BENDIGO HEALTH – RESEARCH GOVERNANCE GUIDELINES FOR COVID-19 INTERRUPTION TO RESEARCH ACTIVITIES: UPDATE 2 - JUNE 2020

Contents

BACKGROUND

Bendigo Health has provided this guidance document to support our researchers and clinicians conducting research at Bendigo Health.

Advice will be updated and reviewed regularly as required.

COVID-19 has and will continue to bring about considerable changes to how we conduct our daily activities, with further changes anticipated over the coming weeks. As a result, all departments that have research underway must ensure that they have appropriate contingencies in place to ensure that the safety and wellbeing of participants is upheld, and that staff are not unnecessarily placed in harm's way or resources unduly expended during these challenging times.

KEY CHANGES EFFECTIVE MONDAY 1st JUNE 2020

1. New studies will require CEO approval.
    - This includes Clinical Trials and Low & Negligible risk, imaging, observation, health and social sciences, audit and quality improvement studies.

2. Recruitment of new study participants that requires *face-to-face contact* with participants may resume from 1st June 2020. Risk assessments (see point 5) for each in-hospital or face-to-face contact must be conducted and documented.
    - This includes Clinical Trials and Low & Negligible risk, imaging, observation, health and social sciences, audit and quality improvement studies.
    - Where possible remote (telehealth, phone calls) should continue.
    - This action has been taken to mitigate risks to participants and staff. It is possible that there may not be sufficient resources (e.g. diagnostic services, clinical workforce, and pharmacy) to support additional trial participants. Please check with associated departments that they have adequate resources to take on new participants given changes in workloads.

3. Please follow the process below if an amendment to remove face-to-face contact from the exiting protocol is possible. Bendigo Health suggests consulting with your research sponsor to negotiate this.

    Submit a detailed description of the following:
    - What is the substitute for face-to-face contact? I.e. Telehealth, phone call?
    - How will this be documented for the research team and how will it be communicated to the participant?
    - Provide a comment on how this change will impact the research.

    This will be reviewed by the HREC and RGO.

The Research Governance Office will work on the following principles:

- Telephone or video communication for consent instead of in-person consent is assumed to be equivalent. Hard copy signatures will NOT be required over and above clear documentation in CRF and the medical record.
- Telehealth consultations and interviews will be assumed to be equivalent to in-person administration of surveys, questionnaires and interviews.
- There may be some studies where usual clinical care, which includes personal contact, forms part of a non-clinical trial research project. This will be assessed on a case by case basis. The researcher will need to justify that there is no additional safety risk to participants.

4. The following non-essential visit activities all **remain** on hold as per the document from the 25th March 2020:
    - Monitoring visits postponed.
      Remote monitoring visits may be possible on an as need basis. Teams should explore this capability with sponsors and participants, subject to what hardware is required (i.e. phone, computer with camera for Telehealth etc.)
    - Site Initiation Visits (SIVs) will be postponed or completed via teleconference.
    - Audits will be postponed.

    Exemptions may be considered under exceptional circumstances and must be approved by the Deputy CMO (Dr Casey Nottage – please contact the Research Office for guidance researchoffice@bendigohealth.org.au).

5. Participant Study Visits and Risk Assessments
    - It is important that you perform a risk assessment **24 hours before** a participant attends for a planned visit (see Appendix A), to determine if it is safe for participants to attend for that visit.
    - It is important that you repeat a risk assessment **at the start of the planned** visit (see Appendix A).
    - A carer for research participants must only attend the planned visit when absolutely necessary. A risk assessment should also be performed for the carer.
    - If possible, consider Telehealth options instead of face to face meetings.
    - Adopt social distancing policies and ensure that waiting areas allow for this.
    - Provisional approval will be given for scheduled face to face visits to NOW be conducted via phone/telehealth. Clear documentation is required in the Medical record and case report form where this has taken place.

PLANNING AHEAD

It is important that you contact your research/trial sponsors to inform them of Bendigo Health's proposed COVID-19 plan and the conduct of research activities during the active phase of the pandemic.
Sponsors should be advised that clinical research staff may need to be deployed to deliver essential clinical services if required.

It is critical that you also obtain from the sponsors their proposed contingency planning around**:**

- Any anticipated interruption in the supply of trial drugs or devices, central kits, study supplies and support to any trial specific portals
- Unavoidable protocol breaches
- Monitoring
- SIV completion
- Possible consenting approaches that would accommodate the COVID-19 'social distancing' or organisational/State quarantine provisions under the prevailing circumstances, and that would still be in alignment with HREC approval and GCP requirements.

In the event that a research participant refuses to attend study visits

- AE and concomitant medication assessments may take place over the telephone by a PI or study coordinators
- The safety pathology may be completed in a local pathology collection centre where possible
- Ensure that participants contact the site with any safety concerns
- To continue access to oral drugs for participants, you should discuss with the sponsor, on a case by case basis, whether dispensing of drugs via a courier or increasing the amount of drug dispensed is possible
- Participants requiring essential imaging may need to attend a local imaging centre.

In the event that a research participant may have COVID19 infection

- Unless requiring admission, participants will not be allowed access to Bendigo Health sites and will not be able to attend any scheduled visits
- Investigators will maintain contact with the participant by phone during the period of isolation by a PI or study coordinator, particularly with respect to safety and treatment interruption
- Participants will not be allowed to visit local pathology centres, imaging centres or GPs, therefore local and central pathology will be curtailed during this period
- Efficacy visits will be delayed until the participant has recovered.

In the event that all non-essential visits (i.e. non treatment visits) are banned

- Participants will be contacted by telephone by PIs or study coordinators to conduct AE and concomitant medication assessments
- Participants will have pathology samples (e.g. bloods/urine) and ECGs testing taken at local pathology collection centres close to their home (where feasible)
- Central laboratory blood collection may need to be suspended on non-dosing days
- Enrolment of participants to dose escalating studies will need to be discussed with sponsors on a case by case basis due to long PK days and the protocol requirement of multiple visits
- Access to oral drugs for participants will be discussed with sponsors on a case by case basis including dispensing of drugs via courier or increasing the amount of drug dispensed
- Safety investigations will be prioritized, however longer visit windows for all other activity needs to be discussed with sponsors
- Participants requiring essential imaging may need to attend a local imaging centre.

In the event that all visitors are not permitted any entrance to Bendigo Health premises

- Study team to advise sponsor that a ban is now in place.

Access to Drugs for Clinical Trials

- Oral drugs may be able to be couriered to participants depending on the drug and temperature requirements. This must be discussed with the sponsor first and then Pharmacy. A copy of the sponsor confirmation should be provided to Pharmacy.
- Investigators/study staff should contact the sponsor to check availability of drug, as drug manufacture and supply may be impacted.
- Pharmacy may have some limited additional storage for extra stock if required.
- Investigators considering provision of an increased amount of dispensed drug should contact the sponsor first and then Pharmacy. A copy of the sponsor confirmation should be provided to Pharmacy.
- Clinical staff assisting trial staff in dispensing trial drugs must be on the delegation log even if it is not signed by the PI, if the PI is unavailable.
- Investigators and study staff will need to consider contingency plans for the possibility that Pharmacy staff are redeployed to other pharmacy services or are unable to provide a service.

In the event that research staff may have COVID19 and/or are unable to come to work

- Trial activity during the period of absences will need to be prioritised and reduced.

- The remaining staff priority will be to ensure that enrolled participants are reviewed and treated.
- If there is no trial staff for a particular clinical trial, where permissible, staff from other clinical trial units may need to assist to execute the minimum requirements to ensure continued participant safety.
- Trial teams must also prepare for the fact that clinical research staff may need to be deployed to deliver essential clinical services if the health care system is overwhelmed.
- Delegation logs should be reviewed and updated.

The following may also be initiated, depending upon number of research staff affected

- All data entry reduced and priority will be given to essential SAE and AE reporting
- All protocol amendments (unless directly related to patient safety) may be suspended
- All administrative tasks will be prioritized based on staff's ability to perform such activities
- RGO and HREC submissions and responses may be delayed
- Data lock timelines may not able to be adhered to.

COMMUNICATION

Communicate your plan with your research participants

It is critical that trial teams continue to effectively communicate with trial participants on how the pandemic may affect their participation in a trial and what contingencies could be put in place to ensure their safety, wellbeing and as far as possible their continuance on the trial.
Where certain trial activities can be conducted remotely, this should be promoted. Ensure that you use lay language.

This specific patient information does not require HREC approval.

BENDIGO HEALTH HUMAN RESEARCH ETHICS COMMITTEE (HREC)

- Meetings will be conducted virtually according to the current planned schedule
- All ethics and governance submission will be in electronic format
- Legal documents such as CTRA's, MTAs and RCAs with e-signatures (as opposed to wet inked) are acceptable. E-signatures include DocuSign, scanned copy or photo image of the entire signature page are acceptable.
- Post-approval amendments for Ethics and Governance will continue as usual.

Reporting to the HREC

As this situation is unprecedented, it is acknowledged that protocol and GCP breaches are inevitable. There is no suitable guidance covering reporting currently available.

As safety in clinical trials is the priority, all significant safety issues, urgent safety measures and serious breaches impacting on participant safety and rights should be reported.

With respect to non-serious breaches, in lieu of reporting individual events, a post COVID-19 deviation report should be submitted on a 4 monthly basis.

The report will require summary information on:

- Number of participants impacted
- Changes to medication dispensing
- Dose interruptions
- Changes to visit schedule and visit activities
- Use of external services (e.g. pathology, imaging, visit sites)
- Missing data.

RESEARCH DEVELOPMENT AND COORDINATION

The Director, Research and Innovation (Dr Angela Crombie acrombie@bendigohealth.org.au) will be the central coordination point for all enquiries for new research.
The office of Research and Innovation has developed guidelines for the application process and research priorities to manage these going forward, see Appendix B.

Research Governance support for new research

The Research Governance Office will work closely with the office of Research and Innovation to prioritise workloads during this time.
Given the anticipated workload in managing disruption to current research and projected loss of staff, the Research Governance Office will be unable to provide a support service to novice researchers in their protocol and documentation development, and will be prioritising established research teams with appropriate supervision for students and junior researchers.

USEFUL RESOURCE

Coronavirus (COVID-19) Update: FDA Issues Guidance for Conducting Clinical Trials (Issued 18th March 2020)
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-guidance-conducting-clinical-trialsv

CONTACTS

The Research Governance Office is available to support research teams during this challenging time. If you need advice please contact us at ResearchOffice@bendigohealth.org.au

UR:

NAME:

DOB:

Address:

Phone number:

APPENDIX A

COVID-19 SCREEN
For all home visits and clinic appointments ask the following:

A. Does client have: Fever **OR** Acute respiratory infection (for example shortness of breath or cough) with or without fever	**Yes**	**No**

OR

B. Has client arrived from overseas in the past 14 days?	**Yes**	**No**

OR

C. Has client had close* or casual** contact with a confirmed or suspected case of COVID-19 (Coronavirus)?	**Yes**	**No**

IF YES TO ANY QUESTION, IMPLEMENT THE FOLLOWING STEPS

- **Do not attend home visits or have client attend clinic setting** – consider phone intervention
- If essential service is determined/required, and client not admitted to hospital, service will:
  - Assess suitability and status by phone
  - If service delivery proceeds, take PPE precautions (see attached table)
- If client is unwell:
  - Advise them to follow Department of Health Advice regarding health care:
    https://www.health.gov.au/resources/publications/coronavirus
    And, provide them with the contact number for the Victorian Department of Health 1800 675 398
  - Contact Bendigo Health Infection Prevention Control 5454 8416. The Bendigo Health Infection Prevention Control Unit may advise the Department of Health and Human Services.

UR:

NAME:

DOB:

Address:

Phone number:

Personal Protective Equipment (PPE) for essential services

Action Required	Action
If YES	Wear PPE for airborne precautions when visiting client: • N95 mask • Protective eyewear • Gown and gloves Clean all equipment with V-Wipes
Duration of PPE following YES	• If symptoms improve maintain airborne precautions until 14 days post client being symptomatic • PPE as above Clean all equipment with V-wipes

Definitions

*Close contact means at least 15 minutes face-to-face contact or the sharing of a closed space for more than two hours with a confirmed case

**Casual contact is a person having any face-to-face contact or sharing of close space with a confirmed case for less than two hours

Name:

Designation:

Signature:

Date:

APPENDIX B

Application process for research, clinical audits and improvement projects during the COVID-19 pandemic: Effective 1 June 2020

Registration of interest

- The easing of restrictions enables us to gradually and safely re-commence research that was put on hold due to the COVID-19 pandemic and to consider participating in new research that is consistent with Bendigo Health's strategic directions.
- There is much interest in the vital support that research and improvement work can provide to the changes occurring in our health service during and post the current pandemic. A centralized point for registration, coordination and support for research and project work is required to prioritise and allocate appropriate human resources and to ensure methodological and ethical rigor.
- **All proposed research,observation, health and social sciences, clinical audit and improvement projects are to be directed to the Director of Innovation and Research, Dr Angela Crombie, via email acrombie@bendigohealth.org.au**
- For urgent enquiries call Angela on 0417 174 339.
- Information to provide includes the research protocol, estimated impact on other departments\staff (e.g. pharmacy, imaging, pathology, ICT, HIS, PRU etc.), any additional resources required, cost and personnel information as per below.
- **All research,observation, health and social sciences, clinical audit and improvement projects proposals must be discussed with the relevant Executive Director(s).**

Personnel

- **All proposals must include the following information for all personnel:**
  - Name
  - Affiliation
  - Current role
  - Role in proposed research
  - Supervision arrangements for junior researchers (where relevant)
  - Expected amount of capacity at various times of pandemic surge
  - **All proposals must be discussed with other departments\staff potentially impacted by the activities** (e.g. pharmacy, imaging, pathology, ICT, HIS, PRU etc.).

Ethics and Governance

- **Please refer to: BENDIGO HEALTH – RESEARCH GOVERNANCE GUIDELINES FOR COVID-19 INTERRUPTION TO RESEARCH ACITIVITIES**
- Director of Innovation and Research will be the initial point of contact with the Research Governance Office (RGO) and will work closely with the RGO to determine priority areas, ethical and governance implications of each proposal.
- Observational, health and social sciences, clinical audit and improvement projects must be registered via the QI function on ERM.
- It is strongly advised to discuss your proposed project with the Director of Innovation and Research who can provide relevant tools and templates to prioritised projects.

Approval process

- **Research must not proceed at Bendigo Health until approved by the Deputy CMO, Dr Casey Nottage and the CEO, Peter Faulkner.**
- Research must have ethical and site specific authorisation to proceed.
- Priority research will be expedited .
- **Observational, health and social sciences, clinical audit and improvement projects must be approved by the Director of Innovation and Research and the Deputy CMO.**

Support

- Given the workload in managing disruption to current research, support for protocol and documentation development will be limited during this time and will be provided to researchers based on organisational priorities.
- For specific support, templates and tools please contact Angela via email acrombie@bendigohealth.org.au, or for urgent enquiries call 0417 174 339.