

From: [James Cokayne \(Ministry of Health\)](#) on behalf of [MOH-ResearchEthics](#)
To: [MOH-ResearchEthics](#)
Cc: [clinicaltrialsNSW](#); [MOH-OHMR](#); [Antonio Penna \(Ministry of Health\)](#); [James Cokayne \(Ministry of Health\)](#); [Anita Van Der Meer \(Ministry of Health\)](#)
Subject: DRAFT COVID-19 Clinical Trial Conduct Guidance - 19 March 2020
Date: Thursday, 19 March 2020 11:11:41 AM
Attachments: [NSW Health Guidance Document COVID-19 and Clinical Trials for Sponsors S.....pdf](#)
[COVID-19 Clinical trial guidance for HRECs and RGOs - 19 Mar 2020.pdf](#)
Importance: High

Dear colleagues,

Please find attached two documents forming OHMR Guidance for conducting clinical trials affected by COVID-19, including the government response to the situation.

Document one is an overview set of principles for sponsors, sites and researchers.

Document two contains more specific guidance based on different scenarios for HRECs and RGOs and researchers.

Draft status:

These documents are currently in DRAFT version but we anticipate that they will receive official sign off soon. We are currently receiving and responding to many queries in relation to this matter and our responses are aligned to the guidance contained within.

In the meantime, we encourage the sector to follow the draft guidelines. Once signed off, OHMR will publish them on our website and distribute them widely.

Development:

The guidance is modelled on the NHS HRA clinical trials and COVID Guidance (referenced within) and we have looked at a number of similar guidelines produced around Australia as well as consulted with numerous sources in the sector. We are grateful to those organisations and people for their rapid feedback and have provided appropriate acknowledgement within.

Feedback:

We welcome any feedback you would like to provide on the guidance. Please respond to this email. The document is likely to undergo a number of subsequent revisions both as the list of issues expands and as the COVID situation develops. Version control will be via the date at the top right corner of page 1 of each of the documents.

Kind regards,

Office for Health and Medical Research

