



Continuing or Recommencing Research during COVID-19 pandemic

General advice for studies conducted at CAHS

COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors is available on NHMRC's website www.nhmrc.gov.au/research-policy/COVID-19-impacts published in the "[Downloads section](#)". It is also available on the [Department of Health Website](#). This advice is supported by CAHS.

If you need assistance or advice regarding your research at CAHS please contact:

CAHS.ResearchSupport@health.wa.gov.au or CAHS.Ethics@health.wa.gov.au

Points to note

- If you notified the HREC you had paused your research you must notify them you are now restarting. This can be done via email to CAHS.Ethics@health.wa.gov.au.
- If you made minor adjustments to your project (that did not include a pause) and notified HREC, you do not need to notify them you are now returning to business as usual. If you have not previously contacted our office in relation to your project and COVID-19, you do not need to contact us now for approval to continue. All research should be in accordance with the protocol approvals already provided. Any changes to research projects should be according to standard processes for review and approval of protocol amendments.
- All research should be conducted in accordance with the protocol and the conditions of HREC and site approval and the NHMRC guidance with respect to the safety and well-being of patients, research participants and their families, as well as healthcare professionals, researchers and other staff involved in patient care and research <https://www.nhmrc.gov.au/research-policy/COVID-19-impacts#download>.
- The ongoing voluntary nature of participation in research should be confirmed with the family and documented if they are continuing and/or resuming onsite visits at PCH.
- Participants should be informed that their decision to continue or not in research will not affect their ongoing treatment or participation in future clinical trials. For full details please refer to <https://www.nhmrc.gov.au/research-policy/COVID-19-impacts#download>.
- Reporting that meets NHMRC requirements for HREC/RGO review should be reported via RGS refer to <https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods>. And <https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx>.
- In accordance with NHMRC direction, decisions to recruit new participants to ongoing trials should take into account the potential benefits and burdens on Australia's health system and should depend on individual trial factors. The focus should remain on the safety and well-being of those most at risk in our institutions and communities. Any new recruitment should reflect the most current public health advice on social distancing. The CPI/PI or delegated medically responsible person should be making any decisions related to safety.



Healthy kids, healthy communities

Compassion

Excellence

Collaboration

Accountability

Equity

Respect

- If your study has an investigational medicinal product as an intervention please ensure you have considered any additional safety oversight requirements in the event a participant has confirmation of COVID-19 and ensure there are appropriate study team contact and reporting procedures in place. This is the responsibility of the study team.
- Any specific amendments to your research project should be managed via the standard review and approval process in RGS (including protocol amendments, relocation of research activity or additional support for equipment such as PPE). Help is available from the CAHS Department of Research team.

Outpatient research clinic appointments

- The use of remote contact as much as possible is encouraged. Consider options to reduce the time of face to face contact such as discussing issues to do with the PICF or appointment expectations via phone in advance of the onsite visit.
- Approved researchers receive specific information about the booking process and requirements for managing research clinic appointments during local area orientation. Adherence to these procedures allows the research department team to continue to support you and provide oversight to the clinical space designated for research appointments. Please follow these procedures as normal, plus any additional guidelines during COVID-19 management.
- Outpatient appointment guidelines linked to the COVID-19 pandemic are available here : <https://ww2.health.wa.gov.au/~media/Files/Corporate/general%20documents/Infectious%20diseases/PDF/Coronavirus/COVID-19-Guidelines-for-Outpatient-Services.pdf>
- Please follow the current guidelines around the conduct of research outpatient clinic appointments. To attend an appointment at PCH please ensure that both the child and accompanying parent are well with:
 - No overseas travel in past 14 days AND
 - No interstate travel in the past 14 days AND
 - No contact with confirmed cases AND
 - No fever ($\geq 38.0^{\circ}\text{C}$) OR acute respiratory symptoms (cough and/or sore throat and/or shortness of breath).
- A maximum of two people may accompany a patient. One of whom maybe a sibling under 16.
- In line with usual booking processes please ensure that a CAHS clinician is available onsite for participant review if required.
- Any incidents associated with the attendance at a clinic (or other relevant context) of a participant known, or later discovered, to be symptomatic should be promptly reported as an adverse event or safety issue.
- Reporting can be completed via use of the form available for institutional reporting on the website titled [CAHS Adverse Event/Serious Adverse Event Notification Form](#) (WA health staff access only).

Find out more



Please refer to (and regularly check) supporting documentation for further information and latest guidelines. cahs.health.wa.gov.au/Research/COVID19-and-research-processes



Contact the CAHS Department of Research if required after checking the process and associated resources. CAHS.ResearchSupport@health.wa.gov.au
CAHS.ethics@health.wa.gov.au CAHS.RGO@health.wa.gov.au