Version 14 July 2022

Covid-19 Guidance for research at Barwon Health

Research is an integral component of clinical services at Barwon Health, thus the guideline for clinical services during the Covid-19 is directly applicable to research activities.
http://covid-19.barwonhealth.org.au/

Level of research activity

- The maximum level of research activity (ongoing or new studies) should match the level of activity that Barwon Health is permitting for Outpatient Services. Outpatient activity is currently unrestricted but continues to be delivered remotely where practical.

Guiding principles

- The health of our patients, study participants and staff are the priority.
- As always, participants should be aware that they are able to withdraw from a study at any point and that doing so would not impact on the care they receive from Barwon Health.
- Where it does not impede efficiency or quality, study procedures should be conducted remotely.
- Studies offering treatment to participants as an alternative to standard care should be supported to continue and managed as flexibly as possible, with measures to minimise contact and the need to attend the hospital.
- Participant visits to Barwon Health are permitted provided the criteria outlined below are met.
- Participant visits outside Barwon Health, such as home visits, are permitted provided an appropriate Covid Safe Plan is in place and diligently actioned.
- A Covid Safe Plan, including attention to density limits, social distancing, hand hygiene, masks, vaccination status, and isolating if unwell or following a relevant exposure must be in place and must be diligently actioned.

Responsibility regarding recommencement and continuation of studies

- Decisions regarding recommencement or continuation of studies remain with the Principal Investigator and Head of Department. Continuation, recommencement or commencement of each study must be given careful consideration when it involves Barwon Health visits. If there is uncertainty about whether participant contacts in a study should proceed, the matter should be escalated to the Chief Medical Officer and Covid Clinical Reference Committee.
- If you are reactivating a pre-Covid protocol, an amendment to HREC/Governance (REGI) is NOT required. If REGI has not already been notified regarding recommencement of a study, please submit a notification/report in ERM to document this return. If the protocol needs to include any non-administrative changes, please submit a protocol amendment to REGI. The Principal Investigator is responsible for determining whether a study's protocol is appropriate.
- Recruitment in projects that have been placed on hold may resume provided this has been approved by the Head of Department.
- The Director of Research will function as the Head of Department for IMPACT projects being conducted within HERB and or the Adrian Costa Clinical Trials Centre.

Research staff

- There is no recommendation for staff to work from home. If you have concerns around this, please raise with your direct line manager.
- All research groups must have a Covid Safe Plan in place for their team/area.

Face Masks

- Face masks must be worn at all times, and at all locations across Barwon Health, including in the HERB.

PPE

Healthcare workers **MUST** wear a P2/N95 respirator mask under the follow conditions:

- **AT ALL TIMES** within a designated acute inpatient COVID-19 red zone.
- **AT ALL TIMES for ALL STAFF** within the following areas**:**
  - Emergency Department/Urgent Care Centre (Barwon Health North).
  - Intensive Care Unit (ICU)
  - Birth Suite/Maternity Assessment Unit.
  - Residential Aged Care Facilities (when resident facing and all times in outbreak/exposure)
  - All Paediatric settings {<12 yrs of age).
  - COVID testing locations within assessment & collection areas.
- **AT ALL TIMES** for staff undertaking COVID-19 testing.
- **Caring for patients undergoing an aerosol generating procedure or behaviour (AGP/AGB outside of the above areas**
- For all other Barwon Health sites, inpatient and Residential Age Care facilities P2/N95 respirator required for exposure, care or contact of the following patients:
  - SCOVID.
  - Confirmed COVID**.**
- **AT ALL TIMES** for staff who are a household or household-like contact or considered a social or workplace contact

Eye protection/disposable gowns/disposable gloves to be worn under the following circumstances:

- **AT ALL TIMES** for exposure, care or contact with:
  - SCOVID
  - confirmed COVID
- **AT ALL TIMES** for staff undertaking COVID-19 testing

As per **standard** and transmission-based precautions.

Research meetings

Risk mitigation strategies and Covid safe measures must be in place for all research related meetings.

- < 2 hours level 2 surgical masks are required
- > 2 hour N95 masks are required
- If a meeting participant is unvaccinated it is preferred that the person wear an N95 for their visit, however if not possible then a surgical mask is required.

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Participant visits

- Participants in a clinical trial offering an alternative to standard care are considered healthcare consumers rather than visitors. Participants in all other research are considered visitors.
- As above, decisions regarding whether in person reviews or visits to Barwon Health are appropriate remain with the Principal Investigator and Head of Department. If there is uncertainty about whether participant contacts in a study should proceed the matter should be escalated to the Chief Medical Officer and the Covid-19 Clinical Reference Committee.
- Where practical, in-person contact with study participants should continue to be minimised through means such as telehealth, hospital in the home and courier delivery of medications.
- If necessary, for a participant to attend site, research personal MUST contact a participant by telephone or text one business day before their intended visit to ensure it is appropriate for them to attend.
- Children under the age of 16 years are not permitted to visit clinical areas of Barwon Health. However, children under the age of 16 years may attend the HERB to participate in research studies, provided that they have a negative Covid-19 rapid antigen test on the day of their visit, and they do **not** meet any of the following exclusion criteria:
    - They have tested positive for Covid-19 and have not met the criteria for discharge from isolation or are awaiting test results.
    - They have a temperature higher than 37.5 degrees or symptoms of acute respiratory infection i.e. breathing difficulties, breathlessness, cough, sore throat, runny nose or fatigue.
    - They are known to be a household or household-like contact
- In general, study participants must be fully vaccinated to attend a review at Barwon Health. However, unvaccinated participants are permitted to attend Barwon Health if:
    - They are participating in a Covid-19 vaccination trial and the participant contact occurs at the Barwon Health Community Vaccination Hub.
    - They are participating in a clinical trial offering an alternative to standard care.
    - They are children younger than 5 years old and they have had a negative Covid-19 rapid antigen test on the day of their visit, and they are attending a review in the HERB.
    - They are age 5-12 years and have a single Covid-19 vaccination and a negative Covid-19 rapid antigen test on the day of their visit, and they are attending a review in the HERB.
    - If a participant is unvaccinated it is preferred that the visitor wear an N95 for their visit, however if not possible then a surgical mask is required.
- One parent or guardian who meets visitor requirements may attend the visit with a child who is participating in research.
- If a participant visit will last > 2 hours, the visitor is required to wear a N95 mask. Fit testing is not required.
- The participant must **not** attend Barwon Health if:
    - They have tested positive for Covid-19 and have not met the criteria for discharge from isolation or are awaiting test results.
    - They have a temperature higher than 37.5 degrees or symptoms of acute respiratory infection i.e. breathing difficulties, breathlessness, cough, sore throat, runny nose or fatigue.
    - They are known to be a household or household-like contact
- Participants must wear a face mask throughout the course of their visit to Barwon Health.

- Researchers must wear a face mask during all participant contacts. Instances where PPE is required are described above.
- Please refer to Barwon Health Clinical Trial **Business Contingency Plan** for a detailed flow chart.
- Older age participants and those with significant comorbidities can attend provided they meet the above requirements.

Aerosol generating procedures

- Aerosol generating procedures (AGPs), including cardiopulmonary exercise testing, should be avoided. Where they are determined to be necessary for participant safety, they should be conducted in accordance with Covid-19 safety procedures, with consideration to ventilation requirements, PPE, and Covid-19 testing. If there is uncertainty about whether AGPs in a study should precede the matter should be escalated to the Chief Medical Officer and the Covid-19 Clinical Reference Committee.

Monitoring of Clinical Trials

- In person visits are permitted provided that the monitor is accommodated in a controlled area away from patient care domains under strict social distancing rules with supervised access and agree to the health services screening procedures and vaccination policy. Monitors are considered visitors and are therefore required to wear a face mask while at Barwon Health.

Investigational Medicinal Product (IMP)

- In certain instances, it may not be appropriate for a patient to collect Investigational Medicinal Products (IMP) from the site. **If authorised to do so** by the Sponsor, IMP may be sent to the patient by mail, courier or taxi.
- Sponsors are responsible for covering this cost
- Please see – **Shipment of IMP** document produced by Pharmacy and available on Prompt.

Contingency planning

- Research Teams are asked to maintain contingency plans appropriate for each study to enable a safe and rapid response to changed circumstances as may be required in the event of a rapid spike in Covid-19 infections and new urgent government advice.

REGI

- REGI staff are available via email, phone and in person from Monday to Friday.
- Submissions of new projects and post-approval items for ethics and governance review and approval continue as usual.
- REGI continue to expect submission of a notification for all amendments and modifications to existing research projects. If modifying study procedures, provide updated documentation for review and approval (NB: Consent forms do not need to be amended unless the modifications to the study protocol change the risks to participants).
- Electronic signatures continue to be endorsed within ERM and for research agreements. Ink can be arranged at request if necessary.

Further Updates

The Research Director will provide updated information via email and REGI website
Please contact Barwon Health Director of Research via his PA Nicola Cooley with any queries – nicola.cooley@barwonhealth.org.au