

MRC Regulatory Support Centre COVID-19 Bulletin 17th April 2020

The COVID-19 pandemic has significantly impacted health research as it has every aspect of our lives. In this bulletin we pull together information about the special research governance arrangements currently in place to help tackle the pandemic. Many of these arrangements will be temporary.

Pausing of non COVID-19 studies

The Department of Health and Social Care announced that all new and existing studies supported through NIHR's Clinical Research Network would be paused to focus on COVID-19 research. [See NIHR's website for the full statement](#). [NHS Research Scotland](#), [Health and Care Research Wales](#) and [Northern Ireland's HSC Research and Development division](#) released similar statements.

Fast tracking approvals for COVID-19 research

The following outline the expedited processes:

- HRA - [COVID-19 web section](#) describes the [fast-track process](#) which is being coordinated across the 4 UK nations; [how to use NHS patient data for COVID-19 research without consent in England and Wales \(NHSX has more on this\)](#); as well as [guidance on seeking consent in interventional COVID-19 research](#).
- HRA are also publicising [approved COVID-19 studies](#) on their website.
- [NHS Research Scotland](#); [Health & Care Research Wales](#) and [HSC R&D Division Northern Ireland](#) also have guidance.

MHRA are prioritising and fast tracking the following, if COVID-19 related:

- [Medical Device approvals](#), the MHRA can authorise the supply of non-CE marked devices;
- Review of [Clinical Trial applications](#); and
- Review of applications for [Clinical investigations of medical devices](#).

MHRA also has guidance on specifications for [COVID-19 tests and testing kits](#).

EMA regularly update their [information on COVID-19](#). They have mechanisms to facilitate and speed up the development of medicines. These include [scientific advice](#), the [PRIME scheme](#), the [accelerated assessment](#), and [conditional marketing authorisation](#).

Using patient data to tackle COVID-19

- [Health Data Research UK is championing the use of health data](#), including new linkage capabilities and coordination of research questions.
- [UK Biobank](#) will receive new data from Public Health England, GPs and Intensive care, which will shortly be available for research.
- A new [NHSX data platform](#) will use real time data to allow better service provision. Discussions are ongoing about research access.
- [NHSX IG pages](#) outline extensions to deadlines for National Data Opt-Out and Data Security and Protection Toolkit submissions as a result of the pandemic.

Accessing human samples from Research Tissue Banks

The [UKCRC Tissue Directory and Coordination Centre](#) (TDCC) is coordinating efforts to help find human samples which can support COVID-19 research. Read how [UK biobanking has been affected by the current pandemic](#).

Useful resources for other studies impacted by the COVID-19 response

- **CTIMPs:** [MHRA guidance on managing clinical trials during COVID-19](#) ([EMA has similar guidance](#)).
- **Other research involving the NHS:** [HRA guidance on amendments to existing studies](#) (e.g. to add a COVID-19 element or for changes due to the wider response).
- **Designated Individuals:** [HTA has guidance for licensed establishments](#).
- **Data Controllers:** [ICO has Q&As on data protection and the coronavirus](#).

Still have a question?

If you have a specific question about any regulatory aspect relating to COVID-19 research which we haven't covered here, please get in touch with us at: rsc@mrc.ukri.org.