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Effective Date: April 2020

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1. Introduction

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. As a Sponsor, the University of Leicester 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 University of Leicester.

This SOP has been developed to address challenges and processes during the COVID-19 pandemic (2020) but can be amended and applied as required to future situations.

2. Scope

This SOP applies to all staff, and any external individuals who are involved in research that is sponsored by the University of Leicester.

3. 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

3.1 Prioritised Studies

The National Institute for Health Research (NIHR) has formulated a process with the Chief Medical Officer (CMO) for England to identify studies that meet Urgent Public Health Research needs. These studies will be prioritised and have access to NIHR funded resources. 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 to the Research Governance Office at rgosponsor@le.ac.uk. A Sponsor review will be completed and indemnity will be issued prior to the study being submitted for regulatory approvals in line with the Health Research Authority guidance on applying for fast-track review. Submissions to all regulatory bodies and host NHS organisations should be done in parallel to avoid delay.

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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.

Sponsor Green Light will be issued when all applicable regulatory and host NHS organisation(s) approvals have been received.

3.2 Expedited Studies

Studies that are focussed on the pandemic but have not been through the NIHR/CMO process (or have not been identified by the NIHR/CMO 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 at rgosponsor@le.ac.uk. 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 to the Research Governance Office. A Sponsor review will be completed and indemnity will be issued prior to the study being submitted for regulatory approvals in line with the Health Research Authority guidance on applying for fast-track review. Submissions to all regulatory bodies and host NHS organisations should 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.

Sponsor Green Light will be issued when all applicable regulatory and host NHS organisation(s) approvals have been received.

3.3 Non-pandemic related Studies

The Research Governance Office will continue to accept applications for non-pandemic related studies during the pandemic and the SOP for Initial Documentation Review (SOP S-1002 UoL) 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 to rgosponsor@le.ac.uk.

Sponsor Green Light will be issued when all applicable regulatory approvals and host NHS organisation(s) have been received.

4. 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 the 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.

4.1 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.

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.
- Confirmation that the amendment meets the NIHR/CMO priority list OR that the amendment does not require NIHR/CMO endorsement but should be considered eligible for an expedited review (as per 3.2 above).

The Chief Investigator (or their delegate) must submit their amendment to the Research Governance Office at rgosponsor@le.ac.uk. A Sponsor review will be completed and where necessary, indemnity will be (re)issued prior to the amendment being submitted for regulatory approvals in line with the Health Research Authority guidance on adding new pandemic related elements. Submissions to all regulatory bodies and host NHS organisations should 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.

Sponsor Green Light will be issued when all applicable regulatory and host NHS organisation(s) approvals have been received.

5. 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.

5.1. 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

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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).

5.2. 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.

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

5.3.1. 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).

For CTIMP studies, it is expected that the list of protocol deviations is submitted to the Research Governance Office via rgosponsor@le.ac.uk at regular intervals (i.e., at the end of each month) until informed otherwise.

For all other studies, the list of protocol deviations is submitted to the Research Governance Office via rgosponsor@le.ac.uk at regular intervals (i.e., every two months) until informed otherwise.

5.3.2. 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 for Identifying and Reporting Deviations and Serious Breaches of GCP and/or the Protocol and S-1016 for the Procedure in the Event of Non-Compliance in Research.

5.3.3. 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.

5.3.4. 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.

5.3.5. Safety Reporting

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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 for Processing and Reporting of Serious Adverse Events, Serious Adverse Reactions and Suspected Unexpected Serious Adverse Reactions.

6. Risk Assessments

Risk Assessments continue to be applicable to all University of Leicester sponsored studies. To ensure compliance with the latest MHRA and HRA guidelines studies, 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. The current versions of the pandemic-specific Risk Assessment and Site File Note are appended to this SOP and can be found on the Research Governance Office website - https://www2.le.ac.uk/institution/ethics/information-for-uhl-and-uol-reseachers-2013-covid-19.

7. 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.

8. 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.

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

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions.

Development and approval Record for this document

Author/Lead Officer:	Dr Cat Taylor
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Approved by:	Professor Nigel Brunskill 
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Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

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Date	Name	Department	Received