



MEMORANDUM

To: Metro South Research Community

Copies to: Metro South Chief Executive
MSH Executive Directors, Divisional Chairs, Research Directors and
Research Managers

From: Prof John Upham – Chair, Metro South Research **Contact No:** 3443 8065
Dr Geoffrey Playford – Clinical
Director Infectious Diseases

Subject: **Clinical Trial Participants and COVID-19 Vaccination Memorandum**

All Principal Investigators and Trial Coordinators should familiarise themselves with the proposed rollout of the COVID vaccines. This advice relates to any COVID-19 vaccines currently approved by the TGA for use in Australia.

For commercially sponsored trials

Principal Investigators should contact their commercial sponsor or CRO (via their study specific CRA) to ascertain if the investigational medicinal product / Device (IMP/IMD) being trialled has any interactions, contraindications or is incompatible with any of the TGA approved COVID vaccines. It will be necessary to determine whether the sponsor requires any changes to the protocol and consent and whether any additional assessments and/or visits may need to be added to the trial procedures to address the potential impact of COVID-19 vaccine with the trial's IMP/IMD, e.g. interactions or contraindications, and how these will be communicated to participants.

For Collaborative Research Group trials

Principal Investigators should contact their Collaborative Research Group leads (Chief Investigator) to determine whether any changes to the protocol and consent and whether any additional assessments and/or visits may need to be added to the trial procedures to address the potential impact of TGA approved COVID-19 vaccine, with the trial's IMP/IMD, e.g. interactions or contraindications, and how these will be communicated to participants.

Prof John Upham
Chair, Metro South Research
10.3.2021

Dr Geoffrey Playford
Clinical Director Infectious Diseases
10.3.2021