**27 March 2020**

# Peter MacCallum Cancer Centre

## Clinical Research

## COVID-19 Advice – Contingency Planning

The Peter MacCallum Cancer Centre provides the following advice to researchers and clinician conducting human research at Peter Mac. This advice should be provided to your project sponsor. **This advice will be updated as required.**

**COVID-19 will require adjustments to how we conduct our daily activities and how we manage and monitor our research projects.**

**All research projects must consider what measures they can introduce to reduce participant and staff exposure to COVID-19 and to reduce impact on hospital resources e.g. trials that offer a treatment more likely to benefit an individual patient whilst having similar or even less impact on hospital resources could be considered a higher priority to keep open**

**The safety of research participants and staff is our priority.**

As per the NHMRC *COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors* (https://www.nhmrc.gov.au/research-policy/COVID-19-impacts) your contingency planning should consider:

- **Priority**: assessment of the importance of and the risks associated with continuing the trial or research project as designed or with necessary modifications.
- **Participation**: assessment of the ability of participants to participate in the trial or research project in accordance with protocol requirements and consideration of alternative models for participation that would not compromise the integrity of the trial.
- **Capacity**: assessment of the resources available for continuing the trial or research project, including research staff, clinical support staff, pharmacy support, other support staff, space, equipment, supplies (including drug supply), etc. A component of a capacity assessment will be consideration of the need to re-allocate research staff to clinical and other areas of patient support.

**Contingency planning will be an ongoing process**.

## A. Clinical Trials – drug or device

The FDA has released a useful Guide regarding clinical trial conduct 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-trials.

*All departments that run clinical trials must review all clinical trials, including those that are currently open and those planned to open in the next six months. Department Managers must have direct involvement in this review process. The review process must carefully consider* ***priority, participation and capacity*** *as outlined in the introduction above.*

For trials that have not yet started recruitment:

- The trial must be put on hold. A Principal Investigator can request an exception, this will require the justification for starting the trial, support from Principal Investigator Department Head and notification of the relevant research Associate Directors (Associate Director Laboratory Research; Associate Director Research Translation; Associate Director Health Service Research and Implementation Science; Associate Director Clinical Research).
- If the trial will start recruitment: Interstate and overseas patients cannot be enrolled.
- If the trial will start recruitment: Include measures that will reduce unnecessary contact and travel while maintaining patient safety, adherence to the protocol, and data integrity e.g. delivery of planned intervention/treatment to participants; administration of intervention/treatment at an alternative site; use of tools such as telehealth to conduct clinical assessments and safety reviews, pathology and/or imaging at local health services. Also consider the impact on the participant and their safety if the planned treatment/intervention can no longer be provided and/or appropriate safety monitoring can no longer be undertaken.
- Contact the trial sponsor regarding their proposed contingency planning.

For trials currently recruiting:

- Further recruitment must be put on hold. A Principal Investigator can request an exception, this will require the justification for continuing recruitment, support from Principal Investigator Department Head and notification of the relevant research Associate Directors (Associate Director Laboratory Research; Associate Director Research Translation; Associate Director Health Service Research and Implementation Science; Associate Director Clinical Research).
- If recruitment is permitted to continue: Interstate and overseas patients cannot be enrolled
- Include measures that will reduce unnecessary contact and travel while maintaining patient safety, adherence to the protocol, and data integrity e.g. delivery of planned intervention/treatment to participants; administration of intervention/treatment at an alternative site; use of tools such as telehealth to conduct clinical assessments and safety reviews, pathology and/or imaging at local health services.
- Consider the impact on the participant and their safety if the planned treatment/intervention can no longer be provided and/or appropriate safety monitoring can no longer be undertaken.
- Contact the trial sponsor regarding their proposed contingency planning.

Any proposed action must still maintain appropriate safety monitoring of research participants.

Please consult with clinical trial sponsors and obtain their agreement, and financial support if required, for any proposed action.

A list of all actions that are a change from protocol mandated procedures must be recorded in the site file.

The Parkville Cancer Clinical Trials Unit (PCCTU) has developed a detailed plan for the PCCTU clinical trial portfolio and will be happy to share their expertise and documents (contact Marian Lieschke, Manager, PCCTU).

Sponsor Activities:

- Monitoring: Onsite visits will not be allowed.
- Monitoring: Data verification will be possible in accordance the Parkville Precinct Remote Monitoring advice document.
- Monitoring: Sponsors will be advised to keep data requests to a minimum and to provide financial support for staff time spent on fulfilling requests.
- Site Selection Visits: Onsite visits will not be allowed. Activity must be deferred or completed via phone/video.
- Site Initiation Visits: Onsite visits will not be allowed. Activity must be deferred or completed via phone/video.
- Audits: Onsite audits will not be allowed. Activity must be deferred or completed via phone/video.

## B. Other Research Projects that require interaction with participants

Examples of this type of projects include interventional clinical trials (non-drug or device) and research, and non-interventional research (including qualitative research and laboratory research recruiting participants to obtain biospecimens).

*All departments must review all other research projects that require interaction with participants, including those that are currently open and those planned to open in the next six months*. *Department Managers and Laboratory Heads must have direct involvement in this review process. The review process must carefully consider* ***priority, participation and capacity*** *as outlined in the introduction above, as well as:*

- The risk of exposure to participants and staff
- The impact of foot traffic in clinical areas
- The impact of conducting the project on hospital resources, particularly staff resources.
- The impact on the project if a staff are unavailable for an extended period to conduct the research.

For research projects that have not yet started recruitment:

- The project must be put on hold. A Principal Investigator can request an exception, this will require the justification for starting the project, support from Principal Investigator Department Head and notification of the relevant research Associate Directors (Associate Director Laboratory Research; Associate Director Research Translation; Associate Director Health Service Research and Implementation Science; Associate Director Clinical Research).
- If the project will start recruitment, include measures that will reduce unnecessary contact and travel e.g. telehealth, online surveys, pathology at local health services, use of stored biospecimens.

For research projects currently recruiting:

- Further recruitment must be put on hold. A Principal Investigator can request an exception, this will require the justification for continuing recruitment, support from Principal Investigator Department Head and notification of the relevant research Associate Directors (Associate Director Laboratory Research; Associate Director Research Translation; Associate Director Health Service Research and Implementation Science; Associate Director Clinical Research).
- For participants currently on project (including in follow-up) include measures that will reduce unnecessary contact and travel e.g. telehealth, online surveys, pathology at local health services, use of stored biospecimens.

Please consult with project sponsors and obtain their agreement, and financial support if required, for any proposed action.

Any proposed action must be recorded as a protocol letter/addendum. Please also consider if the proposed action requires new documents e.g. telephone scripts; survey questions.

## C. Research Projects that DO NOT require interaction with participants

*All departments must review all research projects, including those that are currently open and those planned to open in the next six months*. *Department Managers and Laboratory Heads must have direct involvement in this review process. The review process must carefully consider* ***priority, participation and capacity*** *as outlined in the introduction above, as well as:*

- The impact of conducting the project on hospital resources, particularly staff resources.
- The impact on the project if staff are unavailable for an extended period to conduct the research.

For research projects that have not yet started recruitment:

- The project must be put on hold. A Principal Investigator can request an exception, this will require the justification for starting the project and agreement from Principal Investigator Department Head.

For research projects that have started:

- The project can proceed without change only if hospital resources are not impacted.

## D. Managing interactions with participants: COVID-19 precautions

For all studies involving interactions with participants:

- Participants should be informed of the importance of notifying the research team in advance of attending any trial visits if:
    - they are experiencing one or more symptoms suggestive of COVID-19 infection
    - they have recently (within 14 days) returned from overseas or have been in close contact with someone who is known to have contracted COVID-19 or has symptoms suggestive of COVID-19 infection, or
    - they are experiencing one or more symptoms not suggestive of COVID-19 infection, but suggestive of influenza or other infectious disease or condition that includes respiratory symptoms.
- The PI should ensure that appropriate follow-up with symptomatic participants is arranged and may advise the participant to present to another site or service for assessment, testing and/or further investigation.
- The PI may consider contacting patients on the day prior to trial visits according to resources.

## E. Ethics and Governance

The Human Research Ethics & Governance office will continue to operate, however all staff will be located off site. As a result, email will be the best contact method ethics@petermac.org

The Peter Mac Human Research Ethics Committee (HREC) will continue to accept new project submissions; amendments and other project related submissions.

In the event of reduced capacity:

- Items related to participant safety will be prioritised.
- CoVID-19 related clinical trials and research will be prioritised

The Peter Mac HREC and Human Research Ethics & Governance office will provide advice regarding COVID related amendments and notifications on the HREC and Governance on the office website https://www.petermac.org/research/doing-research-us/ethics-governance

## F. COVID-19 related clinical trials and research

## The conduct of COVID-19 related clinical trials and research will be prioritised.

**Peter Mac Human Research Ethics Committee (HREC)**:
The Peter Mac HREC will expedite the ethical review of CoVID-19 related research by providing out of session review. **Submissions will be accepted at any time.**
Please email **ethics@petermac.org** for submission advice or consult:
https://www.petermac.org/research/doing-research-us/ethics-governance
Submissions are made via an online portal. To reduce delay please notify the office when a project is submitted.

**Peter Mac Research Governance office**:
The Peter Mac Research Governance office will expedite the governance review of CoVID-19 related research.
Please email **ethics@petermac.org** for submission advice or consult:
https://www.petermac.org/research/doing-research-us/ethics-governance
Submissions are made via an online portal. To reduce delay please notify the office when a project is submitted.

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