

26 November 2021

Health and Disability Ethics Committee Chairpersons

Dear Chairpersons,

Letter concerning vaccination status and access to health and disability research

I am writing to you as the Chairperson of the National Ethics Advisory Committee (NEAC).

Mrs Kate O'Connor joined our 11 November meeting and provided a verbal update on the Health and Disability Ethics Committees.

Vaccine Passports and Health and Disability Research

NEAC understands that the HDECs are starting to see study amendments that ask to introduce double COVID-19 vaccination as an inclusion criterion to participate in studies.

Mrs O'Connor explained that this exclusion criterion has, as of yet, only been seen as an amendment to previously approved studies rather than in new applications.

Mrs O'Connor noted that vaccination status as an inclusion criterion raises the question of equity in accordance with the *National Ethical Standards for Health and Disability Research and Quality Improvement, 2019* (the NEAC Standards). As per the NEAC Standards, all persons should have equal opportunity to participate in research.

NEAC agree with this overarching principle of access, and highlight the following Standards:

All groups have the right to benefits from advances in health care and disability support arising from research. For this reason, it is important that researchers design their research to be inclusive. A study's focus and objectives, and the nature and context of the research, should determine its inclusion and exclusion criteria.

9.9 Researchers should not exclude participants on the basis of their age, disability, sex, sexual orientation, gender, place of residence, ethnicity, nationality, religion, education or socioeconomic status, except where excluding or including them on these grounds can be justified for the purposes of the research.

9.9a Inclusion and exclusion of participants affect the extent to which researchers can generalise their findings. Researchers should enrol participants who represent all those to whom the research findings may apply, thereby contributing to an equitable distribution of research benefits and burdens.

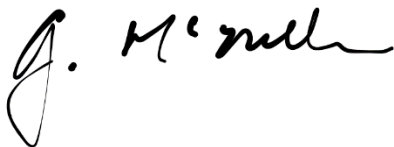
NEAC note that vaccination status could be relevant in vaccine studies, for instance, but not as a general exclusion criterion.

NEAC understands that the HDECs have taken the stance that researchers could adopt measures to keep staff safe without the exclusion of unvaccinated participants. NEAC agrees with this stance, noting the potential impact on equity and fairness if unvaccinated potential participants are by default excluded. NEAC also recognises that while there are no ethical grounds to exclude potential participants generally, there will be logistical barriers created by vaccine passport requirements in terms of accessing sites.

NEAC proposes that HDECs continue to decline amendments to approved studies that aim to exclude potential participants based on vaccination status alone, where there is no scientific justification for their exclusion and require new studies not to have such exclusions, unless justified against the Standards. This may not prevent the actualisation of non-vaccinated participants accessing the studies, due to the local sites and institutions enforcing their own vaccination requirements, however it means that the study protocols will meet the NEAC standards.

The wider issue regarding research during a pandemic and the impact of vaccine passport requirements of institutions conducting research is one that will require more work. There are several NEAC work items that may be relevant. NEAC is updating its Ethical Standards and that presents an opportunity to include further guidance about inclusion and exclusion criteria. Another avenue is to use the principles outlined in *Getting Through Together*, the updated pandemic ethics document, to inform a more detailed position. This document will be out for public consultation in February 2022.

Yours sincerely



John McMillan
Chair, National Ethics Advisory Committee

cc: Nic Aagaard, Manager, Ethics