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.