Peter MacCallum Cancer Centre
305 Grattan Street
Melbourne Victoria
3000 Australia

Postal Address
Locked Bag 1 A'Beckett Street
Victoria 8006 Australia

Phone +61 3 8559 5000
Fax +61 3 03 8559 7379
ABN 42 100 504 883

Locations
Melbourne
Bendigo
Box Hill
Moorabbin
Sunshine

Peter Mac
Peter MacCallum Cancer Centre
Victoria Australia

From: Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC)
To: Projects ethically reviewed and approved by Peter MacCallum Cancer Centre HREC
Date: 30 March 2020
Re: **Human Research Projects COVID Contingency Plan**

At the Peter MacCallum Cancer Centre Human Research Ethics Committee meeting held on 23 March 2020 the Ethics Committee discussed research project actions in response to COVID-19.

The Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC) provides the following advice to researchers and clinicians conducting human research under a Peter Mac HREC ethical approval. This advice should be provided to your project sponsor. **This advice will be updated as required.**

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. In many cases this will result in projects being put on hold.

The safety of research participants and staff is our priority. The HREC expects that researchers and sponsors put the person first and manage this situation in a pragmatic manner while maintaining trial participant safety.

Please refer to COVID-19 guidance released by the NHMRC and FDA. **The Peter Mac HREC endorses the actions recommended in these documents.**

NHMRC *COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors* https://www.nhmrc.gov.au/research-policy/COVID-19-impacts
FDA *Coronavirus (COVID-19) Update: FDA Issues Guidance for Conducting Clinical Trials* (Issued 18th March 2020) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic

A. Clinical Trials – drug or device

The Investigator must regularly review the advice of their institution when deciding what actions are required. In many cases this will result in projects being put on hold to reduce participant and staff exposure to COVID-19 and to reduce impact on hospital resources.

The HREC recommends that trials with participants on treatment or in follow up implement measures that will reduce unnecessary contact and travel while maintaining patient safety, adherence to the protocol, and data integrity.

It is expected that for each continuing clinical trial the Investigator and trial sponsor will consult and agree on what actions are appropriate for each specific trial and individual trial participant. As part of this review please consider the benefits to participants from continued access to the trial drug/intervention and the implications for the participant if they are denied continued participation. Any action must still maintain appropriate safety monitoring of research participants.

If the action(s) will not significantly impact on participant safety, then approval per trial or per action is **NOT** required. This communication is Peter Mac HREC approval of the action(s).

If the action(s) will significantly impact on participant safety, a submission to HREC will be required.

ACTIONS APPROVED: The HREC approves actions, including those described in broad terms below, if they will not significantly impact on participant safety:

- Managing trial participants via telehealth, including physical examinations by a local physician
- Conducting pathology and/or imaging at local health services
- Conducting essential safety testing locally
- Omitting central testing that does not affect safety
- Shipment of oral medication to trial participants
- Administration of IV medication at an alternative site, such as closer to the trial participant's home, if the alternative site has the expertise and clinical support required to manage participant safety for the medication to be administered
- Delays in drug reconciliation
- Informing trial participants of changes to the conduct of the trial that directly impact on their participation e.g. changes in location of appointments; changes in mode of appointment (telehealth). Project teams should discuss with participants and provide information in the manner best suited to the individual case.

NOTE for Participant's whose first language is not English: If trial is currently providing information in the participant's language, appropriate arrangements must be made to continue providing information in the participant's language.

SITES: The approved actions include activities occurring at other sites. Other sites will need to be added to the ethical approval if the following criteria are met:

- If at a site trial specific assessments require a trial specific decision to be made by staff at that site during the visit;
- If trial drug will be dispensed by that site.

If the above criteria are not met then the site does not need to be added to the ethical approval and is considered to be an external service provider.

RECORDING ACTIONS IN SITE FILES: A list of all actions that are a change from protocol mandated procedures must be recorded in the site file. How the actions are recorded in the site file is a matter for the project team and sponsor to decide.

SAFETY REPORTING: There is no change to safety reporting requirements. Consult https://www.petermac.org/research/doing-research-us/ethics-governance/post-approval/safety-reporting

SERIOUS BREACHES: There is no change to serious breach reporting requirements. Consult https://www.petermac.org/research/doing-research-us/ethics-governance/post-approval/serious-breach-reports-peter-mac-ethics

PROTOCOL DEVIATIONS: Do NOT report COVID-19 related protocol deviations to HREC.

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).

The Investigator must regularly review the advice of their institution (and if applicable the project sponsor) when deciding what actions are required. In many cases this will result in projects being put on hold in order to reduce participant and staff exposure to COVID-19 and to reduce impact on hospital resources.

The HREC recommends that ongoing projects with active participants or participants in follow up should implement measures that will reduce unnecessary contact and travel, while maintaining adherence to the protocol and data integrity.

ACTIONS APPROVED: The HREC approves the actions described in broad terms below:

- Measures that will reduce unnecessary contact and travel e.g. telehealth, online surveys, pathology at local health services, use of stored biospecimens.

SUBMISSIONS REQUIRED TO HREC:

- **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. The protocol letter/addendum and any new documents must be submitted to ethics@petermac.org These submissions will be reviewed and noted. **All other reporting** to HREC will continue without change per existing SOPs and Guidelines. See https://www.petermac.org/research/doing-research-us/ethics-governance/post-approval

NOTE: For participant's whose first language is not English: If project is currently providing information in the participant's language, appropriate arrangements must be made to continue providing information in the participant's language.

C. Other Notifications to HREC

Projects put on hold/recruitment hold: Please notify the HREC of all projects put on hold/recruitment hold. It is preferred that a single notification be submitted per department/organisation/trial unit that lists all projects on hold. There is NO requirement to provide notification within a set timeframe, unless a safety reporting requirement would be triggered by the hold/recruitment hold. If no safety reporting requirement is triggered by the hold/recruitment hold, please submit the notification when the listing has been collated.

Clinical Trials: Please notify the HREC of trials that implement measures to reduce unnecessary contact and travel. (NOTE: If submission was already required per the advice in A above do NOT submit again).
It is preferred that a single notification is submitted per department/organisation/trial unit that lists the trials together with a general description of the measures implemented. Please submit the notification when the list of studies has been collated.

Should you have any questions please contact the Human Research Ethics & Governance office: ethics@petermac.org. Submission guidelines, forms and standard operating procedures are available on the ethics website: www.petermac.org/research/doing-research-us/ethics-governance

Kind regards,

Dr Dianne Snowden
Manager, Human Research Ethics & Governance
On behalf of Suzie Linden, Chair Peter MacCallum Cancer Centre Human Research Ethics Committee