UNIVERSITY OF SUSSEX

RESEARCH & ENTERPRISE SERVICES
RESEARCH ETHICS, INTEGRITY & GOVERNANCE

Restarting clinical research – the NIHR Restart Framework

Dear all

Back in March, the Sponsorship Sub-Committee (SSC) agreed the principle that, in response to the current pandemic, those sponsored studies that could **not** make simple adjustments to allow them to move research activities online (with minimal effects for vital health services) should be placed 'on hold'.

An email was sent 26 March ('REQUIRED: Current status of University Sponsored research') from which records were kept of responses. This email is for the attention of the Chief Investigators of studies that have been **placed on hold** and those whose formal Sponsorship (for new studies) has been **withheld** pending a lifting of previous restrictions. The principles will also apply for new studies that will be presented for University Sponsorship going forwards.

Sponsorship Sub-Committee position on the recommencement of research

The Sponsorship Sub-Committee, that oversees the University's Sponsor responsibilities is, in principle, open to a 'proportionate and pragmatic' recommencement of research.

Following the recent publication of the **NIHR's Restart Framework**[1], the SSC has agreed that this be used as the basis for paused studies to make the case for recommencement to the Sponsor.

***** Researchers should familiarise themselves with the detailed published explanations of the Restart Framework on the NIHR website. The following gives University context to this information *****

NIHR Restart Framework

The Framework is based on three guiding principles that will need to be addresses for all studies and an additional principle for NIHR funded studies*:

Guiding Principles

- Study Viability (A)
- Safety (B)
- Capacity and site readiness (C)
- *Prioritisation (D)**

Initial preconditions for planning the restarting/starting research under the principles of the Framework will involve Chief Investigators (CI s) having initially engaged with NHS partners and

[1] https://www.nihr.ac.uk/documents/restart-framework/24886

the research funder to understand if an early case can be made for the study (ies) to recommence.

The Framework recognises that there is not a 'one size fits all' approach for the challenges posed by the restart process and admits that in some cases, as a consequence of events, studies might have to be halted permanently.

A. Study Viability

The principle of on-going viability is complex and multi-facetted and involves scientific, clinical, financial and practical reasons. The Sponsor (via the University's **Research Governance** team) will work closely with CI s to support them in this evaluation, notably in understanding possible additional costs (such as salary, academic time or additional laboratory costs) and the regulatory consequences of necessary amendments to originally approved studies.

The **Brighton and Sussex JCRO**, **Research Development** and **Research Finance** teams should be consulted at an early stage where necessary. For studies that involve doctoral research, supervisors should regularly check University guidelines on extensions, intermissions, funding etc issued by doctoral student support services to make advised recommendations to their students.

Given the significant financial constraints of the University, CI s should *not* assume that any funding shortfalls for additional costs will be covered by their Schools without prior detailed costings and senior authorisation for research expenditure.

B. Safety

The Framework is clear that 'Research should only restart/start when safe to do so'. Whilst the landscape can change very quickly and will vary significantly across the UK, the Sponsor will expect the restart plans to show evidence of reflection on how the study addresses this principle and how it could adapt if the threat level changes.

C. Capacity and site readiness

The question of capacity for undertaking research and site readiness will once again be complex and may also include consideration of factors outside the immediate influence of the NHS.

Studies that involve participants attending the University campus (e.g. CISC) or are dependent on laboratories are required to check whether the facilities to be accessed are included in the current campus restart planning and if other restrictions (such as public transport schedules) may hinder access.

It may not be possible for studies to await confirmation of capacity and site readiness for all previously agreed sites before planning to recommence studies. The Sponsor will expect CI s to make the case for study viability in this instance.

D. Prioritisation

NIHR funded studies should be considered against the three levels of study urgency for the allocation of NIHR CRN support. This principle is not relevant to non-NIHR funded research.

Next Steps

1. CI s should review and complete the Local Restart Assessment checklist (attached) with as much detail as possible and send to researchsponsorship@sussex.ac.uk in readiness for the Sponsorship Sub-Committee of 16 July (closing date for receipt of papers 25 June). Applicants may submits to subsequent meetings if unable to prepare documents in time - http://www.sussex.ac.uk/staff/research/governance/sponsorship/applysponsorship

    - Please give details of mitigation for the issues raised by the guiding principles. Where evidence exists of guidelines or new processes being published by partners that are relevant to the study please give web links or supply key documents.

    - Where studies may have already been considered against the Restart Framework by research partners, the SSC is happy to receive evidence of this in lieu of this checklist and will ask for more details where required.
    - It is vital that you establish with your clinical partners whether research can recommence and any conditions that will apply. Please attach any salient correspondence as evidence.
    - Please consult with your contacts in the Research & Enterprise Services Division for any queries about changes necessary and their cost or regulatory implications.

2. The SSC will receive checklists received and grant approval to restart where a case has been made that meets the above principles. Where questions persist, the SSC will ask for further details or explain why sponsor approval cannot be granted without further detail or assurances.

Antony Walsh
12 June 2020
researchsponsorship@sussex.ac.uk