

MRC guidance for award holders - starting or restarting of non-COVID-19 clinical studies

The COVID-19 pandemic led to the decision by research sponsors, funders, investigators and study sites to pause some non-COVID-19 research, including the setup of new sites or studies. As the pressure on the NHS has begun to fall and clinical services are returning to normal working, the NIHR has released a [framework for restarting paused NIHR research studies and providing NIHR Clinical Research Network support to set up new sites and studies](#).

The NIHR framework provides guidance to local R&D departments about the process for deciding which clinical research studies can be restarted and how to prioritise studies for restarting. Although the framework has been developed for NIHR studies in England, all researchers undertaking clinical research and research involving the NHS/HSC should be aware of the framework as it has implications for restarting studies not on the CRN portfolio, for those supported by other funders and those in the devolved nations.

The decision on whether to restart a paused study, or commence a new approved study, rests with the site R&D, study sponsor, Principal Investigators and associated research facilities. MRC (UKRI) award holders and Principal Investigators who are likely to be involved in this decision-making process should:

- familiarise themselves with the criteria recommended in the framework for assessing study viability, safety issues, local site capacity, and which studies will be prioritised to restart first;
- consider whether there are revisions to the study design or conduct (for example converting follow-up in outpatient clinics to surveys, video or telephone calls), that would ensure research remains viable OR reduces dependence on local NHS service capacity that may be delaying restart;
- ensure that relevant ethics and governance approvals (including amendments) are in place and seek advice from the MRC Regulatory Support Centre rsc@mrc.ukri.org if needed;
- contact RFPD@mrc.ukri.org for further advice relating to implications for your funding award as required.

Please let us know how this is working in practice by emailing RFPD@mrc.ukri.org . MRC is on the Advisory Group for the restart and we will feed in your experiences.

Read on for answers to frequently asked questions

FAQs for award holders – Grant Principal Investigators (PIs) or Institute/Unit Programme Leaders

I want to restart a clinical study that was suspended, paused or otherwise impacted by the COVID-19 pandemic – do I need to inform MRC?

If you can complete the study with the existing funding, within the original timeframes of the award and without any changes to the outputs, then you do not need to contact MRC. You should adhere to T&Cs, etc.

If you need a grant no-cost extension to the award, then you should apply using the Je-S system. Please email RFPD@mrc.ukri.org if you need advice or wish to discuss an extension request related to the impact of COVID-19. You will then need to submit a grant maintenance request via Je-S for the extension. Please see the [Je-S information on submitting grant maintenance requests](#) for further details.

If you need additional funding, then you should initially seek this from your UK research organisation as part of the UKRI COVID-19 grant extension allocation. [Further information](#) and [FAQs](#) are on the UKRI website.

If your requirement for additional funding extends beyond 30 September 2021 then email RFPD@mrc.ukri.org to provide details and discuss options.

If your award is held by an organisation outside the UK or is a programme at an MRC Institute, then this will not be part of the UKRI Covid-19 Grant Extension Allocation. Please email RFPD@mrc.ukri.org to discuss options. Joint Global Health Trials (JGHT) and Health Systems Research initiative (HSRI) awards may also contact JGHT@mrc.ukri.org or HSRI@mrc.ukri.org

If your award has milestones then you should contact your Programme Manager or email RFPD@mrc.ukri.org to discuss this.

If restarting the study will require any changes to project outputs or work packages, then you should email RFPD@mrc.ukri.org for advice.

Is the process the same for Developmental Pathway Funding Scheme (DFPS) awards?

No. Requests relating to DFPS awards (for example alterations to agreed deliverables or their due dates) are referred to as Requests for Change and dealt with directly by the Translational Research Board team.

DFPS award recipients should contact the DPFS inbox (DPFSandDCS@mrc.ukri.org) to seek advice before submitting a Request for Change.

Is the process the same for MRC Institute/Unit Programmes?

No. Principles are the same, but Programme Leaders should first discuss options relating to programme changes or budgets with their Institute/Unit Director. Further advice can then be sought from the MRC Programme Manager or Head of Theme with responsibility for the Institute/Unit relationship.

I want to restart a clinical study that was suspended because of the COVID-19 pandemic and the study sponsor/local research governance team have requested confirmation that restarting is supported by the funder. How do I get confirmation?

Please download a copy of this statement and FAQs for your study sponsor and responsible local research governance team. These confirm that MRC supports the start or restart of all studies where the study is considered viable by the sponsor and

- 1) there is no change to the funding, award timeframe or outputs; OR
- 2) an amendment to the award (for example, to the milestones, protocol, workpackages or outputs) has been discussed and agreed via the [post-award amendment \(PAA\) procedure](#).

If you hold a DFPS award, please contact the DPFS inbox (DPFSandDCS@mrc.ukri.org) to seek advice.

If you are a MRC Institute/Unit Programme Leader please contact your Director.

My study was suspended/impacted by the COVID-19 pandemic and I would like to make changes when I restart so that I can achieve the original aims the study. What should I do?

If your award is not a DFPS award, you should:

- 1) discuss the viability of your study locally with the study sponsor and responsible local research governance team to confirm that the proposed changes are acceptable and feasible, and whether any additional regulatory approvals are required;
- 2) email RFPD@mrc.ukri.org to discuss the next steps.

If you hold a DFPS award, please contact the DPFS inbox (DPFSandDCS@mrc.ukri.org) to seek advice.

If you hold a JGHT or HSRI award please contact JGHT@mrc.ukri.org or HSRI@mrc.ukri.org to seek advice.

If you are a MRC Institute/Unit Programme Leader please contact your Director to seek advice.

My study was suspended/impacted by the COVID-19 pandemic and I am concerned that it may no longer be viable. What should I do?

You should:

- 1) discuss the viability of your study locally with the study sponsor and responsible local research governance team to determine if the study should be closed or can be adapted in some way to allow it to continue;
- 2) email RFPD@mrc.ukri.org to discuss the next steps.

If you hold a DFPS award, please contact the DPFS inbox (DPFSandDCS@mrc.ukri.org) to seek advice.

If you hold a JGHT or HSRI award please contact JGHT@mrc.ukri.org or HSRI@mrc.ukri.org to seek advice.

If you are a MRC Institute/Unit Programme Leader please contact your Director to seek advice.

My sponsor/host Trust/research governance office will not allow me to restart my research even though I think it is viable to do so.

The assessment and prioritisation of clinical research using NHS facilities is a local decision as clarified in the [NIHR Restart Framework](#) and [CSO policy](#). A decision to restart research must be reached locally based on study viability, safety and the readiness and capacity of local health and care organisations to support the research.

Will UKRI provide additional funding or extensions to awards affected by the COVID-19 pandemic?

If your award has been affected by the COVID-19 pandemic, it is possible that you could benefit from the UKRI Covid-19 Grant Extension Allocation. You should approach your research organisation to find out. Each organisation will be following a process agreed with UKRI to inform their allocation of funding. UKRI expects organisations to prioritise support for projects ending by 31 March 2021.

UKRI considers organisations best placed to make the decisions regarding need and allocation. UKRI will not consider direct requests for costed extensions for COVID-19 related issues during the period covered by the allocation (spend up to 30 September 2021). For extensions beyond 30 September 2021, investigators should approach the Council concerned to discuss options.

Requests for no-cost extensions can be made at any time.

If your award is held by an organisation outside the UK or is a programme at an MRC Institute, then this will not be part of the UKRI Covid-19 Grant Extension Allocation. Contact your Programme Manager or email RFPD@mrc.ukri.org to discuss options. Joint Global Health Trials (JGHT) and Health Systems Research initiative (HSRI) awards may also contact JGHT@mrc.ukri.org or HSRI@mrc.ukri.org

What do I do if investigators/staff on my research grant had to transfer back to clinical work because of COVID-19?

If this will have an impact on the viability or outputs from the study, then email RFPD@mrc.ukri.org (see previous FAQs also).

If this will have an impact on the end date of the award, then you should consider applying for a no-cost extension (see previous FAQ on additional funding or extensions).

Research organisations are expected to be able to recover the costs of clinical staff salaries from NHS Trusts so these salaries should not come from the award for the period during which staff are doing COVID-19 related clinical work. You should discuss this with your research organisation.

If you have a concern or issue that is not covered by any of the above FAQs, please contact RFPD@mrc.ukri.org to discuss.