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Government
of South Australia

Hon Chris Picton MP
Minister for Health
and Wellbeing

Mr Herschel Baker
International Liaison Director
Queensland Director
Drug Free Australia
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Dear Mr Baker

Thank you for your email dated 1 April 2022, to the Hon Peter Malinauskas, Premier of South Australia outlining your concerns about the Therapeutic Goods Administration (TGA) and the Human Research Ethics Committees (HRECs) of Australia. As concerns about the TGA and HREC's fall within the remit of the Department for Health and Wellbeing, the Premier asked me to respond on his behalf.

I sought advice from the Department for Health and Wellbeing which provided the following information.

The concerns raised in the article suggests there is a poor understanding of HREC responsibilities. However, it should be noted that the HREC registration and certification process is clear on those responsibilities and this information is publicly available. All HRECs are required to comply with the National Statement on Ethical Conduct in Human Research.

The early phase clinical trials described (phase zero and phase 1) are highly regulated and in South Australia these must be reviewed by the SA Health HREC responsible for the public health organisation where the clinical trial is taking place. Other Australian jurisdictions have similar processes to manage any possible risk to the public.

The statement that there are more than 200 registered HRECs in Australia is correct but may not accurately reflect the regulatory landscape. There are only 43 public and one private organisation with a registered and certified HREC.

Certification is more demanding than the simple registration and is dependent upon satisfactory demonstration that the HREC conforms to the review criteria via an independent assessment by the National Health and Medical Research Council.

All of SA Health's four HREC's are registered and certified. Only other Australian public health HRECs that are registered and certified will be recognised under the National Mutual Acceptance (NMA) system of single scientific and ethical review of multi-centre human research projects across Australian jurisdictions. It is important to note that NMA is not applicable to the early phase trials mentioned.

Minister for Health and Wellbeing

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The recruitment process for appointing members to those committees is rigorous and includes executive oversight. Each HREC must demonstrate that it has the appropriate expertise to review each application.

The article suggests that potential conflicts of interest by HREC members are common. All of the SA Health HRECs have standard operating procedures that include managing potential conflicts that may arise. Anyone who has concerns regarding a specific conflict of interest is strongly urged to follow the appropriate procedure to raise that concern.

The article does not address the additional requirement of governance approval. Further to the Ethical approval, all clinical trials require governance approval through a Site-Specific Assessment (SSA) process. Research governance is concerned with the principles, requirements, and standards of research. It addresses the protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management and monitoring arrangements and promotes good research culture and practice.

The Research Ethics and Research Governance Policy Directives are available on the SA Health website. The Department for Health and Wellbeing is committed to partnering across the Health and Medical Research sector to deliver a state-wide research strategy that provides translational improvements for South Australian health services.

Thank you again for taking an interest in the processes involved in the approval of health and medical research. Medical research, including clinical trials, is an essential part of a high performing health service. Embedding a research mindset into the delivery of clinical service has been demonstrated to deliver the best health outcomes for patients.

Yours sincerely



Chris Picton MP
Minister for Health and Wellbeing

5 / 6 / 2022

cc: Hon. Peter Malinauskas, Premier of South Australia