

16 March 2020

Dear Sponsor or CRO,

As a global healthcare organisation Icon have a duty of care to slow the transmission of COVID-19 and protect those who are most vulnerable, including our patients. Alongside stringent hygiene, social distancing is one of the main ways we can achieve this. In line with this, Icon Group has made the decision to move to a remote working model for our Brisbane head office alongside relevant state-based support roles. This measure will be effective from Tuesday 17 March for staff at our Cordelia Street head office in Brisbane.

While our significant front-line staff base of Clinical Trial Coordinators should remain at sites supporting the conduct of clinical trials for our patients, Icon Research will move our non-clinical staff to a remote working model as far as possible while maintaining clinical trial oversight. Equally we are committed to the company policy of reducing the risk of transmission of COVID-19 amongst our central office staff.

Head office research staff will continue to be available via email and video conferencing platforms in line with current working hours. While Icon Group will continue to assess the evolving situation, we expect remote working to remain in place for at least the next month. We will endeavour to minimise any changes to workload and investigator resulting from this change in work pattern.

We also anticipate a number of changes on site relating to patient attendance and potential protocol compliance as this situation evolves. We have already received expressions of support from sponsors, clinical research organisations and ethics committees to address and reduce the likelihood and frequency of potential deviations from protocol and reporting timelines in the coming weeks.

I would like to ask for your consideration and patience as we adhere to Icon policy, protocol compliance and care for patients and staff concurrently. I have listed a number of frequently asked questions that I have already received on the following page. Please contact me on (07) 3737 4558 or adam.stoneley@icon.team if you have any additional questions or concerns or refer to updated Letters to Sponsors at <https://iconcancercentre.com.au/research/#covid-19>.

Kind regards,

Adam Stoneley

Research Operations Manager, Icon Research

Frequently Asked Questions regarding Icon Remote Working Model

- Is there any guidance from a local health authority regarding COVID-19 management planning?
 - As a private provider of care, Icon Cancer Centre does not operate within a local health authority and has decided to transition to a remote working model only for staff based in our head office in Brisbane.
- Does the site foresee any restriction to on-site monitoring visits?
 - Yes. On site monitoring visits will be cancelled for the next month from the 17th of March until the 17th of April 2020. It is not known whether the remote working model will continue beyond this date but updates and anticipated duration will be provided every week by the Research Operations Manager. While monitoring visits will be cancelled video/phone calls with Clinical Trial Coordinators can be arranged to discuss queries.
- Is there remote access to an electronic medical record or investigator site files for remote source data verification?
 - No. There is no remote access provided to persons external to Icon to either the paper medical record or investigator site files.
- Does the site foresee any restriction to site staff? (i.e. to deal with patient visits, data entry & cleaning, SAE reporting)
 - Yes. The front-line staff base of Clinical Trial Coordinators will remain at sites supporting the conduct of clinical trials for our patients and there is no expectation that patient visits and treatments will be impacted. The Data Management and Research Implementation normally based staff at our head office location are able to work effectively from home and some roles will remain onsite to ensure proximity to critical infrastructure, oversight and communication with teams working in split shifts to minimise transmission risk.
- Does the site foresee any restriction to patient visits?
 - Patient visits and treatments are only likely to be impacted or restricted in accordance with the direction of the investigator for reasons of patient safety.
- Is there any plans to place recruitment on hold?
 - There are no plans to limit recruitment to clinical trials unless this is related to decisions made by the investigator and for patient safety.
- Does the site foresee any issues with patient willingness to return to site for treatment?
 - There is an expectation that trial participants of vulnerable populations may not wish to present to the clinic for research appointments. The Clinical Trial Coordinators will communicate with participants to limit this or seek alternatives including but not limited to tele-health or telephone consultations with investigators.
- Will there be any impact on the activation of clinical trials or conduct of initiation meetings?
 - All initiation meetings up until the 17th of April 2020 will be either postponed or conducted using telephone and video conferencing platforms