

From: Melbourne Health Human Research Ethics Committee and Melbourne Health Office
for Research

Date: 17 February 2021

Re: **Human Research Projects: COVID/SAR-CoV-2 Vaccines**

The Melbourne Health Human Research Ethics Committee (MH HREC) and the Melbourne Health Office for Research (MH Governance) recognise that sponsors of clinical trials and other clinical research have a responsibility to inform research sites of each sponsor's recommendations in relation to immunisation of study participants with SAR-CoV-2 vaccine.

MH HREC and MH Research Governance advice is as follows:

- The use of specific vaccines in Australia will be determined by the Australian health authorities after approval by the Australian Therapeutic Goods Administration.
- Patients considering participating in a clinical trial should be assessed by their treating physician and advised whether or not to have vaccination against SARS-CoV-2, if available, according to local practice, taking into account each individual patient's health needs and circumstances.
- For patients already enrolled in a study, the decision of vaccination for SARS-CoV-2 should be done on a case-by-case basis and at the discretion of the treating physician in consultation with the patient based on a risk/ benefit assessment.

Where Sponsor recommendations meet these requirements the MH HREC and MH Governance do not require submission of sponsor notifications regarding vaccine use.

MH HREC and MH Governance only require notification of:

- Significant Safety Issues that adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

Should you have any questions please contact the Melbourne Health Office for Research at: research@mh.org.au

Kind regards,



Dr Angela Watt
Director Research Governance and Ethics

The MH HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines)