PETER MAC RESEARCH PROCEDURE

Phased Increase in Clinical Research Activity

TARGET AUDIENCE

Staff and students of the Peter MacCallum Cancer Centre (Peter Mac) who conduct or support clinical research that is not undertaken within the Parkville Cancer Clinical Trials Unit.

PURPOSE

This procedure describes the initiation of a strategic phased escalation of clinical research activity at Peter Mac.

Background

After careful consideration and extensive planning the Research Executive, in consultation and with the full support of our Chief Executive Shelley Dolan, introduced measures to reduce on-site clinical research activities at Peter Mac to an absolute minimum and commited to undertaking essential projects only. Reduction in clinical research activity was proactively implemented to reduce potential exposure of participants and staff to COVID-19, and to minimise burden on hospital resources. Trials remaining open were those that offered a treatment more likely to benefit an individual patient whilst having similar or even less impact on hospital resources. With the State and Federal governments' restrictions significantly slowing the rate of new COVID-19 infections, and in consultation with our Infection Prevention Department, Research Executive and Chief Executive, we are now planning a strategic and staged escalation of clinical research activity. Increased clinical research activities will proceed in a phased manner until full reactivation of all research activities at Peter Mac is eventually established. The timing of the phase roll-outs will be guided by consultations with Peter Mac's Infection Prevention and Chief Executive Shelley Dolan. Further increases in research activities will be guided with consideration of advice from State and Federal governments. Important to our escalation strategy is the ability to rapidly phase roll-backs of individual trials if necessary and advised.

Strategy

Increasing critical clinical research that can be resourced appropriately, **but can be reduced if required**, will enable vital progress in our research outputs. As well Peter Mac will address the need to ensure:

- Continuing patient care and access to research opportunities
- Staff welfare
- Long term financial stability
- Reduced reputational risk i.e. missed milestones, contractual obligations

The increase in activity is planned to occur in three phases.

Step 1: Increase open studies/study participation by 20%

Step 2: Increase open studies/study participation by a further 20%

Step 3: Increase open studies/study participation to full operations

Escalation from Step 1 to Step 2 to Step 3 will be determined by staffing levels, access to resources and the status of the COVID19 situation including:

- Increases in COVID-19 community transmission
- Changes to government restrictions
- Infections of Peter Mac research staff and students
- Failure to abide by this procedure

Variations to the implementation of these steps/phases should be discussed with the appropriate Associate Director for agreement.

Operating Principles

- Resumption should be as equitable as possible across departments whilst recognising strategic imperatives
- Peter Mac staff resources in the relevant department must be sufficient and aware of what is required
- The risk to patients of attending Peter Mac for clinical trial appointments and/or in modifying trial schedule is managed in accordance with hospital guidance
- Confidence of the participant population to participate in clinical trials should be considered
- The required monitoring can occur
- Sponsor directives can be adhered to
- Establish the status of trials at a Sponsorship level (open or on hold)

- All staff must undergo compulsory PPE training (LMS)
- Investigational agents are available in sufficient quantities
- Priority is to re-open studies currently on hold rather than open new trials
- Site Initiation Visits may only occur with the approval of the department head and sign off from Research Executive
- Research plans for each department or discipline are to be submitted to the Research Executive for sign off

Order of Priority for Increasing Activity

- Step-wise re-opening of studies on hold
- Studies that do not require inpatient and /or ICU beds and /or biopsies
- Studies that will not place an increased demand on stretched hospital resources including pathology and medical imaging
- Studies that have significant strategic / clinical importance and pose a low/acceptable risk to patients and staff

On a case by case basis with approval from the Research Executive

- Any new study
- Studies requiring inpatient beds and/or ICU beds
- Studies involving tissue collection including biopsies
- Studies that have accrued no patients in the previous 3 months

RESPONSIBILITIES

- All clinical research staff and students have individual responsibility to maintain compliance with the operating principles of this procedure
- Principal Investigators and department head(s) have responsibility for ensuring appropriate staffing and resources to enable compliance with the operating principles of this procedure
- The Research Executive have the responsibility for implementation of this procedure on behalf of the Executive Director Cancer Research.

AUTHORISED BY

Peter Mac Research Executive Committee

AUTHOR/CONTRIBUTORS

Sam McKeown, Annette Hogg, Megan Crane, Jo Phipps-Nelson, Sam Somers, Susan Roache, Karin Thursky, Jayesh Desai, Mark Dawson, Rick Pearson, Ricky Johnstone and Carol Ginns