

IRELAND

Competent Authority:

Regarding advice from Ireland, the Irish regulator, Health Research Products Authority (HRPA) has released their advice for clinical trials here: : [www.hpra.ie/homepage/medicines/regulatory-information/clinical-trials/covid-19-\(coronavirus\)-and-cts](http://www.hpra.ie/homepage/medicines/regulatory-information/clinical-trials/covid-19-(coronavirus)-and-cts)

As this is an evolving situation, the HPRA expect this guidance will be further updated as required, so please revisit this link for ongoing updates.

The HPRA will give priority review to any new clinical trial applications relating to COVID-19, and/or amendments to existing clinical trials necessary as a result of COVID-19, priority reviews can be expedited where necessary.

Ethics Committees:

Updated: 15/04/20

As part of Ireland's response to the COVID-19 pandemic, and in accordance with a recommendation in the WHO Roadmap for R&D, the Minister for Health has established a temporary National Research Ethics Committee (NREC) for COVID-19 to deliver an expedited process for review for all COVID-19-related research studies.

The NREC COVID-19 will support a thorough and robust ethical review of projects in an expedited manner for those seeking to get COVID-19 research studies off the ground in Ireland in the days and weeks ahead, not least for those applicants awaiting the outcome of decisions in the recent rapid response research calls. It will review all COVID-19-related studies that fall under the definition of health research as set out in the Health Research Regulations 2018.

The NREC COVID-19 has been designed as a coordinated response by the Department of Health, the Office for National Research Ethics Committees, the Health Products Regulation Authority (HPRA) and the Health Research Consent Declaration Committee (HRCDC).

It is the intention that responsibility for REC review would transition back to the existing local REC system once the peak volume of applications has been processed and projects are underway.

For full details of the NREC COVID-19, check the HRB website - <https://www.hrb.ie/covid-19-ethical-review/nrec-covid-19-overview/>

Data Protection:

The Health Research Consent Declaration Committee (HRCDC), acting under the Health Research Regulations 2018, can legally grant a consent waiver or "Consent Declaration" in certain circumstances. The HRCDC wish to advise researchers that it is putting in place arrangements to enable it to consider applications as a matter of urgency and to make decisions on those applications as quickly as possible. Applications relating to COVID-19 do not have to wait until a scheduled HRCDC, but will be dealt with as above.

If it is considered by researchers that a consent declaration may be required for urgent COVID-19 research studies, researchers are advised to immediately contact the Secretariat who will work with applicants to facilitate an expedited review by the HRCDC.

See <https://hrcdc.ie/hrcdc-briefing-note-covid-19-related-health-research/>

