Research Ethics and Governance guidance for restarting research activities which have been paused due to COVID-19

Background

The University put in place COVID 19 guidance in March 2020 to deal with COVID 19 implications on research ethics and governance requirements.

https://intranet.birmingham.ac.uk/finance/documents/public/UoB-Sponsor-position-COVID-19-20th-March-2020-FINAL.pdf

Where possible research activity continued as planned and in line with the protocol, taking account of the fast changing developments and necessary study based risk assessed deviations.

Where changes did not affect participant safety and / or data integrity, these were considered non-substantial. For studies that were reviewed by a University Research Ethics Committee (REC), a 'for information only' update should have been sent to the Research Ethics Team, with a copy kept in the study file.

Research projects that needed approval by the Health Research authority and / or MHRA followed guidance as set out by the HRA and MHRA guidance:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/

https://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-trials-in-relation-to-coronavirus/

Restarting guidance

Where lock down arrangements in the UK and other countries are changing, researchers might be in a position to consider re-starting projects. This guidance aims to provide proportionate and pragmatic approaches to the complex task of restarting projects.

The decision on whether or not to restart a paused study or commence a new study rests with the Principal Investigator, the Chief Investigator, funder and Sponsor (if applicable). In addition to the research ethics and governance review, considerations at School or Institute level will inform the decisions that have to be made within the overall context of safe working established within the University space

Research in the UK must not involve any person (e.g. patient, healthy volunteer, research staff) involved in the research undertaking an activity that is not consistent with UK Government guidance on COVID-19. No research procedures such as a laboratory tests or investigations should be undertaken for research purposes alone if it is not consistent with Government guidance on COVID 19. Until NHS Trusts are in a position to open their facilities to the public safely, participants must not be asked to come to a hospital to participate in study specific activities that are not integral to ongoing clinical care.

Any restart plan needs to address participant and researcher safety / wellbeing and take into account capacity of hosting institutions or collaborators as this might vary across the UK and further afield. There might be further COVID-19 pressures and the potential for a 're-pause' should be considered.

Requirements for re-start

The restart of a currently paused study and the start-up of new studies will be dependent on a number of requirements. Before a study is re-started and new participants recruited, the research team must undertake a re-start risk assessment (please see Annex A for an example of a checklist provided by NIHR).

The University's Risk Assessment and Mitigation Plan (RAMP) offers helpful guidance: https://intranet.birmingham.ac.uk/hr/wellbeing/worksafe/policy/Research-Risk-Assessment-andMitigation-Plans-RAMPs.aspx .

This document can also be consulted for useful information on the specific types of risk assessment that might be required for both laboratory and non-laboratory research. It provides risk levels and the appropriate risk assessment approval process (i.e., PI (level 1), local H&S leads (level 2) or College (level 3)).

Restart requirements:

1. *Is the study still viable*
   Researchers should consider if a project is still feasible from a scientific, financial or practical point of view. This review is an opportunity to consider any improvements that might assist restart and completion of the study as it might be possible to amend some studies to achieve viability. For funded project agreement from the funder is essential if a contract amendment is required e.g. is the contracted end date of the project still viable/achievable or is an extension needed, are all funds still available.

   Changes need to be agreed with the Research Ethics Team for studies that were reviewed by a UoB REC.

   Please contact the Research Governance Team for UoB Sponsored studies reviewed by the HRA or MHRA. For sponsored studies there is an expectation that Sponsors and sites will work together to conduct a preliminary assessment of all paused studies ideally by July 2020. Regulatory guidance is available:

   - HRA
     https://www.hra.nhs.uk/covid-19-research/covid-19-guidance-sponsors-sites-and-researchers/

   - MHRA
     https://www.gov.uk/government/collections/mhra-guidance-on-coronavirus-covid-19

2. *Safety of all stakeholders*

   Research should only restart/start when safe to do so and appropriate institutional guidance especially from H+S must be adhered to.

   While there is still a COVID 19 infection risk, we should continue to work at home where possible, considering potential work around to facilitate projects. Study leads need to update / create an appropriate risk assessment and study documentation

(e.g. protocol and participant information) should be updated where there are potential consequences for the participants:

- Risk of exposure to COVID-19 (and measures to mitigate this).
- Government guidance on social distancing, restart of work, and travel
- Local site policies in respect of COVID-19.
- Researchers and participants considered 'vulnerable', who are 'shielded' and who have been involved in a paused study or are considered for a new study, require specialconsiderations
- An assessment of the need for participant testing for COVID-19 and requirements for personal protective equipment (PPE);
- Potential participants' concerns about COVID-19; participants need to feel safe and reassured about the research process.
- Provision of clear guidance on safety issues and measures for participants and staff.
- Assessment of requirement, processes and safety for study monitors/visits/meetings, and consideration of remote working where possible.
- That any mitigations or flexibilities put in place to restart a study do not have an adverse impact on participant safety (e.g. reducing clinic visits).

3. *Consideration of capacity and readiness of collaborators and sites*

Delivery of research might be dependent on collaborator and host site capacity e.g. health and care services affected by COVID-19 in different ways. It is important for researchers to understand and agree readiness of collaborators and sites where this is essential to delivery of the research activity.

Annex A - Study Local Restart Assessment Checklist (example)

This checklist could be provided to assist local Assessment and Prioritisation panels as part of comprehensive local site governance procedures.

#	Factor	Requirement
1	Study viability	- Sponsor and funder have assessed and agreed to restart - Regulatory approvals in place - No impact on support for UPH COVID-19 studies - All necessary research funding is confirmed - Funding to meet any Excess Treatment Costs has been confirmed - Sponsor and funder are satisfied with the arrangements for patient and public involvement in the study
2	Safety	- Risk of exposure to COVID-19 for patients and staff has been mitigated - Physical access complies with government restrictions on social distancing - Assessment of COVID-19 testing and PPE requirements completed - Study arrangements comply with local organisation / site policies in respect of COVID-19 - Site compliance with regulatory requirements has been confirmed by the organisation's R&D Director or equivalent - Clear guidance on safety issues and precautions has been provided to participants and staff - Participants are asked and reassured about any concerns regarding COVID-19 - participants need to feel safe and confident
3	Capacity and site readiness	- Local clinical lead (Principal Investigator) confirmed and in place - Research staff in place - Health and care site / service 'open for business' to the full extent required for the study - Research management and support in place (site R&D office, CTU, LCRN) - All necessary supporting departments (e.g. pharmacy, pathology, radiology) have resource and capacity. Assess study dependencies. - All necessary supplies have been procured and are in place (including IMPs and PPE) - For paused studies, study data have been checked for data integrity to ensure that data remain robust and/or fit for purpose - Physical access arrangements for participants have been

		assessed and are satisfactory - Permission to restart from site legal entity
4	Prioritisation	- Not required if the study does not require NIHR-funded support - Where prioritisation is necessary, this should be on the basis of 'study urgency' (section 6)

UPH = Urgent Public Health