



This issue

NZACRes News **P.1**

HDEC PIS/CFs **P.2**

National Reports **P.2**

New to Research **P.3**

Contact New Zealand sites and organisations to discuss opportunities for new and ongoing research.

NZACRes Online

Visit our Website:

<https://www.nzacres.org.nz/>

Or follow us on LinkedIn:

<https://www.linkedin.com/company/nzacres>

NZACRes News

- **August 2020: AGM**

The Associations [AGM](#) will be held on the 21st August, 9.30 am -10 am. The meeting will be held at the George Hotel, Christchurch and will also be available via remote access. The AGM is free for members to attend in person or online. AGM papers and remote access details have been emailed to members.

- **August 2020: Regional Meeting**

The [Christchurch 1-day Regional Meeting](#) will be held from 10 am – 4 pm on the 21st August at the George Hotel, Christchurch. – CHECK our website for meeting updates due to the changing COVID-19 restrictions.

- **We have updated our Jobs website page**

Check out our [Jobs page](#) on the NZACRes Website. Vacancies can be posted free of charge.

- **Health Data – NEAC National Ethical Standards – Live Online Presentation**

NZACRes is excited to offer, free of charge, a presentation on the Health Data requirements of the NEAC National Ethical Standards. Rochelle Style, an independent consultant and member of the Northern A HDEC, will be presenting via Zoom on the 26th August, 1 pm – 2.30 pm.

Please see our website for details on how to access the [live online presentation](#).

NZACRes will continue to promote, advocate for and support clinical research in New Zealand.

Keep an eye on our website for updates!



**New Zealand
Association of Clinical Research**

Mental Health Awareness

In times of crisis it is important to understand your mental health status and that of others around you.

Many of us carry on as usual, but end up feeling flat and frustrated, wondering why we are not as productive as normal .

These are not normal times, and as we each deal with our physical change in personal and work related circumstances, it is also important to deal with the mental shift.

Online resources from the New Zealand government are available:

<https://www.mentalhealth.org.nz/get-help/covid-19/>

For assistance via telephone

HELPLINES

- **1737** – Free call or text 1737 any time for support from a trained counsellor.
- **Lifeline** – 0800 543 354 or free text 4357 (HELP)
- **Youthline** – 0800 376 633 or free text 234
- **Samaritans** – 0800 726 666



MedCram has been providing free COVID -19 scientific updates on YouTube, or go to [MedCram.com](https://www.medicram.com)

HDEC PIS/CF Templates – Now Available

- **Updated standard main PIS/CF**

The [template](#) has been updated with significant changes regarding the use of data.

- **New PIS/CF for Pregnant Partners**

New [template](#) Patient Information and Consent Form for Partners of Participants who become pregnant.

- **New PIS/CF for Pregnancy Follow-Up Following Birth**

New [template](#) Patient Information and Consent Form for Pregnancy Follow-up. This PISCF is intended to be used after a pregnancy is confirmed and submitted for review through a Post-Approval Form as an amendment.

The Value of Clinical Research Report

- **Published in May 2020, by Medicines New Zealand & NZ Institute of Economic Research (Inc)**

The [report](#) details the economic value clinical trials bring to New Zealand.

Health & Disability System Review

- **Published in April 2020, commissioned by the Minister of Health**

The [report](#) discusses proposals for the New Zealand health and disability system to produce more equitable health outcomes and financial sustainability.

NZACRes will be reviewing the Standard Indemnity & Compensation Agreement (sICA). If you would like to be involved in the consultation and review, please email info@nzacres.org.nz



EYE ON IT

Current Industry Trends

Keep an eye on current industry updates by visiting our website.

<https://www.nzacres.org.nz/>

If you would like to post news or events of interest to members please send details to info@NZACRes.org.nz

CAN WE HELP?

Contact us at

info@NZACRes.org.nz with your suggestions.

Where do you believe NZACRes can add the most benefit to the clinical research industry in New Zealand?

How can NZACRes best support its members and the New Zealand Clinical Research Environment?

New to Research? – Don't reinvent the wheel!

Clinical trials can be complicated and nuanced. The more you know, the more you realise there is to know. Fortunately, there is a lot of information freely available online and those who are new to the industry should take full advantage of these resources.

The basic principles and standards:

The internationally accepted standards for interventional clinical trials are the [ICH GCP E6 \(R2\) guidelines](#). NZACRes has links to free [GCP training](#) on our website.

In New Zealand, the National Ethics Standards for Health and Disability Research and Quality Improvement must also be applied to all research. These [National Ethical Standards](#) are provided by the National Ethics Advisory Committee (NEAC). The standards will provide guidance on the minimum requirements for research in New Zealand, such as essential document storage requirements.

The [Guideline on the Regulation of Therapeutic Products in New Zealand, Part 11](#), is provided by MedSafe and describes the requirements for clinical trials involving new medicines.

Design and documentation:

The ICH GCP E6 guideline provides a list of essential documents that are required for an interventional trial. Every trial needs a protocol. TransCelerate has established a Clinical Content & Reuse Initiative, within which they have developed a [Common Protocol Template \(CPT\)](#). They have also built Libraries of common subject protocols, such as for prostate cancer, diabetes etc. Additionally, the initiative provides other information and tools to assist with the implementation of a trial.

Almost all trials require a [Patient Information and Consent Form](#) (PISCF). The Health and Disability Ethics Committee (HDEC) website provides template PISCF documents. Although the wording does not need to be maintained exactly as written, it is highly recommended that any text changes are comparable in intent.

Prior to submitting a trial for review by the HDEC, [scientific peer review](#) is required. The HDEC provides guidance and a template for the review. If a trial is submitted for MedSafe approval, additional scientific review will not be required.

You should always register your trial. The following are the most common registries used: [ANZCTR](#), [ClinicalTrials.gov](#), [EU-CTR](#).

Submitting an Ethics Application:

Ethics submissions to the HDEC are done [online](#).

The HDEC provides guidance on how to consider and respond to the [cultural questions](#) within the HDEC application as well as [tissue banking](#).

When submitting an application, it is important to provide a current research Curriculum Vitae for the lead investigator. A research CV should be dated within 1 year and should also detail relevant research experience. TransCelerate provides a [template CV and guidance](#).

Contracts:

NZACRes provides [contract and indemnity templates](#) for use in New Zealand.

We wish you every success in your research.