

CLINICAL TRIAL TRANSPARENCY

Policy statement
July 2020

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Health Research Council
of New Zealand

Te Kaunihera Rangahau Hauora o Aotearoa



Background

Transparency is both a core value of the Health Research Council of New Zealand (HRC) and a guiding principle of the *New Zealand Health Research Strategy 2017-2027*.ⁱ

In the context of clinical trials, the HRC recognises the importance of all information on research methods and findings being accessible and all reports being complete and usable.ⁱⁱ This transparency enhances the evidence base for clinical medicine both in New Zealand and internationally while simultaneously providing easily accessible information for the public, patients and their whānau.

Furthermore, *The Declaration of Helsinki*ⁱⁱⁱ establishes the ethical imperative for prospective trial registration and reporting of results and this is reflected in the *National Ethical Standards for Health and Disability Research and Quality Improvement*.^{iv}

The WHO Joint Statement

As demonstration of our commitment to supporting best practice in clinical trials, the HRC became a signatory to the World Health Organization (WHO) *Joint statement on public disclosure of results from clinical trials* (the Joint statement) in July 2020.^v Becoming a signatory was endorsed by the Ministry of Health.

The Joint Statement sets out policy and monitoring requirements for mandatory timeframes for prospective registration and public disclosure of the results of clinical trials. Failure to achieve these requirements has the potential to harm patients, waste resources, lead to publication bias and selective reporting, and slow down the development of new therapeutics.

HRC Policy

The HRC Contract for Research Funding (second schedule) requires that the research provider will 'carry out research activity in an ethical, responsible, diligent and competent manner' and 'ensure the conduct and quality of the research is to the high standard expected of a leading institution in New Zealand and meets all rules and regulations relating to the particular research.'

By becoming a signatory to the Joint statement, the HRC endorses the requirements of the Joint statement as reflective of the ethical and quality standards that must be met by HRC funded clinical trials:

- **researchers must register their study in a WHO approved clinical trial registry before recruitment of the first participant, and**
- **researchers must make summary results publicly available within 12 months from the last visit of the last participant** (for collection of data on the primary outcome).

The infrastructure already exists through the Australia and New Zealand Clinical Trial Registry (ANZCTR)^{vi} for HRC-funded clinical researchers to fulfil their registration and reporting requirements. Many clinical researchers are already engaged in best practice.

The HRC will monitor adherence to the Joint statement through the research contract reporting process and data exchange with the ANZCTR. The HRC will publicise results of clinical trial transparency monitoring on our website.^{vii}

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- i The New Zealand Health Research Strategy 2017-2027 is available from: <https://www.health.govt.nz/publication/new-zealand-health-research-strategy-2017-2027>
- ii More information about the Ensuring Value in Research (EViR) funders' collaboration and development forum can be found at: www.ensuringvalueinresearch.org
- iii The Declaration of Helsinki is available from: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>
- iv The National Ethical Standards are available from: <https://neac.health.govt.nz/system/files/documents/publications/national-ethical-standards-health-disability-research-quality-improvement-2019.pdf>
- v The WHO Joint statement on public disclosure of results from clinical trials is available from: <https://www.who.int/ictpr/results/jointstatement/en/>
- vi The Australia New Zealand Clinical Trials Registry is available at: <https://www.anzctr.org.au/>
- vii The HRC website can be found at: <https://www.hrc.govt.nz/>



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